HEARING TO CONSIDER THE IMPACTS OF THE ENVIRONMENTAL PROTECTION AGENCY'S ACTIONS ON THE RURAL ECONOMY

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

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CONTENTS

	Page
Conaway, Hon. K. Michael, a Representative in Congress from Texas, opening statement	1
Prepared statement	3
Newhouse, Hon. Dan, a Representative in Congress from Washington, submitted letter	65
Peterson, Hon. Collin C., a Representative in Congress from Minnesota, opening statement	4
WITNESS	
McCarthy, Hon. Gina, Administrator, U.S. Environmental Protection Agency, Washington, D.C.	5
Prepared statement	7
Supplementary material	65
Submitted questions	68

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THURSDAY, FEBRUARY 11, 2016

HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The Committee met, pursuant to call, at 10:00 a.m., in Room 1300 of the Longworth House Office Building, Hon. K. Michael Conaway [Chairman of the Committee] presiding.

Members present: Representatives Conaway, Neugebauer, Goodlatte, Lucas, King, Rogers, Thompson, Gibbs, Austin Scott of Georgia, Crawford, DesJarlais, Gibson, Hartzler, Benishek, Denham, LaMalfa, Davis, Yoho, Walorski, Allen, Bost, Abraham, Moolenaar, Newhouse, Kelly, Peterson, David Scott of Georgia, Costa, Walz, Fudge, McGovern, DelBene, Lujan Grisham, Kuster, Nolan, Maloney, Aguilar, Plaskett, Adams, Graham, and Ashford.

Staff present: John Goldberg, Josh Maxwell, Patricia Straughn, Scott Sitton, Stephanie Addison, Faisal Siddiqui, John Konya, Anne Simmons, Evan Jurkovich, Keith Jones, Nicole Scott, and Carly Reedholm.

OPENING STATEMENT OF HON. K. MICHAEL CONAWAY, A REPRESENTATIVE IN CONGRESS FROM TEXAS

The CHAIRMAN. Good morning. This hearing of the Committee of Agriculture to consider the impacts of the Environmental Protection Agency's actions on the rural economy, will come to order. I have asked Mike Bost to open us with a prayer. Michael?

Mr. BOST. If you all would just bow your heads? Dear Heavenly Father, we thank you so much for the opportunity to serve this great nation. Lord, we thank you for the freedoms that we have. We thank you that you have blessed us as you have with the rich resources, and the ability to use those to make the world a better place. Lord, guide us and direct us. Give us wisdom through this hearing. We ask all this in Jesus's name. Amen.

The CHAIRMAN. Thank you, Michael. Well, good morning, and I want to thank Administrator McCarthy for being here this morning. Thank you, ma'am. I appreciate you being here. There is a reason a top issue for nearly every Member of our Agriculture Committee is related to the regulatory agenda of the Environmental Protection Agency. Many Members of this Committee believe that over the years the EPA has pursued an agenda seemingly absent

of any recognition of the consequences for rural America and production agriculture. The EPA is creating regulations and policies that are burdensome, overreaching, and that negatively affect the jobs in the rural economy.

Perhaps the most poignant example is the EPA's recent *Waters of the U.S.* Rule, or, as the EPA likes to call it, the Clean Water Rule. I will be frank, this rule is not about clean water. Everyone wants and deserves to drink clean water. This is not about safe drinking water in Flint, Michigan, which some have purposely confused with the WOTUS overreach. Rebranding government overreach as a part of a social media campaign does not change the content of the rule. This rule is simply the result of the EPA ignoring stakeholders, including states and other Federal agencies, and the American people, in order to egregiously and vastly expand its jurisdiction. This rule is already tied up in the court system, and I would imagine it will be there for a number of years.

This is only one of the many instances where I believe the Agency has ignored Congressional intent. Instead of simply administering the law, EPA challenges Congress to pass legislation that gives the Agency more authority. And, if Congress doesn't act, the EPA will legislate via regulation, directive, memorandum, or in some instances by intimidation. This regulate first and ask questions later approach is starting to backfire. Just this week the Supreme Court intervened in another overreaching regulatory priority of the Obama Administration by staying the implementation of the Clean Power Plan. I am glad that the courts have intervened; however, it should never have come to this. Just because something sounds great in theory here in D.C. does not mean that it will work or have a beneficial impact on our constituents. More times than not those great theories do nothing but increase the cost of doing business.

Farmers and ranchers and foresters all take great pride in their stewardship of the land. They are original conservationists. When a family's livelihood depends on caring for natural resources, there is an undeniable economic incentive to adopt practices that enhance long-term viability. While it may be popular among some to blame farmers and ranchers for any and every environmental concern that crops up, I think that you can acknowledge that nobody cares more about the environment than those who derive their livelihood from it.

Rural America's economy is dependent on agriculture. Today, Committee Members will talk about examples in which EPA's regulatory approach may unjustifiably increase the cost of doing business for America's farmers and ranchers. These include the recent *Waters of the U.S.* rule, the proposed changes to the ozone standard, and the recently modified standards for farmworkers, and many others. Regardless of the degree to which somebody believed individual government regulations might be justifiable, all regulations must be developed in a manner that is based on science, and mindful of the economic consequences. For instance, farmers face increasing pressure from pests and disease. If existing pesticide uses were to be prohibited, the increase in crop losses will undoubtedly impact food prices and food security. If EPA fails to ade-

quately calculate and/or consider the economic consequences of these actions, the consequences could be devastating.

Federal law dictates that the USDA serve as an important advisor to EPA in the regulation of pesticides. Historically USDA's expertise and advice has been evident in the actions EPA has taken to evaluate pesticides and their uses. USDA's perspective, and the knowledge of production agriculture, is critical, since we know that crop protection products can increase farm yields as much as 40 to 70 percent, depending on the crop. It concerns me to hear the farm communities express increasingly urgent concerns about the lack of seriousness with which the EPA takes and incorporates the USDA expertise, advice, and opinions, especially during formal inter-agency reviews.

I anticipate that every Member will wish to engage you in a discussion of specific areas of concern. My hope is that this hearing will serve to open the door to a more cooperative working relationship with EPA generally. Farmers and ranchers believe the EPA is attacking them. They believe little credit is given to them for the voluntary conservation activities that they have engaged in for years. This Committee is going to be an advocate for our farmers, as you would expect.

[The prepared statement of Mr. Conaway follows:]

PREPARED STATEMENT OF HON. K. MICHAEL CONAWAY, A REPRESENTATIVE IN CONGRESS FROM TEXAS

Good morning. I thank Administrator McCarthy for being here today.

There is a reason a top issue for nearly every Member of the Agriculture Committee is related to the regulatory agenda of the Environmental Protection Agency. Many Members of this Committee believe that over the years, EPA has pursued an agenda seemingly absent any recognition of the consequences for rural America and production agriculture. EPA is creating regulations and policies that are burdensome, overreaching, and that negatively affect jobs and the rural economy.

Perhaps the most poignant example is EPA's recent power grab with the *Waters of the United States* rule. Or, as EPA likes to call it—The Clean Water Rule. I'll be frank—this rule is not about clean water. Everyone wants and deserves clean water. This is not about safe drinking water in Flint, Michigan, which some have purposefully confused with the WOTUS overreach.

Rebranding government overreach as part of an illicit social media campaign does not change the content of the rule. This rule is simply the result of EPA ignoring stakeholders, including states, other Federal agencies, and the American people, in order to egregiously and vastly expand its jurisdiction. This rule is already tied up in the court system, and I would imagine it will be there for many years.

This is only one of many instances where the Agency has blatantly ignored Congressional intent. Instead of simply administering the law, EPA challenges Congress to pass legislation that gives the Agency more authority; and if Congress doesn't act, EPA will legislate via regulation, directive, memorandum, or in some cases by intimidation.

This regulate first, ask questions later approach is starting to backfire on the EPA. Just this week, the Supreme Court intervened in another overreaching regulatory priority of the Obama Administration by staying the implementation of the so called Clean Power Plan. I am glad that the courts have intervened. However, it should never have come to this. Just because something sounds good in theory in Washington, D.C., does not mean it will work or have a beneficial impact for our constituents. More times than not, those great theories do nothing but increase the cost of doing business.

Farmers, ranchers and foresters all take great pride in their stewardship of the land. They are the original conservationists. When a family's livelihood depends on caring for natural resources, there is an undeniable economic incentive to adopt practices that enhance long-term viability. While it may be popular among some to blame farmers and ranchers for any and every environmental concern that crops up,

I think that you can acknowledge that nobody cares more for the environment than those who derive their livelihood from it.

Rural America's economy is dependent on agriculture. Today, Committee Members will talk about examples in which EPA's regulatory approach may unjustifiably increase the cost of doing business for America's farmers and ranchers. These include the recent WOTUS rule; proposed changes to the ozone standard, the recently modified standards for farmworkers, and many others.

Regardless of the degree to which some may believe any individual government regulation might be justifiable, all regulations must be developed in a manner that is based on science and mindful of the economic consequences.

For instance, farmers face increasing pressures from pests and disease. If existing pesticide uses were to be prohibited, the increase in crop losses will undoubtedly impact food prices and food security. If EPA fails to adequately calculate and/or consider the economic consequences of these actions, the consequences could be devastating.

Federal laws dictate USDA to serve as an important advisor to EPA in the regulation of pesticides. Historically, USDA's expertise and advice has been evident in the actions EPA has taken to evaluate pesticides and their uses. USDA's perspective and knowledge of production agriculture is critical since we know that crop protection products can increase farm yields as much as 40 percent to even 70 percent depending on the crop. It concerns me that to hear the farm community express increasingly urgent concerns about the lack of seriousness with which EPA takes and incorporates USDA expertise, advice and opinions, especially during formal interagency review.

I anticipate that nearly every Member will wish to engage you in a discussion of specific areas of concern. It is my hope that this hearing will serve to open the door to a more cooperative working relationship with EPA generally. I want to end this opening statement with this one last observation. Farmers and ranchers believe the EPA is attacking them. They believe little credit is given to them for all the voluntary conservation activities that they have been engaged in for years. This Committee is going to be an advocate for those farmers.

I thank you again for being here and look forward to a good discussion.

The CHAIRMAN. I appreciate the Administrator being here this morning, and I will turn to the Ranking Member for any questions he may have.

OPENING STATEMENT OF HON. COLLIN C. PETERSON, A REPRESENTATIVE IN CONGRESS FROM MINNESOTA

Mr. PETERSON. Thank you, Mr. Chairman, and thank you, Administrator McCarthy, for joining us. I appreciate you being here today. And, we have had our share of disagreements, but you have always been willing to listen to my concerns, and we don't always get to the same place, but at least you have been willing to listen. And I am glad that other Members of the Committee will have an opportunity to share what is happening in their districts with you today.

I am on record, along with a lot of others, saying that the EPA is an Agency that has overreached on these rules. I simply don't believe that there is enough understanding within the Agency, or the Administration, about what we do in rural America, and the real consequences of new regulations, and what they could have on agriculture and the rural economy. The proposed Clean Power Plan Rule, which, in my opinion, was rightly put on hold by the Supreme Court this week, is one of them, as well as the proposed *Waters of the U.S.* rule, which, if I read one more time about the farmer exemptions, I am going to tear my hair out, because I have a full time person on my staff that does nothing but untangle these water issues under the current regime. And the problem is we have four Federal agencies deciding what a wetland is, and they don't agree.

And even within the same Agency you can have somebody in one county that will have one opinion *versus* somebody in the next county that has another. I can guarantee you that if this rule goes into effect, it is just going to make that worse. We have had a Memorandum of Understanding between the NRCS and the Corps of Engineers up in our district on our flood mitigation that we have been working on, and it just has not worked. We still have people all over the map. So I don't have a lot of confidence that just putting some exemptions in there is going to fix this. I hope there is some other way we can deal with that.

So I hope today's hearing is, as I said, an opportunity to get a better grasp on what you are up to, and what we need in agriculture and rural communities. I hear concerns from my farmers in my districts all the time about this, and I am sure other Members do as well. So, again, I thank you for your willingness to testify before the Committee today, and I look forward to today's hearings and the questions. I yield back.

The CHAIRMAN. I thank the Ranking Member, and I also want to thank the Administrator this morning, and welcome her to the witness table. I suspect that she understood there would be some differences of opinion, and we hope to be respectful with that. And, with that, I will introduce the Honorable Gina McCarthy, the Administrator for the U.S. Environmental Protection Agency in Washington, D.C. And, ma'am, we are ready to go whenever you are. And, again, thank you for being here.

STATEMENT OF HON. GINA McCARTHY, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY, WASHINGTON, D.C.

Ms. McCARTHY. Thank you, and good morning, Chairman Conaway, Ranking Member Peterson, as well as Members of the Committee. I really want to thank you for the honor and opportunity to be here with you this morning.

As stewards of the land, the EPA and farmers share a common goal in protecting our environment. As lifelong conservationists, farmers', ranchers', and foresters' livelihoods depend on healthy land, clean air and water to produce the food, fuel, and fiber that we rely on. In the 45 years since the EPA's founding we have cleaned up 70 percent of our nation's air pollution, and hundreds of thousands of miles of waterways, all while the economy has tripled. Agriculture advanced too, achieving better yields with less water, lower risk pesticides, and less fertilizer. I would like to highlight some of the EPA initiatives furthering our common goals.

Working with USDA, and partnering with the pork and dairy producers and technical experts, we recently launched an initiative promoting recycling nutrients from livestock waste. Annually livestock producers manage more than 1 billion tons of manure, but that contains valuable nitrogen and phosphorus, which, if we harness as a renewable fertilizer, can minimize water pollution and build healthy soils. Participants will be challenged to use the power of competition to turn innovative concepts into designs, and ultimately into working technologies, creating the solutions that are a win for farmers, the environment, as well as our economy.

The EPA also partners with USDA with the Local Foods, Local Places Project, promoting walkable, healthy, and economically vi-

brant neighborhoods through farmers' markets, co-ops, community gardens, and other local food enterprises. By focusing development in existing neighborhoods, we help support farm economies and protect undeveloped rural lands. Last month we announced 27 new communities, raising the total number of communities served to 62 in 29 states, just since the program started in 2013.

The Clean Water Rule, which we finalized last year, protects the streams and wetlands that one in three Americans rely on for drinking water, and farmers and ranchers also need for their crops and livestock. As Members of this Committee know, recent Supreme Court rulings created uncertainty regarding the application of the Clean Water Act to streams and wetlands. In developing the rule, the EPA and the Army Corps of Engineers responded to requests to define the scope of the Clean Water Act more clearly, more predictably, and more fairly. In doing so, the Clean Water Rule not only maintains current statutory exemptions, it expands regulatory exclusions from the definitions of *waters of the United States* to make it clear that the rule does not add any additional permitting requirements on farmers and ranchers, and promotes their voluntary efforts to protect and enhance clean water. We continue outreach to the agriculture community, responding to their concerns, answering their questions, and reinforcing the fact that all existing agriculture exemptions and exclusions continue to apply under the Clean Water Rule.

Last year the EPA finalized volume standards for the Renewable Fuel Standard Program for calendar years 2014, 2015, 2016, and a volume requirement for biomass-based diesel for 2017. The final requirements boost renewable fuel production and provide for robust, achievable growth of the biofuels industry. Overall, this final rule requires that total renewable standards grow by more than 1.8 billion gallons from 2014 to 2016, requiring 11 percent more biofuel production than the market produced in 2014. Our 2016 advanced fuel standard is nearly 1 billion gallons, or 35 percent, higher than 2014 actual volumes. The biomass-based diesel standards increases every year, to reach 2 billion gallons by 2017. That is a 23 percent increase over 2014 actual volumes.

The EPA took steps to improve the administration of the RFS Program, and continues to approve new agricultural feedstocks, increasing the number of pathways that biofuel producers may use to qualify their biofuel under the program. We improved the quality, transparency, and efficiency of our petition review process for new biofuel pathways, and conducted lifecycle analysis on several new feedstocks. The EPA remains committed to the Renewable Fuel Program, and meeting Congress's intent to responsibly grow renewable fuels over time.

I recently announced increased protections for the nation's two million agricultural workers and their families. Every year thousands of preventable pesticide exposure incidents cause sick days, lost wages, and medical bills. We can do better. The EPA's update reflects extensive stakeholder involvement from the agriculture community, industry, and Federal and state partners. These provisions will help ensure that farmworkers nationwide receive annual safety training, prohibit children from handling agricultural pes-

ticides, and provide workers with the tools needed to protect themselves and their families from pesticide exposures.

Again, thank you. I am happy and I am honored to be here to answer your questions.

[The prepared statement of Ms. McCarthy follows:]

PREPARED STATEMENT OF HON. GINA MCCARTHY, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY, WASHINGTON, D.C.

Good morning, Chairman Conaway, Ranking Member Peterson, and Members of the Committee. Thank you for the opportunity to discuss the EPA and agriculture.

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Nutrient Recycling Challenge

Working with USDA, and partnering with pork and dairy producers and technical experts, we recently launched an initiative promoting recycling nutrients from livestock waste. Annually, livestock producers manage more than 1 billion tons of manure containing valuable nitrogen and phosphorus, a resource as a renewable fertilizer, and used properly, can minimize water pollution and build healthy soils. Challenge participants will harness the power of competition, turning innovative concepts into designs, and ultimately working technologies, creating solutions that are a win for farmers, the environment and the economy.

Local Foods, Local Places

The EPA also partners with USDA in the "Local Foods, Local Places" project, promoting walkable, healthy, and economically vibrant neighborhoods through farmers' markets, co-ops, community gardens, and other local food enterprises. Focusing development in existing neighborhoods helps support farm economies and protect undeveloped rural lands. Last month we announced 27 new communities, serving 62 communities in 29 states since starting in 2013.

Clean Water Rule

The Clean Water Rule protects the streams and wetlands that one in three Americans rely on for drinking water, and farmers and ranchers need for their crops and livestock. As Members of this Committee know, recent Supreme Court rulings created uncertainty regarding the application of the Clean Water Act to streams and wetlands. In developing the rule, the EPA and the U.S. Army responded to requests to define the scope of the Clean Water Act more clearly, predictably and fairly. In doing so, the Clean Water Rule not only maintains current statutory exemptions, it expands regulatory exclusions from the definition of *waters of the United States* to make it clear that the rule does not add any additional permitting requirements on farmers and ranchers and promotes their voluntary efforts to protect and enhance clean water. We continue outreach to the agriculture community, responding to their concerns, answering questions, and ensuring that all existing agriculture exemptions and exclusions continue to apply.

Renewable Fuel Standard

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proved the quality, transparency, and efficiency of our petition review process for new biofuel pathways, clarified qualifying biofuels, and conducted lifecycle analyses on several new feedstocks. The EPA remains committed to the RFS program and meeting Congress's intent to responsibly grow renewable fuels over time.

Agricultural Worker Protection Standards

I recently announced increased protections for the nation's two million agricultural workers and their families. Every year, thousands of preventable pesticide exposure incidents cause sick days, lost wages and medical bills. Changes to the agricultural worker protection standard reduce the risk of injury or illness resulting from contact with pesticides while on the job.

The EPA's updates reflect extensive stakeholder involvement from the agricultural community, industry, and Federal and state partners. These provisions help ensure farmworkers nationwide receive annual safety training, prohibit children from handling agricultural pesticides, and provide workers with the tools needed to protect themselves and their families from pesticide exposure.

Conclusion

Thank you and I am happy to answer your questions.

The CHAIRMAN. Well, thank you, ma'am. The chair would remind Members that they will be recognized for questioning in the order of seniority for Members who were here at the start of the hearing. After that, Members will be recognized in the order of arrival, and I appreciate Members' understanding. So, with that, I recognize myself for 5 minutes.

Again, thank you for being here. With the 6th Circuit's ruling on the Clean Water Plan, difficult to say for those of us from west Texas, the legitimate concern that, given that both of those involve what we believe is an overreach by the Agency, going around Congressional intent, going around the law, can you talk to us about efforts that your Agency will make on the intervening 11 or so months that you will be there to obey the Supreme Court and the 6th Circuit? Will you commit to not trying to go around the courts with other ways to get at what you are trying to get done?

Ms. MCCARTHY. Mr. Chairman, EPA is actually trying to do what Congress told us to do with the authorities we have, and we feel confident that both of those rules will be seen as an appropriate, and proper, and necessary application of the law. If you look at the Clean Water rule, the reason we did it was to try to clarify confusion that the Supreme Court actually raised and created in a couple of their decisions since the beginning of the last decade.

On the Clean Power Plan, it is a pause in terms of the implementation and enforcement of the Clean Power Plan, but the rule is still in effect, and it will add some time to resolve those issues through the courts, but we feel very confident that it is going to be borne out to be a legal, lawful, and necessary law.

The CHAIRMAN. Right. It is not unexpected for you to take that position.

Ms. MCCARTHY. Well, thank you for listening.

The CHAIRMAN. It shouldn't be unexpected.

Ms. MCCARTHY. I appreciate it.

The CHAIRMAN. We have 31 lawsuits, Attorneys General across the country, farmers and ranchers, those who tried to look at it, disagree. What I asked, though, was what will you do now, while those rules, or regulations, are stayed from implementation? Do we need to restrict your funding in the appropriations bill to say no monies will be spent on back door implementation of either the Clean Water Plan or the Clean Power Plan?

Ms. MCCARTHY. Actually, what we are trying to do, sir, is make sure that the guidance that is currently in place in the Clean Water Rule that was issued in 2008 is implemented as well as we can. We are certainly going to respect the decisions of the court. But, as we have heard, there is a lot of confusion. There are a lot of differences in those decisions, so we are working with the Army Corps of Engineers to make sure that we are implementing what is currently in place as best we can, try to avoid some of those confusions, while we hope to bring additional clarity when the Clean Water Rule makes its way through the courts.

On the Clean Power Plan, we will still continue to work with states that, on a voluntary basis, want to move forward with us, and we will continue to provide tools and outreach. But we clearly understand that the courts will be winding through the process of looking at that rule. The issue yesterday meant it is going to take a little longer for that to happen. We will respect that, but, in the meantime, we are going to continue to address greenhouse gases with the authorities under the Clean Air Act that are available to us today.

The CHAIRMAN. Okay. Clearly there is a pretty sizable difference of agreement that the authorities that you used to issue those rules were an overreach, and so I am a little troubled by that. Can you talk to us about the input that you take from USDA with respect to pesticides, and the work that you are doing there? Are you ignoring USDA? I will give you a softball, because I suspect you will say no, but can you help us understand that you do, in fact, value the expertise and the longstanding trust that farmers and ranchers have with USDA in this arena, and the distrust that has been created with the EPA over the other things that are going on? You can't just separate the issues in a vacuum. They are not siloed up. Our farmers and ranchers feel under attack. So talk to us about your respect for the USDA, and their opinions on pesticides.

Ms. MCCARTHY. Well, sir, I work very closely with Secretary Vilsack, and my staff work very closely with USDA. We have great respect for that Agency, the scientific expertise they bring, and their full knowledge of the agriculture community. There are laws that require us, even before we propose rules, to consult with USDA, and we do that. And then we work very closely with them in the inter-agency process to resolve differences. So we have a close collaborative relationship. At times we may disagree, but it is usually about what the law requires us to do, and there is good discussion, and we always try to understand the science together, and make the appropriate decisions.

The CHAIRMAN. All right. Thank you, ma'am. I yield back. The Ranking Member, 5 minutes.

Mr. PETERSON. Thank you, Mr. Chairman. I want to focus on this Clean Power Plan a little bit too. So we are kind of caught between a situation up in my district. The rural electrics get their power from North Dakota, but, obviously we are in Minnesota. Well, Minnesota is apparently working with you guys on whatever you are up to, and North Dakota is one of those that sued you.

So when you say you are going to work with states, does that mean you are going to work with Minnesota, and continue to develop a plan with Minnesota while this is going on?

Ms. MCCARTHY. Well, we will continue to work with them on a voluntary basis, but nothing will be implemented while the stay is in place. So if Minnesota wants help and tools, we would always work with every state that does that. But in terms of actual enforcement of anything, it is clearly on hold until it resolves itself through the courts.

Mr. PETERSON. Well, one of our concerns is there was, apparently, a 2014 proposal, and then it was finalized, and in North Dakota you went from 11 percent to 45 percent emissions reductions, the biggest increase of any state. Well, our rural cooperative out there in North Dakota, they did some updates to their plants, back in 2005 or something, 2004, and put $426 million in improvements in their firewalls and so forth, and then the EPA determined that that was a major overhaul, or whatever it was. So you forced them go under some new program to put in scrubbers, and a whole bunch of other stuff. They sued you. The end result of that was they spent $426 million. And my real question is: what that did is it dropped the equity in that co-op from 24 percent down to 12 percent. Are you aware of that?

Ms. MCCARTHY. Not the specific instance in which you are referring, sir.

Mr. PETERSON. And so they had signed an agreement with the RE West to get financing for this $426 million that you forced them to do. And it says that they can't go below a ten percent equity in that co-op. Well, they are down to 12 percent now. And if this is implemented, they will be down to five percent. So they are going to be in violation of the situation with the EPA. Are you aware of that?

Ms. MCCARTHY. Well, sir, if you are referring to the application of the Clean Power Plan? Is that what we are talking about there? I know that you were referring to some of the regional case decisions.

Mr. PETERSON. They borrowed money to comply with your other situation. And in order to get that money they had to agree not to go below ten percent.

Ms. MCCARTHY. Right.

Mr. PETERSON. So now, if you implement what the Clean Power Plan says, you are going to force them way below ten percent. They don't have the money to do this anymore. You have already taken all their money, and there is no other way in Minnesota—they won't let them build a power plant, so the only thing we can do is get electricity from Canada, if you go ahead and complete this? So we are kind of stuck in this whole thing.

I was going to ask you today to delay this to give us maybe 10 years to try to comply with this so we don't go bankrupt. But now, with this stay, and I don't know where we are at anymore, but, I mean, somehow or another we need more time to——

Ms. MCCARTHY. Well, sir, we are more than happy to work with the state, and, in fact, we have been out there. One of the things we did was extensive outreach on this, and there was concern in some states about whether or not they would internally, in that state, be able to make things work. We added huge amounts of flexibility in this, and we also engaged USDA, the Rural Utilities Service, to work with us and with the rural co-ops. We understand

that they have unique challenges, and we are not going to leave them behind. They deal with some of the poorest communities, that cannot afford to have energy increases.

Mr. PETERSON. That is exactly correct.

Ms. MCCARTHY. And so there are a number of programs that we are bringing to bear, as well as flexibilities that will not require every facility to make investments.

Mr. PETERSON. Well, for whatever reason, they seem to think that you are not going to have flexibility, and not listen to them. I don't know why. And some of this power from these plants goes to North Dakota, but the majority goes to Minnesota, and we are kind of stuck in this whole thing. And, I am glad to hear that you are willing to work with them, but that is not what they have heard. After they spent that $426 million, then you went after them on Hayes, and we were able to get that stopped. That would have been another thing that would have bankrupted them. So they just feel like they are in the middle of a whole deal, and they are not listened to, so if you——

Ms. MCCARTHY. Well, I am happy to personally engage as well. I have been meeting with the rural electric——

Mr. PETERSON. I will send them over to your office, and you can deal with them.

Ms. MCCARTHY.—co-ops, so—okay, sir.

Mr. PETERSON. All right. Thank you.

The CHAIRMAN. The gentleman yields back. Mr. King, 5 minutes.

Mr. KING. Thank you, Mr. Chairman. Ms. McCarthy, I am over here, and I appreciate your testimony, and your service here, a good number of things pop up in our minds that—or come to our attention. I am just looking at a few headlines here, *6th Circuit Puts Controversial Waters of the United States, the WOTUS Rule, On Hold.* There is another article that addresses the Clean Air Act, on hold. And as I am watching this, it seems as though the Agency has been pushing back against, especially our farmer producers, and our people that care about and value their productive real estate.

I just had a couple of phrases here that I have seen emerge from the EPA over the years, and I wanted to start with this: *water is hydrologically connected to.*

You are familiar with that phrase, and you are also familiar with the phrase *significant nexus.*

Ms. MCCARTHY. Yes.

Mr. KING. Now, would you have a judgment on which one of those is the most ambiguous?

Ms. MCCARTHY. Well, the Clean Water Rule actually tries to provide clarity to both of those. The ambiguity arose when the Supreme Court actually raised these issues and suggested that EPA needed to resolve these. That is what the Clean Water Rule is all about.

Mr. KING. And, of course, I am about clarity, of course, too.

Ms. MCCARTHY. Me too.

Mr. KING. So with regard to clarity, with the Renewable Fuel Standard, you have taken a position in past years, back in about 2012 or 2013, that we had short grain supplies, and high grain prices, therefore you rolled back the directive on the RFS. And I

will just focus particularly on corn-based ethanol for simplicity's sake here. And made that judgment administratively, even though the statute required that those gallons be more. I notice now that we have a high volume, over-supply of grain, and low prices that have dropped a little more than ½ since that period of time, and I don't notice that the same logic is applied when it comes time to adjust the RFS for current conditions.

So if it was a good idea to lower the RFS requirement for corn-based ethanol back when grain supplies were short and prices were high, why wouldn't it also be a good idea to raise it, at least up to the statutory standard, when grain prices are low and supplies are high?

Ms. MCCARTHY. So the Renewable Fuel Standard that we came out with provide us an opportunity to get back on track, as well as provide steady growth. The numbers that you are looking at in here is our assessment of what we can achieve attempting full bore to get to the statutory levels, but recognizing that leaps like this, in this short a timeframe, is not possible. So we want to achieve those statutory levels, we understand that is what Congress intended, but there is a growth that we need to recognize, and factors that impact that that we have to take into consideration.

Mr. KING. You are talking about production and capacity? You are talking about——

Ms. MCCARTHY. No, I am not talking about production capacity.

Mr. KING. Then what are you addressing?

Ms. MCCARTHY. I am addressing the ability for us to be able to get that fuel into the system.

Mr. KING. And that is the blend wall?

Ms. MCCARTHY. That is correct.

Mr. KING. And do you believe you have the administrative authority to abolish the blend wall?

Ms. MCCARTHY. Well, these numbers actually push through the blend wall, because we understand that we need to do that to continue investments in infrastructure——

Mr. KING. And that is answer is yes——

Ms. MCCARTHY.—that will be necessary to get to——

Mr. KING. Do you believe you have the administrative authority to do that, to abolish the blend wall?

Ms. MCCARTHY. I believe we are doing everything that the law says, which is to get to these levels as quickly as possible, but you have to think of factors like how reasonable it is to achieve these within this certain period.

Mr. KING. What about going to E15?

Ms. MCCARTHY. Yes.

Mr. KING. Do you have the authority to do that?

Ms. MCCARTHY. We actually approved E15 in use of specific vehicles——

Mr. KING. Year round?

Ms. MCCARTHY.—mostly the modern vehicles.

Mr. KING. Year round?

Ms. MCCARTHY. Yes.

Mr. KING. So we are past the E15 blend wall year round? There is no vapor pressure requirement that restricts it——

Ms. MCCARTHY. There is a vapor pressure requirement. Yes, there is, but we approve the use in the vehicles, and it can be used. There are certain places where——

Mr. KING. Okay. I am addressing practically speaking. I think I should have prefaced my question with that. Then, also, with regard to the testing of fuels, my information is that EPA relied on a Chevron consultant to design the test fuels. Are you familiar with that?

Ms. MCCARTHY. No, sir.

Mr. KING. Okay. I am going to pose some of these questions to you in a written form so you have an opportunity to digest them, and to answer them in a way that is not a high test area in the hearing here. I have a stack of questions I would ask that you respond to with regard to testing requirements, and compliance with the RFS. I would ask you one final question. If you were the Administrator of the EPA at the time that the RFS expires, sunsets, would you believe that you have the administrative authority to extend it beyond its sunset?

Ms. MCCARTHY. I am not aware that the RFS sunsets, sir. What are we referring to?

Mr. KING. Well, I will put that in my question to you too, the specific language that is in the statute.

Ms. MCCARTHY. Okay.

Mr. KING. And so that will all come to you, and we will look forward to working with you.

Ms. MCCARTHY. I will too as well.

Mr. KING. Thank you——

Ms. MCCARTHY. Thank you, sir.

Mr. KING.—very much, and I yield back.

The CHAIRMAN. The gentleman yields back. Mr. Costa, 5 minutes.

Mr. COSTA. Thank you very much, Mr. Chairman. And I want to thank the Administrator for being here this morning, and your efforts to help us solve problems. I want to continue the conversation for a moment on the Renewable Fuel Standard. Obviously there is a diversity of opinion as it relates to this Committee, and Members of the Congress, on how it is applied and implemented. But can you explain the process that the EPA will be taking to ensure that the 2017 rules are not delayed the way the 2014 rules were?

Ms. MCCARTHY. I can, sir. One of the things we made sure was to already propose a 2017 standard for biodiesel so that we could make sure to keep on track. And we have every interest, now that we are on track, to stay that way.

Mr. COSTA. For those of us who believe in alternative fuels and renewable fuels, but think that cellulosic fuels are really the next generation of this development, can you explain the update in the Inspector General's investigation regarding climate impacts on the Renewable Fuel Standard as to using food to produce fuel is the most effective way to do that, and whether that doesn't, in fact, create more pollution issues?

Ms. MCCARTHY. Well, I know that there have been a number of looks at this issue and investigations, but my job, as EPA Administrator, is to implement the law that has been given to me. And——

Mr. COSTA. Which you said is probably the most difficult law you have to implement?

Ms. MCCARTHY. It is a very difficult statute, yes. But it is very clear that cellulosic fuels have not progressed anywhere near what Congress anticipated, which is one of the reasons why those statutory levels are so difficult to meet.

Mr. COSTA. Well, I want to move on to some local issues. As you know, California is a very diversified state as it relates to its agricultural production. The Environmental Protection Agency recently issued a statement on a risk report indicating that citrus and cotton honey contained higher levels of neonicotinoids than other honey, which would be a risk to pollinators. Now, because of the diversification of our crops, clearly we are sensitive. We grow a lot of almonds in California. I think we gave you some. I am an almond grower myself. It does require bees, and we are sensitive to the pollination issues, and therefore the impacts of bee deaths and colony collapses, but why single out two commodities that don't require bees, at least in my state, that, in fact, we go out of our way to accommodate bees because a lot of the proximity of these crops are nearby each other? And, in fact, recent reports have indicated that colonies have propagated, and they are at higher levels now than the decline we experienced a few years ago.

Ms. MCCARTHY. Well, Congressman, we have been to your area of the country before together, and I understand how hard the almond growers actually work, not just to address the pesticide issues, but certainly to conserve water, and I appreciate very much all that work. We are happy to work more closely with you on neonicotinoids. The science is difficult, but it is growing, and it is getting more robust. We think we are following the science in our decisions, and if there are issues——

Mr. COSTA. Okay, but we are going to need——

Ms. MCCARTHY.—that we need to resolve——

Mr. COSTA.—more of your focus——

Ms. MCCARTHY.—we will be happy to do that.

Mr. COSTA.—on this. The Chairman and I last night were in a conversation with some orange growers who are dealing with citrus greening, and they really think that they are being singled out, because of the way in which the Environmental Protection Agency has approached this. And I will provide you more information to follow up. I want to, before my time expires, go to the larger issue that affects all of American agriculture, and that is the application of pesticides and herbicides, and EPA's registration process.

For most of us farmers, we live on our farms. The application of pesticides and herbicides is made with very cautious and cost-effective evaluations. We are concerned about the health impacts. We are concerned about the economic impacts. You are required to reevaluate your process on registrations every 10 years, but it seems the recent announcement portended for the adoption of precautionary principle. Can you comment on your precautionary principle, and do you believe that zero risk is possible when using application of herbicides and pesticides?

Ms. MCCARTHY. Sir, we do not utilize the precautionary principle. Our decisions are based on the law, which is based on risk.

Mr. COSTA. Do you believe zero risk is obtainable?

Ms. MCCARTHY. It is possible with some, but that is not the way in which our laws require us to look at this, and we do not utilize that as the——

Mr. COSTA. There have been court decisions, and my time is about to expire, where various applications of these pesticides and herbicides have been brought to the courts. And, in some cases we believe EPA has refused to defend its scientific decisions on the challenges of these courts. This is very serious. You are supposed to be the clearinghouse.

Ms. MCCARTHY. Yes. Well, we vigorously defend our decisions in court. We do that because we believe we did the right decision, based on science and the law. There are times when even a vigorous defense does not carry the day in the court, and we have to abide by those decisions. But in no way are we backing off of our decisions, and the way in which we have always made them, which is based on the law that exists. And we are continuing to apply that, and vigorously defend it.

Mr. COSTA. Well, thank you, Mr. Chairman, and I will have more information to follow with the witness. Thank you.

The CHAIRMAN. The gentleman's time has expired.

I now recognize Mr. Rogers from Alabama, 5 minutes.

Mr. ROGERS. Thank you, Mr. Chairman, and, Administrator McCarthy, thank you for being here today. I am sure it is not a surprise to you when I tell you that me and my farmer constituents are very worried and upset over the number of regulations coming out of the EPA that negatively impact them. First of all, are you cognizant that there are those concerns by American farmers, and is there anything that you are planning to do to address that perspective that they have of your Agency and its regulations?

Ms. MCCARTHY. Well, yes, I am aware. There is a lot of work that we need to do to establish a stronger trust relationship between the agriculture community and EPA. I have been working hard for the last few years, trying to get out to farms, meeting with every farmer, rancher, and forester that wants to sit down. I am trying to work through the issues, and listen closely, and learn.

Mr. ROGERS. Are there any fundamental changes that you think that you are going to be able to make—plan to make that would remedy or alleviate some of those concerns?

Ms. MCCARTHY. Well, to implement the laws as effectively as I can. As I noted, we have a number of voluntary programs that we are initiating back and forth. We have new advisory groups being started. I think the most important thing we can do is listen to one another, and try to identify the path forward that meets our shared goals, because we certainly share the goals of wanting to protect the environment.

Mr. ROGERS. Well, I agree. I think that listening is a good first step, but you also have to be prepared to act.

Ms. MCCARTHY. Yes.

Mr. ROGERS. And it may mean act in a different way. But anyway, I am glad you mentioned voluntary programs. I believe we need to encourage programs that provide farmers with the resources they need to work with states, and not the EPA, on water quality problems. Congress did not give the EPA regulatory authority over family farmers. I am concerned that the EPA is moving

away from voluntary programs that have verifiable results, and instead intends to create burdensome regulations. Do you agree that voluntary programs are important, and an effective way to help reduce pollution, or is the EPA trying to expand its regulatory authority over non-point source pollution?

Ms. MCCARTHY. Absolutely I agree that voluntary programs, as well as technical support and funding support from the Federal Government, is an essential way in which we need to move forward and work together, and that is the vast majority of our relationship.

Mr. ROGERS. Okay. Where in the Clean Air Act did Congress give the EPA authority to regulate sustainability of agriculture, nonproduction practices on farm fields? I don't see that precedent anywhere.

Ms. MCCARTHY. Under the Clean Air Act, is that what you said, sir?

Mr. ROGERS. Yes.

Ms. MCCARTHY. I do not know whether the word *sustainability* is written into any law. I think it was an outcome of understanding, that we need to understand the lifecycle, and all of the challenges associated with clean air and other requirements that are being placed on our constituencies, including farmers, ranchers, and foresters. And it was an open dialogue to understand how our rules can enhance not just their health and our health, but our viability as a sector. I think that is what sustainability is intended to make sure, that we are thinking about this in a common sense, holistic way, not a narrow, media by media approach.

Mr. ROGERS. I agree, but it didn't give the legal authority to the EPA. What I am looking for is: do you see in that Act the legal authority to regulate sustainability?

Ms. MCCARTHY. We do not regulate sustainability. We do regulate pollutants under the Clean Air Act, one of which are greenhouse gases. If that is what you are referring to, sir, that is because, under the Clean Air Act, the Supreme Court clearly told us that we had to look at greenhouse gases as a potential pollutant, and if we found that they were an endangerment, then we had to take appropriate action. That is what we are actually doing.

Mr. ROGERS. That is the precedent I am looking for. Could you have someone on your staff get me a copy of that Supreme Court interpretation?

Ms. MCCARTHY. Absolutely.

Mr. ROGERS. I would appreciate that. And finally, GAO released a legal decision that the EPA was violating publicity, propaganda, and anti-lobbying provisions contained in previous appropriations bills and your Agency, according to GAO, has been using social media for covert propaganda. What is your side of that?

Ms. MCCARTHY. Well, as you might guess, we don't agree. We do not believe that we have violated any provisions. The GAO looked at thousands of social media posts that we actually do every day, because that is how we do our outreach and education. That is all that they were. They found two instances that raised questions for them. We disagree with their decision, but we certainly are working with OMB to make sure that we have followed every one of their procedures, and we do everything we need to do.

Mr. ROGERS. Thank you, ma'am. I yield back.

Ms. MCCARTHY. Thank you.

The CHAIRMAN. The gentleman's time has expired. Mr. Walz, 5 minutes.

Mr. WALZ. Well, thank you, Mr. Chairman, and thank you Administrator for being here with us today. I appreciate the work that you have put on this. I appreciate the visits you have taken to farm country, and am curious a little bit about what you are hearing out there. But I remain the optimist that I do think it is possible in this nation to produce food, to continue to feed, fuel, and clothe the world, at the same time addressing real world issues of clean air, clean water, and environmental sustainability. And I think that is what we are all trying to get at.

A statement that comes up often with my producers out there—and these are folks that are committed to this, they don't deny the science, they understand the importance of regulatory humility.

Ms. MCCARTHY. Did you say——

Mr. WALZ. *Regulatory humility.* Just a sense of working with—I have used the term before—a bit of a bunker mentality about all these things keep coming down without asking us. And Mr. Rogers was getting at it, and I agree, I am very proud of the work that this Committee did, and many of our folks working on the last farm bill, on the conservation piece of it. That conservation title was lauded by many as being one of the strongest ever across the spectrum, from producers to environmental groups.

And you kind of hinted at it, but are those working? Are those making a difference? Because my attitude on this is we are far better ahead if we can prevent a problem than dealing with it afterwards, and getting into the courts, and everything else that comes with that. Are some of those working? And if you could maybe pick out one that you think is the way to go?

Ms. MCCARTHY. Yes. I think the conservation efforts are absolutely working, and you can see that in many locations. Do we need to do more? Absolutely, but that is the approach in which EPA certainly prefers and takes. And, if I wanted to highlight any, I think that it would be in the Great Lakes area, areas in which we are actively supporting conservation efforts, and doing that in a way that will help us prevent pollution into the Great Lakes, which are causing these harmful algal blooms.

There is a collaborative spirit. There is funding. There is technical resources provided to this. These are the kind of programs we need to have to move forward, and EPA is working every day with USDA and the NRCS to see how we could advance their mission as a way to advance our own. I do not need to duplicate it. I need to respect what they do, and help support that, and identify ways of appropriately expanding that in areas where we find there are challenges.

Mr. WALZ. I think that story needs to get out there, because I agree. This is about helping us reach a common goal, not telling us. And I think that telling us attitude, whether it is perceived reality, or is reality and a lot of people feel that way.

Ms. MCCARTHY. I know.

Mr. WALZ. And, if I could, some of it comes from this statement. This is the one that is confusing on this. Two statements were

made. I think your Agency stated that three to five—approximately, I am not holding you to that—three to five percent more jurisdictional waters, but we were also told, and the red line for me was, if you didn't need a permit before, you won't need one now. You can't have both those statements, can you?

Ms. MCCARTHY. Yes, you actually can, and let me just try to explain it. The increase in jurisdictional water determinations is because the rule is much more specific about what is jurisdictional and what is not, so there is not significant amount of time wasted asking in areas where there is no jurisdiction, or where we well know that, from our history, there is a direct hydrologic connection that is significant enough to warrant protection. But in terms of the agriculture community, there is no added permit burden.

Mr. WALZ. Unequivocally? I can go back——

Ms. MCCARTHY. None.

Mr. WALZ.—to every one of my producers and say, the way you are doing things now, if you were up to standards, nothing changes?

Ms. MCCARTHY. That is correct. We have actually expanded clarity on some of the exemptions and exclusions so that we can make that clearer and clearer as time goes on.

Mr. WALZ. Thank you. I am going to segue again just a little bit, because we mentioned that collaboration with USDA. What conversations happened on RFS, if you could, in dealing with——

Ms. MCCARTHY. With USDA?

Mr. WALZ. Yes.

Ms. MCCARTHY. Lots, at every level.

Mr. WALZ. Extensive all the way through the——

Ms. MCCARTHY. It is, both in how we look at feedstocks, how we look at those lifecycle impacts, to the numbers we should put in, to what can be produced, what can be consumed, what can USDA do, like their advancing of blender pumps, what does EPA need to do to make sure those blenders can actually go out there, and all those blends be utilized? We work pretty constantly on RFS together.

Mr. WALZ. And I appreciate that, and I know you do it to the best of your ability, the idea is to get out there and make those statements, show that collaboration. And, again, coming back to that *regulatory humility,* that we are in this together, we have common goals, but——

Ms. MCCARTHY. That is a term I will take to heart as I leave here. Thank you so much.

Mr. WALZ. Thank you, ma'am.

I yield back.

The CHAIRMAN. The gentleman yields back. Mr. Thompson, 5 minutes.

Mr. THOMPSON. Thank you, Mr. Chairman. I haven't seen a lot of regulatory humility, at least since I have been here. It is more, unfortunately, just my opinion, regulatory arrogance. Administrator, thank you for being here. I appreciate you coming, sitting in the seat, taking tough questions, and your responses. I want to follow up on Mr. Rogers's questioning, the response to the last question on this side, regarding the use of social media.

Ms. MCCARTHY. Yes.

Mr. THOMPSON. I found it interesting, since the EPA disagrees with the regulations that they have been confronted with, and basically they disagree with the regulators that were responsible for that, were wrong, in your interpretation, you are not changing your practices. So my question is, can my farmers do the same thing? Can they? I mean, they disagree with the EPA, where there is a question of authority as a basis of legislative language, as a basis of a now growing trend, and serious numbers of Supreme Court rulings. Do they get the same pass that it seems like your Agency is choosing to do when your feet are held to the fire under regulations?

Ms. MCCARTHY. We are not doing anything that would skirt the decision that GAO made, their interpretation of the law. Our Office of General Counsel believes that they are incorrect in their interpretation.

Mr. THOMPSON. So——

Ms. MCCARTHY. Nevertheless, we have——

Mr. THOMPSON. So what you are saying—okay. We gave you——

Ms. MCCARTHY. But nevertheless, we are actually working with——

Mr. THOMPSON. If my farmers get an army of——

Ms. MCCARTHY.—OMB on what the appropriate response is to that. So they do they have their opinion, we will respond appropriately to it, but we still have a right to say that legally we don't think they were correct.

Mr. THOMPSON. Sounds like——

Ms. MCCARTHY. That is all.

Mr. THOMPSON.—my farmers would be better off if they had an army of government paid attorneys, that is my question, though. That just happened to come up. Many believe that the Chesapeake Bay TMDL represents a massive seizure of state government power by your Agency, and will serve as a blueprint for regulating watersheds around the nation. Now, through its standards, controls, and rigid rules the Agency is setting the stage for taking over many, if not all, land use decisions nationally. Really a private property grab, in effect becoming a national zoning board. The TMDL is already having devastating impacts on farmers. In defending the TMDL, currently on appeal to the Supreme Court, your Agency has defended it, saying that the states are developing their own standards.

Now, let me read to you what one state in the Chesapeake Bay Watershed, Delaware, not my state, wrote of this *voluntary* procedure in its watershed improvement plans. The state wrote that, if the program fails to meet standards acceptable to the Agency, then "the EPA has identified a set of potential consequences to impose. These consequences range from the EPA taking over responsibility for developing the plans to increasing their regulatory oversight, and extending their regulatory authority to additional sources of pollution." In short, this quote is articulating that if each state's watershed improvement plan doesn't meet EPA standards, the EPA can then force its own plan on the states, along with punitive actions.

My question is, with all of this authority, in what sense was there anything voluntary about this process? Your Agency, directly

and indirectly, told states that it wanted what it wanted, made it clear that there would be consequences to not delivering on what it wanted, the standards and plans it expected. How is that voluntary?

Ms. MCCARTHY. Well, sir, let me try to answer that question. The Chesapeake Bay TMDL was an opportunity for a number of states who share a common, both environmental and economic, interest in having a healthy Chesapeake Bay. That program allowed them the opportunity to actually meet compliance, with reducing the standards necessary to get that healthy again in their own way.

Mr. THOMPSON. And as the Chairman of the Subcommittee that includes watersheds, I love the Chesapeake, and——

Ms. MCCARTHY. Right, I know.

Mr. THOMPSON.—we are achieving that, but we are just—I am talking about the overreach here.

Ms. MCCARTHY. But we have never——

Mr. THOMPSON. That is just——

Ms. MCCARTHY.—actually had to intervene. There is great progress being made through the efforts that each state has been taking. They do care about the Chesapeake, and they are making progress. The question was asked, what if people don't do anything? Well, there is no question that TMDLs are a regulatory requirement, and so there are things that we could do if there isn't continued progress as anticipated. We have never had to use that.

Mr. THOMPSON. Well, ma'am, I——

Ms. MCCARTHY. And we don't expect——

Mr. THOMPSON.—would refer you to the transcripts of when our Subcommittee on Conservation and Energy Watersheds met, and your individual in this Philadelphia office clearly said this was not a regulation because it was voluntary, and then it was some of the most confusing testimony we ever heard, because it is being aggressively implemented as a regulatory action, yet, clearly it was overreach to the 10th degree. And I appreciate your response, but the uncertainty is still in there.

The CHAIRMAN. The gentleman yields back. Ms. Fudge, 5 minutes.

Ms. FUDGE. Thank you very much, Mr. Chairman, and thank you, Administrator McCarthy, for being here today. I am going to go strictly local today.

Ms. MCCARTHY. Okay.

Ms. FUDGE. I live on the banks of Lake Erie in Ohio. Lake Erie provides drinking water to millions, and supports thousands of jobs, and contributes over $1 billion to our local economies. Yet harmful algal blooms are only intensifying each year, and we are persistently faced with the threat of open dumping that we believe to be harmful sediment into open Lake Erie, and we believe that it is an adverse decision by the Army Corps.

Despite the great progress made in reversing past environmental damage, we find ourselves locked in an ongoing battle over this seemingly non-controversial issue. The EPA plays a critical role in protecting drinking water and the health of our lakes. What are you and your Administration doing to ensure the continued growth and recovery of Lake Erie?

Ms. McCARTHY. Well, I am familiar with the issue you raise with the Army Corps, and I am hoping my understanding is correct, that the Corps is working with the state, and all the constituents, to identify ways to stop dredge disposal in Western Lake Erie. But as you also know, we are working very hard through our Great Lakes Initiative to actually understand the science in Western Lake Erie, understand where the sources of the nutrients that are contributing to those algal blooms are, and we are actually supporting it with $11 million from EPA's funds to try to help those upstream farms and agriculture to find ways of taking conservation efforts, and other voluntary actions, that will begin to make a real dent in the challenge we are facing in Western Lake Erie.

Ms. FUDGE. Well, thank you, but I certainly hope that you would check further, because it is my understanding at this point that even though a court has decided that it is not appropriate for them to dump the sediment into the open lake, the Army Corps has decided that they are not going to comply with the court order.

Ms. McCARTHY. I didn't hear that.

Ms. FUDGE. And so it is important that we move expeditiously to determine why, and why they have not requested the resources that are necessary to contain the sediment.

Ms. McCARTHY. Okay.

Ms. FUDGE. So I would ask that you would check that further?

Ms. McCARTHY. I am happy to do that.

Ms. FUDGE. Thank you. The growth of urban agriculture is vital to solving the issue of food deserts in many low-income neighborhoods, many of the ones that I serve. In post-industrial cities, such as Cleveland, historical contaminants in the soil can stall the growth of these programs. What role is EPA playing in ensuring urban land is safe for farming?

Ms. McCARTHY. Well, one of the efforts that I mentioned early in my oral testimony was the Local Food, Local Places effort, which adds enormous opportunities for urban communities that are literally food deserts, and to open up and do planning, and to bring Federal resources to the table that is really focused on food first, instead of as an afterthought.

There is a great change that is happening in urban areas, understanding the need for locally grown food, and the value that that can bring not only for the health, but the vitality of the community. I would really encourage anybody's active participation in the Local Food, Local Places initiative, because that can bring brownfield redevelopment resources to the table that would address the soil contamination issues you are identifying. Many of those turn into vital places for communities to gather and grow food, so do not give up in an urban area on the ability to grow food, and to make that part of the community revitalization efforts that everybody is looking for.

Ms. FUDGE. Thank you. And last, seasonal agricultural runoff is a factor to the growing problem, of course, of algal blooms in the lake. What steps is EPA taking to address the lingering pollutants still contaminating river and stream sediment?

Ms. McCARTHY. Well, a couple of things. We have mentioned the Great Lakes Initiative, but most importantly, that is our collaboration with USDA, as well as looking at areas of concern in the Great

Lakes where we know we have significant sediment and water contamination. So it has to be a combination of all of those efforts. It is not just about stopping what might continue to be coming in, but it is looking at those hot spots, if you will, so that we can continue to make progress, which we have made tremendous progress on. But that is one of the three areas that the Great Lakes Initiative is focusing on in the coming years.

Ms. FUDGE. Thank you very much. Mr. Chairman, I yield back.

The CHAIRMAN. The gentlelady yields back. Mr. Neugebauer, 5 minutes.

Mr. NEUGEBAUER. Thank you, Chairman. Thank you for holding this hearing. Administrator McCarthy, in my area, the prevalence of herbicide resistant pig weed has become a major——

Ms. MCCARTHY. I am sorry, where are you? I am sorry, I can't see you. Thank you. This layered look is hard for me.

Mr. NEUGEBAUER. I even got in a taller chair so you could see me. In my area, the prevalence of herbicide resistant pig weed has become a major problem that producers are having trouble combating. With everything else that is going on in the cotton industry right now, fighting this pig weed problem is the last thing they need, and it is becoming one of the greatest costs many producers face. USDA has approved Dicamba and 2,4-D, known as Enlist Duo, for use on cotton varieties with herbicide tolerant traits. EPA is now the sole holdup in getting this new, and severely needed, technology out to our producers. Can you give the Committee any update on where things stand at EPA, and what is the continued holdup by EPA?

Ms. MCCARTHY. Is this the Dicamba? In early 2016 we actually proposed for public comment a regulatory decision on Dicamba for the exact reasons you are talking about. We know that there is significant interest in this. There has been tremendous work on the science side. After the comment period we are going to review those comments, and see how the Agency can move to a final rule, so that we can get this done and over the finish line.

Mr. NEUGEBAUER. Now, could you kind of give me some encouraging timeline here that folks could look forward to?

Ms. MCCARTHY. Sir, we are working as hard as we can. We will get it done as soon as we can. If you would like me to reach back to you after the hearing, I can get more details on where we might be.

Mr. NEUGEBAUER. That would be helpful.

Ms. MCCARTHY. All right.

Mr. NEUGEBAUER. Enlist Duo also ran into some trouble last fall with EPA's decision to request that the court remand registration back to EPA for further review. This is only the first time ever that EPA has attempted to vacate a pesticide registration through a court action currently under FIFRA, and EPA is required to comply with a number of procedural safeguards before a pesticide registration can be canceled, which it has failed to do. What was the Agency's rationale for taking such an unusual step of asking the court to require EPA to review the registration of a product so recently approved for use, and why is the Agency now trying to use the courts as a means of regulation?

Ms. MCCARTHY. Actually, we weren't really trying to do that, sir. The 2,4-D decision that we made on Enlist Duo was a controversial one, as you may know, but we followed the science, and we followed the law. The awkward situation we found ourselves in is after the decision was made, while it was being challenged in court by the those that disagreed with our registration, we identified information that the manufacturer, Dow themselves, had put out, in other public venues, that raised concern that we did not have the full science data to make the decision in the most solid way we could, and actually address what might be synergistic effects.

So instead of waiting for the court to tell us that we had failed in our science decision, we wanted an ability to take that back, to work with Dow, to get additional information to address the issue and to move it forward again, which is exactly what we are doing. We are actually working with Dow about what the science is that they put out in other venues, what data did they have, what data might we need to actually re-do this decision in a way that we think will be legally solid and respectful of the full range of science.

Mr. NEUGEBAUER. Now, as to the question that you have not followed the law procedurally on this. Do you believe you have?

Ms. MCCARTHY. We do, and we think we actually did it in a way that will get to a decision much more quickly. The challenge is that Dow did not give us the full range of data, and we found it in another venue that was publicly available. So when we found that out, we worked with Dow, and we have a system to move forward to respect the full range of science that we are required to look at.

Mr. NEUGEBAUER. I am always interested in a timeline, you said quickly, and I have learned quickly in west Texas and quickly in Washington, D.C. doesn't necessarily have the same meaning.

Ms. MCCARTHY. I will double check when I go back, but I am pretty sure that we have already received a lot of the information that we have asked Dow to do on 2,4-D, so we don't think that there is going to be a significant delay in the reconsideration of this and moving it forward.

Mr. NEUGEBAUER. Well, on those two issues, Administrator, if you could maybe have your folks kind——

Ms. MCCARTHY. I will.

Mr. NEUGEBAUER.—of give me a timeline so that I can report back to the cotton folks?

Ms. MCCARTHY. I am more than happy to do that.

Mr. NEUGEBAUER. With that, Mr. Chairman, I yield back.

The CHAIRMAN. The gentleman yields back. Mr. Aguilar, for 5 minutes.

Mr. AGUILAR. Thank you, Mr. Chairman. Thank you, Administrator, for being here. I too will ask a little bit of a local question, if you don't mind. I represent the community of San Bernardino, that has been in the news recently, obviously, for some terrible acts. While climate change affects us all, this is incredibly personal for me, and the community that I represent. I can recall smog days growing up, where we weren't allowed outside because of the air quality levels, and this is particularly important because our community sits at the base of a mountain range that captures smog and air quality issues that mostly generate from out of the area and blow in with the trade winds.

I believe the National Ambient Air Quality Standards are a great benchmark for communities to strive for in order to improve pollution levels, however, San Bernardino has been in the unique predicament due to the fact that the smog from Los Angeles also contributes to the pollution in our region. Are there resources and tools that the EPA can offer San Bernardino County as it continues to work toward a management plan to improve air quality? If not, does the EPA plan to provide any sort of regulatory relief, or, as Mr. Walz coined, *regulatory humility* for counties and areas that are not in compliance?

Ms. MCCARTHY. Well, let me begin by expressing my sympathies——

Mr. AGUILAR. Thank you.

Ms. MCCARTHY.—to you, and to those in your community. The National Ambient Air Quality Standards rightfully establish by law health standards that we all strive for. We well recognize that California is challenged in meeting those, and there have been some unique tools developed that we had the authority to manage that have provided direct assistance for new technologies and other efforts to support the state's aggressive effort at looking at these areas.

There are also tools built into the law itself, so that, if you have a difficult challenge, you can't meet it, provides additional time and opportunity to get that done. And part of the value of the state planning process, and really the aggressive and—maybe *aggressive* isn't the word, but the collaborative process, the outreach that Region 9 does to its communities to try to work with them hand in hand to address these challenges is really of great value.

So I am more than happy to make sure that folks come and sit down, and see if there are particular issues of support that your community may need to build into a state plan that would help you achieve these standards quickly. But I want to just reinforce the fact that the law does not, nor does EPA, ever require more than can be done. We know that there are transport challenges, and there are unique geographic challenges that California faces. So while we hope to continue to make progress, we understand that that will take time, and it will take a collaboration, and it will take new technologies to advance this. And whatever is coming in from other communities is going to have to be a collaborative, multi-community effort.

Mr. AGUILAR. Sure. We just want to make sure that that is part of the discussion. And there has been a discussion and some flexibility in the past. We just want to make sure that those——

Ms. MCCARTHY. We will keep that up.

Mr. AGUILAR.—standards are still in place. And if we could follow up with your staff to have——

Ms. MCCARTHY. That would be great.

Mr. AGUILAR.—a little bit of a deeper dive, that would be very helpful to my office. But with that, I will yield back, Mr. Chairman. Thank you.

The CHAIRMAN. Thank you, Mr. Aguilar. The gentleman yields back. Mr. Gibbs, 5 minutes.

Mr. GIBBS. Thank you, Mr. Chairman. Administrator, first of all, thank you for being here. Let me start out for clarification, my col-

league, Ms. Fudge from Ohio, on the Lake Erie issue, there are two separate issues, the algae bloom issue in Western Lake Erie, you are correct, they do dredge and dispose on the lake. The issue which she was unclear on is the Cleveland Port issue. The Cleveland Port issue is a dredging issue. It is about PCBs in the State of Ohio, and the Ohio EPA has sued the Army Corps of Engineers over this issue. And it is interesting, your Agency has been silent on this issue. So I want to bring that to your attention, okay? And that is two separate issues there on Lake Erie.

I do want to talk about: in your testimony you talk about *Waters of the United States* Rule. I agree with you on one aspect of it. Farmers do want clean water and drinking water, so we agree on that. But my concern is, and it is evident by what has happened, within 24 hours, when you filed the final rule in the *Federal Register,* nearly 30 states filed a lawsuit. Now it is over 32 states have filed a lawsuit, and numerous organizations and entities are against this. And so it is clear that there is concern about this, and obviously the states, it erodes their states' rights.

And it needs to be made clear, when the Clean Water Act was passed, the intent of Congress was it was supposed to be a partnership between the Feds and the states, where the states would implement and enforce the Clean Water Act under the guidance of the EPA. Now, you made a statement here to answer to one of the questions you insinuated that if the rule had to be extended to include more waters, those waters are regulated. You are insinuating that states aren't regulating waters. Now, I, as a farmer, can't go out and dump my hog manure in any stream that is not WOTUS, *Waters of the United States.* I would be breaking the law. So I want to make it clear to the public that waters that aren't under the authority of the Federal Government are being regulated in that partnership agreement. And you agree with that, correct?

Ms. MCCARTHY. In many states.

Mr. GIBBS. But you do insinuate that, and so——

Ms. MCCARTHY. Well, it wasn't intended, sir. We are partners with the state——

Mr. GIBBS. Okay. Now, I also have a——

Ms. MCCARTHY.—they are primarily responsible.

Mr. GIBBS. I also have a concern that what is going to happen is it is going to require more permits, Army Corps of Engineers, and inefficiencies. But we risk the potential to go backwards in the progress we have made since 1972 in water quality, and protecting the environment in this country. Because when you add on so much more red tape and bureaucracy, people, at some point, throw their hands up in the air and say, "Well, I might not necessarily have gone the extra route I would have done. I am going to do just enough to get by, but I am not going to do it because this is just a bunch of nonsense, and a bunch of red tape." And the bureaucrats go crazy on them, so I want you to be aware of that fact, that this rule can make us actually go backwards in—and we are eroding that partnership agreement that was set up in 1972 with the states. And obviously, over 30 states have sued you over this, you ought to pay attention to that.

Now, I want to also get to the part about the GAO Inspector General report that came out and said that the EPA used covert

propaganda to bias and skew the comment period. I know some of the people are poo-pooing this, this is not a big deal. I think this is a big deal because it goes to the integrity of the whole comment period process. I mean, the process is there so the stakeholders can put in what they need to, comments, and it is up to the regulators to use their due diligence to figure out and make the best rule that works, and protects the environment in this case. And here you have the Inspector General of the GAO come out and say, you broke the law, and it goes to the integrity of the system.

So my question is what has the EPA done to initiate the reporting violation under the Anti-Deficiency Act, a copy to the Comptroller General, and the Congress, and the President, as required by the Anti-Deficiency Act, as you reported to us. What resources were expended on these legal activities, both monetary and full time equivalents? What internal action has been taken in your office to make sure this doesn't happen again, and has any internal action been taken to punish people that broke the law in this case? I will let you answer those questions.

Ms. McCarthy. Well, thank you, sir. I don't think that folks in the Agency broke the law, but let me answer your question directly. We are working with OMB—there is a draft letter at OMB to make sure that we are following our obligations under the law to respond appropriately to the GAO. I think the word *propaganda* is always construed as something horrible. The propaganda that they were referring to was not that we lobbied Congress. It was not that we said——

Mr. Gibbs. No, you were lobbying people to lobby us, because you were trying to educate them——

Ms. McCarthy. No, actually——

Mr. Gibbs.—that this was what you guys want. You guys are actually proponents of this, and now you have all the state EPAs suing you——

Ms. McCarthy. The propaganda——

Mr. Gibbs.—over it.

Ms. McCarthy.—issue was that——

Mr. Gibbs. Wake up.

Ms. McCarthy. The propaganda issue was that we used a system that OMB approves under their guidelines, which was basically a general message saying, I really care about clean water. And the GAO was worried that when other people——

Mr. Gibbs. Because you use a——

Ms. McCarthy.—retweeted that——

Mr. Gibbs.—system called——

Ms. McCarthy.—they didn't identify——

Mr. Gibbs.—Thunderclap where they couldn't——

Ms. McCarthy.—it as an——

Mr. Gibbs.—trace it back to the EPA?

Ms. McCarthy.—EPA message.

Mr. Gibbs. Did you use a system called Thunderclap that couldn't be traced back to the people putting it out? Is that true? Is that——

Ms. McCarthy. I am sorry?

Mr. Gibbs.—my understanding—pirate social media called Thunderclap, I believe——

Ms. MCCARTHY. That was the social media——

Mr. GIBBS. And that that can't be traced back to the people that are putting it out? Is that true?

Ms. MCCARTHY. No. What happened is we put it out, other people re-tweeted it, and when they re-tweeted it, GAO thought that it wasn't their message, it was EPA's message, and we didn't properly identify it as such. That is what they said. But it was a general message, "I like clean water." The other was a blog that had a hyperlink where we referenced a really cool program that——

Mr. GIBBS. Well, all I know is——

Ms. MCCARTHY.—that NGO was doing——

Mr. GIBBS.—as an oversight——

Ms. MCCARTHY.—and they were worried about.

Mr. GIBBS.—oversight, the GAO said you broke the law, so——

Ms. MCCARTHY. But I don't want to minimize it, sir. We will pay attention to what GAO said, and we do have a letter in the process to meet all obligations. We just disagree that it was a problem.

The CHAIRMAN. The gentleman's time has expired. Ms. Adams, 5 minutes. Ms. Adams?

Ms. ADAMS. Thank you, Mr. Chairman, and Madam Administrator, thank you so much for being here. While many are concerned about Federal overreach and environmental management, actions by the State of North Carolina resulted in tens of thousands of tons of coal ash spilling into the Dan River in 2013, and the state refused to use its own authority to enforce proper maintenance and relocation of coal ash ponds at high risk of spilling into other drinking water.

Administrator McCarthy, it is important that we together defend and uphold the EPA's final rule on the disposal of coal combustion residuals from electric utilities. EPA's final rule on coal ash disposal can only be enforced by states or by a citizen that sues a company, or a state that violates the regulation. It is for this reason that I am drafting legislation to strengthen protection and enforcement of rural water sources, which would provide rural communities with the same requirements that citizens in North Carolina now enjoy. Specifically, the bill would require coal ash pond owners and operators to be transparent in their surveying and monitoring of the quality of water in our communities. The bill mirrors laws that have already been passed by the North Carolina General Assembly.

My question is, given the continuing threats of coal ash disposal, what is EPA doing to assess and prevent drinking water contamination and the risk of catastrophic collapse?

Ms. MCCARTHY. Well, as you know, we take this issue very seriously as well. Certainly there have been disasters that we need to make sure don't get repeated. So, as you know, we just recently finalized the Coal Ash Rule. That looks at two things. One is the structural stability of those units, so that we can make sure that they are stable, and they are being properly inspected, and, if necessary, repaired. The second is to make sure that groundwater is protected and actually cleaned up. And that rule has requirements for both of those efforts. And we have information on the web so that people can see what is being done, and what we have identi-

fied, in terms of our assessment of that structural integrity so that information can be available to the surrounding communities.

Ms. ADAMS. Thank you. Will EPA provide technical assistance to low-income and minority communities so they are aware of, and can understand, the information about coal ash dumps that utilities are beginning to disclose?

Ms. MCCARTHY. Congresswoman, this is the first time I am aware that you are contemplating this type of legislation. We are happy to work with you on language around that, and talk about what authorities the Agency might have to support this effort, even in advance of that legislation moving forward.

Ms. ADAMS. All right, thank you. The Center for Public Integrity found that your Civil Rights Office has dismissed nine out of every ten claims by communities alleging environmental discrimination, and have never issued a formal finding of a Title XI violation. Given this poor performance record of EPA's Office of Civil Rights, do you have any thoughts about why EPA hasn't ever made a finding of discrimination under this Title?

Ms. MCCARTHY. Well, it is easy, from that record, to understand that the Agency has faced challenges in dealing with our Title XI complaints. One of the things that I have done since coming here is to try to aggressively tackle that issue. We are really committed to building a model civil rights program, particularly how we handle these. In the last 2 years we have new leadership in our office. We have developed a strategy to manage that docket of complaints more effectively. We, just this fall, released our external compliance strategic plan, a new civil rights toolkit, so we are doing what we need to do to get up to speed. But that doesn't mean we don't have a history that we need to acknowledge, and use that history to inform how we can be a model agency, moving forward. And we are trying very hard to make sure that we do that.

Ms. ADAMS. Well, I certainly hope it improves. It is not very impressive right now. But thank you very much for your comments, and, Mr. Chairman, I yield back.

Ms. MCCARTHY. Thank you.

The CHAIRMAN. Ms. Adams yields back. Mr. Austin Scott, 5 minutes.

Mr. AUSTIN SCOTT of Georgia. Thank you, Mr. Chairman. Ma'am, thank you for being here. I want to go back real quickly to what Mr. Neugebauer from Texas was talking about, with the Dicamba and the 2,4-D issue.

There have been several things that have been approved by the USDA for months, and farmers start planting cotton in his state in March. In my state it is more in April, but it takes time to get the chemicals produced, and through the distribution network, and to the farm. And if you all take much longer, quite honestly, they are not going to be available for us this year. And so I appreciate your commitment to help the farmer. I hope that we will see you act on these pending registrations sooner rather than later. And that is one of the breakdowns that we have between the government and the public, and the farmer is that it seems the people in the agencies have no idea when farmers even plant their crops, and what the agencies are doing to the cost of those crops. And can you tell me what cotton is trading for? Do you know?

Ms. McCARTHY. No, I can't, sir, no.

Mr. AUSTIN SCOTT of Georgia. It is below the cost of production right now, and so are a lot of the other commodities. And so when you take an area like mine, that produces a tremendous amount of cotton every year, and cotton is below the cost of production, you would typically look to another commodity. But they are also below the cost of production. And I appreciate your comment that you are trying to help the farmer and the farm, but the government is getting in the way of the farm being able to survive through these tough economic times. And things like approving these chemicals sooner rather than later would at least help us determine what crop we can plant.

And I want to go to the neonic issue right now, and I certainly understand the value of pollinators. I mean, without bees, you have lost the majority of the food in the world. But there are situations with the pollinator, and the preliminary risk assessment, and specifically cotton, which I was talking about earlier, is a self-pollinating crop, and it doesn't require bees. So did the EPA take that into account as part of its assessment with pollinators, that cotton does not require bees for pollination?

Ms. McCARTHY. I will have to go back, sir. Which chemical are we talking about in particular?

Mr. AUSTIN SCOTT of Georgia. The neonics as a whole, the whole class.

Ms. McCARTHY. Certainly. We certainly are. We are not making broad brush decisions on neonics. We are looking at each of them. And, in fact, the decisions that we have been proposing have been very specific to look at being specific to the crop, as well as the time of year——

Mr. AUSTIN SCOTT of Georgia. Let me——

Ms. McCARTHY.—and what we can do to both protect the bee colonies, as well as make sure that these are available when they are——

Mr. AUSTIN SCOTT of Georgia. Fair enough.

Ms. McCARTHY.—appropriately used.

Mr. AUSTIN SCOTT of Georgia. I will take that as a commitment that you will continue to work with the industry——

Ms. McCARTHY. We will.

Mr. AUSTIN SCOTT of Georgia.—and the registrants——

Ms. McCARTHY. Absolutely.

Mr. AUSTIN SCOTT of Georgia.—and I appreciate that. Are you familiar with the Agency's proposed rule on greenhouse gas emissions and fuel efficiency standards for medium and heavy duty engines in vehicles, Phase II?

Ms. McCARTHY. Yes.

Mr. AUSTIN SCOTT of Georgia. Well, would you agree also that Congress has excluded non-road vehicles that are used solely for competition from EPA regulatory reach?

Ms. McCARTHY. I believe that that is the case, but I am not as familiar with that as I am my standard rulemaking process—ongoing rulemaking——

Mr. AUSTIN SCOTT of Georgia. Fair enough. According to the EPA website, Congress did.

It is one of the things——

Ms. MCCARTHY. I believe so.

Mr. AUSTIN SCOTT of Georgia. We talk a lot about the things that we told you to do, but there also are things that we specifically tell the EPA that you do not have the authority to do. And one of those—I agree with what you said, that you don't have——

Ms. MCCARTHY. I don't think so.

Mr. AUSTIN SCOTT of Georgia.—the authority to regulate competition vehicles. I am concerned about the fact that in this 629+ page rule that is supposed to deal with greenhouse gas emissions for medium and heavy duty engines, that in the catch-all provision that the rule has attempted to bring back in to regulation competition vehicles. And I agree with you 100 percent that you don't have the authority to do that, and so I appreciate you telling me that you——

Ms. MCCARTHY. Well, Mr. Scott, let me get back to you. I am sure if that was part of the proposal, we have received a lot of comments on it. I am happy to close the loop with you on it. We certainly have not finalized that rule. We are considering all the comments. But if you think that there was a disconnect, I am happy to connect with you on it individually, if you would like.

Mr. AUSTIN SCOTT of Georgia. I agree with you that Congress specifically said that you don't have the authority to regulate competition vehicles, and ma'am, I appreciate your time. And it is just that it is very disconcerting, as an American, to see that in 40,000 pages of rules and regs that we have an Agency that would put something in a heavy duty vehicle rule that deals with race cars.

The CHAIRMAN. The gentleman's time has expired.

Mr. AUSTIN SCOTT of Georgia. Thank you.

The CHAIRMAN. Ms. Plaskett, 5 minutes.

Ms. PLASKETT. Thank you, Mr. Chairman. Good morning, Administrator McCarthy. I wanted to talk with you about the Virgin Islands. It has a very important relationship with EPA because of our complete surrounding by water, and our land, and our sea, our greatest resource, both for our farmers as well as for all of the industries that we take up. Several years ago, though, the Virgin Islands was devastated by the closure of our oil refinery, and that oil refinery meant that we lost hundreds of millions of dollars in revenue, and hundreds of millions more in lost economic activity. Just recently, however, the facility was in a bankruptcy sale, and a private equity firm has elected to purchase it. And that may lead to the restoration of more activity on the island. However, there is a concern that we have with regard to the EPA, and the potential of the EPA asking that the Government of the Virgin Islands be a co-permitee on its RCRA, its Resource Conservation and Recovery Act permit. These permits were originally put out, again, for Hovensa in 1999, and at no time during the renewals of those permits had the Virgin Islands Government been included in it. The Virgin Islands Government ownership doesn't even make up five percent of the land in this area. We were, by an Act of Congress, given title to the submerged lands to be entrusted for the citizens, and at no time has the Virgin Islands ever elected to operate a refinery, use the facility, but is really holding those submerged lands in trust.

Now, I understand that Hovensa is no longer the owner, but there is real concern that we have with Region 2 taking the position that the Virgin Islands Government must be included as a co-permitee. It is our belief that Region 2's position is based on an overly expansive interpretation of RCRA, and is an unjustified departure from its longstanding Agency policy. I am sure my colleagues here would see that this could be a problem if this takes precedent, in that the you have your state and local governments, which may, by EPA, be forced to become a co-permitee on hazardous waste areas back home in their own regions. And so we have really been reaching out to EPA, and particularly in Region 2, to see how we can resolve this. And I am not sure if you were aware of this. I wanted to bring this to your attention. Are you aware of any instance that EPA has forced a state or territory to be on a RCRA permit, based on its owning a small portion, five, ten percent of the land that a facility has?

Ms. MCCARTHY. I do not know all the uniqueness of this situation, but it is certainly my understanding that the region has taken a legal position that, because the part of the land in which the facility is located is U.S. Virgin Island land, that there is a connection, and that they should have been on the permit. Now, having just learned this, I can't tell you whether we have done this before, whether there are unique trust responsibilities that we are not looking at, so I am more than willing to go back and look at the region. But it is very clear that RCRA has brought in communities, municipalities, and states into the RCRA responsibility system, even though they are innocent landholders, and that is respected in the process, but they become part of the permit in the process, moving forward.

Ms. PLASKETT. Well, it seems to me to be unclear why you would have an original permit in 1999, and renewals of that same permit when another owner was operating the facility. Our ownership has not expanded at any point in this. We have always had the same five percent of those submerged lands that this body, Congress, put on the Government of the Virgin Islands to hold in trust for its citizens. And now, seemingly when there is no titleholder anymore, because Hovensa has gone into bankruptcy, the EPA Region 2 has decided that the Virgin Islands Government must take on responsibility for hazardous waste and activities that the facility owners were operating in. I mean, what more can a territory take on? What more can a government that is already bankrupt take on its back?

Now you have the owner, Hovensa, leaving, purchased by another entity, and the Federal Government, the Agency, is forcing us to take responsibility, possibly liability, for hazardous activity that a private owner had on 95 percent of that land. It just seems an expansion, because there isn't a private owner anymore to hold the responsibility, to put it on the backs of a local government that can do nothing but say, please don't do this to us.

Ms. MCCARTHY. Well, this seems like a very unique circumstance. I would suggest that we follow up with this conversation, and it is not a decision, or an interpretation, that I have been engaged in. So why don't we do that?

Ms. PLASKETT. I would appreciate that so very much.

Ms. MCCARTHY. All right.

Ms. PLASKETT. Thank you very much.

Ms. MCCARTHY. Sure.

Ms. PLASKETT. Thank you, Mr. Chairman.

The CHAIRMAN. The gentlelady's time has expired. I now recognize the gentleman from Arkansas, Mr. Crawford, for 5 minutes.

Mr. CRAWFORD. Thank you, Mr. Chairman. Thank you, Administrator McCarthy. I know this has been addressed to some extent, but we can take a little deeper dive on this issue with the grassroots campaign effort that took place in your Agency which is specifically prohibited by Title 18 of the U.S. Criminal Code. And I don't think we have gotten a satisfactory answer. Have you or your legal department made efforts before the grassroots campaign was undertaken to ensure the EPA staff is familiar with the kind of activity that is prohibited under the Anti-Lobbying Act?

Ms. MCCARTHY. We actually were following OMB guidelines relevant——

Mr. CRAWFORD. Prior to?

Ms. MCCARTHY.—to the use of Thunderclap, yes.

Mr. CRAWFORD. Okay. That is even worse. If they have received training in the Anti-Lobbying Act, and then engaged in lobbying——

Ms. MCCARTHY. We believe we actually followed those guidelines, yes.

Mr. CRAWFORD. Well, the GAO disagrees with that. And whether or not there can be an intent proven, the subterfuge and the optics of what took place there are certainly worth considering. I think that there are some valuable lessons here in the GAO's findings, not the least of which is that the Administration and your Agency is willing to go so far as breaking U.S. Criminal Code to push an agenda. We already knew that you were willing to go to great lengths to push that agenda, but this brings it into a completely different perspective.

Second, the GAO findings tell us that these actions set a dangerous precedent for future rulemaking. So you have basically compromised the integrity of the rulemaking process.

Ms. MCCARTHY. Sir, they never——

Mr. CRAWFORD. Now, excuse me——

Ms. MCCARTHY.—indicated that we were——

Mr. CRAWFORD. Excuse me, I am on my time——

Ms. MCCARTHY.—any law——

Mr. CRAWFORD.—right now, Administrator.

Ms. MCCARTHY. I am sorry.

Mr. CRAWFORD. In the age of social media and electronic communication, it is deeply troubling that agencies are willing to use these tools to subvert the concerns of the affected public, and drown out opposition to your own views. And it is obvious that you were trumpeting your own views, and not taking into consideration the public's views, when this is a public rulemaking comment period.

So I don't know how, after all those revelations were made, did you expect us to believe that during the WOTUS rulemaking the EPA actually took into account all the views by affected stake-

holders. Or were you just concerned about the views of your political allies? It appears to me that that was the case.

Ms. MCCARTHY. Sir, the GAO never indicated that we referenced a particular rulemaking. They never indicated that we said anything incorrect. They had one concern relative to Anti-Lobbying, which was a hyperlink to a program that we were touting as being really good. One blog from one individual in the Agency out of thousands was done, and it referenced a hyperlink, and they could not go back and prove or disprove whether or not that NGO, at some other place in their webpage, may have had an ability for people to contact Congress on other related issues or this one.

We are certainly sensitive to the fact that that hyperlink referenced an outside of EPA website. There are other agencies that flag that. We are considering and working with OMB on what we can do, but if you look at this, there was no intent, and there was no lobbying on the part of the Agency, or a reference——

Mr. CRAWFORD. Okay. I think——

Ms. MCCARTHY.—to that——

Mr. CRAWFORD.—then, we can take this as an example and a validation of the fact that the rulemaking process is deeply flawed, and needs to be addressed, because this kind of stuff, to me, is not reflective of the opportunity that should be granted to the affected stakeholders. Let me switch gears with you quickly in the time I have remaining. I was just told yesterday that the EPA took action against a farmer who didn't comply with the SPCC rules on on-farm fuel storage by failing to have an SPCC plan for his oil storage tank that was 5,000 gallons in size, but the 2014 WOTUS specifically says that EPA can only require compliance for oil storage tanks in excess of 6,000 gallons until such time as the EPA completes a study, and a new rulemaking process is undertaken.

My understanding is that the study is complete which recommends a lower exemption threshold, but the rulemaking is still not finished. So my question to you is why is the EPA taking enforcement action against individuals who are not out of compliance, and isn't that a violation of the law?

Ms. MCCARTHY. Sir, I am happy to look into it and get back to you. If it just happened yesterday, I am really not familiar with it.

[The information referred to is located on p. 65.]

Mr. CRAWFORD. Well, is that kind of thing a regular practice by the Agency?

Ms. MCCARTHY. I think we have actually been doing a very good job on the SPCC rules. Many of them, because of changes in threshold, like 96 percent of them, are no longer impacted by this rule. And of those——

Mr. CRAWFORD. Okay, let me ask you this——

Ms. MCCARTHY.—four percent, 97 percent self-certify. So we——

Mr. CRAWFORD. Do——

Ms. MCCARTHY.—we are doing pretty good.

Mr. CRAWFORD. Right. Do EPA agents take compliance actions like this because they know that farmers aren't willing to fight enforcement actions because it costs them more in legal costs than it would be to just go ahead and succumb to the EPA pressure? Am I off base in suggesting that?

Ms. MCCARTHY. I don't know why you are suggesting it, sir, but if that is your point of view, you can have it.

Mr. CRAWFORD. It is my point of view, and it is the point of view of the——

Ms. MCCARTHY. But I don't know anything about this enforcement——

Mr. CRAWFORD.—most of the people in my district who farm and are subject to EPA regulation. I yield back.

The CHAIRMAN. The gentleman yields back. Mr. Scott, 5 minutes.

Mr. DAVID SCOTT of Georgia. Thank you, Mr. Chairman. First of all, Ms. McCarthy, I think that you, and the EPA, have drastically manhandled and violated the rights of our farmers, especially dealing with this water issue. You did break the law. You did break the law. Now, let me tell you, Ms. McCarthy, in Section 15 of the Financial Services and General Government Appropriations Act, it expressly prohibits you from lobbying in support, or in opposition, to pending legislation or rule. Further, not only there did you break the law, but in Section 401 of the Department of the Interior's Environment and Related Agencies Appropriations Act, that is applicable right now, prohibited the use of the EPA's appropriations for lobbying. You broke the law. It needs to be admitted. It needs to be recognized. And, furthermore, you spent taxpayers' money in the lobbying. And the GAO reports it is $64,610 that you spent in lobbying from February 2014 to 2015. Now, let us come clean with this, so we can correct this. There is no way you are going to correct this if you don't realize that you have drastically overstepped here. And let us get that cleaned up.

Now, the other part that really gets in my craw is this. I was born on a farm, grew up on a farm, and there is a reason why farmers go and develop ditches, and ponds, and wells, and they are man-made, because that is an insurance policy for the drought. Our animals still have to be fed, they have to drink. There are many times when it doesn't rain for 4, 5, 6 weeks. And that is why we have that. The other point is, this is the farmer's private property, and it is not navigable waters. It is there for the purpose of being able to give us protection when that rain doesn't come. My little farm was a tobacco farm, and when you go to the tobacco beds, you have to put the plant in, and you have to have the water right there to go in with the plant. Suppose it doesn't rain.

Now, that is on that farmer's property. He shouldn't be permitted for his own property. And then he shouldn't be fined, the farmer has to pay for a permit on his own property for a puddle of water, or a ditch, or a pond, or a well that they made themselves so that they could be able to have that insurance on a rainy day. And then to violate all of that, the law itself, to go and lobby, and spend taxpayers' money on it. That is a damnable thing to do to our farmers, who are faced with so many other challenges. The EPA needs to reject this rule, recognize and admit that it broke the law, and then move to correct and say this will never happen again.

Now, finally, in my last second, I don't want to go over time, but I want to raise this issue for our cotton folks on the chlorpyrifos. I guess a better way of saying that is Lorsban. Anyway, we need this for our cotton producers and for our pecan producers. As has been said before, by the Chairman and others, our cotton people

are going through a very serious time economically, and they don't need a doubt of whether or not they can use this pesticide. So will you please make sure we can use that? And hopefully put this business aside for the Clean Water Rule, and let us move forward, and let these farmers have some peace of mind.

Ms. MCCARTHY. Thank you for your passion, sir.

The CHAIRMAN. The gentleman yields back. Mr. DesJarlais, 5 minutes.

Mr. DESJARLAIS. Thank you, Mr. Chairman. Ms. McCarthy, thank you for being here today. Just one follow up on Mr. Scott's question. He pointed out that GAO determined that you violated Federal law. Who was in charge of the covert propaganda and the grassroots lobbying? Who was the person in charge of that?

Ms. MCCARTHY. It is actually just part of our outreach and education, sir. There was no covert propaganda, and there was no lobbying.

Mr. DESJARLAIS. So there is nobody over that particular outreach? There was nobody in charge of that that you are aware of?

Ms. MCCARTHY. Sure. We have communications folks that have been——

Mr. DESJARLAIS. Okay.

Ms. MCCARTHY.—doing it. This——

Mr. DESJARLAIS. Who is the head of that? Who was responsible for that?

Ms. MCCARTHY. I would have to go back and look at the exact time, but we have actually a large education and outreach group. But none of that——

Mr. DESJARLAIS. Nobody was punished for it, though, right?

Ms. MCCARTHY. We don't believe——

Mr. DESJARLAIS. I understand that the person that is over it is now promoted and working for the White House, but that is beside the point. In your opening statement in response to the Chairman, you made it sound like Congress is imploring you to move forward with this WOTUS. Where did the idea for WOTUS come from, and basically who was in charge of drafting this package?

Ms. MCCARTHY. Actually, the WOTUS, or the Clean Water Rule, came because the Supreme Court told us that we needed to make improvements to the law based on science. We needed to prove a connection. We needed to do a better job.

Mr. DESJARLAIS. That wasn't Congress, like you——

Ms. MCCARTHY. So—no, it was——

Mr. DESJARLAIS.—said in your opening statement. It wasn't us.

Ms. MCCARTHY.—followed up—it actually was followed up by—Congress asked us to take action to address concerns. Individual stakeholders, members of the ag community. Absolutely people are looking for us to do a better job than the 2008 guidance, and to respond to the concerns and criticisms that the——

Mr. DESJARLAIS. But you went around Congress and used the rulemaking process, correct?

Ms. MCCARTHY. No, sir. We were actually asked to do a rulemaking for clarification. Whether you disagree with that rule or not is fine——

Mr. DESJARLAIS. What is the cost of this?

Ms. MCCARTHY.—but the EPA didn't generate this on its own.

Mr. DESJARLAIS. What is the cost going to be to implement this rule?

Ms. MCCARTHY. It is actually a net benefit of something in the order of $184 million.

Mr. DESJARLAIS. A benefit, not a cost? I mean, because I have heard it costs anywhere from $180 million up to $500 million, which that would change the way the rulemaking process works, correct? If the cost is over $100 million, you can't go around Congress the way you did.

Ms. MCCARTHY. No, actually, the $100 million threshold means we go through the inter-agency process, which we did.

Mr. DESJARLAIS. Yes. Do you know Howard Shelanski?

Ms. MCCARTHY. Yes, I do.

Mr. DESJARLAIS. Okay. Have you worked with him on this?

Ms. MCCARTHY. Yes, I did.

Mr. DESJARLAIS. Do you know why he won't give the required documents to the Oversight and Government Reform Committee that we have been asking for since March 3 of 2015?

Ms. MCCARTHY. I am not aware of what you are referring to, sir, no.

Mr. DESJARLAIS. Okay. We had a hearing about the rulemaking process, and the fact that this was a major rule, and we have been asking, and actually have had to now subpoena these documents for over a year. You don't have any idea why they are ignoring our request?

Ms. MCCARTHY. I don't know what the situation is.

Mr. DESJARLAIS. You have not had any conversations with him?

Ms. MCCARTHY. No, sir.

Mr. DESJARLAIS. Okay. Is this directive more from the White House?

Ms. MCCARTHY. What directive are you referring to?

Mr. DESJARLAIS. The WOTUS ruling itself.

Ms. MCCARTHY. No——

Mr. DESJARLAIS. The *Waters of the U.S.* Because it is certainly not from Congress. We voted both in the Senate——

Ms. MCCARTHY. No——

Mr. DESJARLAIS.—and the House to stop it.

Ms. MCCARTHY. I just explained to you where the impetus came from.

Mr. DESJARLAIS. Yes. And the courts have blocked this, correct? The implementation.

Ms. MCCARTHY. It is being litigated in one District Court, and it is now with the 6th Circuit, where they are looking at whether or not the District Court has jurisdiction or they do, but you are absolutely right, we are now stayed in terms of its implementation until those court issues are resolved.

Mr. DESJARLAIS. Okay. Well, you act like you are doing us a favor, but yet we have 31 states and many agricultural organizations filing lawsuits against you. So you don't think that maybe there ought to be a reason for pause? Maybe we ought to scrap this thing, go back to the drawing board, and do it right?

Ms. MCCARTHY. We will certainly hear from the courts as to whether we met the legal test in terms of its merits.

Mr. DESJARLAIS. So why did the EPA decide that it was necessary to do this?

Ms. MCCARTHY. Because of the lack of clarity, and the inconsistency, and the unfairness of the current process.

Mr. DESJARLAIS. Okay. But under the Clean Water Act you were restricted to navigable waters. Mr. Scott talked about farm ponds, stock ponds, where cattle drink out of. Is that a navigable water?

Ms. MCCARTHY. The actual navigable water, the Supreme Court has told us that that goes well beyond what we would traditionally think of as navigable, and we have to then protect waters that have the ability to significantly impact the biological, physical, and chemical integrity of navigable waters.

Mr. DESJARLAIS. You understand——

Ms. MCCARTHY. Does it respond to ditches on farm lands? We have done a really good job, if you look at the Clean Water Rule, to make sure that we are clarifying the word *ditch*. That is in the Clean Water Rule, not in——

Mr. DESJARLAIS. It would take another 10 minutes for you to describe what is a ditch and what is not a ditch, but I will just end with the fact that America is frustrated right now with big government. That is the number one issue with Americans——

Ms. MCCARTHY. Okay, sir.

Mr. DESJARLAIS.—is the overreach of Federal agencies. So I would hope that you would withdraw a little bit, take your time, and get this right.

Ms. MCCARTHY. Thank you, sir.

Mr. DESJARLAIS. Thank you for being here.

The CHAIRMAN. The gentleman's time has expired. Ms. Lujan Grisham, 5 minutes.

Ms. LUJAN GRISHAM. Thank you, Mr. Chairman. Administrator, as you are aware, on August 5, 2015 the EPA team that was investigating the contamination at the Gold King Mine in Colorado accidentally released 3 million gallons of waste water into the Animus River, which then flowed into the San Juan River, which is in New Mexico, part of it, and Lake Powell, and I think that you actually estimated that in that accidental release there were 880,000 pounds of metal that was deposited into the Animus River as a result of the release. Now, while the initial plume dissipated within several days, I want to alert you, you may already be aware, that there remain very serious concerns about the long-term impacts, both environmentally and for public health. And I am aware that both the State of New Mexico, through primarily their Environment Department, but certainly in my communications with the Governor, and the Navajo Nation and its President, that they have real concerns over a proposed 1 year EPA monitoring plan, which doesn't do anything about monitoring groundwater, plants, crops, wildlife, and certainly doesn't take into consideration continued runoff. I hope we don't have it too soon, but a spring runoff, which means that all that sediment gets moved again.

And so I would agree that the state is correct in assessing that there needs to be a long-term monitoring impact, that there ought to be a plan that involves their independent review. They are there. They are familiar. They are aware, which I realize is difficult, 20/20 hindsight, we all wish we had that. You want that ex-

pertise so you don't have these kinds of issues, you don't have these kinds of accidents, and that you don't have information that may not be accurate, or really relevant, to the area in which you are testing.

Can you talk to me about your conversations with the State of New Mexico and the Navajo Nation, and whether you are entertaining to support them, and fund them, and give them the resources to assure that the public health of the citizens of that state are protected?

Ms. McCarthy. Well, we are certainly going to do just that, in a couple of different ways. We know a lot of those states, and the Tribes, that were impacted by this spill have been discussing with us reimbursement of their expenses, your state did a great job at responding to that. We are sitting down with them, looking at both a short-term monitoring program and a long-term one that doesn't just look at the area of the spill, but does a much broader look at the watershed in general. And how we cannot just do that with EPA scientists, but they can be engaged because they have scientific expertise. And universities in your area have great scientific expertise.

EPA has identified funding for that, and we are going to work with them to make sure that we do the monitoring that is necessary to understand any impacts in the watershed.

Ms. Lujan Grisham. Great, because I think that robust partnership will bring about credibility. I can't agree with you more about that expertise, which leads me to the second question I want to ask, which is related to the MS4 watershed permits in the Middle Rio Grande. It is a completely separate issue, but it includes 15 individual entities and jurisdictions. The Middle Rio Grande region is one of three in the country that were chosen to pilot a regional watershed approach, and it is the only region in the western United States to participate. And the problem is, as you are looking at all of these water issues, or Clean Water related activities you are including requirements that are developed for eastern climates. And I don't think that we are using the right expertise. And I will tell you that everyone in these affected jurisdictions is really struggling in their relationship with you, because the aspects of the permit do not make sense in arid environments. And they, quite frankly, conflict with all of our state water laws, and many of our Federal water laws compacts.

Stormwater regulation needs to have the flexibility to make sure that local managers can suggest alternatives that make sense for an arid region. Are you aware that we are having these conflicts, and do you see a way for us to have much more flexibility so we meet your overall goals, and are participating productively, but we can do it correctly?

Ms. McCarthy. Well, all of our water programs, by law and by intent, is a partnership between EPA and the states. I did not know that there were concerns that had been raised that have not yet been resolved in these discussions, and they have to be resolved. They have to be resolved in a way that makes sense for those communities. And you are absolutely right, flexibility is the key to doing that.

Ms. LUJAN GRISHAM. I am out of time, Mr. Chairman. Thank you for your patience again, and we will work with you to get this resolved. Thank you, sir.

Ms. MCCARTHY. That would be great. Thank you.

The CHAIRMAN. The gentlelady's time has expired. Mr. Gibson, 5 minutes.

Mr. GIBSON. Thanks, Mr. Chairman. Ma'am, I represent parts of upstate New York, 11 counties, 162 towns. Among those, the town of Hoosick. And in Hoosick we have a village, Hoosick Falls. It is a very proud area, and for good reason, hardworking, good folks. And these are really challenging times for Hoosick Falls right now due to a chemical that has been detected, PFOA. We have not had potable water in Hoosick Falls now for over 6 weeks. We are working on that. We have carbon filtration process ongoing. We do think in several weeks we will have potable water. And, at the same time, we are not monitoring blood levels of the citizens, and we are beginning the long process of a comprehensive health study. And we are soon to begin the process of identifying the source of contamination, and ultimately identifying an aquifer that we can be confident in, going forward.

Ma'am, in March of 2015 we contacted the EPA, and the response then was that PFOA was an unregulated chemical, and that it did not pose a health risk. At the end of the year, specifically on the 17th of December, EPA came out with a statement and said that the water is not potable, and, furthermore, that it posed a risk to health. And so my question is, how do you go about making this determination, and what changed from March to December?

And before you answer that, in my research, as I have worked on this, I have come to find out that there are many unregulated chemicals. And, ma'am, I think we need a method. We are going to have to have a method that we then go through all these unregulated chemicals, and have a way, hopefully with analytics and automation where we can compress and go through all the health data so that we can come to these determinations. Because I can tell you, my people, they are hurting, and they are very disappointed, and we are looking for answers.

Ms. MCCARTHY. Well, I share your concerns, and your interest in finding ways in which we can more effectively and quickly address these new chemicals that are entering into some of our water systems, and we are finding across the country. Now, I believe that our region has been pretty aggressive in working with the community, and I want to thank you, and the community, for how quickly people have been reacting to this situation, getting bottled water out, getting a new carbon system in.

EPA has been trying very hard to keep up with new chemicals that we are finding, to do the science behind that. There is a systematic process to do that. That is written into the law and the rules, about recommending first, identifying, going through a listing process that is public before you can regulate, and actually working with the states and local communities to adopt those regulations.

Mr. GIBSON. So, ma'am——

Ms. MCCARTHY. So it is——

Mr. GIBSON.—just so I——

Ms. MCCARTHY.—a long process.

Mr. GIBSON.—understand—I am hearing you. So is that the answer to my question, is——

Ms. MCCARTHY. No, it is not. That is the preface of how difficult it is now, and why I agree with you that we need to do better. We are looking at more automation in how we do the science around this. But, frankly, if Congress would continue their push that they are on in re-upping the Toxic Substances Control Act, we would have more ability to understand what chemicals are going into products in the system, and what challenges they may pose, so that we can be better able, in the end, to find out where they are, and what they are doing, and the science behind those.

Mr. GIBSON. So from March to December, was there something that changed in our understanding of PFOA, or was it just a latency in understanding that there was a danger out there? This is what I am not clear on.

Ms. MCCARTHY. Yes. I will have to go back and talk to the region, because I am not sure that I can specifically answer your question. I believe that the testing that was provided to the region early on was in a system that wasn't currently in use. But when we found out that there were existing drinking supply wells that were being used, part of the challenge for us was that our recommended levels in some cases was fairly high, is currently being reconsidered.

We were trying to give the best information that we had, based on the science we knew, and that is why there was continued debate back and forth on the level, and what was safe, and what wasn't. But that is because the science was changing, and the tests were changing, and what we knew to be the case, in terms of what people were drinking, was changing as well.

Mr. GIBSON. Okay. Ma'am, we will stay in touch on this. Mr. Chairman, I am going to have to submit for the record a second question that has to do with the Hudson River. And, with that, I yield back.

The CHAIRMAN. The gentleman yields back. Ms. Kuster, 5 minutes.

Ms. KUSTER. Thank you, Mr. Chairman, and thank you to the Administrator for being with us today. Always great to have a New Englander in our Committee. I will be quick. I have two questions. The first one relates to this *Waters of the United States* rule, in conjunction with the EPA regulation on pesticides, and the Fish and Wildlife ruling regarding the long-eared bat. And my question on behalf of farmers, landowners, and timber owners in New Hampshire is how will your Agency coordinate with USDA and Fish and Wildlife to minimize confusion about the interplay between these three rules? If you follow.

Ms. MCCARTHY. That is a very good question that I am not sure I can answer. I will have to get back to you, because you have just baffled me with the bat question, connecting with the Clean Water and the other issues I understood.

[The information referred to is located on p. 66.]

Ms. KUSTER. Yes. I mean——

Ms. MCCARTHY. That one threw me——

Ms. KUSTER.—basically, I am trying to get some guidance, because I have more trees than people, so it is a big timber area. I have farmers, I have landowners working on conservation. And as these three rules come together, it is obviously going to limit the way they can use their property. And I just want to try to get them some guidance, because I just wonder if there is coordination. That is basically what I am looking at.

Ms. MCCARTHY. Well, certainly I haven't been a part of it, so I better figure it out.

Ms. KUSTER. That would be great. Thank you. Thank you very much.

Ms. MCCARTHY. Okay.

Ms. KUSTER. Yes, the bat threw me the first time too, but apparently it is an important bat.

Ms. MCCARTHY. Well, they all are. They all are.

Ms. KUSTER. And then the second question, this relates to the Clean Power Plan, and the biomass energy. I am the co-Chair with my Republican colleague, Mr. Westerman, of the Biomass Caucus here in the Congress. I understand that the Supreme Court issued a stay this week on the Clean Power Plan.

My question goes beyond the stay. There is confusion in the biomass energy world regarding whether or not biomass will be treated as a carbon neutral form of energy. We have submitted letters to you. I am just curious whether a determination has been made, and whether biomass will be treated as carbon neutral under the Clean Power Plan.

Ms. MCCARTHY. Well, that is a question I understand, so thank you. You helped me recover a little bit. Biomass is actually a really important part of, and we expect it to be, many states' compliance strategies that they would use for the Clean Power Plan. And so we know that there have been questions raised. The rule itself identifies biomass that we think is carbon neutral that would be enormously helpful to consider, but we also recognize that there are other things that the states are looking for, for guidance.

So we have actually notified folks that we are going to be pulling together a workgroup, and we are doing webinars on this to get people up to speed so that we can have the right questions, and develop the right answers, for how a state can feel confident to have biomass be an effective part of their compliance strategy. We are sure it will be, but there are uncertainties about what EPA might approve, and we want to make sure that we are working with everybody to get that done.

Ms. KUSTER. So I would love to just issue an invitation from the Biomass Caucus. We would love to set up an event here on the Hill with your team to educate Members of Congress, as I say, bipartisan from all over the country, to learn more about this interpretation, and then we can help to take that——

Ms. MCCARTHY. That would be great. I know that many of your Members have prompted this——

Ms. KUSTER. Great.

Ms. MCCARTHY.—workshop to happen. Maybe we could do it right after, and we can give you a sense of where we are.

Ms. KUSTER. Okay. That would be great. I have to go to another committee, but I will have my staff stick around to connect with you. Thank you——

Ms. MCCARTHY. Thank you.

Ms. KUSTER.—so much. Thanks for being here, and I yield back.

The CHAIRMAN. The gentlelady yields back.

Ms. KUSTER. With time to spare.

The CHAIRMAN. I noticed that. Thank you very much. Mr. LaMalfa, 5 minutes.

Mr. LAMALFA. Thank you, Mr. Chairman. Ms. McCarthy, I appreciate your attendance here today, and willingness to answer all these questions. Just to tag off of something Austin Scott talked about a while ago, where there is a great concern amongst the racing community, and the car enthusiasts, that you have a regulation coming down on basically stock cars that have been converted for racing. If you want your outfit to be known as the Entertainment Prevention Agency amongst millions of racers around the country, I would certainly recommend not pursuing that, so please check into that, and——

Ms. MCCARTHY. I will, sir——

Mr. LAMALFA.—let me hear your answer on that.

Ms. MCCARTHY. Thank you.

Mr. LAMALFA. Now, a follow up on something from a couple months ago with one of your colleagues too. We have in my district something known as Iron Mountain Mine, above Redding, California. It is above the Sacramento River, which affects water supplies for 20 million Californians, and many, many hundreds of thousands of acres of agriculture. Iron Mountain Mine's situation wouldn't be that much different than the Gold King Mine, and the Animus River situation as well. So I had asked for a report a couple months ago from that. So would you please see to it that I can get that report so that I know that our——

Ms. MCCARTHY. Yes, sir.

Mr. LAMALFA.—situation there is stable on that? Because we certainly can't have that affecting that many Californians on that mine. So thank you.

Ms. MCCARTHY. Sure.

Mr. LAMALFA. On the issue of Section 404, and the exemptions that are provided for agriculture under the Clean Water Act, normal farming activities, ranching, forestry, *et cetera,* including repeat plowing, seeding, cultivating, minor drainage, harvesting for that production of the food and the fiber and forest products, conservation practices, *et cetera,* no additional requirements, for example, that an activity be continuous are included.

Some of my constituents are continuous cropping on these lands, otherwise you lose your ability to have that exemption. Nowhere in the law does it specify that, but that is what is being carried out in my district by EPA or your associates. Sometimes we refer to them as henchmen, but in the Army Corps of Engineers that are carrying out some very outside the law activities with this regulation. So do you agree that section 404 does make no additional requirements that an activity be a continuously cropped, as we see it in the law?

Ms. MCCARTHY. I am not aware of it, but I certainly will have to get back to you on it, sir.

[The information referred to is located on p. 66.]

Mr. LAMALFA. Okay. So continuous cropping activities, we feel, are not required under the——

Ms. MCCARTHY. And I don't know what actions you are referring to, so I should dig into it.

Mr. LAMALFA. Well, they are coming down hard on people, fining them, or making them, in some cases, seek permits to do what they have been doing. Or if they just let the land idle for a few years, which is good, fallowing the land, and——

Ms. MCCARTHY. That is what people do, sure.

Mr. LAMALFA. Sure. And for market conditions, whatever those might be. You shouldn't have to have a new permit—which sometimes folks seeking permits are afraid they are going to end up with a 3 year waiting process for getting the permit issued to them, is the EPA or Army Corps going to pay their land payments and tax payments while they sit and wait for these decisions?

I have another one so I have to go fast, I apologize. Section 110 of the Consolidated Appropriations Act of 2016 specifically prohibits funds from this Act for being used to require a permit for the regulation. That is what was alluded to my colleagues a while ago. Are you aware of that exemption under section 404 as well, under that appropriation? It was an appropriation amendment that specified no funds are to be used, so——

Ms. MCCARTHY. For which specific——

Mr. LAMALFA. It was under Section 110 of the Appropriations Act of 2016 that no funds are to be used under Section 404 requiring these permits.

Ms. MCCARTHY. No, I am not aware of it. I will look at it.

Mr. LAMALFA. Okay. Well, that is a direct law put in place. So I will look forward to your answers on that.

Ms. MCCARTHY. Thank you.

Mr. LAMALFA. Again, moving quickly here, EPA and Army Corps of Engineers continue to rely upon EPA's interpretation of the Clean Water Act, imposing these regulations that stray far from the Congressional intent. Again, indeed, you mentioned several times following the law. It is pretty clear in the law and the exemptions, and then follow up by these amendments and the Appropriation Act that we have done here. So we believe that we are the ones that set that course there, and that the EPA is to follow it.

So as long as they have exceptions to the exemptions, and that is where it is very problematic. There are exemptions on that, but if the EPA is looking for exceptions to exemptions in your rulemaking, then who is making the law here? That is what a lot of people are really concerned about, is that we are not the lawmakers anymore. Will you direct your Agency to cease regulating activities that the Clean Water Act exempts?

Ms. MCCARTHY. We should not be doing anything other than exempting those activities.

Mr. LAMALFA. Okay. Thank you. My time has expired. I will have some follow up questions. I appreciate, again, your answers today.

The CHAIRMAN. The gentleman's time has expired. Mrs. Walorski, 5 minutes.

Mrs. WALORSKI. Thank you, Mr. Chairman. And, Administrator, thanks so much. I am over here. I said hello earlier, and I again wanted to invite you to northern Indiana, to my district, for a couple of reasons. So I have sat here, and you have too, for 2 hours, and here is the issue in my district. In northern Indiana, who I represent, we have one of the largest manufacturing districts in the country, not just the Midwest. In the southern part of the state, we have coal mines, and we are strewn throughout with ag, heavy agriculture, as well.

And so, I look at this, and I have said since the day I came to Congress, and even prior, Indiana is a good role model for being good stewards of the environment, being good stewards of the economy. And I could show you in my district places where we are really out of the box, and we are doing things that are incredibly creative to be such good stewards of the environment. But nobody is a better steward of the environment than the family farmer, because their complete livelihood depends on taking care of that area. So I do agricultural tours every single time I am in the district, and on the last agricultural tour, we have been able to diversify. We have been able to do great things in our state. We have been able to do some really clean water, things that are exemplary.

When I came away from there—and I am old enough to remember when the EPA was really considered a partner with industry, a partner with farmers, and really kind of came alongside, especially in our state. We have an incredible Indiana Department of Environmental Management that comes alongside. Not to be punitive, not to penalize, but to incentivize, and to keep people from really getting in trouble. I came away from this agricultural tour really having an understanding that, in my mind, what I heard from my farmers, is that today's EPA has become a punitive revenue generator for big government.

And it bothers me, because I sit on this Committee, and I know there are a lot of well intentions, but when it comes to this WOTUS rule, and I understand exactly why the frustration is so high in this room on both sides. This is not a partisan issue today. This is an issue of Americans, and farmers, and Members that represent them trying to come to grips with an understanding, in a state like Indiana, we are in a target virtually in every single portion of what we do and what we lead our nation in, in coal, in ag, and in heavy manufacturing. The toll on jobs because of this issue of heavy handed government; there is really no other way to explain it. I understand your intention, but I also understand that I have been around long enough that we have been able to have great gains in this country with a partner in the EPA.

And when we talked about humility, and we talked about attitude, there is a gigantic tone problem. When I come out of my district hearing from people from all over the state saying, it is a punitive regulating system, and when EPA comes calling, we don't even have chance to even implement rule number one, and here comes implementation of rule number two. And I am curious, especially on WOTUS, because I agree with my colleagues here. I would ask you to pull this rule and bring stakeholders around this, and

let us do it right. Let us do it balanced. I am not calling for one extreme or the other. I believe there is a balance between good stewards of the economy, and I can tell you that my state does that.

But my question is this. So when we talk, on one hand you say the EPA doesn't intend to regulate every ditch. On the other hand, we look at actual implementation of the rule. The ditch exemption appears to leave some room. So here is my question. So is the ditch exemption automatically given if a business, farmer, or local government believes it is exempt, or do they have to prove it is exempt?

Ms. MCCARTHY. The way in which the law works is that, if there is a question that you are going to be destroying or polluting what might be a water——

Mrs. WALORSKI. A question from the EPA?

Ms. MCCARTHY. No. That would be the individual landowner might be concerned that their activity would be doing that, and they may be——

Mrs. WALORSKI. On their private land?

Ms. MCCARTHY. On their private land or elsewhere——

Mrs. WALORSKI. Yes.

Ms. MCCARTHY.—then that question is raised by that landowner, and they ask the appropriate questions. That usually and often goes to USDA or others, and filters its way through. But we are not changing the dynamic of how the rule or how the guidance was implemented——

Mrs. WALORSKI. Yes, but let us just say worst case scenario. Worst case scenario, some farmer ends up with somebody, somehow, says that he is not in compliance, and he must do X, Y, Z. Would the *Waters of the U.S.* Rule, as it is now, and what we are talking about with this exemption, could a farmer potentially face any kind of legal action if he was strongly on the side that he is not out of compliance, and somebody from EPA comes in and says, you are? If this goes all the way to the end, could somebody, like a farmer, be penalized, and face legal action, and have to defend himself on a question of water on his own land?

Ms. MCCARTHY. There have been enforcement cases. There have not been a great deal, compared to the way in which people get to work together to answer these questions, and to get permits done. I will honestly tell you, in my heart of hearts, we worked very hard on this rule to make the clarity you need so that you, as a farmer, can actually be assured that if someone asks that question, you know the answer.

Mrs. WALORSKI. Yes, I know. In all honesty, you missed the mark, and I would again ask that this rule be repealed, and we go back and——

Ms. MCCARTHY. Right.

Mrs. WALORSKI.—allowed to come to the table. Thank you, Mr. Chairman.

Ms. MCCARTHY. I appreciate it.

Mrs. WALORSKI. Sorry for the extra time.

The CHAIRMAN. The gentlelady's time has expired. Mr. Abraham, 5 minutes.

Mr. ABRAHAM. Thank you, Mr. Chairman. Thank you, Administrator McCarthy, for being here. I will echo, certainly, the bipartisan support you have seen here, that our farmers, ranchers, foresters, aquaculture farmers, they are their own best stewards of their property. They are not going to do anything to harm their livelihood, but, more importantly, nothing to harm their children and their family.

To Mr. Austin Scott's reference of asking you the price of cotton, I won't put you on the spot and ask you the planting season of cotton, or corn, or soybeans, or anything like that. But it lends to the question: I am fearful that the EPA, as a bureaucracy, wants to literally drive the car, but doesn't know how to start the car. And when you don't know the basic facts of growing times, when you apply pesticide, and how important those windows are to maintain agricultural integrity, then it begs the question of who should know these answers? And my answer to myself is you should know.

We talked about pesticides, so I am going to go to my questions here, and with respect to your Agency's roles in reviewing and approving the use of pesticide, does the EPA examine the health and safety of an herbicide under the Federal Insecticide, Fungicide, Rodenticide Act any differently if its proposed use is tied to a genetically engineered plant *versus* if it is not? And does the Agency meet its registration obligation equally in both cases? So I guess my question, is it common for products tied to GE plants to be at your Agency several years while registration dates are renegotiated multiple times?

Ms. MCCARTHY. My understanding is that we have had a great deal of success in eliminating extensions of time overall for all of our program. Actually, quite remarkably. We are mostly keeping to those windows. Are there additional challenges with genetically engineered products? If they are, then that is where the science comes in, and we explore it. They are not treated differently than looking at how we always look at pesticides, which is by the science, trying to stick with the legal timelines in windows that we have to make our decisions.

Mr. ABRAHAM. And I will follow up with a question on the science issue. The President has stressed the importance and the value of transparency, and EPA's actions to ensure the use of sound science and reliable data. EPA is increasingly reliant on epidemiological and modeling data, looking at the occurrences, correlations, and extremely unlikely scenarios to essentially overrule volumes of actual hard science, laboratory and monitoring data, historically relied on around the world for decades. Why was this fundamental change in policy not put out for public notice and comment so that impacted stakeholders would have an opportunity to comment on this transition to such a heavy reliance on just the worst case scenario presumptions, modeling, studies?

Ms. MCCARTHY. I am not aware that there has been any change in policy direction, sir, so I am happy to look at the specific decision that you are referring to.

Mr. ABRAHAM. I will look forward to that answer, because I am under the understanding that there has been quite a transition away from the hard science in looking at——

Ms. MCCARTHY. So I am happy to answer it, if that is a concern.

Mr. ABRAHAM. And my last question: let us keep dealing with this raw data, this hard science. I have heard about serious matters regarding EPA policies based on human research data that may not be reliable. For years EPA has relied on hundreds of quality studies, evaluating all aspects of human susceptibility to pesticides. These included studies designed to make sure that children would be protected, and certainly we want that. Even though EPA uses those high quality assessments for 20 years, EPA now relies primarily on epidemiology studies, and some journal articles in which EPA has never, I am told, again, seen the raw data to determine if these studies are reliable or accurate. Case in point, I am told that Columbia University, who conducted a key study, refused to provide the raw data to EPA, even though EPA partially funded the study.

EPA has likely relied on information based on raw data that cannot be reviewed for accuracy. And I am running out of time, and I will submit this question, is it correct that the EPA has not gotten access to that raw data, or are you simply refusing to disclose them? And if you have the information, why are you not disclosing that information for the public to review? And I will look forward to your answers to that question. I yield back, Mr. Chairman.

The CHAIRMAN. The gentleman yields back. Mr. Newhouse, 5 minutes.

Mr. NEWHOUSE. Thank you, Mr. Chairman. Administrator McCarthy, thank you for being here. Let me start by calling your attention to a letter I sent to you last month in regard to a company called Omak Wood Products. It is Omak, Washington, Okanogan County. As you know, we have had, the last 2 years, record setting catastrophic fires, wildfires.

Ms. MCCARTHY. Yes.

Mr. NEWHOUSE. It has had a tremendously negative impact on our communities. This Omak Wood Products Company is one of the largest employers in this small community. I think over 185 people work at the mill, $60 million impact to the community. Unfortunately, they have announced recently that they plan to shut down at the end of February. The people in the City of Omak are working very, very hard to find someone to come in and take over the mill. One of the issues, though, is they don't have an operating permit. Two years ago EPA promised a re-write of the permit that would more accurately reflect the operations at the plant. And I can tell you, without that permit, they are having a very difficult time finding anybody interested in reopening the plant. So if you could look into that, I would very much appreciate your attention.

Ms. MCCARTHY. I would be happy to do that.

Mr. NEWHOUSE. I have a copy of that letter. It is submitted for the record, but I can give you another copy, if you——

[The information referred to is located on p. 65.]

Ms. MCCARTHY. That would be great. Thank you.

Mr. NEWHOUSE. I have a couple of questions, Administrator. Section 303 of the Clean Water Act clearly gives the states the authority to develop water quality standards and then submit those plans to you to confirm that they comply with the CWA.

Ms. MCCARTHY. That is correct.

Mr. NEWHOUSE. I don't think Section 303 gives EPA power, though, to establish those criteria for the state, and last year EPA indicated it would reject the State of Washington's water quality standards on the basis of two things. First, that it doesn't account for the consumption of 175 grams of fish per day which, I might add, is the equivalent of eating 38 cans of tuna a month. And second, for people who actually consume that much fish, it doesn't account for the cancer risk level of 10^{-6}, or $1/1{,}000{,}000$. So I am concerned that your Agency's proposed rule is significantly more stringent than required to protect human health, it is inconsistent with existing policy, and could cost my state billions of dollars for compliance. Could you discuss for me just real briefly, I know we have a short amount of time on how EPA arrived at these levels, and explain why your Agency is seeking to impose standards that far exceed your own water quality guidelines for states?

Ms. MCCARTHY. Well, I am very familiar with this issue, in terms of work that is going on between the State of Washington and EPA, where the State of Washington has recently proposed water quality standards. We have been starting a process to do that ourselves. We are perfectly happy to defer to the state on their water quality standard, should those come out in a way that we think does two things, is safe for human health, as well as protect the Tribal treaty rights which we are obligated to protect, under treaty law.

Mr. NEWHOUSE. Okay. Well, let me follow up, then, real quickly. For your proposed cancer risk level, in order to have a 10^{-6} you would need to reduce some of the agents on the EPA's toxic pollutant list to get this less than the naturally occurring levels. That means that the river, as it flows naturally, would not meet the levels.

A 2013 study conducted by Washington State industries, counties, and municipalities found that even the most advanced technology available, and with billions of dollars in upgraded resources, few facilities would be able to meet those standards. So my question is, where does EPA think it derives the authority and the power to tell states they have to meet these standards that they have no part in formulating, and, number two, are in no way grounded in sound science?

Ms. MCCARTHY. Well, we can certainly have this conversation, because I know we are running out of time, but I will assure you that the region working on this, our Region 10, is in close contact with Washington and stakeholders in the business community there to understand how we can come to a conclusion, either through the state effort or our own, to be reasonable, rational, make sure we have standards that can be achieved, and that no way take away the flexibility that states have in terms of how they achieve it.

Mr. NEWHOUSE. I appreciate that answer. I do have more questions, but I will have to submit them for the record. Again, thank you for being here.

Ms. MCCARTHY. Thank you.

The CHAIRMAN. The gentleman yields——

Mr. NEWHOUSE. Thank you, Mr. Chairman.

The CHAIRMAN.—back. Mr. Kelly, for 5 minutes.

Mr. KELLY. Thank you, Mr. Chairman, and thank you, Administrator, for being here. My first question is: 3 years ago Mississippi farmers and beekeepers created a Mississippi Bee Stewardship Program to enhance cooperation and communication between beekeepers and pesticide applicators. This has increased not just goodwill between these two groups, but we expect to find that this has increased pollinator health as well.

Unfortunately, despite the good work that Mississippi is doing, the EPA is undermining those relationships. While both our farmers and beekeepers thought they had addressed many of their pollinator and pesticide issues, farmers in my state are losing access to key products, and will be unable to protect their crops from pests, threatening their livelihood. Additionally, beekeepers have concerns that an economic hit to the farmers would mean that they would be unable to host bees on their farms. Please explain to me what EPA is doing to ensure that my constituents will have the time proven products and the new effective products available to meet their needs.

Ms. MCCARTHY. Well, one of the things we should really talk about where this concern is coming from, because I know, in working through the pollinator strategy, we recognize that one of the key things that needed to be done is an agreement and an understanding between beekeepers and their own farmers about how to protect those pollinators, while at the same time allowing those crops to be properly managed. So if there is a disconnect there, I would really love to understand that, because it was one of the highlights that said the Federal Government doesn't need to get involved in this, as long as that communication is working and happening. And so if we have missed the boat, I would really love to be able to work with you on it to figure out how we might turn that around.

Mr. KELLY. And I will. I will make sure that we get you that information so you understand, because they actually started before you asked them to and now they feel like they are——

Ms. MCCARTHY. Exactly. This is the conversation we wanted to have happened.

Mr. KELLY. Okay. I was going to joke about our accents, because I didn't know if we needed an interpreter or not, because we speak a little different English.

Ms. MCCARTHY. I can understand you.

Mr. KELLY. But after the hearing today, I am not sure that we are not different in more ways than just our accent. And one of the smartest terms I heard today was *regulatory humility*.

Ms. MCCARTHY. Yes.

Mr. KELLY. And I can tell you, I have not seen that displayed. And, if you look back, you have 32 states who have filed a lawsuit over WOTUS. I think you have both the House and the Senate who the majority of Members, regardless of which party, think it is not being implemented correctly. I think you have courts that are saying that it is not being implemented correctly. And what I see is the EPA sticking a flag in and saying, we are right, and the rest of America is wrong. We are right, and we will defend—and I have heard several times you say, we defend this action. I don't agree with what the court said on that. I don't agree with GAO that we

broke the law. I don't agree with this. We will defend our science, we will do this. That is not humility. That is the opposite of that. That is arrogance. I am smarter than you, I don't care how many of you are, and how many different backgrounds you come from, but I am smarter than you, and I am right, and you are wrong. And a Member asked you earlier, repeal WOTUS. Do away with it. It is not that it is a bad idea, but the rule that we have now, I can tell you that the majority of America does not believe protects them, and they believe it is punitive, and not helpful. We need clean water. No one understands that more than me.

One of the most crucial resources we have in America is clean drinking water, is water to water our crops. We all want the same thing. But the rule that we have now does not accomplish that. But we are so entrenched that we have to have this rule. And if you would repeal the rule, step back, get with Congress, get with farmers, get with environmentalists, get a whole group of people in a room and say, what do we want to achieve, and what is the most effective way to do that? And let us all take our pride out of it, because we are all prideful, regardless of what we are. But to get back to the humility, and get the smart people in the room, get a group or a commission together, and let us come out with a WOTUS that works. Because I can tell you, businesses, farmers, legislatures, courts, everyone right now knows that this WOTUS rule that we have is not the right rule. Let us quit sticking a flag in the ground and defending something that doesn't work, and let us come up with something that does protect our clean drinking water. And, Mr. Chairman, I yield back.

The CHAIRMAN. The gentleman yields back. Mr. Goodlatte, 5 minutes.

Mr. GOODLATTE. Thank you, Mr. Chairman, and welcome, Administrator McCarthy. I want to go back further than WOTUS and talk about the EPA's Chesapeake Bay TMDL scheme, because that really is the precursor to what is going on nationwide with WOTUS. I think that you would agree that the Bay TMDL is both significant and unique for a variety of reasons. In fact, early in the implementation process, EPA documents mentioned that many specifics of the Bay TMDL were novel in comparison to past EPA TMDLs, and that this blueprint could serve as a template for other watersheds throughout the nation. Further, the concerns voiced by agriculture, forestry, and home building industries, in addition some local communities, and to the TMDL's numerous legal challenges, speak to the enormous impact that the EPA's actions have had, and will continue to have, in the Bay region. Given this, shouldn't the EPA have conducted an analysis to estimate the cost of such an important rule?

Ms. MCCARTHY. It is my understanding that we have been in that process of——

Mr. GOODLATTE. Since 2009, and you are almost to the halfway assessment point, and you have implemented this process, but have never done a cost-benefit analysis to determine whether the cost of this to all of these parties isn't—and the taxpayers of my district, and all the other districts in these six states isn't greater than the benefits to the Bay?

Ms. MCCARTHY. Well, sir, what we tried to do was to allow states the flexibility to choose their own paths forward. And, because of that, it would have been extraordinarily difficult to provide any certainty about what that cost might be——

Mr. GOODLATTE. That is actually not what happened, if I may, because the states have, for the past quarter century, done just that. And in fact, that is what the Clean Water Act provides for. It says that the Federal Government gets to set the standard, and the states get to write the plan, and implement the plan to meet the standard. And a lot of progress was made over those 25 years. Sedimentation has been reduced in the Bay by more than 50 percent, nitrogen and phosphorous by more than 40 percent, before this TMDL ever even began. And yet the EPA said, that is not good enough, and went ahead with putting pressure on the states, threatening the states that if they didn't change the way they did it, that there would be costs and other consequences to them.

So, in fact, up until March of 2009, your Agency had assured us that no TMDL would be implemented before there was an economic analysis. So how much has your TMDL cost the affected states, and on average, how much has the TMDL cost the average farmer or producer in the Chesapeake Bay Watershed?

Ms. MCCARTHY. I can't answer that question yet.

Mr. GOODLATTE. I know you can't, because you never did the homework. You never did the work necessary to prove that this was a worthwhile undertaking. The Commonwealth of Virginia estimated that the cost just to Virginia alone would be more than $16 billion. But the EPA never came back and said, "Well, here is a calculation of the added benefits, benefits beyond what was already taking place." The Chesapeake Bay is getting healthier, has been getting healthier for many, many years. That is a good thing. We all support that. But when you take the law into your own hands, and do it contrary to what the Clean Water Act provides, you get lawsuits, rather than progress.

Your Agency has been implementing the TMDL for several years now, and, in fact, I understand that next year you will be releasing the Chesapeake Bay TMDL midpoint assessment.

Therefore it would seem that you would have had ample time to conduct such an analysis of the cost and the benefits of it. Why did you not conduct an economic analysis prior to implementation, or at least at some point in the last few years?

Ms. MCCARTHY. Sir, we are in the midst of that process. I do not know when it will be completed. My understanding is that it is being worked on by the Agency.

Mr. GOODLATTE. You may well be well past the midpoint assessment before you ever determine whether this should have been done in the first place. And, therefore, all of the costs that have gone forward, if they were not justified, then the EPA should not have issued regulations without having that done first. Does the EPA not view the financial impact of the rules it inflicts upon America's farmers, and homeowners, and taxpayers, and small communities that dot the Shenandoah Valley in my district, do you not view that financial impact to be of importance?

Ms. McCARTHY. One of the reasons why we are doing the TMDL the way we are is to allow not just us to consider the most cost effective paths forward, but allow the communities themselves.

Mr. GOODLATTE. Mr. Chairman, my time has expired, but I really have to express my ongoing dismay that this Agency, for all these many years that we have been talking about this, have received just that, talk, and no information that would justify this major impact on these six states, which have, quite frankly, the guinea pigs for the rest of the country, which is now facing a similar assault under WOTUS, and why both of those measures are now before our courts. Thank you, Mr. Chairman.

The CHAIRMAN. The gentleman's time has expired. Mr. Moolenaar, 5 minutes.

Mr. MOOLENAAR. Thank you, Mr. Chairman. Administrator McCarthy, thanks for being here with us today.

Ms. McCARTHY. Thank you.

Mr. MOOLENAAR. I am from Michigan, and am neighboring Genesee County, and would like to talk with you about the Flint water situation. And, as of yesterday, there were some concerns raised by a family in Flint, and you may have heard these concerns, but their point was: Melissa Mays, as reported in the *Detroit Free Press,* said that we saw more information on Google than we did from the EPA. We asked them for help, and got nothing. And I guess what I would like to ask is have you been to Flint.

You were there, I believe, on February 2, and really put the focus of blame on the state. And the Governor has apologized, people have lost their jobs in the state over this matter. The EPA Region 5 Administrator, Susan Hedman, resigned. Was that over the Flint water situation?

Ms. McCARTHY. Her explanation to me was that it was because she knew that she had already become a focus of attention, and she thought the entire focus should be on what we do for the people of Flint. It was a courageous act on her part.

Mr. MOOLENAAR. Do you still maintain, as you did when you came to Flint, that the EPA did everything right?

Ms. McCARTHY. I did not maintain that. What I said was that a situation like Flint should never have happened.

Mr. MOOLENAAR. Right.

Ms. McCARTHY. I explained what I thought were inadequacies of the state oversight and primacy. They are the ones that have the authority under the law, and they are the ones with the primary obligation. But I in no way said that EPA had done some kind of thorough analysis of what else we could have, or should have, done.

Mr. MOOLENAAR. Well, let us just analyze it for a minute here, because my understanding is the EPA was aware as of February of last year that corrosion controls that would have prevented lead from leeching from the pipes were not being implemented, that there were serious concerns about raised levels of lead. In fact, above the enforcement action level of the EPA.

EPA was aware of that, and did nothing. And we are almost a year later, and the EPA did nothing. Can you explain to me why that happened?

Ms. McCARTHY. Well, I would say that, I believe, in April of last year was when the state actually told us, and corrected a

misimpression they gave us, that corrosion control was not happening. EPA vigorously, from that point forward, recommended to the state that they take action to get corrosion control up and running. Were there other things that we could have done, or should have done? That is the focus of our attention at this point.

Mr. MOOLENAAR. If I could——

Ms. MCCARTHY. But we did oversee this and recommend the appropriate steps for the state to take.

Mr. MOOLENAAR. Okay. So you are saying that was in April?

Ms. MCCARTHY. I believe so.

Mr. MOOLENAAR. My understanding is that on February 25 a resident from Flint, Ms. Walters, who had four children who have lead poisoning——

Ms. MCCARTHY. Right.

Mr. MOOLENAAR.—contacted Miguel Del Toro, a manager at your EPA——

Ms. MCCARTHY. Yes.

Mr. MOOLENAAR.—Midwest Water Division, informing him that Flint is not treating water with standard corrosion controls that prevent lead pipes from leeching lead. Also, Del Toro, your employee, learned that the taps were being pre-flushed for several minutes prior to sampling when they did water tests on this. So that is February 25. The EPA has been notified that the corrosion controls are not being implemented, and that the testing process is flawed.

Now, my understanding is, under the Safe Drinking Water Act, you have the authority for action authorized when there is imminent and substantial endangerment to health. And so my question is, if you knew this in February, why was there no action taken for almost a year?

Ms. MCCARTHY. Well, my understanding in February was that we did ask the State of Michigan whether or not corrosion control was happening. They gave us an indication that it was. We relied on that, but at the same time, we did work specifically to test Ms. Walters's home, and it is not unusual, nor is it an indication of corrosion control happening or not, to have a high lead level in a particular home. That can occur for a variety of reasons, including a disruption in the street. So one house does not dictate whether corrosion control is happening and effective. But in no way did Miguel ignore this individual's circumstance——

Mr. MOOLENAAR. And believe me, I am not saying——

Ms. MCCARTHY.—or contact the state.

Mr. MOOLENAAR. I am not saying Miguel did it. I am saying the upper levels of the EPA did, and that is where I am, because Miguel actually e-mailed colleagues at the EPA, relaying his concerns about this faulty testing mechanism. And also, in follow up tests, when they actually used the right testing mechanism, there were lead levels of nearly 400 parts per billion, 27 times the EPA's threshold. That is March 3, again, almost a year ago, and still nothing happened.

Now, I want to go again to June 24, again, when Mr. Del Toro wrote to the head of the EPA's Drinking Water Division, calling Flint's lack of corrosion controls a major concern. Again, no action from the EPA. Finally, I am told, that, rather than taking action,

a legal opinion was requested on the authority of the EPA to step in, I have to believe that anyone who looks at the documentation of the law would be able to give the opinion that the EPA has authority in this matter. Wouldn't you agree with that?

Ms. MCCARTHY. Well, when you say no action was taken by EPA, you minimize the communication that EPA had that we normally have with states, that are very clear that corrosion controls should have been done from day one, and it needed to continue.

Mr. MOOLENAAR. If you——

Ms. MCCARTHY. It was the State of Michigan that was challenging whether or not additional testing was necessary to make that determination.

Mr. MOOLENAAR. And people have lost their jobs over that. Now the question is, if you knew that it wasn't happening, why did you not take action?

Ms. MCCARTHY. I can explain to you my interaction with that, but it is a much longer conversation——

Mr. MOOLENAAR. Well——

Ms. MCCARTHY.—than that. We clearly did everything we could to get the State of Michigan to do what they were supposed to do. When I became aware and engaged, that is when you saw an enforcement action taken.

Mr. MOOLENAAR. And my understanding is the communications between the EPA Region 5 regarding this matter have been requested. The Governor has released all of his communications. When can we expect to see the documentation on the communications from Region 5 EPA?

Ms. MCCARTHY. We have numerous FOIA requests that are in——

Mr. MOOLENAAR. But this is pretty important.

Ms. MCCARTHY. There is nothing actually more important right now than getting that city clean water. And you will see a large Federal presence, including EPA, who is responsible to get that done.

Mr. MOOLENAAR. Okay. Well, when——

The CHAIRMAN. John, you are well over.

Mr. MOOLENAAR. Thank you, Mr. Chairman.

Ms. MCCARTHY. But I will respond, sir.

Mr. MOOLENAAR. Well, I would like to know when you are going to have those documents public, I guess is the question.

Ms. MCCARTHY. Okay. I will be happy to take that back. We have a number of requests. I don't know what the schedule is.

The CHAIRMAN. The gentleman's time has expired.

Mr. MOOLENAAR. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Davis, 5 minutes.

Mr. DAVIS. Thank you, Mr. Chairman. Administrator McCarthy, thanks for being here. Did your staff prepare for a question from me about individual septic systems being included in the definition of a *sewage treatment facility* in the WOTUS rule?

Ms. MCCARTHY. No.

Mr. DAVIS. They did not?

Ms. MCCARTHY. Should I slap them?

Mr. DAVIS. Yes. I believe last time, at a Transportation and Infrastructure Committee hearing, I said they should be fired if they

didn't do it, because this would be my fourth time. Do you believe individual septic systems are included in the language that says sewage treatment facilities should be exempt from the WOTUS clarification?

Ms. McCarthy. I am not familiar with the issue, sir, so I don't want to venture a yes or no answer.

Mr. Davis. I will remind you, at a joint hearing between the House and the Senate on Transportation and Infrastructure, I did ask you the same question——

Ms. McCarthy. Really?

Mr. Davis.—and your response was that we don't regulate individual septic system discharge for non-source point pollution. But you do, and I still have yet to have my question answered if they would be considered under the sewage treatment facility exemption under the existing WOTUS rule. I don't have a lot of time left. I have some other issues I want to get to.

Ms. McCarthy. Sorry. I am sorry, go ahead.

Mr. Davis. That is okay. I will get back to you, and I will give you guys another chance at the next hearing. But I am disappointed that your staff once again did not have a prepared answer on this, knowing that I was going to ask for the fourth time. That just makes me, as a Member of Congress, feel as though this is more of a check the box issue for the EPA, and those who work with, and——

Ms. McCarthy. I wouldn't want——

Mr. Davis.—I am sorry that they did not prepare you for that. But I——

Ms. McCarthy. I have great respect, and I would not want you to think that.

Mr. Davis. I, as a former staffer, would not put you in a situation like that again. This is very disappointing to us, and I am disappointed in those that are sitting behind you. I do want to ask you, I know you mentioned earlier in the hearing, that you are trying to ensure that there is a better working relationship between the ag sector and the EPA. There are a lot of folks that don't think that the EPA actually accounts for the economic consequences of some of your regulatory proposals. I also asked you at our last hearing we had whether or not you have worked with the USDA to appoint a member of agriculture to the EPA Science Advisory Board. That was my language in the farm bill that I offered 2 years ago. What is the status of getting that person appointed?

Ms. McCarthy. On the standing committee?

Mr. Davis. Yes.

Ms. McCarthy. Yes. We actually, as recently as last week, met with USDA so we can finalize that standing committee. We understand how important it is, and we have been working hard to make sure that we respect people's interest in getting the right applicant pool, and we will be working with USDA on those choices.

Mr. Davis. I appreciate that. It has been 2 years since the passage of the farm bill. This is something that I asked you about before.

Ms. McCarthy. That I am aware of.

Mr. Davis. I just don't think the EPA's actions, again, I don't expect you to take away from every hearing our concerns, but I do

expect the folks who are sitting behind you to follow up. And my legislative intent was to get somebody from agriculture to work with you so that maybe, when you came here today, you wouldn't have had to talk about how you are going to work to bridge that relationship, to bridge that gap with our agricultural community. It is very disappointing.

And you can wonder why our ag sector, when it has taken 2 years for a simple request to appoint somebody from agriculture to a standing advisory board, has not been done, why they don't trust the EPA. It is very, very disappointing on my end. I would hope that by the next time we meet, and I know we will, that we could see much more progress on this. Two years has been long enough, and agriculture deserves that attention that you mentioned you want to give it.

Ms. MCCARTHY. Yes.

Mr. DAVIS. You would prove it a lot by accomplishing this and getting somebody in ag on that science advisory committee. So, with that, I want to make my Chairman very happy by yielding back the remainder of my time.

The CHAIRMAN. The gentleman yields back. Mr. Yoho, 5 minutes.

Ms. MCCARTHY. Thank you.

Mr. YOHO. Thank you, Mr. Chairman, I appreciate it. Ma'am, thank you for being here. First, I thank you for your Agency's work and continued efforts in combating citrus greening in my State of Florida. Experts believe that over 70 percent of our groves are infected, and we have seen a dramatic decrease in production. USDA estimates this season's harvest to be 69 million boxes, and that is the smallest crop we have had in 50 years. That is down from the 240 million boxes. Could you speak to what your Agency is doing to help the situation? I know you guys are doing good work on that. Is there anything that you need from us to help facilitate that?

Ms. MCCARTHY. Sir, we are taking this situation extraordinarily seriously, as you indicate that it is. And I know that we met with the Florida Senate and House delegations to talk about what we have already done on our recent registrations to bring more tools to the table, but we are also in the middle of looking at an emergency exemption request that will look at the potential to authorize use of antibiotics. And we are working with both CDC and FDA, which is the process for that, and we are going to try to get that done as soon as possible.

Mr. YOHO. I appreciate that. And if we can help facilitate that, or extrapolate work from other crops, whether it is the apples, or the grapefruits, or any of that, our state, and those people that love oranges, would be greatly appreciative.

Ms. MCCARTHY. We are happy to call on you. Thank you for that offer.

Mr. YOHO. And I am concerned that my farmers are not getting access to the tools they need to provide food for the world. Without the pesticides and other scientific advances, 40 percent of global crop production could be lost because of the effects of weeds, pests, and disease. And I understand that the average research and development costs for just one new pesticide crop protection product to reach the market is roughly $256 million, and the average timeframe for a pesticide to be approved by the EPA and reach the

market is about 10 years. And I understand we have to do our due diligence to make sure that a product is safe, but we have had products that were approved by the EPA, and then pulled after this kind of effort. And what are your thoughts on that?

Ms. MCCARTHY. Well, we certainly should look at what the full range of effort has been, and what the average is, but I want to look at more recent data, and see if we have been able to do a much better job at advancing that. It is clear we want to do our job to make sure that it is safe, and being effectively applied——

Mr. YOHO. Absolutely.

Ms. MCCARTHY.—but——

Mr. YOHO. I mean, we need to do that.

Ms. MCCARTHY. I don't think that the timelines you have indicated are the timelines that the Agency operates under at this point, sir. But if there is more work that needs to be done, we should do it.

Mr. YOHO. And then I just want to say that I am concerned about how long it takes for the EPA to approve new products, as we just talked about, for the farmers or the growing communities. And I am also concerned that the EPA is drifting away from its goal set by Congress, which includes decisions based on sound science, rather than on input from outside groups trying to limit the use of the safe options for farmers. Some of the nonprofit groups will oppose the use of pesticides, no matter what their value in protecting U.S. farmers, and addressing world hunger, no matter how safe they are. But those interest groups should know that the crop protection can greatly reduce malnutrition for millions of children and adults over the next few years by safely protecting crops, and safely increasing yields. They will also keep costs in the U.S. lower. Will you commit to me today that, as the law requires, you will base your decisions in the EPA on sound science, and only on sound science?

Ms. MCCARTHY. Yes. It is sound science, and the law.

Mr. YOHO. And we see this with some of the pesticides that the outside groups are saying, this is bad, neonicotinoids on the honeybees——

Ms. MCCARTHY. Sir, I want to indicate, relative to your first question, one of the most important things is to get new chemicals onto the market that are much less harmful, and much more effective, so you are absolutely right on both those questions, and their linkages, and that is what we have to work toward.

Mr. YOHO. All right. And I would like for you to show strong leadership. Your Agency has so much power to put a pause on the WOTUS, as many people have talked about in here. With 26 states suing the Federal Government and the EPA, until we can reach a better solution, if you could just back off, and I would agree with Mr. Kelly, the things he brought up.

And then the standard of testing methodology that we have seen in the lead situation in Michigan, what I have seen is you have to run the water, or don't run the water. There is not a standard that everybody is using. And if you don't have a standard, you get skewed results. So I hope you address that, and I am out of time, and I yield back.

Ms. MCCARTHY. We have grave concerns, and we will.

The CHAIRMAN. The gentleman's time——

Ms. MCCARTHY. Thank you.

The CHAIRMAN.—has expired. Mr. Allen, 5 minutes.

Mr. ALLEN. Thank you, Mr. Chairman, and thank you, Administrator McCarthy, for being here today. And, of course——

Ms. MCCARTHY. There you are.

Mr. ALLEN. Yes, I am right here, so——

Ms. MCCARTHY. I am so sorry. I don't know how I lost you.

Mr. ALLEN. Well, those lights are kind of bright. I have learned a lot here today at the hearing. I hope that you and your staff are taking good notes, and learning a little bit about some of the things that we have to deal with. I am a new Member of Congress. I am from Georgia, and, of course, you have heard the concerns about our farmers and others. But what I have learned is there is an obvious disconnect between the American people and your Agency, and your ability to carry out the laws that are established by the United States Congress.

I guess my question is, what have you learned from this hearing today, and what do you plan to do about it?

Ms. MCCARTHY. I think that I have learned that we have not just differences of opinion, but an understanding of what the Agency is doing, our intent in doing that, and that we have a lot of work to do to have a trusting relationship to both be able to talk to one another, but to listen to those concerns, and effectively get them into our policies and regulations.

Mr. ALLEN. Would you do this: we are the people's House, and we report to the people. What I would like to see is a plan by your Agency to do just what you said you plan to do. In other words, if you would lay out a strategy somehow that we are going to get on the same page, and how are we going to do that, because we have differences in science. You have an important job. There is no question that we have issues. We brought those issues before you today. I mean, Flint, out in Colorado, there are mistakes that have been made.

I will say that, just from my observation, as a long-term member of the business community, that part of that strategy needs to be prioritization. In other words, you are doing things that are affecting the economy, and affecting our farmers' ability to operate their farms, but then you are letting these other things slip through the cracks. So you need to reprioritize your systems, and I would like to see that in your strategy.

The last question that I have is relative to the economic impact. When you, say *Waters of the U.S.,* again, we have talked about where did that rule come from? And you need to understand that over ½ of our farmers are retiring, and have been since 2009. And only 56 percent—is there a second generation that is coming along? Obviously, you feel our frustration, and our frustration is their frustration. When you start talking about taking people's property away from them because they have retained water so that they can sustain their farm, that is a serious, serious issue. You have millions of comments on the thing, and continue with the rule. So you can certainly understand the concern there.

But from an economic standpoint, is your Agency at all connected to the fact that this economy is growing at less than two percent,

and has been for the last 7 years, and that what responsibility does your Agency have for that lackluster growth? Have you actually gotten together and talked and is the growing of the economy important to you?

Ms. MCCARTHY. Always, yes.

Mr. ALLEN. I mean, these are jobs we are talking about. We are talking about—every American deserves the opportunity at a good job. We have, some say 90 million people who are not working today. And one of your strategies that I would recommend is that you go back and look, and see what your Agency could do to grow this economy, and how you could grow the economy. And any further comments, as far as what you are—what you are going to move forward, while I have 44 seconds remaining?

Ms. MCCARTHY. No, sir. I will certainly take to heart what you suggest. I do think we try very hard to understand how we can meet our mission, but do it in a way that actually advances the economy, moving forward. But I have no question that there are challenges in agriculture, and that those challenges have to be part of the discussion we have when we interact with this sector.

Mr. ALLEN. And you realize that has to be a bottom up approach? In other words, the farmers have to be included in that process?

Ms. MCCARTHY. Yes.

Mr. ALLEN. I yield back, Mr. Chairman.

The CHAIRMAN. The gentleman yields back. Ms. McCarthy, we are almost there. Two more questioners. Mr. Benishek, 5 minutes.

Ms. MCCARTHY. Thank you, Mr. Chairman.

Mr. BENISHEK. Thank you, Mr. Chairman.

Ms. MCCARTHY. Hello.

Mr. BENISHEK. Welcome, Ms. McCarthy.

Ms. MCCARTHY. Thank you.

Mr. BENISHEK. Last September the EPA published an interim recommendation for environmental standards and eco labels for use in Federal procurement. And one of the recommendations for lumber excludes several credible standards that are widely used in the United States, including the Sustainable Forest Initiative, and the American Tree Farmer System standards. And we understand that this recommendation was made without consultation with the Department of Agriculture, who not only have a lot of expertise in forest management and forest projects, but who also publicly stated that the Sustainable Forest Initiative, and the American Tree Farmer System standards can be used to verify sustainability of forest products. Furthermore, it is supposedly based on a determination by the Department of Energy that has no formal analysis behind it. So can you explain the basis of this recommendation for Federal procurement?

Ms. MCCARTHY. Well, sir, I do know that it is related to the Federal Government wanting to make sure that their purchasing reflected the full range of interests of the public.

Mr. BENISHEK. Well, we already——

Ms. MCCARTHY. I am——

Mr. BENISHEK.—the Forest Service, or the Department of Agriculture has already determined that this is a sustainable thing. So what other factor are you taking into account?

Ms. MCCARTHY. We were actually utilizing a certification program that was up and running that we thought had credibility because of its history. But we have recently been asked to consider opening that up other certification that——

Mr. BENISHEK. What is the certification program that you are using?

Ms. MCCARTHY. It is basically a third party certification, and I apologize.

Mr. BENISHEK. Well, which one is that?

I mean, these are the two most widely used certification processes in timber management in the country, the ones that I have outlined.

Ms. MCCARTHY. Yes, and we are certainly opening up the discussion so that we can expand that. We have no interest in taking away the opportunity to use legitimate and very well tested third party certification.

Mr. BENISHEK. Why wouldn't you consult with the Department of Agriculture prior to making this kind of a rule?

Ms. MCCARTHY. I am not sure that wasn't done, sir, but I certainly can check.

[The information referred to is located on p. 66.]

Mr. BENISHEK. Well, it is——

Ms. MCCARTHY. And you are right, if it is a forestry issue, we should be consulting appropriately with all the right Federal partners on this.

Mr. BENISHEK. So when is that going to be fixed, then?

Ms. MCCARTHY. Say that again?

Mr. BENISHEK. You said you are going to look into it, so when is that going to happen?

Ms. MCCARTHY. We already are looking into it. I just can't put my finger on it, sir, but I know that it is part of the work that we are doing, ongoing. I can get back to you on what the timeline might be.

Mr. BENISHEK. So is the timeline a month?

Ms. MCCARTHY. I don't know, sir, I can get back to you.

Mr. BENISHEK. Three years?

Ms. MCCARTHY. I can get back to you.

Mr. BENISHEK. All right. I yield back.

The CHAIRMAN. The gentleman yields back. Mr. LaMalfa for an additional 5 minutes. He had a couple of questions.

Mr. LAMALFA. Thank you, Mr. Chairman, for your indulgence. Ms. McCarthy, once again, I will try and just keep this to asking for an offline clarification, and then a couple yes and nos. So I——

Ms. MCCARTHY. Okay.

Mr. LAMALFA.—appreciate your time, and your grace with which you have answered the questions today. Just to bring your attention quickly, a Presidential memorandum recently issued, it is called *The Mitigating Impacts on Natural Resources from Development, and Encouraging Related Private Investments.* I don't expect you to know this, and not to put you on the spot here, but, again, *Mitigating Impacts on Natural Resources from Development, and Encouraging Related Private Investments.* It is a fairly new Presidential memorandum.

It appears to be carrying the weight of an Executive Order, and seems like quite a significant departure from current policy. Looking like it is going to go back and re-assess every possible impact that a man-made activity might have on public land, or any natural resource on Federal projects. So do you plan to follow this policy, and can you walk me through, in a letter later on, how you do plan—are you aware of that title?

Ms. MCCARTHY. I have not been made familiar with the details, so I will have to get back to you on how——

Mr. LAMALFA. I believe it was out in October.

Ms. MCCARTHY.—my Agency would respond. We have very little ownership of Federal lands.

[The information referred to is located on p. 67.]

Mr. LAMALFA. Okay. Well, it might have an effect on all Federal lands, we are still catching up, I would appreciate it if your office can clarify to that in a letter offline here. And on the previous questions I had on Clean Water Act, again, regarding plowing, this is very important to several of my constituents have gotten in some hot water up in the district there on the section 404 exemption of the Clean Water Act.

Current Clean Water Act regulations provide that plowing "will never involve a discharge, unless it changes any of water in the United States to dry land." I am familiar with that with growing rice, about the 1985 sodbuster, swampbuster regulations came in through FSA, where we are not to take swamps, or change waterways, things of that nature. Big things. Since we do have this section 404 exemption, does this regulation really, truly mean what it says? Because that is what my growers are wondering, that there is an exemption for section 404 under plowing.

Ms. MCCARTHY. My understanding is for plowing, yes.

Mr. LAMALFA. Okay. Was this regulation intended to assure farmers that their plowing would not be regulated under the Clean Water Act?

Ms. MCCARTHY. That would be its intent, yes.

Mr. LAMALFA. Okay. And it might be repetitive here, but I have to do this. Does it mean that plowing is not regulated under the Clean Water Act unless it actually changes waters to dry land?

Ms. MCCARTHY. Waters to dry land?

Mr. LAMALFA. Something deemed as *waters of the United States.* If it is changing it from water——

Ms. MCCARTHY. Or the other way around——

Mr. LAMALFA.—unless you are doing something——

Ms. MCCARTHY.—change land to water.

Mr. LAMALFA. Water—yes. A watered land to a dry land, which is what I talked about maybe in the swampbuster, sodbuster, and FSA. So you agree with that?

Ms. MCCARTHY. Yes.

Mr. LAMALFA. Okay.

Ms. MCCARTHY. I think.

Mr. LAMALFA. Can farmers continue to rely on this is the important takeaway here. Can they continue to rely on the regulation, as interpreted under section 404, as an exemption, and continue plowing their fields?

Ms. MCCARTHY. Yes.

Mr. LAMALFA. Okay. All right, Mr. Chairman, thank you. Thank you for your time and indulgence. I yield back.

The CHAIRMAN. You bet. The gentleman yields back. I have a couple of questions up here. When you were talking to Mr. DesJarlais earlier about water jurisdiction, you said that biological, chemical, and physical indicators must exist to determine if the water is jurisdictional, yet the rule uses biological, chemical, or physical. So can you clarify which is which?

Ms. MCCARTHY. It would be an *or*.

The CHAIRMAN. Or? Okay.

Ms. MCCARTHY. Yes.

The CHAIRMAN. All right. So that would——

Ms. MCCARTHY. It basically means that you have an ability to——

The CHAIRMAN. An or is a lot broader——

Ms. MCCARTHY.—pollute and destroy the downstream water.

The CHAIRMAN. All right.

Ms. MCCARTHY. That is right.

The CHAIRMAN. So *or* is a much broader interpretation. Also, and I know you are tired of talking about the GAO report on social media, but whatever you do, however you do it, there ought to be an audit trail. There ought to be a path by which we can track back to how it happened, and who happened, all those kind of good things. But use of a tool like Thunderclap, which hides that—can you commit that whatever you are going to do with social media that you will leave in play, or you will use tools, or leave in place an audit trail, an ability to see where it came from, and who did it within your organization? Are you—and not use——

Ms. MCCARTHY. Well, I certainly know who worked on these issues internally——

The CHAIRMAN. Well, I know that, but I——

Ms. MCCARTHY.—and GAO really was concerned that we—sorry——

The CHAIRMAN. We are almost there.

Ms. MCCARTHY.—retweet——

The CHAIRMAN. Right.

Ms. MCCARTHY.—was not able to be tracked back to EPA. So one of the things I tried to explain, although I don't agree with GAO, I am not disrespecting their decision. So we will work with OMB. It is Office of Management and Budget that did the guidance on how you use this Thunderclap——

The CHAIRMAN. Okay.

Ms. MCCARTHY.—and we followed it. And we will make sure that we——

The CHAIRMAN. All right.

Ms. MCCARTHY.—address the——

The CHAIRMAN. There are other innovations coming in. There is one called Kik, and others that allow you to anonymously do things, and we don't want our——

Ms. MCCARTHY. The one thing you can be sure of, it will never be me.

The CHAIRMAN. I got you. Well, second, let me apologize for how cold it is in this room. There are other offices——

Ms. MCCARTHY. It is cold in this room.

The CHAIRMAN.—in our suite that are like ovens, and so apparently our system doesn't know the difference between wintertime and summertime, so——

Ms. MCCARTHY. So I can now——

The CHAIRMAN. I apologize to that.

Ms. MCCARTHY. That is okay.

The CHAIRMAN. We do have a number of Members, and we, the Committee, have a number of questions we would like to submit for the record. We would appreciate a timely response to those. Not like you don't have enough to do, we are going to add to that. But we would like a timely response to that.

Again, thank you for being here this morning. I know you anticipated that this was not going to be the most fun you could have on a Thursday, but——

Ms. MCCARTHY. I thought it was incredibly informative——

The CHAIRMAN. I——

Ms. MCCARTHY.—and respectful——

The CHAIRMAN. Well, thank you——

Ms. MCCARTHY.—so thank you.

The CHAIRMAN.—very much. You are very kind with that. Thank you for being with us for 3 hours this morning. I appreciate that.

Under the rules of the Committee, the record of today's hearing will remain open for 10 calendar days to receive additional material and supplementary written responses from the witness to any questions posed by a Member. This hearing of the Committee of Agriculture is adjourned. Thank you.

[Whereupon, at 1:01 p.m., the Committee was adjourned.]

[Material submitted for inclusion in the record follows:]

SUBMITTED LETTER BY HON. DAN NEWHOUSE, A REPRESENTATIVE IN CONGRESS FROM WASHINGTON

January 28, 2016

Hon. GINA MCCARTHY,
Administrator,
U.S. Environmental Protection Agency,
Washington, D.C.

Dear Administrator McCarthy,

This letter is in regard to Omak Wood Products LLC located in Omak, Washington in Okanogan County. As you may know Okanogan County was home to record setting wildfires over the last two summers. This has had an extremely negative effect on the community, Federal forests and the Colville Confederated Tribe.

Three years ago Omak Wood Products opened for operation. Contributing over $60 million to the local economy and employing over 185 people, Omak Wood Products has been an economic driver and one of the largest employers of this small community. Now the mill has announced plans for a complete shutdown at the end of February.

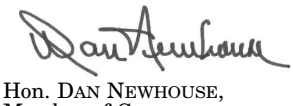
The community of Omak has worked tirelessly to find another investor so there will be no lapse in operation and loss of jobs. However, Omak Wood Products has not been issued an operating permit, which leaves any potential investor in a state of uncertainty.

Two years ago the EPA promised a re-write of the permit to more accurately reflect the current operations of the mill. Without the updated permit investors are unwilling and unable to move forward in the process of keeping the mill in production.

It is imperative that the permit is re-written and issued immediately, so investors can continue with their process of acquiring the operation.

I ask that you act swiftly in issuing this permit, to ensure jobs are not lost and an already struggling economy is not dealt another devastation. Thank you for your consideration of this request.

Sincerely,



Hon. DAN NEWHOUSE,
Member of Congress.

SUPPLEMENTARY MATERIAL SUBMITTED BY HON. GINA MCCARTHY, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY

Insert 1

Mr. CRAWFORD.—then, we can take this as an example and a validation of the fact that the rulemaking process is deeply flawed, and needs to be addressed, because this kind of stuff, to me, is not reflective of the opportunity that should be granted to the affected stakeholders. Let me switch gears with you quickly in the time I have remaining. I was just told yesterday that the EPA took action against a farmer who didn't comply with the SPCC rules on on-farm fuel storage by failing to have an SPCC plan for his oil storage tank that was 5,000 gallons in size, but the 2014 WOTUS specifically says that EPA can only require compliance for oil storage tanks in excess of 6,000 gallons until such time as the EPA completes a study, and a new rulemaking process is undertaken.

My understanding is that the study is complete which recommends a lower exemption threshold, but the rulemaking is still not finished. So my question to you is why is the EPA taking enforcement action against individuals who are not out of compliance, and isn't that a violation of the law?

Ms. MCCARTHY. Sir, I am happy to look into it and get back to you. If it just happened yesterday, I am really not familiar with it.

The EPA is are unaware of any situation such as the one described. The EPA respects the limits of its legal authorities as provided by law. The EPA's job is to assure compliance with the environmental laws as passed by Congress so that communities can be safeguarded from exposure to unhealthy pollutants and the environment can be protected.

Insert 2

Ms. KUSTER. Thank you, Mr. Chairman, and thank you to the Administrator for being with us today. Always great to have a New Englander in our Committee. I will be quick. I have two questions. The first one relates to this *Waters of the United States* rule, in conjunction with the EPA regulation on pesticides, and the Fish and Wildlife ruling regarding the long-eared bat. And my question on behalf of farmers, landowners, and timber owners in New Hampshire is how will your Agency coordinate with USDA and Fish and Wildlife to minimize confusion about the interplay between these three rules? If you follow.

Ms. MCCARTHY. That is a very good question that I am not sure I can answer. I will have to get back to you, because you have just baffled me with the bat question, connecting with the Clean Water and the other issues I understood.

The Clean Water Rule does not itself establish any new requirements regarding either the use of pesticides or compliance with the Endangered Species Act. As a result, issuance of the Clean Water Rule does not change current requirements regarding application of pesticides to waterbodies or provisions of the ESA, including provisions associated with listing of the long-eared bat. New Hampshire is one of the four states where the Pesticide General Permit (PGP) applies statewide. The EPA coordinated closely with USDA on the development of the 2011 permit. The EPA continues to coordinate closely with USDA and is currently consulting with the NMFS and FWS in the development and re-issuance of the 2016 PGP. Consideration of relevant endangered or threatened species will occur during that consultation.

Insert 3

Mr. LAMALFA. On the issue of Section 404, and the exemptions that are provided for agriculture under the Clean Water Act, normal farming activities, ranching, forestry, *et cetera,* including repeat plowing, seeding, cultivating, minor drainage, harvesting for that production of the food and the fiber and forest products, conservation practices, *et cetera,* no additional requirements, for example, that an activity be continuous are included.

Some of my constituents are continuous cropping on these lands, otherwise you lose your ability to have that exemption. Nowhere in the law does it specify that, but that is what is being carried out in my district by EPA or your associates. Sometimes we refer to them as henchmen, but in the Army Corps of Engineers that are carrying out some very outside the law activities with this regulation. So do you agree that section 404 does make no additional requirements that an activity be a continuously cropped, as we see it in the law?

Ms. MCCARTHY. I am not aware of it, but I certainly will have to get back to you on it, sir.

When Congress enacted CWA Section 404(f) in 1978, the statute included the term "normal" to characterize farming, ranching, and forestry practices covered by the exemption. "Normal" farming, ranching, and forestry practices are those that are established or ongoing. The agencies have not interpreted "normal" to mean "continuous" but rather that farming, ranching, or forestry has been previously established and ongoing on the property. If lands are left fallow, for example, as part of crop rotation or to rest soils, such lands remain subject to the exemptions. The agencies are always glad to answer landowner questions regarding the [section] 404(f) exemptions and to help landowners conduct their activities in waters consistent with the statute.

Insert 4

Mr. BENISHEK. Last September the EPA published an interim recommendation for environmental standards and eco labels for use in Federal procurement. And one of the recommendations for lumber excludes several credible standards that are widely used in the United States, including the Sustainable Forest Initiative, and the American Tree Farmer System standards. And we understand that this recommendation was made without consultation with the Department of Agriculture, who not only have a lot of expertise in forest management and forest projects, but who also publicly stated that the Sustainable Forest Initiative, and the American Tree Farmer System standards can be used to verify sustainability of forest products. Furthermore, it is supposedly based on a determination by the Department of Energy that has no formal analysis behind it. So can you explain the basis of this recommendation for Federal procurement?

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Mr. BENISHEK. Why wouldn't you consult with the Department of Agriculture prior to making this kind of a rule?

Ms. MCCARTHY. I am not sure that wasn't done, sir, but I certainly can check.

Under Executive Order 13693—*Planning for Federal Sustainability in the Next Decade*—the EPA issued recommendations to assist Federal purchasers in identifying and procuring environmentally sustainable products. The EPA's Interim Recommendation for the lumber/wood category is based on the Department of Energy's Fiscal Year 2016 (FY16) Priority Products List.

As a result of stakeholder inquiries since the release of the Interim Recommendation, the EPA has met and is continuing to work with USDA and DOE's Office of Sustainable Environmental Stewardship to gain further information. The EPA's Standards Executive is reaching out to the Sustainable Forestry Initiative, the American Tree Farm System, and the other forestry labels that stakeholders have requested the EPA consider. The EPA will be in touch with these groups regarding the agency's review of forestry labels and their alignment with the National Technology Transfer and Advancement Act, the OMB Circular A–119, and related Federal policies that guide the EPA's use of voluntary consensus standards and private-sector conformity assessment activities. In addition, the EPA continues its progress with piloting the Guidelines for Assessing Standards and Ecolabels for Use in Federal Procurement, and hopes that information gleaned from this process will inform thinking related to the lumber/wood category. Finally, DOE continues to conduct research to inform their FY16 Priority Products List. The EPA looks forward to reviewing all of this additional data to inform if and how the lumber/wood category of Interim Recommendations might be revised.

The EPA has, and will continue to provide, mechanisms for public input as we develop these recommendations. The agency issued *Federal Register* Notices on the initial draft guidelines in 2014 and in March 2015 for the launch of our pilot work.[1] Those FRNs were open to public comment and they marked the beginning of our efforts to engage multi-stakeholder panels whose counsel will be considered as we move to finalize our recommendations. Further, any Federal acquisition requirements stemming from the recommendations would include a public comment process prior to incorporation into the Federal Acquisition Regulations. As such, FAR Case 20 15–033 has been developed in order to integrate the new requirements of E.O. 13693 into the FAR. All next steps related to this case, including as to when it will be available to the public, are viewable at *http://www.acq.osd.mil/dpap/dars/far_case_status.html*.

Insert 5

Mr. LAMALFA.—appreciate your time, and your grace with which you have answered the questions today. Just to bring your attention quickly, a Presidential memorandum recently issued, it is called *The Mitigating Impacts on Natural Resources from Development, and Encouraging Related Private Investments.* I don't expect you to know this, and not to put you on the spot here, but, again, *Mitigating Impacts on Natural Resources from Development, and Encouraging Related Private Investments.* It is a fairly new Presidential memorandum.

It appears to be carrying the weight of an Executive Order, and seems like quite a significant departure from current policy. Looking like it is going to go back and re-assess every possible impact that a man-made activity might have on public land, or any natural resource on Federal projects. So do you plan to follow this policy, and can you walk me through, in a letter later on, how you do plan—are you aware of that title?

Ms. MCCARTHY. I have not been made familiar with the details, so I will have to get back to you on how——

Mr. LAMALFA. I believe it was out in October.

Ms. MCCARTHY.—my Agency would respond. We have very little ownership of Federal lands.

The Presidential Memorandum, "Mitigating Impacts on Natural Resources from Development and Encouraging Related Private Investment," was issued on Novem-

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[1] *Federal Register* Notice, February 27, 2014, "Draft Guidelines for Product Environmental Performance Standards and Ecolabels for Voluntary Use in Federal Procurement" (79 FR 11102) [*See Attachment 1*]. *https://www.gpo.gov/fdsys/pkg/FR-2014-02-27/pdf/2014-04329.pdf*.

Federal Register Notice, March 19, 2015, "Agency Information Collection Activities; Proposed Collection and Comment Request; Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement" (80 FR 14372). [*See Attachment 2*] *https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06275.pdf*.

ber 3, 2015, and applies to the Departments of the Interior, Defense, and Agriculture and to the EPA and NOAA. A key goal of the Memorandum is to "increase private investment in natural resource restoration" and to accomplish this by ensuring that "[f]ederal policies are clear, work similarly across agencies, and are implemented consistently across agencies." Section 1 calls on agencies to "adopt a clear and consistent approach for avoidance and minimization of, and compensatory mitigation for, the impacts of their activities and the projects they approve." Clear policies with respect to mitigation are expected to offer opportunities for increasing private investment in natural resource restoration. General "principles" guiding this effort are defined in section 3, and section 4 calls on selected agencies to review and update specific manuals, handbooks, and policies. As indicated in section 5(b), the Memorandum is to be "implemented consistent with applicable law."

SUBMITTED QUESTIONS

Response from Hon. Gina McCarthy, Administrator, U.S. Environmental Protection Agency

September 6, 2016

Hon. K. MICHAEL CONAWAY,
Chairman,
House Committee on Agriculture,
Washington, D.C.;

Hon. COLLIN C. PETERSON,
Ranking Minority Member,
House Committee on Agriculture,
Washington, D.C.

Dear Mr. Chairman/Congressman Peterson:*

Thank you for the opportunity to respond to the questions for the record following the February 11, 2016, hearing on impacts of the Environmental Protection Agency's actions on the rural economy. Enclosed are the EPA's responses to the questions.

If you have any further questions, please contact me or your staff may contact Sven-Erik Kaiser at [**Redacted**] or [**Redacted**].

Sincerely,

NICHOLE DISTEFANO,
Associate Administrator.

Questions Submitted by Hon. K. Michael Conaway, a Representative in Congress from Texas

Question 1. The GAO report on illegal grassroots lobbying points to the tweet "I love clean water" as one of the violations. What we have failed to discuss was EPA's use of the innovative tool "Thunderclap" to push that tweet to more viewers, around 1.8 million. In addition to twitter, EPA used Facebook and YouTube for an aggressive social media campaign for the WOTUS rule. Did EPA count responses to the social media campaign as comments in support of the rule? How many of those people actually read and understood the details of the rule?

Answer. The EPA did not count responses on social media as comments. For any statements made in the preamble of the final rule or to the public regarding the number of comments received, the EPA only counted comments submitted to the docket or sent to the dedicated e-mail address for this rulemaking.

Question 2. The 6th Circuit Court of Appeals, in its order to temporarily stay the rule, found that the burden of the WOTUS Rule outweighed any harm to the agencies in keeping the *status quo.* What are your thoughts on this?

Answer. The EPA and the U.S. Army Corps of Engineers revised their longstanding definition of the term "*waters of the United States*" to provide the public with more consistent, predictable, and understandable regulations defining the scope of the Clean Water Act (CWA). The result is a new rule intended to be faster, easier, and cheaper to implement saving the public time and money. Delaying implementation of the Clean Water Rule prevents the agencies from providing the pub-

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* **Editor's note:** There were identical letters sent to the Chairman and Mr. Peterson. For the purpose of publishing they have been combined.

lic with these significant improvements. The agencies are, however, fully complying with the 6th Circuit order by staying implementation of the Clean Water Rule and implementing the prior regulations consistent with the best science and the law.

Question 3. Assuming the Administration will continue to keep the final rule as written, and that the rule is to be implemented, will you consider delaying implementation of the rule to provide the time necessary for the Agencies to get adequately trained and for the regulated community to understand how Federal jurisdictional decisions will be made so that they can comply?

Answer. The agencies are using the time created by the stay to address questions regarding the Clean Water Rule raised by states, local governments, and the public, and to provide agency field staff with additional training to ensure we are in the best possible position to fairly and effectively implement the rule when the stay is lifted. We will also continue to update information and respond to questions when the new rule goes into effect to provide the public with the transparency and clarity needed to make use of the new rule more timely and less costly.

Question 4. How is EPA ensuring that the new *Waters of the United States* (WOTUS) Rule is not being utilized or implemented, in light of the current nationwide stay? What actions has EPA taken to ensure that all EPA regions and staff are not using or implementing the Rule?

Answer. The EPA and the U.S. Army Corps of Engineers distributed national guidance to their field offices on the same day the 6th Circuit stay was issued directing all field staff to cease implementing the Clean Water Rule and instead resume application of the agencies' prior regulations defining the scope of CWA jurisdiction. The agencies regularly work with their field staff to respond to questions and to ensure the stay is being implemented consistent with the court's decision.

Question 5. Do you believe that the Army Corps is capable of executing the Clean Water Act 404 program without EPA's involvement? Why or why not?

Answer. The EPA and the U.S. Army Corps of Engineers have worked together effectively in the implementation of the CWA section 404 program for more than 40 years since enactment of the statute in 1972. The agencies will continue to build from their experience to make future implementation of the section 404 program even more responsive to permit applicants as we work to protect human health and the environment.

Question 6. When dealing with interagency disagreements and responses to public comments during the development of the WOTUS Rule, who had the final say on what was and was not considered a *Water of the U.S.?*

Answer. Final decisions regarding the Clean Water Rule were made jointly by senior policy managers at the Department of the Army and the EPA following extensive collaboration and discussion and consistent with science and the law.

Question 7. EPA has made it a point to state that ditches are not included as jurisdictional in the final *Waters of the United States* rule. However, if a ditch can be classified as a tributary, and ditches are generally formed through excavation activities, could you clarify what types of ditches are truly exempt?

Answer. The agencies have stated consistently that most ditches were subject to regulation under the CWA during the 1970s, 1980s, and 1990s—and that actual regulation was inconsistent and unclear causing uncertainty for landowners such as farmers and ranchers. A key goal of the Clean Water Rule is to eliminate this uncertainty and make clear for landowners, for the first time, the types of ditches that are and are not covered by the CWA. An important part of the new Clean Water Rule is a list of waters, including many types of ditches, that are always excluded from regulation under the CWA. The new rule makes clear that most ditches on farmlands, including all ditches that flow only after it rains, or ditches excavated from dry land, are never covered under the CWA. In addition, the new rule preserves all farming, ranching, and forestry exemptions, including ditch exemptions. These exemptions in Federal law allow landowners to construct irrigation ditches and maintain drainage ditches, for example, without needing to get permits or approval from the government.

Question 8. Would the ditch exemption be automatically given if the business, farmer, or local government believes their ditch is exempt, or do they have to prove the ditch is exempt? Will they have to ask for the exemption?

Answer. The agencies wrote the Clean Water Rule to make it clear and understandable. The rule does not change the longstanding application of the section 404(f) exemptions. The public, for example, is not required to obtain confirmation or approval from the government that an exemption applies. The agencies are available at no cost, however, to answer questions regarding jurisdiction, and the U.S.

Army Corps of Engineers can provide landowners with written jurisdictional determinations regarding the status of ditches on their property.

Question 9. What actions have the Agency taken to ensure the Clean Water Act's prior converted cropland exemption is being preserved?

Answer. The Prior Converted Cropland (PCC) exclusion was written into the agencies' CWA regulations in 1993 to provide the public with certainty regarding the jurisdictional status of these wetlands. This regulatory exclusion was not changed by the Clean Water Rule, and the preamble to the final rule makes clear that there will be no change in the implementation of the exclusion as the Clean Water Rule is put into effect. The public can be certain the PCC exclusion will continue to be implemented as it has been since 1993.

Question 10. What actions have the Agency taken to ensure the Clean Water Act exemptions for normal farming activities under Section 404(f) are being preserved?

Answer. The agencies issued regulations following enactment of the CWA section 404(f) exemptions in 1978 and these regulations were not changed by the Clean Water Rule. The agencies made clear in the Preamble to the final Clean Water Rule and in information published on their websites that there will also be no change to implementation of the section 404(f) exemptions resulting from the Clean Water Rule. The public can be certain that the section 404(f) exemptions will continue to be applied as they have been since their enactment in 1978.

Question 11. On December 14, 2015, the Government Accountability Office (GAO) published a legal opinion finding that the EPA violated Federal law by engaging in *covert propaganda* and *grassroots lobbying*. How do you plan to rectify what many in the agricultural community consider a flawed rule from a flawed process?

Answer. In promulgating the Clean Water Rule, the EPA complied fully with the CWA and all laws applicable to the rulemaking process. The GAO opinion did not comment on or examine the EPA's rulemaking process. The GAO evaluated the EPA's use of certain social media platforms tools during the time of the rulemaking to determine whether they violated restrictions that prohibit using Federal funds for either (1) indirectly lobbying Congress in support of, or in opposition to pending legislation or (2) publicity that is self-aggrandizing, purely partisan, or conceals the agency's role in sponsoring the material. After examining a database of social media outreach materials, the GAO took issue with only a single EPA blog post with two hyperlinks to articles on third party websites and the EPA's use of a social media tool called "Thunderclap." The alleged violations had no impact on the EPA's rulemaking process or on the EPA's compliance with any law applicable to the rulemaking, including the Administrative Procedure Act.

Question 12. What role did USDA play in the development of the WOTUS rule? When did EPA begin the process of developing the rule? When did you first engage USDA?

Answer. The agencies consulted with other Federal agencies, including the U.S. Department of Agriculture, throughout the process of developing the Clean Water Rule. USDA provided comments on the Clean Water Rule to the Office of Management and Budget (OMB) consistent with the interagency review process governed by Executive Order 12866. EPA and the U.S. Army Corps of Engineers used these comments in working to meet a key Clean Water Rule goal of improving clarity and predictability for farmers and reducing regulatory burdens on agricultural lands. The agencies began consulting with the USDA staff as a part of the process to prepare jurisdictional guidance during the first term of the Obama Administration and throughout the subsequent process of developing the Clean Water Rule. USDA has consistently emphasized agriculture's outstanding stewardship track record in delivering water resource benefits locally, regionally, and nationally.

Question 13. Some observers suggest that the proposed 70 parts per million (ppm) standard for ozone is below naturally occurring background levels. By reducing the ozone standard to 70 ppm, large swaths (largely rural) of the country will likely be designated as nonattainment. If this is correct, the new standard would be virtually unachievable. In light of this, how does EPA justify the billions, if not trillions, of dollars of burdensome costs that could be expected to be borne ultimately by the American people and their communities to attempt to comply with an impossible standard?

Answer. The EPA projections show that the vast majority of U.S. counties will meet the revised standards by 2025 without taking additional action to reduce emissions. Existing and proposed Federal rules, such as Tier 3 vehicle standards, Mercury and Air Toxics Standards, and measures to address the 2010 sulfur dioxide National Ambient Air Quality Standards (NAAQS) will help states meet the standards by reducing ozone forming pollution.

Uncontrollable background concentrations of ozone, from sources like natural events, *e.g.,* wildfires, or foreign emissions, are not expected to preclude attainment of a revised ozone standard with a level of 70 ppb. In addition, Congress established requirements for implementing the health based NAAQS standards that recognize issues like background ozone and interstate transport to ensure that states are not responsible for emissions they cannot reasonably control. The Clean Air Act does not require states to demonstrate attainment of NAAQS in all areas. Areas that are significantly affected by emissions outside their control may receive special consideration.

When setting the level of a NAAQS, the EPA is prohibited by law from considering the costs of implementation. Courts, including the Supreme Court, have held uniformly that the EPA may not consider issues of implementation costs when establishing NAAQS. The Clean Air Act directs the EPA to set NAAQS at a level requisite to protect public health with an adequate margin of safety and to protect the public welfare from any known or anticipated adverse effects of air pollutants.

Question 14. Our country has made great strides in reducing our ozone levels—roughly 33% reduction since 1980—by keeping the standards practical and attainable. However, EPA is now pursuing a standard that cannot be achieved and therefore whose health benefits would never be realized. What is EPA's justification for creating an ozone standard that is set so low that it cannot be reasonably achieved while recognizing that the health benefits from such a standard will never be reached?

Answer. The EPA believes that a primary ozone standard with a level of 70 ppb will substantially improve public health protection across the country and will provide the adequate margin of safety the law requires—including for children, who are one of the groups most at risk from ozone exposure. The public health benefits of a 70 ppb ozone NAAQS are significant—estimated at $2.9 to $5.9 billion annually in 2025. It is also worthwhile to note that the EPA projections show that the vast majority of U.S. counties will meet the revised standards by 2025 without taking additional action to reduce emissions. Existing and proposed Federal rules, such as Tier 3 vehicle standards, Mercury and Air Toxics Standards, and measures to address the 2010 sulfur dioxide NAAQS will help states meet the standards by reducing ozone forming pollution.

Question 15. What specific impact would being designated as a nonattainment area under the new standard have on job creation and economic growth in rural communities?

Answer. Once the EPA sets a new air quality standard, or revises an existing standard, the Clean Air Act requires the EPA to designate areas as meeting the standards (attainment areas) or not meeting them (nonattainment areas) based on local air quality. The agency also may designate an area as unclassifiable, meaning there is not enough information to make a determination. States make area designations recommendations, and the EPA works closely with states and Tribes as it finalizes the initial designations and boundaries for any nonattainment areas.

All states with nonattainment areas must develop emission inventories and implement a preconstruction permitting program designed to provide additional air quality safeguards for those areas. For nonattainment areas classified "moderate" or higher, which are unlikely to be rural areas, states must develop state implementation plans showing how the areas will meet the standards. These plans must include reasonable available control technology standards for certain types of ozone producing emission sources in the nonattainment area. They also can include Federal measures that will result in local emissions reductions, such as national mobile source requirements. States may take area-specific considerations into account in developing these plans.

Question 16. EPA finalized the recent 2015 stringent ozone standard when it hadn't even released implementation rules for the last standard set in 2008. In fact, states were forced to make designations under the standard without final implementation rules from EPA. Doesn't it make sense to get the 2008 standard implemented before burdening states with double-regulation?

Answer. The EPA and state co-regulators share a long history of managing ozone air quality under the Clean Air Act, underpinned by a wealth of previously issued EPA rules and guidance. The overall framework and policy approach reflected in the implementing regulations for the 2008 ozone standards provide an effective and appropriate template for the general approach states would follow in planning for attainment of the 2015 ozone NAAQS. Planning and implementation work to meet the 2015 ozone standard will build on progress states have already made to plan for and meet the 2008 standards. In particular for areas where states are still actively working toward attaining the 2008 ozone NAAQS, the EPA is committed to helping

air agencies identify and take advantage of potential planning and emissions control efficiencies that may occur within the horizon for attaining the 2015 standards. Following past precedent, the EPA intends to propose revoking the 2008 standards and provide transition rules intended to help avoid any potential inefficiencies as states begin implementing the Clean Air Act's requirements for the 2015 standards.

Question 17. The National Association of Clean Air Agencies testified to EPA that the new ozone standard "will have a profound impact on the work of state and local air pollution control agencies." Did EPA assess what impact implementing the new ozone standards would have on state and local agencies already implementing the 2008 standard—shouldn't these standards be harmonized?

Answer. As provided in the previous answer, the EPA and state co-regulators share a long history of managing ozone air quality under the Clean Air Act, underpinned by a wealth of previously issued EPA rules and guidance. Planning and implementation work to meet the 2015 ozone standard will build on progress states have already made to plan for and meet the 2008 standards. The overall framework and policy approach reflected in the implementing regulations for the 2008 ozone standards provide an effective and appropriate template for the general approach states would follow in planning for attainment of the revised ozone NAAQS. In particular for areas where states are still actively working toward attaining the 2008 ozone NAAQS, the EPA is committed to continue helping air agencies identify and take advantage of potential planning and emissions control efficiencies that may occur within the horizon for attaining the 2015 standards. Following past precedent, the EPA intends to propose revoking the 2008 standards and provide transition rules intended to help avoid any potential inefficiencies as states begin implementing the Clean Air Act's requirements for the 2015 standards.

Question 18. EPA chose to project the costs of its new ozone standard to 2025, 8 years after counties will be designated as nonattainment. What consequences will those counties face while designated nonattainment?

Answer. The Clean Air Act requires that within 3 years of the EPA setting a new air quality standard, or revising an existing standard, the EPA must designate areas as meeting the standards (attainment areas) or not meeting them (nonattainment areas) based on local air quality. The agency also may designate an area as unclassifiable, meaning there is not enough information to make a determination. Governors make initial designations recommendations, and the EPA works closely with states and Tribes as it determines initial designations and boundaries for nonattainment areas.

All states with nonattainment areas must develop emission inventories and implement a preconstruction permitting program designed to provide additional air quality safeguards for those areas. States with nonattainment areas classified as "Moderate" or higher must develop state implementation plans showing how the areas will meet the standards. These states also must adopt reasonable available control technology standards for certain types of emission sources in the nonattainment. They also can included Federal measures that will result in local emissions reductions, such as national mobile source requirements.

Question 19. EPA chose to project the costs of its new ozone standard to 2025. Since EPA bases its entire economic analysis on predicted 2025 air quality, will the Agency support extending compliance deadlines under the standards to 2025?

Answer. The Clean Air Act governs the process and timing for initial area designations and associated compliance deadlines after the EPA establishes a new or revised NAAQS. Following Clean Air Act requirements, the EPA anticipates the following schedule for the 2015 ozone NAAQS:

- By October 2017: the EPA issues final area designations; those designations likely would be based on 2014–2016 air quality data. If preconstruction permitting program requirements for the nonattainment area do not already exist, Federal permitting regulations apply until they are replaced by state adopted programs;
- 2019: States submit area-specific inventories of ozone producing emissions;
- 2020 to 2021: For nonattainment areas classified as "Moderate" and above, states, and any Tribes that choose to do so, complete development of implementation plans, outlining how they will reduce pollution to meet the standards. State and Tribal plans can include Federal measures, and any local or statewide measures needed to demonstrate that a nonattainment area will meet the standards by its attainment date; and
- 2020 to 2037: Nonattainment areas are required to meet the primary (health) standard at varying deadlines throughout this time, depending on the severity of an area's ozone problem.

Question 20. I am concerned that EPA continues to propose new programs like the Urban Waters program and the Resilient Finance Center rather than finding ways to support these goals through the Agency's core programs. What is EPA doing to ensure that these programs aren't creating a fragmented approach to water resource protection?

Answer. The Urban Waters Program and the Water Infrastructure and Resiliency Finance Center are examples of initiatives that cross water program boundaries and are most effectively supported in ways that reflect this multi-program relationship. The Water Infrastructure and Resiliency Finance Center, for example, identifies financing approaches to help communities make better informed decisions for local needs such as drinking water, wastewater, and storm water infrastructure. The Center increases collaboration between state and local governments and the private-sector, expands public-private partnerships, and increases the use of Federal credit programs. These are all actions that reach beyond the activities of one core Federal water program and, instead, serve to enhance and strengthen multiple Federal, state, and local objectives. We believe that managing these programs outside a single core program, therefore, allows the EPA to more effectively integrate and support multiple water efforts and to take advantage of these initiatives and reduce potential fragmentation in Federal, state, and local clean water programs.

Question 21. Will EPA use the time the Supreme Court has provided everyone to better understand electric grid operations so you will better understand and account for the cost and reliability issues associated with your assumptions about unprecedented growth in renewables? Do you agree with President Obama and Secretary Vilsack that agricultural products can help reduce the nation's carbon emissions? Why does the Clean Power Plan by default treat carbon from agricultural crops the same as fossil fuel emissions?

Answer. On February 9, the Supreme Court granted a motion to stay the Clean Power Plan. As a result of that action, states are not currently required to submit a state plan or a request for extension by September 6, 2016.

A core principle of the Clean Power Plan (CPP) is the importance of providing states the flexibility to develop their own approaches to address carbon dioxide (CO_2) emissions. This flexibility recognizes the unique circumstances of each state when it comes to their energy mix, and their approaches to energy efficiency and renewable energy. In the CPP, states have the flexibility to choose whether or not to include biomass as part of their state plans, and if so, the flexibility to describe the types of biomass that are being proposed for use under their state plans, how those proposed feedstocks or feedstock categories should be considered as "qualified biomass" (*i.e.,* a biomass feedstock that is demonstrated as a method to control increases of CO_2 levels in the atmosphere), and explain the proposed valuation of biogenic CO_2 emissions.

The EPA generally acknowledges the CO_2 and climate policy benefits of waste-derived biogenic feedstocks and certain forest- and agriculture-derived industrial by-product feedstocks. The final rule also provides that states may demonstrate that the use of agricultural and forest biomass feedstocks appropriately control increases of CO_2 levels in the atmosphere.

Question 22. How long has EPA been working on its Biogenic Accounting Framework for agricultural crops? When does EPA anticipate finishing that process?

Answer. As part of the EPA's effort to advance the technical understanding of the role of biomass in addressing greenhouse gas emissions, in November 2014 the EPA released the second draft of its scientific report, Framework for Assessing Biogenic Carbon Dioxide for Stationary Sources. The revised report takes into account Science Advisory Board peer review recommendations on the 2011 Draft Framework, as well as the latest information from the scientific community and other stakeholders. In February 2016, the biomass SAB Advisory panel delivered its draft final peer review report to the full chartered SAB for a quality review. The full chartered SAB held a public, in person quality review meeting at the end of March 2016 and offered its recommendations on the draft final peer review report to the biomass SAB Advisory Panel. EPA is reviewing recommendations from the full chartered SAB as well as those finalized by the biomass SAB Advisory Panel. More information on the chartered SAB meeting can be found at *http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/BOARD*.

Question 23. The public is threatened by insect-borne diseases—West Nile Virus is a good example. Some of the critical products used to control mosquitoes are also the backbone of Integrated Pest Management plans. These include a class of pesticides known as OP's. Tell me more about EPA's plans for OP's used to protect public health against very dangerous and prolific pests. How is EPA considering the importance of these products to human health in its risk assessments? Is EPA fol-

lowing established protocols for consultations with CDC and other Federal agencies with public health expertise?

Answer. The EPA recognizes that certain organophosphate pesticides are important tools in strategies to control pests that vector diseases. The EPA considers the benefits, both public health and others, of these pesticides, along with their risks, before making any regulatory decisions. The EPA consults with the Centers for Disease Control and Prevention when making a regulatory decision for any pesticide used to control a pest of public health significance. In addition, EPA consults with the Secretary of Health and Human Services on the identification of pests of significant public health importance and solicits the views of the Secretary on certain environmental pesticide regulations. The EPA also frequently consults with other interested stakeholders to ensure that the agency has a complete picture of the benefits and have properly evaluated any proposed mitigation. Fortunately there are a number of other EPA registered products that can be used for effective mosquito control.

The EPA is currently evaluating the organophosphates in our statutorily mandated registration review program. The agency will take comment on our assessments before consideration of any risk management. In addition, the EPA will engage with the registrants and the public health community to ensure that we are considering all relevant data in our assessments. Where states, localities, other Federal agencies, and user groups have relevant information that could aid in the analysis, the agency will utilize this information as well. Similarly, as new scientific information becomes available that changes our understanding of potential risks as well as pesticide efficacy, we can revisit our decisions.

Question 24. Exactly how many new products or product uses have been brought into the market, and, how many products and uses have been restricted or effectively lost under your tenure as Administrator?

Answer. Approximately 170 new active ingredients and more than 1,700 new uses of previously registered active ingredients have been registered during my tenure. During the same time period, the EPA made about 165 registration review decisions on active ingredients and approximately 300 uses have been canceled. Registration review is the agency's current re-evaluation program, which focuses on the pesticide active ingredient rather than products or uses.

Of the 165 registration review decisions on active ingredients, about ½ of these decisions required no changes or minor label changes. Labeling changes can include removing uses, reducing application rates and adding protections for vulnerable populations to address specific human health and ecological concerns. They also improve clarity so that the user can better understand the label and use the product safely. The other ½ of the decisions made involved voluntary cancellation by the registrants primarily for business reasons.

Question 25. Rather than going through normal public process to propose to cancel a registration—has the Agency ever asked a court to order to vacate a registration? If so, please describe those circumstances.

Answer. Subsequent to registering Enlist Duo, the EPA became aware of previously existing information about possible synergistic effects that had not been considered as part of the initial registration decision. As a result, the agency could no longer represent to the Court that its conclusions were correct regarding whether issuance of the registration met the standard in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and whether the buffer zones included in the registration support the finding that the registration will have no effect upon threatened or endangered plant species. The EPA therefore sought from the Court an order of remand with *vacatur.* This is the first time that the EPA has asked a court to vacate a pesticide registration.

Question 26. EPA is supposed to take into account the benefits of a product, such as protection of the public health from disease-carrying pests, protection of our nation's buildings and infrastructure, protection of the food supply. However, recent EPA activities appear to focus disproportionately on the hazard side of that assessment while discounting factors like exposure and benefits. What additional data does the EPA need in order to better account for pesticide benefits?

Answer. Under FIFRA, the EPA must ensure that a pesticide does not cause "unreasonable adverse effects." An important factor in that determination is the consideration of other factors including the benefits associated with the use of the pesticide. The EPA typically starts the evaluation of a pesticide by conducting risk assessments to determine if there are any "risks of concern" before weighing the other factors. However, before taking any registration action, the EPA considers the benefits the pesticide offers and the impacts of any mitigation option on the users of the

pesticide (that is, any loss of benefits). A risk-benefit analysis is applied to ecological and occupational risks under FIFRA.

When considering the use of a pesticide on food, the agency must consider all dietary risk from residues that result from a pesticide use and establish a tolerance (or exemption) under the Federal Food, Drug, and Cosmetic Act (FFDCA). Generally, the safety standard for the review of pesticide chemical residues under the FFDCA is a risk-based standard that requires the EPA to make a "reasonable certainty of no harm" determination when it establishes a pesticide tolerance to regulate the amount of pesticide residue in food. When making a determination under FFDCA, the EPA normally considers options for meeting the safety standard and tries to select the one with the least impact on the user community. If the safety standard of FFDCA is not met, benefits cannot be considered in order to allow the use of the pesticide.

Benefits may be considered when making a regulatory decision under FIFRA when considering ecological or risks posed to workers. In assessing the benefits of the use of agricultural pesticides, the EPA largely relies on information generated by the land-grant university system, USDA, and other stakeholders. Information on non-agricultural uses, including public health, residential, and industrial uses, is more limited and the EPA relies heavily on our public process to solicit information about the pests targeted by specific pesticides and the advantages a specific pesticide may have in particular situations.

Question 27. I understand that EPA will complete and release its 5 year reissuance of the Clean Water Act-based Pesticide General Permit. What changes should we expect to see in the reissued Pesticides General Permit based on the new Clean Water Rule expansion?

Answer. The Clean Water Rule does not itself establish any new requirements regarding the use of pesticides. As a result, issuance of the Clean Water Rule does not change the National Pollutant Discharge Elimination System (NPDES) requirements regarding application of pesticides to waterbodies. The EPA's experience with the Pesticide General Permit (PGP) during the last four years demonstrates it is working well to ensure that use of pesticides is being managed to minimize potential regulatory burdens while effectively protecting the nation's water resources and public health. Conditions and requirements in the EPA's proposed PGP remain largely unchanged from the 2011 PGP. Final decisions regarding re-issuance of the PGP will reflect public input and coordination with stakeholders.

Question 28. Please provide a comprehensive list of *all* Agency actions, not just rulemakings, over the last 8 years and those planned through the end of 2016 that restricted or have the potential to restrict existing or new uses of pesticides.

Answer. The pesticide registration review process began in 2006 with the first decisions being made a few years later. To date, 165 decisions have been made. Of these decisions, 83 involved requests from the registrants to voluntarily cancel their registrations, in most cases for business decisions that were independent of the agency's review. For the remaining 82, many required no change to the registration or minor label clarification to make it easier for the user to understand and use the product correctly. The EPA's anticipated registration review schedule can be found at *www.epa.gov/pesticide-reevaluation/registration-review-schedules* [*See Attachment 3*].

During the same time period, the EPA has registered approximately 170 new pesticide active ingredients and over 1,700 new uses of already-registered active ingredients, providing numerous new products for use in agricultural and non-agricultural settings. These newly registered products are designed to address emerging pest pressures and will have a significant role in the marketplace.

Of these regulatory decisions to restrict or cancel certain registrations, the EPA made these decisions after careful consideration of all available data and consistent with existing statutory requirements. For example:

- In 2010, the EPA announced its decision to terminate all uses of endosulfan due to unacceptable risks to farmworkers and wildlife. The EPA signed a Memorandum of Agreement with the registrants of endosulfan that resulted in voluntary cancellation and provided for a phase-out of all existing endosulfan uses in the United States in order to allow time for growers to transition to newer alternatives;
- In 2012, the EPA limited the use of chlorpyrifos by significantly lowering pesticide application rates and creating "no-spray" buffer zones around public spaces, including recreational areas and homes, due to concerns for unacceptable risks to children and bystanders;

- In 2014, the EPA canceled propoxur pet collars. In the fall of 2013, the EPA completed the propoxur pet collar risk assessment. The EPA's risk assessment indicated risks of concern to children from exposure to pet collars containing propoxur;
- In 2015, the EPA reached an agreement with Reckitt Benckiser, the manufacturer, to cancel all distribution of 12 consumer use d-CON products that did not meet the EPA's current safety standards, raising concerns for risks to children and pets. Additionally, eight of the 12 products pose unacceptable risks to certain wildlife;
- In 2015, the EPA proposed to revoke all chlorpyrifos tolerances due to concerns with estimated exposure from drinking water in certain watersheds. A final tolerance rule is anticipated in March 2017;
- On November 24, 2015, while the issuance of the initial registration was being challenged in Federal court, the EPA sought the remand and *vacatur* of the Enlist Duo registration because the EPA became aware of previously existing information about possible synergistic effects that had not been provided to the EPA or considered as part of the initial registration decision. The EPA cannot be sure, without a full analysis of the new information, that the current registration does not cause unreasonable effects to the environment, which is a requirement of the registration standard under FIFRA;
- On July 2, 2013, the Pollinator Stewardship Council and others, petitioned for review of the sulfoxaflor registration in the Ninth Circuit Court of Appeals. On September 10, 2015, the Court issued its opinion, finding that the registration was not supported by substantial evidence to demonstrate no unreasonable adverse effects to honey bees would result from the registration of [sulfoxaflor]. Although the initial sulfoxaflor submission contained all the data the EPA determined was necessary by the EPA for registration of a new agricultural insecticide, the Court vacated the registrations and remanded them to the EPA to "obtain further studies and data regarding the effects of sulfoxaflor on bees as required by the EPA regulations." The *vacatur* of the sulfoxaflor registrations became effective November 12, 2015. As the registrations were no longer in effect under FIFRA, on the same date the EPA issued a cancellation order to address existing stocks. Although the product registrations were vacated, the tolerances for sulfoxaflor residues on treated commodities that were established under the FFDCA, remain in place; and
- On March 4, 2016, the EPA issued a notice of intent to cancel the registration of four pesticide products containing the insecticide flubendiamide owing to the registrants' failure to comply with a required condition of their registrations. The particular condition obligated the registrants to request cancellation if, after receiving additional required data, the EPA determined that use of flubendiamide did not meet the FIFRA standard for registration. Prior to issuing the notice, the EPA concluded that the continued use of flubendiamide will result in unreasonable adverse effects on the environment, particularly benthic invertebrates, which are an important part of the aquatic food chain, particularly for fish.

Over the past 8 years, the EPA has issued a number of regulations with the intention of providing clarity to the regulated community and other stakeholders or to update information that has become inaccurate or out of date. Examples of these rulemaking efforts include:

- Minimum Risk (Published 12/28/2015): This final rule more clearly describes the active and inert ingredients permitted in products eligible for the exemption from regulation for minimum risk pesticides. These changes maintain the availability of minimum risk pesticide products while providing more consistent information for consumers, clearer regulations for producers, and easier identification by states, Tribes and the EPA as to whether a product is in compliance with the exemption;
- Crop Grouping (Published Phase 1: 12/7/2007; Phase 2: 12/8/2010; Phase 3 8/22/2012; Phase 4: anticipated 2016): These final rules are likely to reduce the number of residue chemistry studies required to establish a tolerance for a crop within these crop groupings because instead of testing each crop individually, only the representative crops would need to be tested. Thus, the new crop groups ease the process for an entity to request and for the EPA to set pesticide tolerances on greater numbers of crops. Pesticides will be more widely available to growers for use on crops, particularly specialty crops;

- Data Requirements for Antimicrobials (158W) (Published 5/8/2013): the EPA revised the data requirements for antimicrobial pesticide products to reflect current scientific and regulatory practice, and to provide the regulated community with clearer and transparent information about the data needed to support pesticide registration decisions for antimicrobial products. The EPA would use this information to conduct risk assessments for a particular pesticide;
- Prions as Pests (Published 2/28/2013): In 2003, the EPA determined that a prion (proteinaceous infectious particles) is a "pest" under FIFRA and that a product intended to reduce the infectivity of prions on inanimate surfaces (*i.e.,* "prion product") is considered to be a pesticide. The EPA believes that regulating prion-related products protects human health and the environment against unreasonable adverse effects and ensures that such products are effective;
- Export Labeling (Published 1/18/2013; Revisions Published 12/19/2014): the EPA revised the regulations pertaining to the labeling of pesticide products and devices that are intended solely for export. Pesticide products and devices intended solely for export are now able to meet the agency's export labeling requirements by attaching a label to the immediate product container or by providing collateral labeling that is either attached to the immediate product being exported or that accompanies the shipping container of the product being exported at all times when it is shipped or held for shipment in the United States. Collateral labeling ensures the availability of the required labeling information, while allowing pesticide products and devices that are intended solely for export to be labeled for use in, and consistent with the applicable requirements of the importing country; and
- Data Compensation (Published 2/5/2014): the EPA revised its regulations governing procedures for the satisfaction of data requirements under FIFRA, which are codified in 40 CFR Part 152, subpart E. These provisions include, among other things, procedures for the protection of exclusive use and data compensation rights of data submitters. The EPA updated the regulations to accommodate statutory changes and changes in practice that have occurred since 1984; to make minor changes to clarify the regulations; and to make changes that would simplify the procedures and reduce burdens for certain data submitters. The revisions did not otherwise make substantive changes to the requirements.

At times, however, the EPA has determined that significant changes to its regulations are needed to improve public health. For example, in November 2015, the EPA finalized revisions to the Agricultural Worker Protection Standard. This final rule revised the Federal regulations issued under FIFRA that direct agricultural worker protection (40 CFR Part 170). The changes reflected current research on how to mitigate occupational pesticide exposure to agricultural workers and pesticide handlers, and strengthened the protections provided to agricultural workers and handlers under the worker protection standard. The changes improved elements of the existing regulation, such as training, notification, communication materials, use of personal protective equipment, and decontamination supplies, thus preventing exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations, child farmworkers, and farmworker families; and the general public. The EPA is working closely with affected stakeholders, including state agricultural agencies, to ensure that they have the necessary information and training to implement these new protections.

Similarly, the EPA is now working to develop a final rule to revise the Federal regulations governing the certified pesticide applicator program (40 CFR Part 171). This action is intended to improve the competence of certified applicators of restricted use pesticides (RUPs) and to increase protection for noncertified applicators of RUPs operating under the direct supervision of a certified applicator through enhanced pesticide safety training and standards for supervision of noncertified applicators. State agricultural agencies, as well as many other stakeholders, provided valuable comments and suggestions in response to the EPA's proposed rule. We will work with stakeholders to ensure that the revised competency standards can be implemented effectively by state agencies.

Question 29. Federal law includes very specific actions that a Federal agency must take before promulgating new regulations. The Office of Pesticide Programs has circumvented this process by sending pesticide registrants letters that outline new regulatory provisions. This "regulation by letter" procedure was used by EPA in 2013 to mandate registrants include pollinator statements and a graphic on certain products, and in 2009 for a labeling initiative. What is EPA's rationale for circumventing

the Administrative Procedure Act (APA), which includes notice and comment, economic and small business impact analysis, *etc.?*

Answer. The EPA does not "regulate by letter" and FIFRA does not provide for such a regulatory mechanism to make changes to pesticide registrations. The EPA pesticide program is a licensing program that is based on an adjudicatory system. As a licensing program, the agency must ensure that the license complies with the law and continues to comply with the law. As such, decisions to grant a new license or change/modify an existing license are not subject to APA rulemaking, but the procedural requirements of FIFRA. When the EPA receives new information and determines that the license may lead to unreasonable adverse effects on the environment, the agency may offer the registrant a way to correct the imbalance in a timely manner. The August 2013 letter regarding labeling changes for the neonicotinoid insecticides is one example. However, if the registrant chooses not to address the concerns raised in such an offer, the agency can take appropriate steps under FIFRA to compel any necessary changes to the pesticide registration to mitigate unreasonable adverse effects on the environment. The letter itself is not self implementing; in the absence of voluntary agreement from a registrant, FIFRA prescribes steps that the agency must take to impose new mitigation measures.

Question 30. EPA's honeybee acute toxicity proposal would restrict approved crop protection tools from use when a grower is under a pollination contract. The proposal clearly did not have the support of conventional or organic growers, or the national beekeeper organizations, or the USDA, which sent a letter to the Agency criticizing the proposal. Honeybees are not native species; they are essentially livestock and the property of the beekeeper. Why is EPA attempting to regulate contracts between private parties? Has the Agency produced an analysis to show the benefit expected if the rule is implemented?

Answer. With greater attention put on protecting pollinators as well as their important role in agricultural production, the EPA's acute mitigation strategy, *EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products,* is aimed at providing greater protection to bees where acute risk is presumed to be the highest, namely when nearly certain exposure (*i.e.,* contract pollination scenarios) and presence of an acutely toxic pesticide coincide. The intent of the proposed acute mitigation strategy is to protect managed (contracted) bees at commercial pollination sites, and also likely provide protection for other pollinators near the treatment area.

The proposed approach is to clarify and strengthen the existing language for the acutely toxic compounds in the immediate term. The agency will also assess each compound under the registration review program, with a robust data set identified in our *Risk Assessment Framework for Pollinators* that also evaluates potential sublethal and chronic impacts to pollinators at both the individual and colony level. As a result, chemical-specific, risk based labeling will be developed. As part of its planning and analysis prior to issuing its proposal, the agency did consider the potential cost to growers.

The EPA is currently reviewing the wide range of comments it received in response to the proposal. Based upon comments received, we are developing options on moving forward. While doing so, the agency will continue to weigh both the level of protection to bees, and the potential impact to growers.

Question 31. Environmental activists recently sued the EPA claiming that the Agency should regulate seeds treated with systemic pesticides as pesticides themselves and regulate those seeds under FIFRA. Congress has expressed its intent that seeds are not subject to the same regulatory requirements as applied pesticides, and in recent years has found that treated seeds are safe and offer significant value to farmers, which is consistent with EPA's long-held view. Furthermore, restricting seed treatments would likely lead to them being replaced with spray or soil applications and that switch would not result in improved environmental protection. Do you intend to vigorously defend the Agency's determination that economically-beneficial coated seeds are "treated articles"?

Answer. With respect to the litigation filed by public interest groups, on March 14, 2016, the EPA filed a motion with the district court in the Northern District of California to dismiss the case against the EPA. A hearing on this motion was held on May 12, 2016, and the following day the court issued an order deferring a decision on the merits of the EPA's motion to dismiss until the EPA produced an administrative record. The EPA has complied with the court's order and expects the court to address its jurisdiction (the subject of the motion to dismiss) during summary judgment proceedings. Under the current litigation schedule, summary judgment motions are to be filed in September and should be argued in October 2016.

Question 32. Seed treatments deliver a very precise application that shields seeds from the insects and diseases that exist in the soil during early developmental stages. Do you agree that seed treatments reduce the environmental impact of the production process by decreasing the number of spray applications of agrichemical products lessening exposure to non-target species, including humans, pollinators and the environment?

Answer. In general, the EPA agrees that seed treatments are effective at reducing environmental exposure and impact, as compared to spray applications of agrichemical foliar products, to humans and the environment. In addition, the EPA has engaged in discussions with the American Seed Trade Association, equipment manufacturers, and pesticide registrants to encourage broader adoption of best management practices intended to reduce the potential for drift of contaminated dust during the planting of pesticide-coated seeds that have resulted in incidents to honeybees. These efforts have included the development of alternative lubricants used in pneumatic planters to reduce dust generated through the abrasion of treated seed during planting as well as the development of more effective seed coatings to enhance pesticide adherence to the seed.

Question 33. When this Committee passed both H.R. 872 in the 113th Congress and H.R. 897 last year we discussed the outbreaks of West Nile Virus and even concerns about Malaria across many regions of the country. Today, there is a new threat to human health called the Zika virus, which is also transmitted through mosquitos. The World Health Organization has gone so far as to declare a public health emergency of international concern. There are no vaccines or a reliable diagnostic test. I believe that America will be better adept to combat the spread of the virus with our world renowned researchers and response by the public health community. However, our country is currently being hamstrung by an ill-advised court decision that was in contradiction with EPA's own assessment under the Clean Water Act and the Federal Insecticide, Fungicide, and Rodenticide Act. In some states, the burden and liabilities of obtaining a duplicative NPDES permit are limiting or delaying mosquito control applications that protect human health. Will the Administration support the passage of this important legislation?

Answer. The Administration believes that legislation removing CWA Act protections for public health and water quality is not the answer for effective and timely action to respond to the threat of mosquito-borne illness.

Question 34. Major farm organizations have written EPA concerning the need for new, effective weed management tools. Prominent academics, farm group leaders and many others have said multiple modes of action are the most effective way to deal with weed resistance issues while preserving environmentally beneficial cropping systems like no-till or conservation tillage. Yet when it comes to crop protection product registrations at EPA, some innovative products that can help growers meet these goals have been either sitting at your Agency for several years, or in some cases courts have intervened to vacate registrations. What conversations are you having with USDA and the industry to minimize the concerns raised in court actions and to ensure the near-term availability of new, more effective weed management chemistries?

Answer. The EPA recognizes the negative impacts of weed resistance and understands the needs of growers for new weed control technology. The EPA's review of herbicides proposed for use on genetically modified seed requires thorough and scientifically rigorous assessments for both human health and the environment. The agency has intensified communications and information sharing with USDA in handling these actions, and is building a framework for a streamlined process that also addresses new measures for avoiding the onset of new resistance issues.

Because the emergence of herbicide resistance is an increasing problem in the United States, the EPA has been working directly with the USDA and industry to construct a comprehensive resistance management program. By developing these new strategies, the EPA hopes to promote a more efficient registration process while simultaneously preserving the longevity of important new herbicide tools. Meanwhile, the agency will continue to work closely with the USDA in the review of herbicides submitted in association with herbicide-tolerant traits to ensure that our two agencies perform a thorough scientific review of the potential impacts on human health and the environment associated with the proposed use of additional herbicides on herbicide-tolerant crops.

In addition, in the spring of 2016, the EPA requested public comment on two Pesticide Registration Notices (PRNs) that focus on strategies to combat or slow pesticide resistance, and preserve the useful life of pesticide chemistries. One of these PRNs aims to improve resistance management information contained on the labels

of all conventional pesticide products.[1] The other PRN focuses on the agency's proposed strategy for addressing herbicide resistance.[2] The EPA expects to finalize these two PRNS in late 2016.

Question 35. EPA recently asked the 9th Circuit Court of Appeals to remand a pesticide registration back to EPA for further review because of concerns under the Endangered Species Act. This is the only time ever where EPA has attempted to vacate a pesticide registration through a court action. Currently under FIFRA, EPA is required to comply with a number of procedural safeguards before a pesticide registration can be canceled, which they have failed to do. What was the Agency rationale for taking such an unusual step of asking a Court to require EPA to review the registration of a product so recently approved for use and why is the Agency now trying to use the Courts as a means to regulate?

Answer. The EPA felt compelled to seek remand and *vacatur* because the EPA discovered, after granting the registration for Enlist Duo, that Dow had made claims of "synergistic herbicidal weed control" in its Provisional and Non-provisional patent applications to the U.S. Patent and Trademark Office for Enlist Duo. This new information suggests the two active ingredients used in combination could result in greater toxicity to non-target plants than believed by the EPA at the time the agency granted the registration. This information was not provided to the EPA by Dow prior to the EPA issuing the Enlist Duo registration. This new information could lead the EPA to a different decision on the restrictions on use of Enlist Duo, including those necessary to ensure the protection of listed species in the context of the Endangered Species Act.

Because the EPA had become aware of previously existing information about possible synergistic effects that it did not consider, the agency could no longer represent to the Court that its conclusions were correct regarding whether issuance of the registration met the standard in FIFRA and whether the buffer zones included in the registration support the finding that the registration will have no effect upon threatened or endangered plant species. The EPA therefore sought from the Court an order of remand with *vacatur*.

Question 36. The United States has the world's most rigorous pesticide registration and review processes. We regulate pesticide by assessing 'risk' to determine whether and how a product can be used safely. In evaluating risk, 'hazard' (whether something can cause harm) and 'exposure' (whether something you'll be exposed to harm) are balanced against the benefits of using a product. This is something EPA should be confident in and proud to defend. As a matter of fact, EPA does a great job defending the merits of our risk-based system when commenting on the EU's precaution-based regulatory scheme. But, recently it seems when EPA regulatory decisions are challenged in the U.S., you seem reluctant to defend or, even more troubling, unable to properly provide evidence of the Agency's scientific decisions. How can you better inform the public and skeptics that the products EPA registers are thoroughly tested and protective of human health, vulnerable species and the environment?

Answer. The EPA agrees that it has one of the world's most rigorous registration and reevaluation processes. The agency always strives to base its decisions on the best available science. However, science is constantly evolving, and new scientific information can come to light at any time and change our understanding of potential risks from pesticides. If any pesticide is found to present risks to human health or the environment that cannot be mitigated or managed through other measures, the agency has to make a finding that the pesticide no longer meets the FIFRA standard for registration or under the Federal Food, Drug, and Cosmetic Act for pesticide tolerances. In that case, then the agency will move quickly to take appropriate regulatory action. Any such action, however, would have to be supported by the best available, peer-reviewed science. The EPA scientific assessment approaches are publicly available at *http://www2.epa.gov//pesticide-registration/understanding-science-behind-epas-pesticide-decisions* [*See Attachment 4*].

Question 37. There have been several instances where courts, local governments or other organizations have challenged EPA regulatory decisions. What can Congress do to educate the public, localities, courts and other institutions about the rigors of the pesticide registration process and to increase the public's confidence in EPA's pesticide registration decisions?

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[1] *https://www.epa.gov/pesticide-registration/prn-2016-x-draft-guidance-pesticide-registrants-pesticide-resistance.*

[2] *https://www.epa.gov/pesticide-registration/prn-2016-xx-draft-guidance-herbicide-resistance-management-labeling-education.*

Answer. As stated in the response above, the EPA agrees that it has one of the world's most rigorous registration and reevaluation processes. The agency always strives to base its decisions on the best available science. In addition, the EPA believes that by makings its decisions in a transparent manner, including through the active solicitation of public participation in the process, we demonstrate the scientific soundness of our decisions.

Question 38. The Committee has heard about a serious matter regarding EPA policies based on human research data that may not be reliable. For years, EPA relied on hundreds of quality studies evaluating all aspects human susceptibility to pesticides called organophosphates—otherwise known as OP's. These included studies designed to make sure that children would be protected. Even though EPA used those high-quality assessments for 20 years; EPA now relies primarily on three epidemiology publications and some journal articles in which EPA, I am told, EPA does not have access the raw data to determine if these studies are reliable or accurate. The Committee has been advised that Columbia University—who conducted the key study—refused to provide the raw data to EPA even though EPA provided funding for the study. So, it appears EPA is relying on information based on raw data that cannot be reviewed for accuracy. If it is correct that EPA has not gotten access to that raw data, Federal regulations designed to enhance the credibility of the Federal rulemaking process have likely been violated. Data Quality Act violations and conflict of interest violations could have also occurred.

EPA held a meeting in May 2013 with researchers from Columbia University about the Columbia Study. Is there a transcript of the discussion that took place at that meeting? Were minutes taken at the meeting and made available?

Answer. The agency wrote a summary of the 2013 meeting with researchers from Columbia University. This summary is contained in "Appendix 6 Columbia Center for Children's Environmental Health (CCCEH) Epidemiology Data Acquisition 'Raw Data Request'" of EPA's December, 2014 human health risk assessment for chlorpyrifos which can be found at *www.regulations.gov* in docket ID number: EPA–HQ–OPP–2008–0850–0195, (*Drew, et al.,* D424485, December 29, 2014) [*See Attachment 5*].

Question 38a. Did the Federal Government provide any funding for any or all of the three epidemiology studies, most notably the study from Columbia University's Center for Children's Health commonly referred to as the Columbia Study, the "CHAMCOS" study and, also, the Mt. Sinai study which were relied upon by the Agency to raise issue about potential effects on infants and children in the human health assessment and Proposed Rule to revoke tolerances for chlorpyrifos? Please provide details on any and all funding EPA provided for any portion of the three studies.

If yes:

Question 38a. (***Yes i.***) Does the Agency have in its possession all the raw data from the studies? (Raw data would include but is not limited to interview data with participants, blood and urine analysis, interviews with the children, *etc.*)

Question 38a. (***Yes ii.***) For which of these studies does EPA possess the raw data?

Question 38a. (***Yes iii.***) Why have the data not been made available to registrants affected by the Agency's actions or in response to FOIA requests?

If no:

Question 38a. (***No i.***) Why not? How does this lack of possession and lack of availability of the data not conflict with the 2009 Presidential memorandum which says that if scientific and technical information is developed and used by the Federal Government, it should ordinarily be made available to the public? [". . . mandating disclosure of scientific and technical information developed and used by the Federal Government."] Why is the Agency not complying then with the goal of that memorandum for transparency in the use of scientific information in policy making?

Question 38a. (***No ii.***) How can EPA say that its use of epidemiology data for chlorpyrifos is transparent when the Agency did not obtain and consider the underlying raw data for the studies it relied upon or provide minutes from the meeting with the researchers?

Question 38a. (***No iii.***) Without the raw data, how can the Agency confirm there is no negative data, null results or confounding factors that would have changed the Agency's conclusions about the studies? How is such a decision consistent with EPA's reliance for chlorpyrifos risk assessment purposes on epidemiology studies for which the Agency cannot obtain and consider the raw data?

Question 38a. (***No iv.***) EPA says that it is relying on "uncertainty" created by the epidemiology studies to set the FQPA additional safety factor for chlorpyrifos. But

hasn't EPA created this uncertainty by failing to obtain and consider the raw data for the epidemiology studies the Agency is relying upon?

Combined answer. The EPA provided funding for the Columbia Center for Children's Environmental Health (CCCEH), the Mount Sinai Center for Children's Environmental Health and Disease Prevention Research, and Center for the Health Assessment of Mothers and Children of Salinas (CHAMACOS) cohort at the Center for Environmental Research and Children's Health (CERCH). The EPA and the National Institute of Environmental Health Sciences (NIEHS) jointly provided funding to the CCCEH under the 1997 and 2003 Request for Applications (RFAs). The approximate EPA funding for the 5 year CCCEH awards was $3.9 million under the 1997 RFA (matched by NIEHS) and $3.6 million under the 2003 RFA (NIEHS provided $3.5 million).

Similarly, the EPA and the NIEHS jointly provided funding to the Mount Sinai Center for Children's Environmental Health and Disease Prevention Research under the 1997 and 2003 RFAs. The approximate EPA funding for the 5 year Center awards was $3.9 million under the 1997 RFA and $4.0 million under the 2003 RFA (matched by the NIEHS with $4.1 million under the 1997 RFA and $3.8 million under the 2003 RFA).

The EPA and the NIEHS also jointly provided funding to the CERCH under the 1997, 2003, and 2009 RFAs. The approximate EPA funding for the 5 year Center awards was $4.5 million under the 1997 RFA (NIEHS provided $4.2 million), $3.6 million under the 2003 RFA (NIEHS provided $3.3 million), and $3.6 million under the 2009 FRA (NIEHS provided $4.2 million).

In the summer of 2015, Dr. Dana Barr of Emory University provided the agency with limited raw urine and blood data in her possession from the three cohorts. However, the files provided from Dr. Barr are not useful for the agency's current purpose of assessing risk to chlorpyrifos. The files provided from Dr. Barr do not contain the biomonitoring data from the key publications from CCCEH which describe associations between blood levels of chlorpyrifos and neurodevelopmental deficits in children. The EPA does not have any of the other measurements of the children in the cohort (*e.g.,* chlorpyrifos blood data, interviews, test or IQ scores). The CCCEH researchers have not provided these data, asserting that the pesticide component of the cohort study was privately funded, not federally funded, and therefore disclosure of underlying data is not required. The agency received two FOIA requests specifically asking for raw data on the three U.S. children's cohorts. For the first FOIA request, EPA–HQ–2016–002089, the requester was provided all the responsive records (*i.e.,* the files provided by Dr. Barr) and the request was closed March 2, 2016. For the second request, EPA–HQ–2016–003947, the agency did not have any additional files beyond those provided for the first request. The second FOIA was closed on March 23, 2016.

While the EPA strives to ensure that data underlying research it relies upon are accessible to the extent possible, it does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the Federal courts have made clear that the EPA is not required to obtain or analyze the raw data in order to rely on such studies. If the EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.

In the past, the EPA sought to obtain the original raw data used to support certain epidemiological analysis of *in utero* exposure to chlorpyrifos and subsequent adverse neurodevelopmental health outcomes in children generated by the CCCEH to support the human health risk assessment of chlorpyrifos. Prior to the 2013 meeting with CCCEH investigators, the EPA thought these data would be important to both clarify the exposure-response relationship observed in the epidemiology study relative to the current regulatory endpoint (acetylcholinesterase inhibition), and also to resolve uncertainties regarding study participants co-exposure to other environmental contaminants, among other areas of uncertainties. CCCEH researchers did not agree to provide these data; however, the researchers met with the EPA and discussed the agency's questions about the data to help determine whether further review of the raw data might assist the EPA in resolving uncertainties. As a result of this meeting, the EPA concluded that access to the raw data would not provide answers to the EPA's questions. Indeed, based on discussions in that meeting as well as further work conducted by agency staff, the EPA has gained additional information to better clarify and characterize the major issue areas identified as uncertainties.

In the summer of 2015, the EPA again requested the raw data from Columbia University. The Columbia University investigators again denied the EPA's request. However, the investigators did provide additional summary information on the blood biomonitoring data. The agency has made this additional information publicly available. The EPA continues to engage with Columbia University on this topic.

Question 39. Related to the use of these epidemiology studies, in 2011, EPA said that it was reviewing a Scientific Advisory Panel report regarding the Agency's Draft Epidemiology Framework and would, also during 2011, release a revised version of the framework for public comment.

Why has the Agency not completed this task?

Question 39a. How can the Agency's reliance on the Draft Epidemiology Framework to integrate the epidemiology studies into the risk assessment for chlorpyrifos be reasonable when, contrary to EPA's promise, the framework has not been revised consistent with SAP recommendations and made available for public comment?

Answer 39–39a. Although use of epidemiology is common in other agency regulatory programs, epidemiology studies focusing on pesticides have only become available in the last few years. Thus, epidemiology data are less frequently used in evaluation of pesticides. The EPA decided that additional experience was needed in applying the "Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" prior to its finalization. Obtaining such experience is consistent with the recommendations of the Federal Insecticide, Fungicide, and Rodenticide Act Science Advisory Panel (FIFRA SAP) (2010) to "conduct a broader analysis" to improve the written description of the process of integration of epidemiology with other lines such as animal toxicity data. The ongoing work on chlorpyrifos and the organophosphates are examples of such experience. The FIFRA SAP commended the agency for developing the draft Framework and was "impressed with the documentation presented." The agency also notes that the FIFRA SAP was supportive of the key components of the draft Framework, namely the use of problem formulation to assess data availability and quality early in the process and the modified Bradford Hill criteria as an internationally accepted tool for assessing epidemiology and laboratory animal data. Because the FIFRA SAP was basically supportive of the overall approach, the agency believes use of the draft Framework in its current form is appropriate prior to the finalization of the document.

Question 39b. What are the number and total cost of all of the animal studies conducted by registrants that EPA has required and/or evaluated over the years to assess the potential toxicity and health risks of the OP pesticides, for which the proposed reliance on the three controversial epidemiology studies would trump, invalidate, or dismiss all of the animal study results?

Answer. The EPA has established data requirements (40 CFR) so that the agency can conduct appropriate risk assessments, including risks to human health. The relevant studies are associated with the toxicological data requirements for a food use. There are generally 30 studies that may be required but some pesticides may have more studies and some may have fewer. The organophosphate (OP) pesticides typically have completed all of the required studies since their initial registration, through reregistration, and to date during registration review. The EPA does not know the cost of generating these data for any particular company or chemical.

The agency has not limited the number of studies reviewed to the three epidemiology cohorts. In fact, the agency has reviewed hundreds of studies from laboratory animals, cell systems (including human), biomonitoring, and epidemiology on a variety of scientific areas related to human health effects. These studies were evaluated together in a weight of evidence analysis.

Question 39c. What is the biological mechanism of toxicity that accounts for supposed differences between the controversial epidemiology studies and the mountain of reliable data from animal toxicology studies? What is the biological plausibility of the results observed and any conjectured mechanisms of action? What are all of the possible confounding factors that could affect, influence, or produce the results observed, and how have they been accounted for in the reports that EPA has relied on? Who/what is/are the unexposed cohort that shows that the effects allegedly found in the controversial epidemiology studies could reasonably be attributable to pesticide exposure?

Answer. The EPA conducted detailed evaluations of the scientific literature on the neurodevelopmental potential of chlorpyrifos and other OPs as part of reviews by the FIFRA SAP in 2008 and 2012 along with the 2014 human health risk assessment for chlorpyrifos and the 2015 literature review for all the OPs. This includes review of registrant submitted studies along with studies from the scientific literature. Biological plausibility of the findings from the epidemiology studies are found in numerous studies conducted in laboratory animals and using new tech-

nologies, including human cells. There are a large number of animal studies using rats and mice from a dozen laboratories worldwide which have reported neurodevelopmental effects in offspring exposed to chlorpyrifos in the womb or after birth. Some *in vitro* studies, like those recommended by the NAS in the 2007 report on *Toxicity in the 21st Century,* conducted at very low concentrations have suggested several biological mechanisms which could underlie effects at low exposure levels as seen in the epidemiological studies.

These studies present strong evidence that developmental neurotoxicity of chlorpyrifos and other OPs may not be due to acetylcholinesterase inhibition *per se,* but to other actions on critical aspects of neuronal development. There are a number of biologically plausible molecular events proposed for chlorpyrifos and other OPs effects on the developing nervous system, with ongoing academic research pursuing many of these potential pathways. Some of the more promising mechanisms represent molecular initiating events (binding to the morphogenic site of AChE, muscarinic receptors, or tubulin), cellular responses (alterations in neuronal proliferation, differentiation, neurite growth, or intracellular signaling) and responses at the level of the intact nervous system (serotonergic tone, axonal transport). Overall, there is good evidence that neurodevelopmental effects may not be solely a function of acetylcholinesterase inhibition.

The EPA is including epidemiologic research results from three prospective birth cohort studies. These include: (1) The Mothers and Newborn Study of North Manhattan and South Bronx performed by the Columbia Children's Center for Environmental Health (CCCEH) at Columbia University; (2) the Mt. Sinai Inner-City Toxicants, Child Growth and Development Study or the "Mt. Sinai Child Growth and Development Study;" and (3) the Center for Health Assessment of Mothers and Children of Salinas Valley (CHAMACOS) conducted by researchers at University of California, Berkeley.

In these epidemiology studies, mother-infant pairs were recruited for the purpose of studying the potential health effects of environmental exposures during pregnancy on subsequent child development. Each of these cohorts evaluated the association between prenatal chlorpyrifos or OPs exposure with adverse neurodevelopmental outcomes in children through age 7 years and to limited extent up to 11 years old. The CCCEH Mother's and Newborn study and the Mt. Sinai Child Growth and Development study participants were likely exposed to chlorpyrifos and other OPs through the diet and through residential use of the pesticide for indoor pest control. The CHAMACOS cohort participants were employed as farm laborers or were residing in homes with farm laborers. The CHAMACOS study participants likely experienced exposure to OPs through the diet and from occupational exposure (primarily inhalation and dermal routes), as well as probable indirect take-home exposures.

Biomonitoring data were collected from individuals within each cohort. The unexposed children in the epidemiology studies are those whose biomonitoring data are low and often below the limit of detection, *i.e.,* so low as to not be measurable. The unexposed children are derived from the same populations and location in the same living and economic conditions as the exposed or highly exposed children. In this way, important issues such as socioeconomic status are similar across the entire group of exposed and unexposed.

The EPA focused its review on research results from these three epidemiological cohort studies due to the considerable strengths in study design, conduct, and analyses. Investigators from each study cohort utilized a strong study design (prospective birth cohort), measured pesticide exposure using several different methods including biomarkers, and measured neurodevelopment effects in children using well-established assessment tools in both clinical and research settings. In addition, the investigators have accounted for potentially confounding variables including socioeconomic status and other environmental exposures. Evaluation of these confounding variables is important to reduce the chances of a false positive study result. Across these cohort studies, investigators collected relevant information on demographic characteristics and other environmental exposures and used this information in the statistical analysis. Other environmental exposures considered by the investigators were blood lead, environmental tobacco smoke, polyaromatic hydrocarbons (PAHs), methylmercury, or other non-OPs. The EPA and the FIFRA SAP (2008 and 2012) believe that the cohort study authors were able to appropriately measure and model the effect of potential confounding variables on the study outcomes.

The agency held another meeting of the FIFRA SAP on April 19–21, 2016 to review a new analysis using the blood biomonitoring data from the Columbia University epidemiology study.

Question 39d. Given the pesticide uses registered today, what is the relevance of the pesticide exposures that allegedly caused effects observed in the controversial epidemiology studies to the current regulatory picture?

Answer. Agricultural use of OPs remain today for many crops across the United States. Agricultural workers (including women who may be pregnant) who mix, load, and/or apply pesticides, as well as those who work in previously treated fields (*e.g.,* harvesting citrus fruit) are exposed to high levels of OPs. In addition, some areas of the country are predicted to have OPs or their more toxic degradates in drinking water. Exposure to OPs through food to the entire country is also expected.

Question 39e. Please explain in layman's terms the process for "Systematic Review of scientific literature for laboratory animal studies & epidemiology studies" used by the Agency. How does this differ from the Agency's review of studies and data it requires registrants to conduct and submit in support of pesticide registrations? How do the two processes supplement, complement, or contradict each other? [*http://www.epa.gov/sites/production/files/2015-10/documents/op-risk-assessment-approach.pdf.* Also *https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html.*]

Answer. In recent years, the National Academies' National Research Council (NRC) has encouraged the agency to move towards systematic review processes to enhance the transparency of scientific literature reviews that support chemical-specific risk assessments to inform regulatory decision making (NRC 2011, 2014). The NRC defines systematic review as "a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies" (NRC 2014). According to the NRC, systematic reviews "have several common elements: transparent and explicitly documented methods, consistent and critical evaluation of all relevant literature, application of a standardized approach for grading the strength of evidence, and clear and consistent summative language."

The EPA's approach to reviewing scientific data include: data collection, data review, and integration procedures. Therefore, the agency's standard review approaches for assessing toxicology data submitted by registrants and for integrating the registrant supported data with information from the open literature are consistent with the NRC's recommendations for systematic review. As such, although the terminology may differ, the approaches are consistent and similar.

Question 39f. With such a requirement for an extensive base of these studies, how, according to your own Framework, does the Agency weigh an epidemiology study that is not conducted to the same standards as that required for a registrant study and where you do not even have in your possession the raw data?

Answer. Most laboratory animal studies submitted to the agency by the registrants follow the EPA and Organisation for Economic Co-operation and Development (OECD) guidelines and thus have specific and defined study designs. Epidemiology studies do not have such OECD guidelines; moreover, epidemiology studies can vary significantly in their study design.

The EPA developed a "Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" in 2010 which was reviewed by the FIFRA SAP and received public comment. The Panel commended the agency for developing the draft Framework and was "impressed with the documentation presented." The agency also notes that the Panel was supportive of the key components of the draft Framework, namely the use of problem formulation to assess data availability and quality early in the process and the modified Bradford Hill criteria as an internationally accepted tool for assessing epidemiology and laboratory animal data.

In the draft Framework, the agency describes several areas for consideration of the quality of epidemiology studies: exposure assessment, confounding factors, statistical analysis, potential bias in observational research, interpretation of null studies, external validity (generalizability). The SAP concurred with these identified scientific areas for consideration and suggested additional ones including sample size and associated statistical power, and outcome assessment. The EPA has assessed all of these considerations as part of the evaluation for chlorpyrifos and the OPs. The EPA focused its review for OPs on research results from the three epidemiological cohort studies due to the considerable strengths in study design, conduct, and analyses demonstrated in these investigations. Investigators from each study cohort utilized a similarly strong study design (prospective birth cohort); measured pesticide exposure using several different methods including environmental indicators as well as specific and non-specific biomarkers of chlorpyrifos; ascertained developmental outcomes using validated assessment tools well-established in both clinical and research settings; and, measured, analyzed, selected and statistically adjusted

for potentially confounding variables including socioeconomic status and other environmental exposures using reasonable and appropriate methods.

The EPA believes the draft framework is consistent with updates to the World Health Organization/International Programme on Chemical Safety mode of action/human relevance framework, which highlight the importance of problem formulation and the need to integrate information at different levels of biological organization. Similarly, the EPA's draft Framework is consistent with recommendations from the NRC in its 2009 report on *Science and Decisions*[3]* that describes the importance of using problem formulation at the beginning of a complex scientific analysis.

Question 39g. From 1996 when FQPA was enacted through the current date, EPA has made multiple, specific formal findings based on extensive reliable databases that FQPA safety factors for OP insecticides can be reduced or eliminated. The Agency has proceeded to regulate the uses of these pesticides in the marketplace on that basis, and has therefore determined that the residue tolerances are safe. FFDCA § 408(b)(2)(A)(1) requires the Administrator to ". . . modify or revoke a tolerance if the Administrator determines it is not safe." What specific determination have you now made that the chlorpyrifos tolerances are "not safe"?

Answer. The EPA periodically reviews existing registered pesticides to ensure they can be used safely, without unreasonable risks to human health and the environment. The periodic review of pesticide registrations is required by FIFRA. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. The EPA will review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration.

As part of registration review, the EPA assesses any changes that have occurred since the last registration decision to determine whether the pesticide still satisfies the statutory standard for registration. The EPA considers any new data or information on the pesticide and decides whether a new risk assessment must be conducted. In the case of chlorpyrifos and the OPs, many of the epidemiology studies, mechanistic studies, and laboratory animal studies on the neurodevelopmental effects of OPs were published after reregistration was completed in 2006. As such, there is significant new information relevant to the human health effects of this group of pesticides which require a re-analysis of scientific information relevant for the FQPA Safety Factor.

As section 408(b)(2)(C) of the FFDCA instructs the EPA, in making its "reasonable certainty of no harm" finding, that in "the case of threshold effects, an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of data with respect to exposure and toxicity to infants and children." Section 408(b)(2)(C) further states that "the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." Given the totality of the evidence, there is sufficient uncertainty in the human dose-response relationship for neurodevelopmental effects which prevents the agency from reducing or removing the statutory 10X FQPA Safety Factor.

Question 40. For the chlorpyrifos risk assessment, the Office of Pesticide Programs conducted a highly refined dietary assessment for possible residues on food and found no risks of concerns. Why then does the Agency rely on only an unrefined, screening level assessment to claim risks from drinking water as the basis for the Proposed Rule?

Answer. The December 2014 drinking water assessment conducted by the EPA is a refined, higher tier assessment that examined potential exposure to chlorpyrifos and its transformation product, chlorpyrifos-oxon, at a national and a regional scale in order to locate where concentrations in drinking water may be of concern. The assessment followed a tiered approach, investigating not only maximum pesticide label rates, but also lower rates to identify uses and watersheds that would not be expected to be problematic. The uses that exceeded the drinking water level of concern in the regional analysis were further explored, *e.g.,* evaluating exposure on a watershed basis. This "proof of concept" example showed an overlap of potential chlorpyrifos use sites that may result in an exceedance of the drinking water level

[3] NRC (National Research Council). (2009). *Science and decisions: Advancing risk assessment.* Washington, D.C.: The National Academies Press. *http://www.nap.edu/openbook.php?record_id=12209.*

* **Editor's note:** the document referred to is retained in Committee file.

of concern with watersheds that supply source water for community drinking water systems. The exercise demonstrated that chlorpyrifos applications result in variable drinking water exposures that are highly localized and that the highest exposures generally occur in small hydrologic regions where there is a high percent cropped area on which chlorpyrifos use could occur.

The EPA finished a regional analysis for two regions of the country, the Pacific Northwest and South Atlantic-Gulf, to demonstrate the feasibility of this methodology and to solicit public comment on the approach. The EPA is currently finalizing the regional assessment for the remaining regions of the United States. In addition to the refined spatial scale at which the analysis was completed, two additional aspects of this drinking water assessment that contribute to its complexity and sophistication are the incorporation of surface water monitoring data and drinking water treatment effects. Results of surface water monitoring are presented and compared to model-estimated concentrations. This analysis showed that when modeling scenarios are parameterized to reflect reported use and estimated drinking water concentrations are adjusted to reflect percent cropped area, the estimated modeled concentrations are within an order of magnitude of the measured concentrations reported in the monitoring data. Finally, typical water treatment processes were considered in predicting residues in finished drinking water.

Question 41. The EPA has stated that its drinking water assessment for chlorpyrifos is incomplete. Has the Agency ever before based a proposed tolerance revocation on an incomplete drinking water assessment?

Answer. The national scale drinking water assessment for chlorpyrifos was completed in 2014 and showed that many uses at maximum label rates and rates lower than maximum would result in concentrations exceeding the drinking water level of concern. Because of these results, further analysis was conducted to look at the spatial distribution of estimated drinking water concentrations at a regional scale. This exercise is a higher level refinement and not generally completed or required for most pesticides. As such, the EPA finished a regional analysis for two regions of the country, the Pacific Northwest and South Atlantic-Gulf, to demonstrate the feasibility of this methodology and to solicit public comment on the approach. The EPA is currently finalizing the regional assessment for the remaining regions of the United States.

Question 41a. While the Agency reached this high level of refinement for the food dietary assessment since the passage of FQPA in 1996, why has the Agency not reached a comparable level of refinement in their assessment methodologies for drinking water over that same time period of 20 years?

Answer. The level of sophistication of the EPA's drinking water assessments has greatly improved over the past 20 years. Drinking water assessments, including the assessment conducted for chlorpyrifos, now include the ability to account for the impact of different soils, agronomic practices, meteorological data, application methods and timing, buffers, volatility, and application technology, just to name a few areas where our modeling capabilities have improved. Current drinking water assessments also better account for the percentage of community drinking water intake watersheds that could be treated by the pesticide and drinking water treatment effects. Monitoring data, when available, also plays a larger role in our ability to predict and characterize pesticide concentrations under actual use conditions.

Question 41b. Since the Agency has had that much time to refine their drinking water assessment methodology, why then is there a rush to decision on chlorpyrifos?

Answer. The chlorpyrifos drinking water assessment is highly refined and incorporates all currently available data and methodologies for predicting exposure through drinking water. The timeline for decision making was set by the U.S. Court of Appeals for the Ninth Circuit.

Question 41c. Why does the Agency refuse to use reliable data from tens of thousands of water monitoring samples for chlorpyrifos and other pesticides, and instead insist on using modeling procedures that are not validated by data, and produce conflicting conclusions?

Answer. The EPA uses mathematical models as well as monitoring data to generate exposure estimates for drinking water and aquatic exposure assessments. Modeling and monitoring data are both important tools that provide different types of information that can be used for assessing pesticide concentrations in water. Models calculate estimated drinking water concentrations using laboratory data that describe how fast a pesticide breaks down to other chemicals and how it moves in the environment. In addition, modeling provides an efficient tool for exploring the impact of different environmental factors such as soil type and meteorological conditions on estimated pesticide concentrations in water. Although computer modeling provides an indirect estimate of pesticide concentrations, these concentrations can

be estimated continuously over long periods of time, and for places that are of most interest for a particular pesticide. Modeling is a useful tool for characterizing vulnerable sites, and can be used to estimate peak concentrations from infrequent, large storms (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*) [*See Attachment 6*].

Monitoring data provide snapshots of pesticide concentrations in time at specific locations. When the monitoring sites reflect areas that have a likelihood of pesticide occurrence in water (based on pesticide use as well as local runoff or leaching vulnerability), when sampling occurs during the time frame in which pesticides are expected to be used, and when the sampling is frequent enough to estimate exposures for the endpoints of concern, it is more likely that the EPA will be able to incorporate that data quantitatively. Monitoring data will typically underestimate upper bound or peak concentrations due to insufficient sampling frequency. While this is more of a concern for surface water monitoring, it can still be a consideration for groundwater monitoring. Therefore, monitoring data often are expected to provide a lower bound estimate of exposure for purposes of risk assessment. Statistical methods are being developed to address the uncertainty in estimating upper bound pesticide concentrations from monitoring data.

Often, sampling frequency and location are limiting factors in comparing monitoring results to modeling or in using monitoring data quantitatively. However, monitoring data can also be valuable in adding context to the exposure assessments. For instance, detections of a given pesticide can provide a measure of a lower bound of exposure. While the data may not be robust enough to ensure a high-end exposure has been observed, the detections do indicate that transport has occurred in the study. At a minimum, qualitative data can provide a balance against modeled estimates and can be useful for characterization of risk conclusions.

The EPA uses all reliable laboratory and field/monitoring data to assess pesticide exposure in drinking water. In the case of chlorpyrifos, water monitoring data from the U.S. Geological Survey (USGS) National Water-Quality Assessment Program (NAWQA), USEPA/USGS Pilot Reservoir Monitoring Program, USDA Pesticide Data Program (PDP), and California Department of Pesticide Regulation (CDPR) were evaluated in the 2011 preliminary drinking water assessment with reference to an acute exposure to chlorpyrifos and its degradation product chlorpyrifos-oxon. For the 2014 assessment, additional water monitoring data from Washington State Department of Ecology and Agriculture (WSDE/WSDA) Cooperative Surface Water Monitoring Program, Dow AgroSciences (Orestimba Creek), and Oregon Department of Environmental Quality were evaluated and presented as part of the drinking water assessment update.

Additionally, model simulations were completed to represent two different water monitoring datasets—WSDE/WSDA and Orestimba Creek. For both of these water monitoring programs, enough information was available, including chlorpyrifos use information, as well as the percent cropped area, to parameterize the model. In these simulations, the modeled concentrations were within an order of magnitude of the measured concentrations. This suggests that the modeling results are not overly conservative and provide reliable estimates in the absence of all the necessary information to put monitoring results into proper context.

Question 42. The Agency has publicly advocated for harmonization in tolerances among trading partner countries.

Why has EPA taken the step of this Proposed Rule with no agreement among other countries and seemingly no evaluation of or concern about potential impact on trade?

Answer. In making its tolerance decisions, the EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. However, the EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe. The timing of this proposal is the result of a U.S. Court of Appeals for the 9th Circuit Court order to respond to that petition by October 31, 2015. This proposal also implements the agency findings made during the registration review process required by section 3(g) of FIFRA (*7 U.S.C. 136*(a)(g)) which the EPA is conducting in parallel with its petition response. That process requires the EPA to re-evaluate existing pesticides every 15 years to determine whether such pesticides meet the FIFRA registration standard set forth in FIFRA section 3(c)(5), *7 U.S.C. 136*a(c)(5). In part, that standard requires the EPA to ensure that dietary risks from the pesticide meet the FFDCA section 408 safety standard. Section 408 directs that the EPA may establish or leave in effect a tolerance for pesticide only if it finds that the tolerance is safe, and the EPA must revoke or modify tolerances determined to be unsafe (FFDCA 408(b)(2)(A)(i)). Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide

chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." In its Revised Human Health Risk Assessment, the EPA determined some exposures to chlorpyrifos may be unsafe. The Revised Human Health Risk Assessment* is available at *www.regulations.gov* in the chlorpyrifos docket (EPA–HQ–OPP–2008–0850–0195).

Question 42a. What is your obligation under the World Trade Organization Sanitary Phytosanitary Agreement (WTO SPS) in this respect, and how has it been fulfilled?

Answer. The EPA ensures that its tolerance decisions are in keeping with the World Trade Organization's Sanitary and Phytosanitary Measures Agreement. Consistent with that agreement, the effective date the EPA is proposing for the revocation of chlorpyrifos tolerances in the proposed rule ensures that the tolerances will remain in effect for a period sufficient to allow a reasonable interval for producers in the exporting countries to adapt to the requirements of these modified tolerances. The EPA plans to issue a notice by the fall of 2016 with updates to part of its risk assessment, including a refined drinking water assessment. With the issuance of the notice, the EPA will notify the WTO and ask for further comment on the proposed rule and underlying science. The EPA will consider WTO's comments prior to issuing a final decision.

Question 43. By establishing a policy of "no net loss" for natural resources, doesn't the Presidential Memorandum: *Mitigating Impacts on Natural Resources from Development and Encouraging Related Private Investment* change how NEPA operates by requiring agencies to avoid, minimize, and fully mitigate impacts to natural resources? Will EPA follow the policies of the memorandum in the NEPA process? Is it correct that NEPA does not "mandate protection of the environment," but requires impacts to be identified? By establishing a policy of "no net loss" for natural resources, doesn't the Presidential Memorandum change the function of NEPA by requiring agencies to authorize only actions that avoid, minimize, and fully mitigate impacts to natural resources?

Answer. The EPA and other Federal agencies have extensive experience consistently implementing the provisions of the National Environmental Policy Act (NEPA) while working to achieve a "no net loss" of natural resources goal. The administration established a nationwide "no net loss" of wetlands goal in 1989, for example, that has been very successful in reducing annual conversion and destruction of wetlands without changing the operation of NEPA. The EPA is confident, based on our experience, that the new Presidential Mitigation Memorandum does not alter the way NEPA has traditionally been implemented or change its basic function.

Questions Submitted by Hon. Collin C. Peterson, a Representative in Congress from Minnesota

Question 1. The EPA has been reviewing biogenetic carbon-dioxide emissions for a few years now and it's seemed to come to a head with the Clean Power Plan. My understanding is that under the current framework for biogenetic carbon-dioxide, agricultural residue is treated the same as fossil fuels in Clean Power Plan compliance, unless it's sustainably grown. Using agricultural residues for energy production, bioproducts, and biofuels already happens. We want our farmers to be a part of the solution and I'm a bit perplexed how grown plants are treated the same as fossil fuels. Can you explain the current framework the EPA is using to assess biogenetic carbon-dioxide emissions? And are you consulting with USDA in regard to determining "sustainably grown" so our farmers can participate?

Answer. On February 9, 2016, the Supreme Court granted a motion to stay the Clean Power Plan (CPP). As a result of that action, states are not currently required to submit a state plan or a request for extension by September 6, 2016.

In the final CPP, states have the flexibility to choose whether or not to allow affected sources to use biomass as a compliance option to meet their emission standards. The CPP gives states the flexibility to describe the types of biomass that are being proposed for use under their state plans, how those proposed feedstocks or feedstock categories should be considered as "qualified biomass" (*i.e.,* a biomass feedstock that is demonstrated as a method to control increases of CO_2 levels in the atmosphere), and explain the proposed valuation of biogenic CO_2 emissions.

The EPA generally acknowledges the CO_2 and climate policy benefits of waste-derived biogenic feedstocks and certain forest- and agriculture-derived industrial byproduct feedstocks. The final rule also provides that states may use agricultural and forest biomass feedstocks if they adequately demonstrate that the use of such feedstocks appropriately controls increases of CO_2 levels in the atmosphere.

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* **Editor's note:** the document referred to is retained in Committee file.

As part of the EPA's effort to advance the technical understanding of the role of biomass in addressing greenhouse gas emissions, in November 2014, the EPA released the second draft of its scientific report, *Framework for Assessing Biogenic Carbon Dioxide for Stationary Sources.* The revised report takes into account Science Advisory Board peer review recommendations on the 2011 Draft Framework, as well as the latest information from the scientific community and other stakeholders. The EPA developed the revised Framework as a policy-neutral framework for assessing biogenic CO_2 emissions from stationary sources—it was not developed as technical guidance in conjunction with any specific policy or program. The EPA's continued refinements of the Framework will parallel the EPA's consideration of biomass in the context of its policies and programs.

As in the case of other scientific and policy processes, for biomass topics we consult with relevant experts, such as our colleagues at USDA, states, stakeholders, and academic and research scientists to provide information and examples of existing and potential programs recognized as carbon-beneficial and therefore possible approaches to achieving the goals articulated in the President's Climate Action Plan.

Question 2. I was contacted by an ag procession plant in my district and discovered that not only do plants have to have an OSHA worker protection plan, but apparently EPA also requires a worker protection plan. And now with the Food Security Modernization Act (FSMA), there will be a third requirement that will also involve worker training. Is there any coordination between OSHA and DPA in regard to what these worker protection plans encompass? Is there flexibility for plants to use one plan to cover both requirements? **Or** do they literally have to have two separate plans?

Answer. First, to the extent that these concerns with the Agricultural Worker Protection Standard (WPS) rule were raised in regard to an agricultural processing plant, please note that post-harvest uses of pesticides are excepted from the requirements of the WPS (170.303(b)(5)), so the WPS does not apply to the use of pesticides in agricultural processing plants and such processing plants are not otherwise affected by the WPS.

Second, the WPS also does not require a written worker protection plan. Employers only need to comply with the provisions of the rule, but are not required to develop a written plan describing how they will meet the requirements of the rule. The EPA has also coordinated with the Occupational Safety and Health Administration to ensure there is not overlap of our regulations.

Questions Submitted by Hon. Christopher P. Gibson, a Representative in Congress from New York

Question 1. The Hudson River Natural Resource Trustees—USF&W and NOAA—have publicly called for additional environmental dredging of the Hudson River Superfund site by GE and asked EPA to delay GE's decommissioning of its cleanup operations before certifying the cleanup as complete. Would EPA be willing to meet with these environmental leaders to discuss the Agency's reasoning behind its Hudson River dredging decision?

Answer. The EPA has discussed the decommissioning of General Electric's sediment processing facility and other operations with the Federal Natural Resource Trustees for the Hudson River. In particular, the U.S. Fish and Wildlife Service (FWS) and the National Oceanic and Atmospheric Administration (NOAA) actively participate in meetings of the Hudson River Community Advisory Group (CAG), and both NOAA and FWS have taken part in CAG meetings at which the EPA explained its reasons for approving GE's facility decommissioning.

Question 2. According to my constituents, EPA responded in December 2015 to the Natural Resource Trustees' that the cleanup is inadequate and will not meet EPA's own goals. In this response to Hudson River environmental leaders, EPA Assistant Administrator Mathy Stanislaus and Regional Administrator Judith Enck agreed to an expedited 5 year review to determine whether the Hudson River Superfund cleanup has met its goals. The following month, R.A. Enck published an Op-Ed in the *Albany Times Union* stating the cleanup has achieved its goals.

What will EPA do to ensure the 5 year review is conducted without bias, expeditiously in conformance with EPA guidance, and in a manner that ensures the input of the Trustees as equal partners and of the key environmental and other stakeholders?

Answer. The second 5 year review for the site is underway and is being conducted in accordance with the EPA guidance. The EPA is working closely with all stakeholders to ensure a thorough and unbiased 5 year review. The stakeholders, including the Federal trustees, New York State Department of Environmental Conservation and Department of Health, and representatives of the Community Advisory

Group (including non-governmental organizations) were invited by the EPA to participate on the Five Year Review team. Five Year Review team meetings are being held monthly through the fall.

Question 3. Is EPA considering any additional options that have not already been pursued to promote further clean-up and safeguarding of the Hudson River?

Answer. The second 5 year review is underway and the EPA is working closely with all stakeholders to ensure a thorough 5 year review. The stakeholders, including the Federal trustees, the New York State Department of Environmental Conservation and Department of Health, and representatives of the Community Advisory Group (including nongovernmental organizations) were invited by the EPA to participate on the Five Year Review Team. The EPA supports the trustees' continuing efforts to safeguard the Hudson River and will continue to cooperate and communicate with Federal and state natural resource trustees on the Hudson River remediation.

Questions Submitted by Hon. Vicky Hartzler, a Representative in Congress from Missouri

The following questions relate to the Agency's Worker Protection Standards (WPS) rule [40 CFR 170 et seq.] which was signed by the Administrator on September 28, 2015 and published in the *Federal Register* on November 2, 2015.

Statutory Requirements

Section 25(a)(2)(B) of the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. 136w(a)(2)(B)) states: "At least 30 days prior to signing any regulation in final form for publication in the *Federal Register,* the Administrator shall provide the Secretary of Agriculture with a copy of such regulation." Section 25(a)(3) (7 U.S.C. 136w(a)(3)) of FIFRA also states: "At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition and Forestry of the Senate."

Question 1. Please state for the record the date on which EPA provided to the Secretary of Agriculture the final copy of the WPS rule that was signed on September 28, 2015.

Answer. The EPA sent the draft final Worker Protection Standard rule to the Secretary of Agriculture on May 13, 2015. This draft final rule did not include provisions for authorized or designated representatives. After further deliberations, the EPA decided to restore these provisions, with certain limitations and modifications. The EPA provided the revised draft final rule to USDA on June 22, 2015. As required under section 25(a)(2)(D) of FIFRA, the EPA announced the notification to the Secretary of Agriculture for this review in the *Federal Register* (80 FR 28838, May 20, 2015).

Question 2. Please state for the record the date on which EPA provided to the House Committee on Agriculture the final copy of the WPS rule that was signed on September 28, 2015.

Answer. As required under section 25(a)(3) of FIFRA, the EPA sent the pre-promulgation draft of the final rule to the U.S. House of Representative's Committee on Agriculture and to the U.S. Senate's Committee on Agriculture, Nutrition, and Forestry on May 14, 2015. In addition, as required under the Congressional Review Act (5 U.S.C. 801 *et seq.*), the EPA submitted a report containing the final copy of the rule that was signed on September 28, 2015, and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States on October 9, 2015.

The WPS rule (40 CFR 170.311) grants a designated representative the right to certain pesticide information used on a farm upon presentation of a written, signed authorization by a worker. Please answer the following questions related to this provision.

Question 3. With a letter to the House Agriculture Committee from Assistant Administrator Jim Jones dated May 12, 2015 Mr. Jones enclosed a "draft final rule revising and updating the agricultural Worker Protection Standard." Please cite the section of the rule submitted to the Committee on May 12, 2015 that contains language granting either to "authorized representatives" or "designated representatives" access to farm-specific pesticide information.

Answer. The May 12, 2015 draft final rule did not include provisions for authorized or designated representatives. The proposed rule, published March 19, 2014, in-

cluded provisions relating to authorized representatives in the draft sections 170.5 and 170.11(b)(2) and on pages 15479–15480 of the preamble a discussion of the provisions, but as of May 12, 2015, the EPA was not intending to finalize those provisions. After further deliberations, the EPA decided to restore these provisions, with certain limitations and modifications. The EPA provided the revised draft final rule to USDA on June 22, 2015. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the final version of the rule was submitted to Congress on October 9, 2015.

Question 4. Please provide to the Committee copies of any comments, including e-mails, memos or other documents, submitted to EPA from the U.S. Department of Agriculture or other executive department offices, including the White House, that relate to the original proposed provision relating to "authorized representative" and to the provision in the final rule relating to "designated representative."

Answer. USDA's comments, and the EPA's responses to the proposed rule and the final rule, are included in the public docket as part of the Executive Order documentation, and those comments and responses related to the authorized representative and the designated representative are available from under docket ID EPA–HQ–OPP–2011–0184.[4] This provision was not an area of significant deliberation during the interagency review process for this rulemaking.

Question 5. In the final WPS rule (*Federal Register,* page 67513, November 2, 2015), EPA states that it "has been convinced by comments in support to retain the option for a designated representative."

Please provide the Committee copies of the comments to which the Agency refers in the *Federal Register* notice.

Answer. The EPA received a significant number of comments in support of and in opposition to retaining the proposal for the designated or authorized representative. Few of the comments presented new information or information substantially different from that known to the EPA at the time the proposed rule was published, and as a result, the comments—both pro and con—collectively convinced EPA that it was correct in its initial opinion that a designated representative provision is reasonable and appropriate. However, some commenters provided recommendations that appear to be appropriate remedies for legitimate concerns about the proposed requirement. The EPA reconsidered the proposed option and alternatives, and concluded that retaining the option for a worker to designate a representative was necessary for their ability to access pesticide hazard information, but specified in more detail the requirements for designating a representative and for a designated representative's request information. See 40 CFR Part 170.311(b)(9).

Although the EPA considers the collective comments—pro and con—as confirming the agency's decision to include a designated representative provision in the WPS, the comments below in support of the designated representative option for enhancing access to pesticide hazard communications information provide additional insight.

- Migrant Clinicians Network.[5]
- Farmworker Advocacy Network.[6]
- American Public Health Association.[7]
- Florida Legal Services.[8]
- Telamon Corporation.[9]

Question 5a. Were any of the comments received by the Agency after the close of the comment period?

Answer. Some comments were received after the comment period closed. All were included in the docket, regardless of the date they were submitted; and were considered in developing the final rule. These comments received after the close of the comment period were not significantly different and did not raise issues or present new information than those submitted by the close of the comment period.

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[4] *https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-2520* [*See Attachment 8*].

[5] *https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-2291* [*See Attachment 9*].

[6] *https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-2250* [*See Attachment 10*].

[7] *https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-1846* [*See Attachment 11*].

[8] *https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-2166* [*See Attachment 12*].

[9] *https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-0179* [*See Attachment 13*].

Question 5b. Were any of these comments the result of *ex parte* communications? Please supply copies of those comments?

Answer. All comments related to the Worker Protection Standard rulemaking received by the EPA during the period between proposal and publication of the final rule were added to the docket, where they became a matter of public record available for review (except for those portions of comments submitted under business confidentiality claims or containing personal privacy information). Written comments appear in the docket as submitted.

Question 6. The *Federal Register* notice of November 2, 2015 says that "EPA is unaware of issues related to worker representatives in those states." [referring to Texas and California].

Please provide the Committee with any analysis or documents used by EPA in analyzing the Texas and California provisions.

Answer. The only documents the EPA reviewed related to the Texas and California provisions were the regulations for Texas and California related to agricultural worker representatives.

The Texas Agricultural Hazard Communication Act at (*http://www.statutes.legis.state.tx.us/Docs/AG/htm/AG.125.htm.htm*) [*See Attachment 14*] establishes procedures for the designated representative's access to information about hazardous chemicals to improve the health and safety of agricultural workers. In addition, Texas provided comments on the proposed rule related to the provision, noting that the requirement to provide the information should coincide with the record retention schedule and should be in writing.

The California Code of Regulations, Sections 6723 and 6761 at (*http://www.cdpr.ca.gov/docs/legbills/calcode/subchpte.htm#a0303*) [*See Attachment 15*], establish requirements for employers to provide, upon request from an employee representative, access to any records or documents required to be maintained under the regulation.

Question 6a. Please provide the Committee any documents or analysis prepared or utilized by EPA that demonstrates that the Texas and California provisions have directly resulted in greater worker safety.

Answer. The EPA is not aware of any documents or analyses that assess improvements in worker safety as a direct result of these provisions.

Question 7. Please provide the Committee with documents or memoranda it used to analyze the OSHA regulation and its applicability in requiring similar provisions in an agricultural setting.

Answer. The EPA considered the requirements of the U.S. Occupational Safety and Health Administration's regulation at 29 U.S.C. section 1910.1020 (*https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10027*) [*See Attachment 16*], and believes similar requirements should apply to agriculture. As cited in the preamble to the proposed Worker Protection Standard (March 19, 2014), in adopting the Hazard Communication Standard (HCS), OSHA stated there was evidence to indicate potential for chemical exposure in every type of industry, and that lack of knowledge about those hazardous chemicals puts employees at significant risk of experiencing material impairment of health (52 FR 31852; August 24, 1987;) (59 FR 6126; February 9, 1994). The OSHA rule applies to general industries, maritime, and construction employers who are responsible for records of employee exposure to toxic substances or harmful physical agents, among other requirements, but expressly does not apply to agricultural employers per 29 CFR Part 1928.21(b). The OSHA rule requires that the employer provide to the designated representative (or requesting employee) access to the employee's exposure record upon their request, in a reasonable time, place, and manner.

The Worker Protection Standard requires agricultural employers to maintain pesticide application records and Safety Data Sheets when workers are on the establishment. These records provide the exposure and hazard information, parallel to those required under OSHA's rules for other industries. Farmworkers, in terms of demographics, are similar to construction workers, in that their jobs may be short term, of low economic status; and they may be low literacy and non-English speaking. The EPA believes that agricultural production can comply with these requirements with little disruption. The EPA recognizes that a significant number of workers face disadvantages that can reasonably make them reluctant to ask their employers for information related to their pesticide exposure, and finds that access to the information through a designated representative, similar to the requirement in OSHA's HCS, is feasible and appropriate to protect worker safety.

Question 8. Does the authorization from the worker to the designated representative need to be notarized?

Answer. The authorization does not need to be notarized.

Question 9. Once a farmer is presented with a written, signed authorization, does the farmer have a legal obligation to provide the information?

Answer. Under the Worker Protection Standard, the designated representative authorization must also be accompanied by a request letter containing certain information. If a valid designated representative authorization is accompanied by a valid request for information required by the WPS to be provided, then the farmer does have a legal obligation to provide only the information required by the rule.

Question 10. Once the designated representative has the information, are there restrictions on what the designated representative may do with the information? (If so, please cite the section of the regulation restricting use of the information.)

Answer. The Worker Protection Standard does not place restrictions on what the farmworker or designated representative may do with the information.

Question 11. Once the designated representative has obtained the information from the farmer, does the designated representative have any obligation to transmit or share that information with the worker who authorized access to the information? (If so, please cite the section of the regulation.)

Answer. The Worker Protection Standard does not impose on the farmworker or designated representative any obligation to transmit or share that information with the worker who authorized access to the information.

Question 12. The section of the WPS immediately preceding that related to designated representatives (§ 170.309(8)) states that "any treating medical personnel or any person acting under the supervision of treating medical personnel" may request pertinent information and may do so either orally or in writing. Thus, it appears that the access granted to designated representatives serves a purpose other than providing for the medical treatment of a worker who has been exposed to a pesticide.

What purposes, other than those related to the health or exposure of a worker to a pesticide, does § 170.309(9) serve?

Answer. Workers and handlers may be reluctant to request the information for themselves due to their inability to communicate effectively with, or fear of, their employer, or because they may not be able to understand the information without help. The required information can be of value to workers before medical care is sought: First, having information available in non-emergency situations could help workers be aware of symptoms before they occur, help them avoid exposure, and possibly enhance the reporting of illnesses. Second, having access to the required information in advance of any medical need means emergency medical personnel would not have to lose critical time tracking down information instead of treating the ill or injured person. Third, having information available in non-emergency situations could help workers be aware of symptoms of chronic illnesses, potentially enabling them to seek treatment earlier in the course of the illness.

Because of the potential burden to agricultural employers, the rule does not require that the required pesticide application information and Safety Data Sheets that provide the hazard information must be provided in any language other than English, although many farmworkers and pesticide handlers are not literate in English or even their native languages. Therefore there are potentially many circumstances these individuals could need the assistance of a designated representative to have "meaningful access" to the information such as having it translated in order to be able to make use of the information. Additionally, many farmworkers could be limited in their ability to get transportation back to an employer's establishment after employment but would need the assistance of a designated representative to access the information they desire.

Question 12a. Please cite EPA's statutory authority to require a farmer to grant access to third parties for proprietary pesticide information when that access is not related to worker safety?

Answer. As discussed in the response to the previous question, the ability for a worker or handler to have meaningful access to the required pesticide application and hazard information is very much related to worker safety. In the 1992 rule, and continued in this revision, access to exposure information and first aid and other medical information is required for medical personnel in cases of injury or illness. For the reasons cited above the worker may not be able to access or make use of the information provided and would need a designated representative to get meaningful access to that information in order to understand the hazards of the chemicals he/she is working around, be better able to protect themselves, recognize potential signs of exposure or illness, and know how to respond appropriately if needed. The EPA's statutory authority to establish requirements to protect worker safety is outlined in the rule and derives from FIFRA's mandate to prevent unreasonable adverse effects on "the environment", which FIFRA section 2(j) defines as including

humans. Agricultural workers are clearly part of "the environment" for purposes of FIFRA, as discussed in U.S. Senate. S. Rep. No. 92–883 (Part II), 92nd Congress, 2nd Session at 43–46 (1972). *U.S. Code Congressional and Administrative News* 1972, p. 4063.

Question 13. § 170.305 of the regulation states that a "*designated representative* means any persons designated in writing by a worker or handler to exercise a right of access on behalf of the worker or handler to request and obtain a copy of the pesticide application and hazard information required by § 170.309(h) in accordance with § 170.311(b) of this part."

Are there any provisions in the WPS restricting who may be a designated representative? (If so, please cite the section of the regulation.)

Answer. There are no restrictions on who may be a designated representative.

Question 13a. Would the WPS permit organizations like anti-pesticide activist groups to serve as designated representatives?

Answer. Any person or organization can serve as the designated representative if they have been properly designated in writing and the request conforms to section 170.311(b)(9).

Question 14. If a designated representative had information related to pesticide use on a farm and wished to publish that information broadly, are there provisions in the WPS to prevent that from happening? (If so, please cite the section of the regulation)

Answer. The Worker Protection Standard does not include provisions that would prevent a farmworker or designated representative from publishing the information required under section 170.309(h).

Question 15. If a designated representative had gained information related to pesticide use on a farm through a written declaration authorized under § 170.311(b) and wanted to use that information publicly to exert pressure on a farmer to stop the farmer from using that pesticide, are there provisions in the WPS to prevent that from happening? (If so, please cite the provision)

Answer. The Worker Protection Standard does not include provisions that would prevent a farmworker or designated representative from using the information required under section 170.309(h) publicly.

Question 16. Many hired workers in agriculture—by most estimates more than 50% of the hired labor force—work in agriculture by presenting documents that contain false names, social security numbers, green cards or other information. An employer, such as a farmer, is legally required to accept such documents if they appear to be genuine. Because of this fact, it may be possible for an individual to present himself or herself to a farmer claiming to be a designated representative for a worker with a name that does not appear on the farmer's records. If the designated representative states that the individual worker did work on the farm but under a different name, what is the farmer's legal obligation?

Is the farmer's legally obliged to release the pesticide information? (If not, please cite the section of the regulation releasing the farmer from legal responsibility)

Answer. Where a person claiming to be a designated representative presents the name of a worker or handler that does not appear on the employer's records, the employer could refuse to provide the requested information unless other evidence, documentation or information known to the employer reasonably supports a conclusion that the worker or handler being represented by the designated representative was actually employed on the establishment.

Question 16b. If the farmer does not release the information, is the farmer protected under the WPS? (Please cite the specific provision).

Answer. Yes. If a designated representative's request for information does not meet the requirements of section 170.311(b)(9), an employer's refusal to provide the requested information would not be a violation of FIFRA.

Question 16c. If a designated representative has been found to be abusing this provision of the WPS, what sanctions would that individual face? (Please cite the specific provisions)

Answer. The Worker Protection Standard does not include provisions that would provide sanctions against a designated representative.

Question 17. Given the concerns that have been raised by the agriculture community over the designated representative provision, would EPA be willing to suspend implementation of the provision and revise it after consultation with representatives of the agricultural community and re-proposing it in the *Federal Register?*

Answer. The EPA included a representative access provision in the proposed rule, specifically requested comment on potential problems it could cause (79 FR 15444, 15479), and received many pertinent comments from a broad range of commenters,

few of which identified likely problems that were significantly different from those contemplated by the EPA at the time of proposal. The EPA does not expect that an additional comment period would produce significantly different information, but in any case, any person who has such information may submit it at any time for the EPA to review.

If the agency is presented with evidence that this provision of the rule is creating undue burden for the agricultural community, or the provision is being abused by certain designated representatives, the agency will consider whether the evidence warrants regulatory action in response. However, the EPA does not believe there are sufficient grounds for changing the rule at this time.

Questions Submitted by Hon. Jeff Denham, a Representative in Congress from California

Question 1. The National Association of Clean Air Agencies testified to EPA that the new 2015 ozone standard "will have a profound impact on the work of the state and local air pollution control agencies." This is troubling, especially considering many of these same agencies are still working on the 2008 ozone standard, which has yet to be fully implemented.

Given its geographical layout and persistent droughts, California's Central Valley has had to expend exceptionally more resources to keep up with every reaching air standards.

What type of assurance is the EPA giving our states and local governments, municipalities, and businesses that the EPA is not setting them up to fail by constantly moving the clean air goalpost?

Answer. The EPA and state co-regulators share a long history of managing ozone air quality under the Clean Air Act (CAA), underpinned by a wealth of previously issued EPA rules and guidance. The overall framework and policy approach reflected in the implementing regulations for the 2008 ozone standards provide an effective and appropriate template for the general approach states would follow in planning for attainment of the revised 2015 ozone NAAQS. In particular for California areas where the state and districts are still actively working toward attaining the 2008 ozone NAAQS, the EPA is committed to continue helping these air agencies identify and take advantage of potential planning and emissions control efficiencies that may occur within the horizon for attaining the 2015 standards. Following past precedent, the EPA intends to propose revoking the 2008 standards and provide transition rules intended to help avoid any potential inefficiencies as states begin implementing the Clean Air Act's requirements for the 2015 standards.

Question 2. Taking into account EPA's accidental release of farm information to environmental activist groups in 2013, farmers and ranchers in my district are understandably concerned about the lack of data security measures preventing the EPA from collecting superfluous farm information.

In light of the 2013 incident—as well as other highly damaging breaches into OPM and DOD—what improvements has the EPA made, or is the EPA making, to ensure it only collects the information it needs, and that such information is secure?

Answer. The EPA is continually working to improve its processes for collecting and managing data related to environmental protection programs. For example, the EPA recently established through rulemaking the minimum set of NPDES program data based on the EPA's current reporting requirements (see Appendix A to 40 CFR Part 127) [*See Attachment 7*]. During the development of this rulemaking, the EPA carefully considered input from authorized state programs, provided in comments and meetings, to match the minimum set of NPDES program data to the existing regulations and practice, including how these data are currently used by the EPA and authorized state programs. The EPA and states streamlined the NPDES electronic reporting requirements down to the minimum number of data elements needed to oversee management of the NPDES programs in the most efficient manner possible

In addition, due to comments received during the NPDES Electronic Reporting Rule [see: Comment Response Document for the NPDES Electronic Reporting Rule (Final Rule),* EPA–HQ–OECA–2009–0274–0575, available at: *http://www.regulations.gov*], the EPA is masking facility specific information for unpermitted CAFOs that are not in violation of the CWA, responding to particular privacy concerns raised regarding operators living in close proximity to these facilities.

More broadly, the EPA is taking steps to improve the agency's information security posture and meet the Administration's cybersecurity cross-agency priority goals.

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* **Editor's note:** the document referred to is retained in Committee file.

The EPA improved the use of strong authentication for logging onto the EPA network, improved anti-phishing protections, and coordinated with the Department of Homeland Security to improve asset and vulnerability management and malware defenses.

Question 3. Your Agency's honeybee acute toxicity proposal could restrict the use of over 3,000 crop protection products when a grower has contracted for pollination services. These products are primarily derived from 76 Active Ingredients. How did EPA decide on these Active Ingredients? Were risk assessments and benefits analysis conducted, as is required by law, before this proposal was published?

Answer. EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products is aimed at providing greater protection to bees where acute risk is presumed to be the highest, namely when certain exposure (*i.e.,* contract pollination scenarios) and presence of an acutely toxic pesticide coincide. For this proposed risk mitigation strategy, the agency focused only on a subset of compounds identified as highly toxic to bees, which are likely to have the greatest adverse effect on bees. The 76 active ingredients are those that have been determined via testing to have an acute contact toxicity value less than 11 micrograms per bee, based on data required to be submitted by pesticide registrants. Limiting our focus to these compounds was intended to gain the greatest benefits of protection to bees with the least impact to growers. The agency will assess each compound under the registration review program, with a more thorough and robust data set as identified in our *Risk Assessment Framework for Pollinators.* As a result, additional chemical-specific, risk-based labeling will be developed based upon the results of these subsequent assessments.

As part of its planning and analysis prior to issuing the proposal, the EPA considered the potential cost to growers. The agency is currently reviewing the wide range of comments it received in response to the proposal and is considering how to proceed. Based upon the comments received, we are developing options on moving forward. Throughout this process, the agency continues to weigh both the level of protection to bees, and the potential cost to growers.

Question 4. I'm sure you're aware of the advances residue-detecting technologies have made, with some being able to detect parts-per-billion. With this kind of preciseness, a tolerance-restricted pesticide could be found on an unrelated crop in a negligible but detectable amount, say by way of cross breezes or other unintentional factors. Is EPA taking this into consideration, to ensure that incidents such as these do not condemn an entire crop?

Answer. The EPA is aware of the issues associated with the stated concern and note that enforcement questions related to the presence in or on food of a pesticide chemical residue for which there is no established EPA tolerance or tolerance exemption is under the purview of the U.S. Food and Drug Administration (FDA), not the EPA. Questions regarding the FDA's practices with respect to testing and enforcement activities related to low level pesticide chemical residues found in or on food should be directed to the FDA.

Question 5. Some special interest groups have been demanding that the EPA now operate outside its existing FIFRA scope and regulate pre-treated seeds. Given that there is still no solid scientific evidence to necessitate a change in oversight does the EPA intend to continue respecting this distinction?

Answer. With respect to the litigation filed by public interest groups, on March 14, 2016, the EPA filed a motion with the district court in the Northern District of California to dismiss the case against the EPA. A hearing on this motion was held on May 12, 2016, and the following day the court issued an order deferring a decision on the merits of the EPA's motion to dismiss until the EPA produced an administrative record. The EPA has complied with the court's order and expects the court to address its jurisdiction (the subject of the motion to dismiss) during summary judgment proceedings. Under the current litigation schedule, summary judgment motions are to be filed in September and should be argued in October 2016. Treated seeds that meet the requirements of the treated article exemption at 40 CFR Part 152.25(a) are exempt from regulation under FIFRA and the EPA has not proposed to amend that regulation.

Question Submitted by Hon. Ted S. Yoho, a Representative in Congress from Florida

Question. Administrator McCarthy, it is my understanding that on October 27, 2015, FOIA request EPA–HQ–2016–000771 was submitted to EPA. This FOIA requests copies of communication from 2011 to the present between the U.S. Environmental Protection Agency, U.S. Food and Drug Administration and U.S. Department of Agriculture related to the biopesticide active ingredient banda de *Lupinus albus* doce (BLAD) and the end use product Problad Plus (EPA Registration Number

84876–1). It is my understanding no information related to this request has been provided or released to date. Can you explain any reasons for this delay? Can you provide an expected timeline when information should be released?

Answer. The EPA responded to request EPA–HQ–2016–000771 and sent all requested records. This FOIA request is closed.

Questions Submitted by Hon. Mike Bost, a Representative in Congress from Illinois

Question 1. Resistance Management is a critical concern for all farmers. Corn farmers have experienced increasing resistance problems with using traited corn. Resistance has developed in weeds, and pests like Corn Rootworm. Soil Applied Insecticides are registered by EPA for use on corn, including corn with traits, and have been proven effective in controlling rootworm and also improving yields. Is EPA planning to restrict the use of Soil Applied Pesticides with traited corn?

Answer. The EPA has not taken any regulatory actions to restrict the use of soil applied insecticides on corn. In response to signs of resistance to Bt traits in the corn rootworm, the EPA has developed new, more protective requirements designed to delay corn rootworm resistance to genetically engineered Bt corn. The EPA announced its new requirements in February 2016. As part of those requirements, the EPA is recommending against the use of soil applied insecticides for control of corn rootworm on corn rootworm traited corn except under limited circumstances and in consultations with experts. This recommendation is based on published scientific literature that indicates the use of soil applied insecticides for corn rootworm can present an additional resistance risk to Bt traits and on advice from the EPA's FIFRA Scientific Advisory Panel. Information and materials from this SAP meeting is available at *https://www.epa.gov/sap/meeting-materials-december-4-6-2013-scientific-advisory-panel* [*See Attachment 17*].

Question 2. I am very concerned that EPA has not been coordinating with USDA on matters crucial to farmers and consumers regarding the importance of crop and environmental protection and on the economic benefits to farmers who use pesticides to protect their crop yields to feed America and the world. I understand that USDA has been willing to work with EPA. However, USDA is appropriately concerned about not being consulted about the calculation of the benefits provided to agriculture and farm production through the use of pesticides.

For example, the Chief Economist at USDA sent a letter on April 6, 2015, to EPA criticizing EPA for publishing an analysis on the economics of soybean production which USDA said was misleading, incomplete, incorrect, and that "as a whole USDA disagrees with the assessment."

The letter further said that "USDA is disappointed that EPA published the report . . . without offering USDA an opportunity . . . to correct the misrepresentations of economic costs and benefits that underlie this report." I certainly agree with USDA that USDA and EPA need to work together and note that Federal regulations require that coordination or an opportunity for USDA to provide input to EPA if that determination would result in the suspension, cancellation, or change in classification of a pesticide.

In August, USDA sent a second letter to EPA, signed by Sheryl Kunickis, Director of Research, Education and Economics, saying that the May 29, 2015, EPA proposal on mandatory pesticide label requirements would be especially harmful to "numerous specialty crop farmers and the rural economics they contribute to across the U.S." USDA was also concerned about the fact that the EPA "proposal has the potential to negatively impact . . . organic production . . . ."

Consultations between EPA and USDA are required in the Federal Insecticide, Fungicide, and Rodenticide Act in sections 2 (minor uses), 3 (minor uses), 4 (public health issues), and section 6 (suspensions, cancellations, imminent hazards; advance notice of EPA actions, and other FIFRA provisions mandate the opportunity for USDA input). Some consultations are required by regulation or OMB Circulars.

For all of 2015 and through the date of your response in 2016, can you please describe in appropriate detail consultations, discussions, and meetings EPA has conducted with USDA on the above examples on the following types of actions: determinations of economic benefits to farmers, including specialty crop farmers, regarding the use of specific pesticides; label requirements and changes; issues related to minor crops; public health matters; and the consideration of decisions to restrict, limit, cancel, or suspend the use of pesticides?

In your answers please include specific information including dates, participants, actions taken, and the outcome of those consultations, discussions, and meetings.

Answer. The following provides some examples of the discussions the EPA has had with USDA from January 1, 2015, through March 15, 2016. These consultations are summarized in the table below.

The EPA typically consults with USDA through the Office of Pest Management Policy (USDA–OPMP). OPMP then coordinates with other entities associated with USDA, including the Integrated Pest Management (IPM centers), as appropriate. For some reviews, therefore, the EPA is not in direct contact with all the participants. The EPA regularly coordinates and consults directly with USDA's Animal and Plant Health Inspection Service's (APHIS) Biotechnology Regulatory Services (BRS) on matters related to biotechnology and agriculture. Similarly, the EPA consults directly and regularly with Interregional Project 4 (IR–4) on matters related to uses of pesticides on minor crops (*i.e.,* crops grown on less than 300,000 acres). In addition, for the past several years, the EPA has scheduled monthly meetings with OPMP to provide for coordination on a wide variety of pesticide regulatory matters.

The EPA and BRS coordinate on genetically-engineered (GE) crops which are resistant to herbicides and insects. In addition, EPA and BRS coordinate on GE microorganisms. The EPA has also coordinated closely with USDA–APHIS–BRS on the registration of herbicides containing rimsulfuron and nicosulfuron designed for use on Inzen sorghum (Inzen sorghum is a type of sorghum that is conventionally bred to be resistant to the effects of rimsulfuron and nicosulfuron herbicides). The registration of these herbicides could benefit sorghum growers who cultivate the Inzen sorghum line by providing improved weed control. Although Inzen sorghum is the product of conventional breeding and is not a GE crop, the EPA reached out to BRS. BRS assisted with an analysis which showed the potential for resistant trait conventionally bred into the sorghum to cross with wild relatives which could become resistant to the herbicides that are proposed for use on Inzen sorghum and subsequently pose challenges to their control in agricultural production. The EPA issued these registrations on February 3, 2016.

USDA and HHS reviewed the EPA's assessment of an application for a new use of deltamethrin for the purpose of mosquito control. The review was led by USDA–OPMP (Office of Pest Management Policy), but the participating offices are not known. No comments were submitted. EPA found that the proposed use was a 'minor use' as defined by FIFRA 2(ll)(2), 'lack of economic incentive.' As such, the registrant was eligible for a new period of exclusive use over the data submitted in support of the registration.

In addition to consultations over specific pesticides, the EPA engages with USDA over basic concepts that contribute, over time, to pesticide decisions. USDA also reviews rules proposed and finalized by EPA under FIFRA and as part of the interagency review coordinated by the Office of Management and Budget. For example:

- The EPA has been collaborating with USDA, as well as FWS and the National Marine Fisheries Service (NMFS) to develop interim scientific methods to assess the potential risks of pesticides to Federally endangered and threatened species and designated critical habitats, based on recommendations from the April 2013 National Academy of Sciences report, "Assessing Risks to Endangered and threatened Species from Pesticides." Specifically, USDA has provided expertise on pesticide uses for the draft pilot Biological Evaluation for diazinon and assistance with the use of the National Agricultural Statistics Service Cropland Data Layer to help define the footprint of agricultural use patterns;
- The EPA is in regular communication with USDA regarding biotechnology per the Federal Coordinated Framework for the Regulation of Biotechnology. For over 15 years, the EPA, USDA, and FDA have participated in monthly biotechnology calls where each agency shares regulatory updates, hot topics, and information on international activities. The EPA, FDA, and USDA–APHIS–BRS also have Memoranda of Understanding in place regarding coordination and information sharing as well as other MOU's associated with specific topic areas, *e.g.,* coordination and collaboration on the potential environmental release of GE microorganisms. Additionally, through the Emerging Technologies Interagency Policy Coordination Committee, the EPA is working with USDA on updating the coordinated framework for biotechnology;
- For over three years, the EPA has been in regular communication with USDA–ARS regarding corn rootworm resistance management issues. During the corn growing season, the EPA participates in monthly conference calls with corn rootworm entomologists, including USDA researchers. The EPA received comments from USDA's OPMP (EPA–HQ–OPP–2014–0805–0076) in response to its solicitation for public comment on a corn rootworm mitigation strategy. The EPA modified its proposal to account for those comments and comments from others. Prior to releasing the proposed draft strategy and prior to announcing an agreement in January 2016, the EPA communicated with OPMP to notify OPMP of the release;

- The EPA is consulting with USDA–ERS (Economic Research Service) to better understand the value of pollinators, especially managed honey bees, and how pesticide use may influence the habitat for wild pollinators. This information will help the EPA better characterize the risks pesticides pose to managed and wild pollinators;
- USDA reviewed the final rule to revise the Worker Protection Standard (WPS) and the proposed rule revising the standards for Certified Applicators. The review was coordinated by USDA–OPMP. The Animal and Plant Health Inspection Service (USDA–APHIS) and Forest Service (USDA–FS) participated significantly in the review of the Certified Applicators proposed rule; both entities run certification programs. An outcome of the discussion with USDA was that the EPA expanded the definition of farms and familial relationships eligible for the owner and immediate family exemptions to the WPS;
- The EPA and USDA have been coordinating closely for several years on the important issue of herbicide resistance. Weed resistance to herbicides has become a major economic and agronomic problem in U.S. agriculture in field crops such as corn, soybeans, cotton, and wheat, as well as minor and specialty crops. The EPA has proactively engaged USDA–OPMP and USDA–APHIS's Biotechnology Regulatory Service (APHIS–BRS) in this key area. This joint effort also includes the Weed Science Society of America (WSSA) and other stakeholders, where in 2012, WSSA published two special editions of their Journal of Weed Science that were the culmination of collaboration between EPA, USDA and WSSA. In addition to weed resistance to herbicides, the EPA is working with USDA and other stakeholders in efforts to manage insect and plant pathogen resistance to pesticides; and
- The EPA, USDA–OPMP, and USDA–APHIS–BRS have on several occasions participated jointly in a wide range of outreach and education efforts. In July 2015 the EPA and OPMP participated in a tour of herbicide-resistant weed problems in Iowa agriculture. Joining the group were weed scientists from the University of Kentucky and Iowa State University. In other outreach activities, USDA/OPMP joined EPA to discuss herbicide resistance and other issues of mutual interest at a meeting with the Commodity Research and Opportunities Partnership (CROP), an organization that represents corn, cotton, wheat, sorghum, and soybean growers.

While the EPA does not have detailed records of every consultation held with USDA regarding pesticide regulatory matters, the following table provides examples of the wide variety of interactions between the EPA and USDA over the past 2 years:

Subject	Meeting Dates	Participants
Pesticide-specific consultations		
Rimsulfuron and Nicosulfuron registrations on sorghum	January 29, 2015; February 27, 2015	USDA–APHIS–BRS
Sulfonylurea herbicides	May 27, 2015	USDA–OPMP
Deltamethrin minor use assessment	Draft reviewed by USDA and HHS, October–November, 2015	USDA–OPMP
Neonicotinoid insecticides	April 30, 2015, presentation by AgInfomatics on benefits	USDA–OPMP; USDA–IR–4
Endangered Species		
Endangered Species Risk Assessments for Pesticides	Continued discussions from January 1, 2015 to present including bi-weekly conference calls and a week-long interagency workshop with EPA, FWS, and USFWS in January 2016	USDA–OPMP, USDA–NASS
Federal Endangered Species Task Force (FESTF) meeting	July 14, 2015	USDA–OPMP, USDA–NASS
Biotechnology		
Biotechnology Coordination Calls	Monthly for 15+ years	EPA, USDA, FDA
Discussion of USDA–FAS' mission, new breeding technologies and how the products may impact trade in agricultural commodities.	March 10, 2016	EPA, USDA–FAS
Biotechonology MOUs	On-going discussions	EPA, USDA–APHIS–BRS
Working with USDA on the Emerging Technologies Interagency Policy Coordination Committee to update the coordinated framework for biotechnology	August 2015 and ongoing discussion	EPA, USDA–APHIS, USDA–OSEC
Corn Rootworm Resistance Management	Monthly during corn growing season for 3+ years	EPA, USDA ARS

Subject	Meeting Dates	Participants
Pollinators		
Value of pollinators	September 2, 2015, and on-going discussions	USDA–ERS
Pollinator habitat	December 1, 2015, and on-going discussions	USDA–ERS
Pollinator health task force	As needed since May 2014 (EPA and USDA co-chair the task force)	USDA–OSEC, USDA–OPMP, USDA–ARS, USDA–FSA, USDA–NRCS
Rules		
Worker Protection Standard revisions	May to July, 2015	USDA–OPMP
Certified Applicator revisions	April to July, 2015	USDA–OPMP, USDA–APHIS, USDA–FS
Herbicide Resistance		
Herbicide Resistance Internationally	March 16, 2015, seminar by Dr. Steve Powles, University of Western Australia	USDA–OPMP
Herbicide Resistance Management	September 24, 2015, with WSSA representatives	USDA–OPMP
	October 23, 2015	USDA–APHIS–BRS
Herbicide Resistance Management Proposal	February 10, 2016, Weed Science Society of America	USDA–OPMP
	March 16, 2016, Federal IPM Coordinating Committee meeting	USDA–OPMP, USDA–ARS, USDA–NRCS, USDA–NIFA, USDA–NASS, USDA–IR–4
Methyl Bromide		
Golden nematode—conference call to discuss alternatives for quarantine and control in Idaho	September 22, 2015	USDA–APHIS, EPA—Region 10
Outreach/Education		
Iowa Crop Tour on herbicide resistant weeds	July 7–10, 2015	USDA–OPMP
Interagency Meeting on weed control issues	February 10, 2016	USDA–APHIS–BRS, USDA–OPMP
Commodity Research & Opportunities Partnership (CROP)—representing corn, cotton, wheat, sorghum, and soybean growers	October 8, 2015	USDA–OPMP
Discussion with USDA on Sorghum-Johnsongrass Gene Flow Seminar & Persistence of Crop Alleles in the Weed Populations	September 9, 2015	USDA–APHIS–BRS
Webinar with Tribal Nations on Genetically Engineered crops	June 11, 2015	USDA–APHIS–BRS
Glyphosate resistance economics (webinar)	July 14, 2015	USDA–ERS
USDA Stakeholder Workshop on Coexistence—resistance management for biopesticides and herbicides	March 12–13, 2015	USDA–OPMP
Sulfonylurea herbicide meeting with registrants	April 1, 2015	USDA–OPMP
Golden nematode—conference call to discuss alternatives for quarantine and control in Idaho	September 22, 2015	USDA–APHIS, EPA—Region 10

Question 3. Reliable data and analyses are critical to sound regulation. I have heard about a serious matter regarding EPA policies based on human research data that may not be reliable.

For years, EPA relied on hundreds of quality studies evaluating all aspects human susceptibility to pesticides called organophosphates. This included studies designed to make sure that children would be protected. Even though EPA used those high-quality assessments for 20 years the Agency now relies primarily on three epidemiology studies and some journal articles. Limiting the diversity of data creates a greater likelihood of inaccurate results. Why has EPA changed this process? Has limiting the number of studies increased the likelihood of inaccurate assessments? Was this change reviewed by a Scientific Advisory Panel? Was it subject to notice and public comment? Why is the Agency keeping this data from the public?

Answer. The EPA periodically reviews existing registered pesticides to ensure they can be used safely, without unreasonable risks to human health and the environment. The periodic review of pesticide registrations is required by FIFRA. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. The EPA will review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration.

As part of registration review, the EPA assesses any changes that have occurred since the last registration decision to determine whether the pesticide still satisfies the statutory standard for registration. The EPA considers any new data or information on the pesticide and decide whether a new risk assessment must be conducted. In the case of chlorpyrifos and the organophosphate pesticides, many of the epidemi-

ology studies, mechanistic studies, and laboratory animal studies on the neurodevelopmental effects of organophosphate pesticides were published after reregistration was completed in 2006.

The EPA developed a "Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" in 2010 which was reviewed by the FIFRA SAP and received public comment. The Panel commended the agency for developing the draft Framework and was "impressed with the documentation presented." The agency also notes that the Panel was supportive of the key components of the draft Framework, namely the use of problem formulation to assess data availability and quality early in the process and the modified Bradford Hill criteria as an internationally accepted tool for assessing epidemiology and laboratory animal data.

The agency has not limited the number of studies reviewed. In fact, the agency has reviewed hundreds of studies from laboratory animals, cell systems (including human), biomonitoring, and epidemiology on a variety of scientific areas related to human health effects. These studies were evaluated together in a weight of evidence analysis.

Therefore, there is significant new information relevant to the human health effects of organophosphate pesticides.

Question 3a. I have recently been told that one of the studies that the EPA relies upon was conducted by Columbia University and that they have refused to provide the raw data to the Agency even though EPA partially funded the study. Is that true? At any point has EPA been allowed to review the raw data? Do you believe that its use is in compliance with the Administrative Procedures Act? How many times has this study been utilized for registrations and registration reviews? Was that study and its underlying data reviewed by a Scientific Advisory Panel? Was it subject to notice and public comment?

Answer. The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the Federal courts have made clear that the EPA is not required by Federal law to obtain or analyze the raw data in order to rely on such studies. The EPA therefore believes its consideration of these data is consistent with the Administrative Procedure Act. If the EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.

In the past, the EPA sought to obtain the original raw data used to support certain epidemiological analysis of *in utero* exposure to chlorpyrifos and subsequent adverse neurodevelopmental health outcomes in children generated by the Columbia Center for Children's Environmental Health (CCCEH) to support the human health risk assessment of chlorpyrifos. Prior to the 2013 meeting with CCCEH investigators, the EPA thought these data would be important to both clarify the exposure-response relationship observed in the epidemiology study relative to the current regulatory endpoint (acetylcholinesterase inhibition), and also to resolve uncertainties regarding study participants co-exposure to other environmental contaminants, among other areas of uncertainties. CCCEH researchers did not agree to provide these data; however, the researchers met with the EPA and discussed the agency's questions about the data to help determine whether further review of the raw data might assist the EPA in resolving uncertainties. As a result of this meeting, the EPA concluded that access to the raw data would not provide answers to the EPA's questions. Indeed, based on discussions in that meeting as well as further work conducted by agency staff, the EPA has gained additional information to better clarify and characterize the major issue areas identified as uncertainties.

In the summer of 2015, the EPA made another attempt to obtain the raw data from Columbia University. The Columbia University investigators again denied the EPA's request. However, the investigators did provide additional summary information on the blood biomonitoring data. The agency has made this additional information publicly available.

Also in summer of 2015, Dr. Dana Barr of Emory University provided the agency with limited raw data in her possession from the three cohorts. However, the files provided from Dr. Barr are not useful the agency's current purpose of assessing risk to chlorpyrifos. The files provided from Dr. Barr do not contain the biomonitoring data from the key publications from CCCEH which describe associations between blood levels of chlorpyrifos and neurodevelopmental deficits in children. The agency has received two FOIA requests specifically asking for raw data on the three US children's cohorts. For the first FOIA request, EPA–HQ–2016–002089, the requester was provided all the responsive records (*i.e.,* the files provided by Dr. Barr) and the request was closed March 2, 2016. For the second request, EPA–HQ–2016–003947,

the agency did not have any additional files beyond those provided for the first request. The second FOIA was closed on March 22, 2016.

The agency has taken a stepwise, objective and transparent approach in evaluating, interpreting, and characterizing the strengths and uncertainties associated with all of the available lines of scientific information related to the human health effects of chlorpyrifos. This stepwise approach has included multiple reviews by the FIFRA SAP and other experts in addition to multiple opportunities for public comment.

The stepwise evaluation began with the September 2008 FIFRA SAP meeting involving a preliminary review of the literature for chlorpyrifos, with a particular focus on women and children (USEPA, 2008). In 2010, the EPA developed a draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" which provides the foundation for evaluating multiple lines of scientific evidence, including epidemiology, in the context of the understanding of the adverse outcome pathway (or mode of action (USEPA, 2010). The draft framework, which includes two key components: problem formulation and use of the modified Bradford Hill criteria, was reviewed favorably by the SAP in 2010 (FIFRA SAP, 2010). The EPA's draft framework is consistent with updates to the World Health Organization/International Programme on Chemical Safety mode of action/human relevance framework, which highlight the importance of problem formulation and the need to integrate information at different levels of biological organization.

Because the SAP was basically supportive of the overall approach and the framework is consistent with recent, similar efforts by the WHO, the agency believes use of the draft framework in its current form is appropriate prior to the finalization of the document. The EPA used the draft framework for the 2014 chlorpyrifos revised risk assessment and the preliminary risk assessment for seven organophosphates in 2015. Currently, we are incorporating comments from the SAP and the public, and plan to finalize the framework in 2017.

In 2011, the agency released "Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review," focusing on the AChE inhibiting potential of chlorpyrifos (USEPA, 2011) and included assessment of exposures from dietary (food, water), occupational and residential pathways. The 2011 preliminary risk assessment was released for public comment. Also in 2011, the chlorpyrifos physiologically based pharmacokinetic-pharmacodynamic model (PBPK–PD) was reviewed by the FIFRA SAP (FIFRA SAP, 2011). [This model was used in the 2014 revised human health risk assessment described below.]

In 2012, the agency convened another meeting of the FIFRA SAP on chlorpyrifos which incorporated the newest experimental data related to AChE inhibition and both cholinergic and non-cholinergic adverse outcomes, including neurodevelopmental studies on behavior and cognition effects (FIFRA SAP, 2012). Similarly, the agency also performed a more in-depth analysis of the biomonitoring data and of epidemiological studies from three major children's health epidemiology cohort studies in the U.S., as well as developed plausible hypotheses on MOAs/AOPs leading to neurodevelopmental outcomes (USEPA, 2012a). Following the 2012 SAP meeting, the agency solicited additional input from Federal experts in the areas of Magnetic Resonance Imaging (MRI) and neurobehavioral testing in children to further clarify results obtained by examination of the epidemiological studies.

In December, 2014, the agency released "Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review"* which went through public comment in 2015.

Similarly, the agency's "Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides" was released for public comment in September, 2015.

The agency held another meeting of the FIFRA SAP in April 2016, to review a new analysis using the blood biomonitoring data from the Columbia University epidemiology study.

Question 3b. It has also been brought to my attention that one of the authors of the study, **Frederica Perera, Dr.P.H., Ph.D., of the Columbia University School of Public Health, is a member of the Board of Trustees of the Natural Resources Defense Council.** The Natural Resources Defense Council has sued the EPA on a number of occasions to challenge pesticide registrations and often the supporting risk assessments. Has the EPA's Office of Inspector General been made aware of this conflict of interest? Has the Agency suspended use of the Columbia University epidemiology study in its risk assessment process until these concerns can be addressed?

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* **Editor's note:** the document referred to is retained in Committee file.

Answer. While recipients of Federal grants are subject to conflict of interest rules designed to insure that the competition for grants is fair and that the use of grant funds is appropriately managed, they are not otherwise subject to conflict of interest restrictions disqualifying them from eligibility to receive a grant based on affiliations with organizations that have sued the agency or supported particular regulatory activities. Accordingly, the EPA has not related this matter to the EPA Inspector General, nor has the EPA suspended its consideration of these data.

Question 3c. If it is correct that EPA has not gotten access to that raw data, Federal regulations designed to enhance the credibility of the Federal rulemaking process have likely been violated. Data Quality Act violations and conflict of interest violations may have also occurred.

Answer. The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the Federal courts have made clear that the EPA is not required by Federal law, including Federal rulemaking procedures, to obtain or analyze the raw data in order to rely on such studies. If EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.

The EPA's consideration of epidemiological data supporting the EPA's chlorpyrifos assessment is in keeping with the EPA's guidelines implementing the Information Quality Act. Those guidelines recognize that in some circumstances complete access to all methods and data cannot occur due to privacy, trade secrets, intellectual property, and other confidentiality protections. In those instances, EPA guidelines provide that the EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken. Original and supporting data may not be subject to the high and specific degree of transparency provided for analytic results; however, the EPA should apply, to the extent practicable, relevant agency policies and procedures to achieve reproducibility, given ethical, feasibility, and confidentiality constraints.

Questions Submitted Hon. David Rouzer, a Representative in Congress from North Carolina

EPA National Enforcement Initiatives

Question 1. One of EPA's current enforcement initiatives for the Fiscal Years 2014–2016 expands enforcement action against our nation's animal agriculture operations. EPA is currently undergoing a process to modify the NEIs and this presents an opportunity that we support—returning this priority to the standard enforcement program—which is prudent considering the current NEI has not produced demonstrable water quality benefits. Administrator McCarthy, will you work to ensure that the new enforcement initiatives are based on sound science and demonstrated environmental benefits, rather than a doubling-down of efforts that have only acted to generate further distrust of EPA by America's farmers and ranchers?

Answer. The EPA identifies National Enforcement Initiatives based on public and stakeholder input, as well as extensive science-based analysis about public health threats from pollution. We recently announced the EPA's selection of the FY 2017–2019 National Enforcement Initiatives. Building on progress we've made from the current cycle of initiatives, the EPA determined that to protect American communities, it was important to retain its national initiative to prevent animal waste from contaminating surface and ground water. This will help focus important time and resources on protecting communities from improperly managed animal waste, which can result in water quality impairment, fish kills, algal blooms, contamination of drinking water sources, and transmission of disease-causing bacteria and parasites associated with food and waterborne diseases.

NPDES Electronic Reporting Rule

Question 2. This rule (finalized by EPA on September 25, 2015) will result in EPA collecting farm information from states that goes beyond the scope of the Federal program. Taking into account EPA's accidental release of farm information to environmental activist groups in 2013, the lack of data security measures to prevent EPA from collecting non-NPDES farm information is very concerning to our nation's farmers and ranchers. Administrator McCarthy, can you ensure us that no superfluous information will be collected by the EPA through the electronic reporting rule?

Answer. The minimum set of NPDES program data that the EPA will collect through the NPDES Electronic Reporting Rule does not go beyond the scope of the Federal program and is based on the EPA's current reporting requirements (see Appendix A to 40 CFR Part 127) [*See Attachment 7*].

During the development of this rulemaking the EPA carefully considered input from authorized state programs, provided in comments and meetings, to match the minimum set of NPDES program data to the existing regulations and practice, including how these data are currently used by the EPA and authorized state programs. The EPA, in close collaboration with the states, streamlined the NPDES electronic reporting requirements down to the minimum number of data elements needed to oversee management of the NPDES programs in the most efficient manner possible. In particular, these data are necessary to properly identify potential sources of wastewater and storm water pollution and to assess the effectiveness of authorized NPDES programs.

In particular, the EPA worked with authorized NPDES programs to ensure that the final rulemaking accurately captures EPA's existing Federal NPDES reporting requirements on Concentrated Animal Feeding Operations [*e.g.,* 40 CFR Part 122.21(i)(1), 122.23, and 122.42(e)(4)]. Additionally, besides inspection information, authorized state programs are only required to share with the EPA data on facilities that are required to obtain NPDES permits under Federal requirements.

Question 3. Last September, the EPA published Interim Recommendations for environmental standards and ecolabels for use in Federal procurement. EPA's recommendation for lumber excludes several credible standards that are widely used in the United States, including the Sustainable Forestry Initiative (SFI) and American Tree Farm System (ATFS) standards, which represent 70% of the certified acres in the U.S. EPA has signaled that this recommendation is mandatory for Federal procurement. Under what circumstances may a Federal procurement officer purchase wood products that do not meet this FSC requirement, such as those certified to SFI or ATFS? And, given the significant volume of sustainably harvested timber that is seemingly excluded from Federal purchasing, please explain the process for EPA amending this recommendation in the future.

Answer. Under Executive Order 13693—*Planning for Federal Sustainability in the Next Decade*—the EPA issued recommendations to assist Federal purchasers in identifying and procuring environmentally sustainable products. The EPA's Interim Recommendation for the lumber/wood category is based on the Department of Energy's Fiscal Year 2016 (FY16) Priority Products List.

As a result of stakeholder inquiries since the release of the Interim Recommendation, the EPA has met and is continuing to work with USDA and DOE's Office of Sustainable Environmental Stewardship to gain further information. The EPA's Standards Executive is reaching out to the Sustainable Forestry Initiative, the American Tree Farm System, and the other forestry labels that stakeholders have requested the EPA consider. The EPA will be in touch with these groups regarding the agency's review of forestry labels and their alignment with the National Technology Transfer and Advancement Act, the OMB Circular A–119, and related Federal policies that guide the EPA's use of voluntary consensus standards and private-sector conformity assessment activities. In addition, the EPA continues to progress with piloting our *Guidelines for Assessing Standards and Ecolabels for Use in Federal Procurement* (the Guidelines), and hopes that information gleaned from this process will inform thinking related to the lumber/wood category. Finally, DOE continues to conduct research to inform their FY16 Priority Products List. The EPA looks forward to reviewing all of this additional data to inform if and how the lumber/wood category of Interim Recommendations might be revised.

The EPA has, and will continue to provide, mechanisms for public input as we develop these recommendations. The agency issued *Federal Register* Notices on the initial draft guidelines in 2014 and in March 2015 for the launch of our pilot work.[10] Those FRNs were open to public comment and they marked the beginning of our efforts to engage multi-stakeholder panels whose counsel will be considered as we move to finalize our recommendations. Further, any Federal acquisition requirements stemming from the recommendations would include a public comment process prior to incorporation into the Federal Acquisition Regulations (FAR). As such, FAR Case 20 15–033 has been developed in order to integrate the new requirements of E.O. 13693 into the FAR. All next steps related to this case, including as to when

[10] *Federal Register* Notice, February 27, 2014, "Draft Guidelines for Product Environmental Performance Standards and Ecolabels for Voluntary Use in Federal Procurement" (79 FR 11102). [*See Attachment 1*] *https://www.gpo.gov/fdsys/pkg/FR-2014-02-27/pdf/2014-04329.pdf.*

Federal Register Notice, March 19, 2015, "Agency Information Collection Activities; Proposed Collection and Comment Request; Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement" (80 FR 14372). [*See Attachment 2*] *https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06275.pdf.*

it will be available to the public, are viewable at *http://www.acq.osd.mil/dpap/dars/far_case_status.html*.

Question 4. President Obama stated on January 21, 2009 that "The Freedom of Information Act should be administered with a clear presumption: In the face of doubt, openness prevails. . . . All agencies should adopt a presumption in favor of disclosure, in order to renew their commitment to the principles embodied in FOIA, and to usher in a new era of open government. The presumption of disclosure should be applied to all decisions involving FOIA."

However, on September 10, 2015, a Federal district court opinion issued September 10, 2015, noted that EPA "continues to demonstrate a lack of respect for the Freedom of Information Act process . . . ." "The Court is left to wonder whether EPA has learned from its mistakes or if it will merely continue to address FOIA requests in the clumsy manner that has seemingly become its custom. Given the offensively unapologetic nature of EPA's recent withdrawal notice, the Court is not optimistic that the Agency has learned anything."

In addition, a recent (January 2016) report of the House Committee on Oversight and Government Reform strongly criticized the failure of Federal agencies to properly implement FOIA. Major problems included long delays and redacting information that should be made public. Improper redaction is a very serious "invisible" problem since FOIA requesters cannot determine if the Agency is following the law. What specific steps will EPA undertake to do a better job in responding to FOIA requests?

Would you support legislation providing independent agencies—such as the Inspector General offices of the various Departments—the authority to confidentially sample FOIA responses and determine if the Agency is improperly redacting material? In my view, that is likely to be the only way to determine if an Agency is complying with the law regarding redactions.

Answer. The EPA takes its FOIA responsibilities seriously and is focused on creating more efficient work processes to ensure FOIA responses are prepared effectively and at lower cost. This includes adopting industry best practices for the delivery of information technology services in areas such as cloud computing, mobile technology and workplace standards. The EPA received close to 11,000 new FOIA requests in FY 2015 and successfully processed over 11,000 requests, reducing its FOIA backlog by several hundred requests.

The EPA also has improved its records management policies and procedures, including recent updates to the Records Management Policy (*https://www.epa.gov/sites/production/files/2015-03/documents/cio-2155.3.pdf*) [*See Attachment 18*] and new procedures to assist employees in the management of various types of electronic records. In addition, the agency's FOIA Expert Assistance Team was established in the fall of 2015. The team, part of the Office of General Counsel, is charged with overseeing and coordinating efforts on the agency's most complex FOIAs. The EPA has also deployed new technology tools, such as centralized searching and electronic review, to efficiently process large or complex requests.

The EPA already provides the Inspector General and Congress with information in non-redacted format upon request. In addition, the EPA has recently finalized the update of agency-wide and office level FOIA procedures to clarify roles and responsibilities for responding to requests, including line by line review and limited redaction.

Question 5. Americans are at an increasing threat from vector-borne diseases. West Nile Virus and encephalitis have been serious problems for the last several years, but new diseases such as dengue fever and chikungunya are now an increasing threat to Americans and particularly infants. Sadly, new vector-borne threats continue to emerge. In Mexico and South America, the mosquito-borne Zika virus is responsible for infants being borne with significant birth defects. EPA is proposing very aggressive action to restrict the use of some critical mosquito control products. How is the Agency incorporating new public health threats into its risk assessments for products used in vector control?

Answer. The EPA is not currently proposing any actions to restrict the use of mosquito control products. The agency has recently released preliminary risk assessments that show risks of concern for some compounds; however, these are preliminary in nature and subject to change if additional data come to light. When refined risk assessments still show a concern, changes in use patterns or applications can sometimes be effective in mitigating the risk and allowing the compound to still be used in mosquito control.

When making a regulatory decision, the EPA considers the benefits (both public health and other) of these pesticides, along with their risks. The EPA consults with CDC when making a regulatory decision for any pesticide used to control a pest of

public health significance. The EPA also frequently consults with other interested stakeholders to ensure that the agency has a complete picture of the benefits and have properly evaluated any proposed mitigation.

Question 6. The Federal rulemaking process includes very specific actions that a Federal Agency must take before promulgating new regulations. Some recent activities by the Office of Pesticide Program appear to circumvent the rulemaking process by sending pesticide registrants letters that outline new regulatory provisions. This "regulation by letter" procedure was used by EPA in 2013 to mandate registrants include pollinator statements and a graphic on certain pesticide products, and in 2009 for the Agency's pyrethroid and pyrethrin labeling initiative. What is EPA's rationale for circumventing the Administrative Procedure Act (APA), which includes notice and comment, economic and small business impact analysis, *etc.?* Will EPA provide the Committee with assurances that it will abandon this policy of "regulation by letter" and instead follow the procedures and analysis required by the APA?

Answer. The EPA does not "regulate by letter" and FIFRA does not provide for such a regulatory mechanism to make changes to pesticide registrations. The EPA pesticide program is a licensing program that is based on an adjudicatory system. As a licensing program, the agency must ensure that the license complies with the law and continues to comply with the law. As such, decisions to grant a new license or change/modify an existing license are not subject to APA rulemaking, but the procedural requirements of FIFRA. When the EPA receives new information and determines that the license may lead to unreasonable adverse effects on the environment, the agency may offer the registrant a way to correct the imbalance in a timely manner. The August 2013 letter regarding labeling changes for the neonicotinoid insecticides is one example. However, if the registrant chooses not to address the concerns raised in such an offer, the agency can take appropriate steps under FIFRA to compel any necessary changes to the pesticide registration to mitigate unreasonable adverse effects on the environment. The letter itself is not self implementing; in the absence of voluntary agreement from a registrant, FIFRA prescribes steps that the agency must take to impose new mitigation measures.

Question 7. What farmers and communities in my district care about is the ability to defend against pest threats to their crops, food, homes and health. We have heard a lot today about what actions EPA has or is planning to take that impact the use of pesticides. I believe it would be very helpful to this Committee for EPA to develop a comprehensive list of all the Agency actions, and, not just rulemakings, during the last 8 years and those planned through the end of this year that restricted, or have the potential to restrict, existing or new uses of pesticides. Will you work with the Committee to determine what actions should be on that list so that Members can determine whether and how best to conduct appropriate oversight pursuant to our statutory obligations?

Answer. The EPA routinely provides opportunities for public comment on many pesticide regulatory actions. For example, before registering a new active ingredient or a significant new use of an already-registered active ingredient, the EPA engages stakeholders through its public participation process. Similarly, all registration review activities, including work plans, risk assessments, and proposed decisions, are the subject of public comment periods to ensure that stakeholders can provide the EPA with the highly quality information needed to make pesticide regulatory decisions.

The pesticide registration review process began in 2007 with the first decisions being made a few years later. To date, 165 decisions have been made. Of these decisions, 83 involved requests from the registrants to voluntarily cancel their registrations, in most cases for business decisions that were independent of the agency's review. For the remaining 82, many required no change to the registration or minor label clarification to make it easier for the user to understand and use the product correctly. Our anticipated registration review schedule can be found at *www.epa.gov/pesticide-reevaluation/registration-review-schedules* [*See Attachment 3*].

During the same time period, the EPA has registered approximately 170 new pesticide active ingredients and more than 1,700 new uses of already registered active ingredients, providing numerous new products for use in agricultural and non-agricultural settings. These newly registered products are designed to address emerging pest pressures and will have a significant role in the marketplace.

Of these regulatory decisions to restrict or cancel certain registrations, the EPA made these decisions after careful consideration of all available data and consistent with existing statutory requirements. For example:

- In 2010, the EPA announced its decision to terminate all uses of endosulfan due to unacceptable risks to farmworkers and wildlife. The EPA signed a Memo-

randum of Agreement with the registrants of endosulfan that resulted in voluntary cancellation and provided for a phase-out of all existing endosulfan uses in the United States in order to allow time for growers to transition to newer alternatives;

- In 2012, the EPA limited the use of chlorpyrifos by significantly lowering pesticide application rates and creating "no-spray" buffer zones around public spaces, including recreational areas and homes, due to concerns for unacceptable risks to children and bystanders;
- In 2014, the EPA canceled propoxur pet collars. In the fall of 2013, the EPA completed the propoxur pet collar risk assessment. The EPA's risk assessment indicated risks of concern to children from exposure to pet collars containing propoxur;
- In 2015, the EPA reached an agreement with Reckitt Benckiser, the manufacturer, to cancel all distribution of 12 consumer use d-CON products that did not meet the EPA's current safety standards, raising concerns for risks to children and pets. Additionally, eight of the 12 products pose unacceptable risks to certain wildlife;
- In 2015, the EPA proposed to revoke all chlorpyrifos tolerances due to concerns with estimated exposure from drinking water in certain watersheds. A final tolerance rule is anticipated in March 2017;
- On November 24, 2015, while the issuance of the initial registration was being challenged in Federal court, the EPA sought the remand and *vacatur* of the Enlist Duo registration because the EPA became aware of previously existing information about possible synergistic effects that had not been provided to the EPA or considered as part of the initial registration decision. The EPA cannot be sure, without a full analysis of the new information, that the current registration does not cause unreasonable effects to the environment, which is a requirement of the registration standard under FIFRA;
- On July 2, 2013, the Pollinator Stewardship Council and others, petitioned for review of the sulfoxaflor registration in the Ninth Circuit Court of Appeals. On September 10, 2015, the Court issued its opinion, finding that the registration was not supported by substantial evidence to demonstrate no unreasonable adverse effects to honey bees would result from the registration of [sulfoxaflor]. Although the initial sulfoxaflor submission contained all the data the EPA determined was necessary by the EPA for registration of a new agricultural insecticide, the Court vacated the registrations and remanded them to the EPA to "obtain further studies and data regarding the effects of sulfoxaflor on bees as required by EPA regulations." The *vacatur* of the sulfoxaflor registrations became effective November 12, 2015. As the registrations were no longer in effect under FIFRA, on the same date the EPA issued a cancellation order to address existing stocks. Although the product registrations were vacated, the tolerances for sulfoxaflor residues on treated commodities that were established under the FFDCA, remain in place; and
- On March 4, 2016, the EPA issued a notice of intent to cancel the registration of four pesticide products containing the insecticide flubendiamide owing to the registrants' failure to comply with a required condition of their registrations. The particular condition obligated the registrants to request cancellation if, after receiving additional required data, the EPA determined that use of flubendiamide did not meet the FIFRA standard for registration. Prior to issuing the notice, the EPA concluded that the continued use of flubendiamide will result in unreasonable adverse effects on the environment, particularly benthic invertebrates, which are an important part of the aquatic food chain, particularly for fish.

Over the past 8 years, the EPA issued a number of regulations within the intention of providing clarity to the regulated community and other stakeholders or to update information that has become inaccurate or out of date. Examples of these rulemaking efforts include:

- **Minimum Risk** (Published 12/28/2015): This final rule more clearly describes the active and inert ingredients permitted in products eligible for the exemption from regulation for minimum risk pesticides. These changes maintain the availability of minimum risk pesticide products while providing more consistent information for consumers, clearer regulations for producers, and easier identification by states, Tribes and the EPA as to whether a product is in compliance with the exemption;

- **Crop Grouping** (Published Phase 1: 12/7/2007; Phase 2: 12/8/2010; Phase 3 8/22/2012; Phase 4: anticipated 2016): These final rules are likely to reduce the number of residue chemistry studies required to establish a tolerance for a crop within these crop groupings because instead of testing each crop individually, only the representative crops would need to be tested. Thus, the new crop groups ease the process for an entity to request and for the EPA to set pesticide tolerances on greater numbers of crops. Pesticides will be more widely available to growers for use on crops, particularly specialty crops;
- **Data Requirements for Antimicrobials** (158W) (Published 5/8/2013): the EPA revised the data requirements for antimicrobial pesticide products to reflect current scientific and regulatory practice, and to provide the regulated community with clearer and transparent information about the data needed to support pesticide registration decisions for antimicrobial products. The EPA would use this information to conduct risk assessments for a particular pesticide;
- **Prions as Pests** (Published 2/28/2013): In 2003, the agency determined that a prion (proteinaceous infectious particles) is a "pest" under the FIFRA and that a product intended to reduce the infectivity of prions on inanimate surfaces (*i.e.,* "prion product") is considered to be a pesticide. The EPA believes that regulating prion-related products protects human health and the environment against unreasonable adverse effects and ensures that such products are effective;
- **Export Labeling** (Published 1/18/2013; Revisions Published 12/19/2014): The EPA revised the regulations pertaining to the labeling of pesticide products and devices that are intended solely for export. Pesticide products and devices intended solely for export are now able to meet the agency's export labeling requirements by attaching a label to the immediate product container or by providing collateral labeling that is either attached to the immediate product being exported or that accompanies the shipping container of the product being exported at all times when it is shipped or held for shipment in the United States. Collateral labeling ensures the availability of the required labeling information, while allowing pesticide products and devices that are intended solely for export to be labeled for use in, and consistent with the applicable requirements of the importing country; and
- **Data Compensation** (Published 2/5/2014): The EPA revised its regulations governing procedures for the satisfaction of data requirements under FIFRA, codified in 40 CFR part 152, subpart E. These provisions include, among other things, procedures for the protection of exclusive use and data compensation rights of data submitters. The EPA updated the regulations to accommodate statutory changes and changes in practice that have occurred since 1984; to make minor changes to clarify the regulations; and to make changes that would simplify the procedures and reduce burdens for certain data submitters. The revisions did not otherwise make substantive changes to the requirements.

At times, however, the EPA has determined that significant changes to its regulations are needed to improve public health. For example, in November 2015, the EPA finalized revisions to the Agricultural Worker Protection Standard. This final rule revised the Federal regulations issued under FIFRA that direct agricultural worker protection (40 CFR 170). The changes reflected current research on how to mitigate occupational pesticide exposure to agricultural workers and pesticide handlers, and strengthened the protections provided to agricultural workers and handlers under the worker protection standard. The changes improved elements of the existing regulation, such as training, notification, communication materials, use of personal protective equipment, and decontamination supplies, thus preventing exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations, child farmworkers, and farmworker families; and the general public. We are working closely with affected stakeholders, including state agricultural agencies, to ensure that they have the necessary information and training to implement these new protections.

Similarly, the EPA is now working to develop a final rule to revise the Federal regulations governing the certified pesticide applicator program (40 CFR part 171). This action is intended to improve the competence of certified applicators of restricted use pesticides (RUPs) and to increase protection for noncertified applicators of RUPs operating under the direct supervision of a certified applicator through enhanced pesticide safety training and standards for supervision of noncertified applicators. State agricultural agencies, as well as many other stakeholders, provided valuable comments and suggestions in response to the EPA's proposed rule. We will

work with stakeholders to ensure that the revised competency standards can be implemented effectively by state agencies.

Questions Submitted by Hon. Ralph Lee Abraham, a Representative in Congress from Louisiana

Question 1. In response to my question about whether EPA treats herbicides used with crops improved through biotechnology differently than it treats all other herbicides, you stated that such herbicides "are not treated differently than looking at how we always look at pesticides, which is by the science trying to stick with the legal timelines and windows that we have to make our decisions." Furthermore, you indicated the Agency is reducing the number of renegotiation extensions overall under the Pesticide Registration Improvement Act. Yet it is my understanding that EPA has consistently imposed disproportionate burdens and delays on registration activities related to biotechnology that it does not impose on similarly situated products that are not related to biotechnology.

Please provide this Committee with examples of registration timelines, including all applicable registration renegotiations (the number of times a PRIA date was renegotiated and for how long) that support your statement that registrations tied to biotech traits are completed in the same general timeframe from submission to final label as registrations with no biotech crop application.

Answer. The EPA assesses risks and benefits for each pesticide registration application, striving to complete regulatory decisions within the timeframes designated under PRIA. The EPA employs the same process to review applications for herbicide uses on biotech crops as it does for other applications, identifying any risks of concern and conducting assessments to understand and address those risks. As with all applications, the EPA must address risk issues identified in the course of scientific review as well as comments received through the public participation process. Overall, the EPA has reduced the number of renegotiation extensions under PRIA. However, different chemicals and use patterns may present different risks, sometimes requiring more in depth and complex assessments to address them. More complex risks assessments may exceed average review timeframes in order to produce scientifically sound and legally defensible decisions.

The most complex reviews for new registration can involve the review and evaluation of requests to register pesticides for use on herbicide tolerant crops. While the number of applications in recent years are small, the review times range from approximately 2 years to approximately 6 years. These review times depend upon many factors, including any risk concerns identified and the time needed to negotiate risk mitigation strategies to address any potential unreasonable adverse effects, the need to wait to make a registration decision under FIFRA until other agencies make necessary safety findings under other relevant statutes, and the need to make the requisite findings under the Endangered Species Act.

An example of added complexity to a registration's risk assessment for an herbicide use on herbicide tolerant crops is in the case of the Endangered Species Act. The EPA intends to complete endangered species assessments for new herbicide tolerant crop uses based on the Overview Document-compliant method. An assessment that is Overview Document-compliant follows the procedures and methods described in the Overview Document* (see *www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf*). The EPA will complete these effect determinations as resources allow. To maximize impact within these limited resources, the initial registrations (*e.g.,* Enlist Duo) are not nationwide in scope, and to the extent practical will focus on situations where EPA can make "no effect" decisions.

Question 2. Please provide this Committee with examples of registration decisions, other than those related to biotechnology, where EPA has intentionally delayed its approval until after another Federal agency takes action on the crop associated with a pesticide's use pattern.

Answer. While we are not aware of any other actions where the EPA's decision rested on another Federal agency taking action first, there have been circumstances where the EPA determined that consultation with another Federal agency would improve the decision making for a particular registration application. The new active ingredient decision for the antibiotic kasugamycin is an example of a non-biotechnology registration decision in which the EPA consultation with other Federal agencies was a contributing factor in the need to renegotiate the PRIA due date. To better understand the potential for bacterial resistance resulting from pesticidal use of the antibiotic, the EPA consulted with both the Centers for Disease Control and the Food and Drug Administration.

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* **Editor's note:** the document referred to is retained in Committee file.

Questions Submitted by Hon. Dan Newhouse, a Representative in Congress from Washington

Question 1. Last year, a Federal judge in Washington State ruled several dairies in my district were culpable of "open dumping" of manure under the Resources Conservation and Recovery Act—commonly referred to as RCRA—based solely on escalated nitrate levels in nearby wells. This is unprecedented for a number of reasons, but primarily that nitrates were ruled as a "solid waste" under RCRA. Especially given that EPA's regulations under RCRA find the definition of solid waste, "does not apply to agricultural wastes, including manures and crop residues, returned to the soil as fertilizers or soil conditioners." While there are environmental laws our nation's dairies are subject to—and that's a good thing—it seems clear to me that RCRA was not intended to be one of them. Administrator McCarthy, I would be interested to know if EPA has any desire or intent to revisit the regulations promulgated under RCRA based on this judge's misguided decision?

Answer. The EPA has no current plans to develop or issue regulations under the resource Conservation and Recovery Act related to animal feeding operations.

Question 2. In the dairy RCRA decision, the judge said of USDA's Natural Resource and Conservation Service (NRCS) manure lagoon construction standards, that, "even assuming the [manure] lagoons were constructed pursuant to NRCS standards, these standards specifically allow for permeability and, thus, the lagoons are designed to leak." This is another reason why take such exception with this judge's decision, because in my experience in agriculture, I know that NRCS is the gold standard in technical assistance to farmers. Briefly, and generally, I was wondering if you could give your thoughts on NRCS and your Administration's relationship with them. Do you have confidence in NRCS standards?

Answer. The EPA supports the goals of USDA's Natural Resources Conservation Service waste treatment lagoon standards providing that lagoons should be constructed, operated and maintained without polluting air or water resources; that additional measures should be considered to prevent a sudden breach or accidental release into surface water bodies, riparian areas, and critical habitat; and that additional measures of safety should be taken to prevent lagoon seepage into underlying shallow aquifers or aquifers that provide domestic water supplies.

Question 3. Administrator McCarthy, as you are aware, Section 7 of the Endangered Species Act directs EPA to consult with Fish and Wildlife Services if a proposed action may impact an animal or plant listed as endangered. Over the past several years, EPA has been the target of lawsuits claiming it has failed to consult with Fish and Wildlife or the National Marine Fisheries Service on pesticide registration. In recent years, I understand your Agency has been working with the Services on implementing a collaborative approach, and is piloting that approach on a handful of active pesticide ingredients undergoing review. While I appreciate that EPA is now trying to meet its consultation requirements, I am concerned that the initial draft reviews for the first three active ingredients considered under this pilot are approximately *3,000 pages each.* How do you expect this work to be productive or helpful to manufacturers, the farmers that use these products, or the species it's supposed to be protecting?

Answer. The EPA acknowledges there is a large amount of information posted in support of the pilot biological evaluations (BEs) for chlorpyrifos, diazinon and malathion. However, the background information that has been made available is the basis for the EPA's effects determination for all threatened and endangered species and designated critical habitat in the United States. The main sections, which include the problem formulation and exposure and effects characterization, are approximately 250–350 pages, and the remaining appendices and attachments include supplemental information that interested parties can refer to if they wish to see the underlying data for our analysis.

The EPA released the draft BEs for these three pesticides on April 6, 2016. On May 5, 2016, the EPA, Fish and Wildlife Service (FWS), National Marine Fisheries Service (NMFS), and USDA held a public webinar for all external stakeholders to discuss the process and interim scientific methods used to make effects determinations for the three pilot chemicals, including a roadmap on how to navigate the various sections, appendices, and attachments of the draft BEs. There were 189 attendees for the webinar.

The agencies recognize the need for further refinement of the interim scientific methods including an early screening step that effectively allows for a focus of resources on ESA-listed species and designated critical habitat where exposure to pesticides is likely to result in adverse direct and indirect effects. In addition, on June 29 and 30, 2016, the agencies held a 2 day workshop to offer a forum for stakeholder

suggestions for refining some of the interim scientific methods used in the draft BEs: 105 attended the workshop in person and 58 more over the phone.

Question 4. In the 2014 Farm Bill, there was a requirement directing the EPA, Fish and Wildlife, and National Marine Fisheries provide two reports updating our Committee on the progress of developing a workable approach on collaborative ESA consideration in pesticide registration. We did receive one of those reports in November 2014, but the second one is long overdue. Do you have a sense of when we might expect that next report?

Answer. The agencies are currently working on the second Report to Congress and expect to provide this final report by the end of 2016.

Question 5. Administrator McCarthy, you testified at the hearing that EPA is working closely with the businesses and the regulated community on how Washington State's new water quality standards will be implemented. However, it was my understanding that, the regional administrator and regional manager for the Office and Water and Watersheds told a broad coalition of business and industry early in the process that EPA was unwilling to negotiate the fish consumption rate or cancer risk level. Can you tell me specifically what has EPA done to work with the regulated communities in Region 10 and Maine on human health criteria?

Answer. The EPA has met with industry representatives (as well as environmentalists, Tribes, and local governments) on many occasions to discuss water quality standards designed to protect public health in the Pacific Northwest. Additionally the EPA Region 1 Regional Administrator held an open conference call for interested stakeholders to discuss Maine WQS in February 2015. In all of these discussions, the EPA has been clear that it is our preference that states develop water quality standards to protect the state's designated uses for its waters (*e.g.,* fishing, swimming) using the best available science.

Question 6. For thirty years or more, EPA, FDA, and the best available science have concluded that there is essentially no additional risk of cancer at exposures based on risk levels of 10^{-6} as applied to the exposure of the general population (in the case of water quality standards a fish consumption rate) as long as the average consumption rate for more high exposed populations does not create a risk of more than 10^{-4}. What scientific human health research has EPA developed or relied on to conclude that in Maine, Oregon, Idaho and Washington that high Tribal consumption rates must be protected to 10^{-6}?

Answer. The EPA encourages states to consider local and regional data when it is available in developing water quality standards that protect the uses of its waters such as for fishing. In many areas of the country, such as in Maine, Oregon, Idaho and Washington, Tribes have protected treaty rights that provide for reserved fishing rights. Additionally local and regional data show that these Tribal members consume much more fish. In Maine, the Wabanaki study shows rates of Tribal fish consumption from 286 grams per day to over 500 grams per day. In the northwestern states there are several fish consumption surveys that show that Tribal fish consumption rates over 1,000 grams per day. To provide for the Federal treaty rights of these Tribal members, the EPA expects states to consider these site-specific higher fish consumption rates as well as a 10^{-6} cancer risk.

Question 7. EPA and other Federal agencies have long considered standards that protect within the range of risk levels of 10^{-6} to 10^{-4} to represent a *de minimis* risk of incurring cancer. What scientific research has EPA developed or relied on to conclude that 10^{-6} is now an upper bound risk level for the protection of public health?

Answer. The EPA considers 10^{-6} as a *de minimis* risk level but allows states to choose higher risk levels to protect their populations. However, treaties in Washington envision fish free from contaminants. To comply with these Tribal treaty rights, 10^{-6} is a close approximation of a *de minimis* level of risk. The 10^{-6} risk level is appropriate when the EPA or states take treaty rights into consideration when developing water quality standards.

Question 8. EPA has stated numerous times over many Administrations—including in its 2000 Human Health Methodology—that there is no real difference between 10^{-6} and 10^{-5} in terms of risk management, as long as more highly exposed populations are protected to 10^{-4}. It is easy to understand why, as it is the difference between a theoretical additional risk of one millionth of a percent (0.000001%) and one hundred thousand of percent (0.00001%). Even at a risk level of 10^{-4}, the additional risk over an entire lifetime is an additional on ten thousandth of a percent (0.0001%). This is why Federal agencies, including EPA, have long considered these risk levels to represent the equivalent of no additional risk of additional cancers. If EPA applied its current and long-standing risk management guidance to Washington State, we would expect no new cases of cancer based on exposure to waters meeting the standards. Imposing more stringent risk management

levels, reinventing a new zero, would provide no additional benefit to public health. What scientific research has EPA developed or relied on to conclude that risk levels of 10^{-6} and 10^{-5} no longer represented essentially the same level of risk? What scientific research has EPA developed or relied on to conclude that water quality standards now require a more stringent application of risk levels in developing water quality standards?

Answer. The EPA's use of a 10^{-6} cancer risk level is a risk management decision, which EPA considers appropriate for the general population. It is important to note that when developing the 2000 Human Health Methodology for deriving numeric water quality criteria, identified in your question, we undertook a review of language from other agency mandates (*e.g.,* The Clean Air Act, the Food Quality Protection Act) and believe the target of a 10^{-6} risk level is consistent with agency-wide practice. While the Methodology presents a range of acceptable cancer risk levels for the general population, states and authorized Tribes are specifically encouraged to consider highly exposed population groups when determining a protective cancer risk level including, in the case of the State of Washington, taking into account the important principles of treaty rights and environmental justice.

Question 9. Throughout the Pacific Northwest, background concentrations of PCBs and Arsenic exceed the criteria EPA has proposed for Washington State, and the criteria that EPA has advised in comments should be developed by Idaho and Washington. Can EPA provide an analysis of impact its proposed PCB and arsenic criteria would have on section 303(d) listings of impaired water bodies, and what those listings would mean under the prohibition of new expanded discharge until the criteria are met? Can EPA provide an economic impact analysis of the impact its proposed PCB criteria will have on private and public facilities that hold NPDES permits and on permitted storm water discharges?

Answer. The EPA evaluated the potential costs to NPDES dischargers, and the potential for incremental water body impairments, associated with state implementation of the EPA's proposed criteria. This analysis is contained in the record for the EPA's proposed rule for the State of Washington. Since the proposed rule was published, the EPA obtained additional water quality monitoring data from the State Department of Ecology's Environmental Information Management database for PCBs and will identify additional potential incremental impairments, if any, in any revised economic analysis that the EPA develops for the State of Washington.

Question 10. The economic impact analysis EPA provided with its proposed rule in Washington State represents that there was no surface water data that indicated ambient concentrations of PCBs above the EPA proposed criteria. The Washington State Department of Ecology has published studies showing that all of Puget Sound and its major tributaries, including the Strait of Juan de Fuca, have PCB levels above the EPA proposed criteria. Can EPA explain why this data was not considered in its economic impact analysis? Has EPA identified treatment technologies that can achieve the proposed PCB criteria? If so, what does it cost to install and operate those technologies?

Answer. Since preparing the economic analysis for the proposed rule, the EPA has obtained additional PCB monitoring data and will analyze these data and report the potential incremental impairment results, if any, in any revised economic analysis that the EPA develops for the State of Washington. Currently, the quantification limit in the State of Washington for PCBs is 0.1 μg/L, which is several orders of magnitude greater than the proposed revised criteria of 0.0000073 μg/L for freshwater and marine waters.

Question 11. EPA's scientists have consistently stated that a Probabilistic Risk Assessment (PRA) approach represent the more advanced and better scientific approach to risk assessment. Why isn't EPA using a PRA approach to develop water quality criteria and other standards? Does the Agency have plans to move to that approach, considering its commitment to using the best science, and if so, when would that take place?

Answer. The EPA is evaluating current probabilistic risk assessment approaches to water quality standards in the literature. As of now, no states have submitted human health criteria based on such an approach.

Question Submitted by Hon. Trent Kelly, a Representative in Congress from Mississippi

Question. Three years ago, a coalition of Mississippi beekeepers and farmers came together to identify how they could work collaboratively and do their part in tackling some of the bee health concerns. After numerous meetings and conversations this group ultimately concluded that agricultural pesticide exposure had little impact on honeybee health in Mississippi but instead factors like Varroa mites and

the diseases they carry were much bigger issues, which need to be addressed. However, this coalition did acknowledge that communication between beekeepers and farmers would further reduce the risk of pesticide exposure and the group decided to launch a voluntary effort called the Mississippi Bee Stewardship Program. The goal of this program was to enhance communication and cooperation between our state's beekeepers and agricultural pesticide applicators. This stewardship program encompasses a pragmatic set of best management practices which deal with things like hive placement on the farm, identification of hive locations, and pesticide applicators being aware of the presence of foraging bees. A "bee awareness" flag was even designed to help people on the farm know where bees are located. This program has energized the agricultural industry is Mississippi and has created a more cooperative environment among beekeepers and farmers. The coalition I referred to earlier is now in the process of conducting assessments to determine the effectiveness of the enhanced communication with the hope that it has reduced and will continue to reduce pesticide exposure to bees.

Last summer, the White House commissioned a Federal Task Force to focus on developing policy initiatives that would lead to improved pollinator health. Among the initiatives highlighted in the Task Force's report, included efforts to deal with habitat loss and additional research on pollinator parasites and diseases, and more local efforts to manage relationship between farmers and beekeepers, which was the interest in supporting the development of "state managed pollinator protection plans." The Mississippi Bee Stewardship Program has been held up nationally as a model of the desired state management plan approach and our state's department of agriculture should commended for taking this more flexible approach that collaboration rather than going in a more prescriptive, one-size-fits-all, direction.

Unfortunately, following the greater sense of good will and collaboration that was formed between beekeepers and farmers through the development of the Mississippi Bee Stewardship Program, recent actions by EPA in regard to key chemistries that farmers rely upon (Sulfoxaflor, or Tranform®) and further attacks on imidacloprid and seed treatments are beginning to undermine those relationships. Growers and beekeepers in Mississippi thought that they had addressed their pesticide/managed pollinator issues and could see the path forward but now I am hearing about concerns from many of my farm constituents about losing or diminished access to key pesticide products due to EPA's interest in protecting managed honeybees.

These products are vital to the protection against devastating pests that threaten farmers' crops and livelihood. The announcements and proposals from EPA are creating concerns in the relationships between farmers and beekeepers and will result in less collaboration in the future. It is perceived that the loss of these key crop protection products is the result of numerous lawsuits or environmental activists' claims over the process that EPA utilizes in the data collection and pesticide registration & review process. In addition, I am hearing from individual beekeepers in my state that have major concerns that if the farmers lose these key chemistries and are forced to sustain a major economic loss, they will not have a place to host their bees on the farms, thus creating a domino economic effect on the beekeepers as well.

Recently, we were notified that farmers are beginning to tell beekeepers they cannot host bees on the farm in Mississippi due to concerns and frustrations that key products to protect their crop are being taken away by EPA from the threats and frivolous lawsuits filed by beekeepers and environmental groups. This is of great concern to me. In this situation, EPA's responses to claims and pressure from a fraction of the beekeeping industry and challenges from environmental groups is going to ultimately harm innocent beekeepers and find them with no farm to host their bees, driving wedge in the positive relationships that have developed over the last several years and impacting the beekeeper's ability to make a living.

Many of these beekeepers are not a part of the national beekeeper groups and do not have their perspective represented or heard. What further outreach to beekeepers that host bees on farms and farmers is EPA planning in order to discuss these concerns?

My office would be happy to facilitate these conversations.

Answer. The question well describes the complex stakeholder dynamics, conflicting agendas, and cautions regarding both the vocal and silent voices that makes pollinator protection and pesticide use a challenging issue. The EPA also understands the concern about existing and new chemistries and their importance to both growers and beekeepers.

The agency agrees that the Mississippi State Plan, and the work done in Mississippi between growers and beekeepers, is a model. Indeed, the Mississippi State Plan, the North Dakota State Plan, and several others, were the first to demonstrate that a local response to the issue of pollinator protection was the best way

to match the needs and resources of the local community with this issue. That work formed the basis for developing the efforts around Managed Pollinator Protection Plans (MP3s).

In March 2016, the EPA, in collaboration with USDA, the National Association of State Departments of Agriculture and the Honey Bee Health Coalition, held a 2 day symposium on MP3s. The Symposium was designed to bring together a wide range of stakeholders in order to share the tools, insights and relationships necessary for states, Tribal and other stakeholders to pursue the development of MP3 plans effectively and efficiently.

Because MP3s are locally based, reflecting those that live and work in a state or Tribe, they serve as a forum for state and local stakeholders to participate. The EPA has been encouraging and emphasizing communication between growers and beekeepers as a key component of MP3s. As another component of MP3s, the EPA and USDA are also working with the National Integrated Pest Management (IPM) Center to investigate and promote commodity-based, and/or local-based best management practices that balance pollinator protection and crop production. The National IPM Center will work with State IPM Coordinators to identify crop/pesticide/pollinator needs and support them through information development and dissemination.

Through continued work to evaluate and develop MP3s, the EPA intends to support the states and Tribes in identifying their needs and finding solutions for pollinator protection and crop production.

Questions Submitted by Hon. Suzan K. DelBene, a Representative in Congress from Washington

Question 1. Last September, the EPA published Interim Recommendations for environmental standards and ecolabels for use in Federal procurement. EPA's recommendation for lumber excludes several standards that are widely used in the United States, including the Sustainable Forestry Initiative (SFI) and American Tree Farm System (ATFS) standards, which represent 70% of the certified acres in the U.S. and 95% of the certified acres in Washington State. EPA has signaled that this recommendation is mandatory for Federal procurement. Under what circumstances may a Federal procurement officer purchase wood products that do not meet this FSC requirement, such as those certified to SFI or ATFS? And, given the significant volume of sustainably harvested timber that may be excluded from Federal purchasing, please explain the process for EPA amending this recommendation in the future.

Answer. Under Executive Order 13693—*Planning for Federal Sustainability in the Next Decade*—the EPA issued recommendations to assist Federal purchasers in identifying and procuring environmentally sustainable products. The EPA's Interim Recommendation for the lumber/wood category is based on the Department of Energy's Fiscal Year 2016 (FY16) Priority Products List.

As a result of stakeholder inquiries since the release of the Interim Recommendation, the EPA has met and is continuing to work with USDA and DOE's Office of Sustainable Environmental Stewardship to gain further information. The EPA's Standards Executive is reaching out to the Sustainable Forestry Initiative, the American Tree Farm System, and the other forestry labels that stakeholders have requested the EPA consider. The EPA will be in touch with these groups regarding the agency's review of forestry labels and their alignment with the National Technology Transfer and Advancement Act, the OMB Circular A–119, and related Federal policies that guide the EPA's use of voluntary consensus standards and private-sector conformity assessment activities. In addition, the EPA continues its progress with piloting the *Guidelines for Assessing Standards and Ecolabels for Use in Federal Procurement,* and hopes that information gleaned from this process will inform thinking related to the lumber/wood category. Finally, DOE continues to conduct research to inform their FY16 Priority Products List. The EPA looks forward to reviewing all of this additional data to inform if and how the lumber/wood category of Interim Recommendations might be revised.

The EPA has, and will continue to provide, mechanisms for public input as we developthese recommendations. The agency issued *Federal Register* Notices on the initial draft guidelines in 2014 and in March 2015 for the launch of our pilot work.[11]

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[11] *Federal Register* Notice, February 27, 2014, "Draft Guidelines for Product Environmental Performance Standards and Ecolabels for Voluntary Use in Federal Procurement" (79 FR 11102). [*See Attachment 1*] *https://www.gpo.gov/fdsys/pkg/FR-2014-02-27/pdf/2014-04329.pdf.*

Federal Register Notice, March 19, 2015, "Agency Information Collection Activities; Proposed Collection and Comment Request; Assessment of Environmental Performance Standards and

Continued

Those FRNs were open to public comment and they marked the beginning of our efforts to engage multi-stakeholder panels whose counsel will be considered as we move to finalize our recommendations. Further, any Federal acquisition requirements stemming from the recommendations would include a public comment process prior to incorporation into the Federal Acquisition Regulations. As such, FAR Case 20 15–033 has been developed in order to integrate the new requirements of E.O. 13693 into the FAR. All next steps related to this case, including as to when it will be available to the public, are viewable at *http://www.acq.osd.mil/dpap/dars/far_case_status.html*.

Question 2. What actions has the EPA taken to educate organic and conventional pesticide users about biopesticides?

Answer. The EPA is committed to encouraging the development and use of low-risk biopesticides as alternatives to conventional chemical pesticides. In 1994, the EPA created the Biopesticides and Pollution Prevention Division (BPPD) and specifically focused it on raising the profile of biopesticides and helping them get licensed. BPPD, in the Office of Chemical Safety and Pollution Prevention—Office of Pesticide Programs, is responsible for regulatory activities associated with biologically-based pesticides, and is recognized as the international authority on biopesticides. In partnership with USDA and the IR–4 Specialty/Minor Crop Project at Rutgers University, the EPA supported 88 projects through the Biopesticide Demonstration Grant Program. From 2004–2010, the program invested more than $1.3 million to research the efficacy of biopesticides for specialty and minor crops.

The EPA is actively working with growers and grower organizations interested in using biopesticides. Our intent is to ensure growers have the information they need to incorporate biopesticides into their pest management programs.

In recent years, the EPA has attended several food producer and marketer meetings that have included representatives of small fruit and vegetable growers. The EPA is establishing relationships with these stakeholders to provide them with information on the benefits offered by biopesticides.

Additionally, the EPA is implementing a biopesticide strategy that includes developing case studies on biopesticide successes, especially instances in which biopesticides have offset conventional pesticide use without negatively impacting grower costs.

Question 3. As the number of biopesticide registration actions has increased, has EPA directed any additional resources to the Biopesticide and Pollution Prevention Division? What steps has EPA made or is EPA planning to take to ensure biopesticide Pesticide Registration Improvement Act (PRIA) timeframes are met and to reduce the number of biopesticide renegotiations?

Answer. In recent years, the EPA has provided additional staffing resources to help address the growing number of registration requests for biopesticides.

Over the past 5 years, the EPA reduced the renegotiation rate from 61.6 percent in Fiscal Year (FY) 2010 to 18 percent in FY 2015. At this point in FY 2016, the renegotiate rate is approximately 14.6 percent, which is lower than the rate for conventional pesticides. We have achieved these reductions through a number of measures:

- More thorough screening of applications upon submission to ensure that they meet the outlined criteria for completeness at the beginning of the review process;
- Identification of registration package deficiencies early in the review process. This allows time for companies to fix packages without having to renegotiate; and
- At industry's request, providing training seminars for registrants and consultants to help ensure packages are submitted correctly.

Questions Submitted by Hon. Sean Patrick Maloney, a Representative in Congress from New York

Question 1. Currently, hundreds of residents in my district lack access to a clean water source as a result of contaminated groundwater from the Hopewell Precision superfund site. Thankfully, after years of effort, a solution is at hand. The EPA is working with stakeholders to finalize the design of infrastructure that will connect the impacted homes to a viable water source. I appreciate the real progress that we've made on this issue, and want to recognize EPA Region II Administrator Ju-

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Ecolabels for Federal Procurement" (80 FR 14372). [*See Attachment 2*] *https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06275.pdf.*

dith Enck for her tireless work on this. Ultimately though, successful completion of the project will require funding from the EPA.

I ask you that you fully fund this project, and do all you can to ensure that those impacted finally get the access to a clean water source. I also ask that you work with my office on this priority, and let me know how I can help make sure this gets done.

Answer. The EPA anticipates the decision to fund the site should be made this fiscal year. While the costs of the entire cleanup of the Hopewell Precision Site will not be fully funded this year, it is anticipated that the full cost of the cleanup will be funded over several budget cycles which will not impact the multi-year schedule for completion. The first stage of work is hiring a contractor, which will take several months from the initiation of funding.

Question 2. As you know, the EPA has been overseeing General Electric's work to remove Polychlorinated biphenyls (**PCBs**) from the Hudson River. I appreciate the significant progress that the EPA and GE have made in this effort in the last few years. But I am concerned that unless further action is taken there is a significant risk that an unacceptable level of PCBs could remain in the Hudson.

In December 2015, my office helped to facilitate a meeting between the EPA and local stakeholders to address those concerns. I appreciate that the EPA took the time to meet with us. I was extremely gratified to see the EPA announce in the wake of the meeting its intent to conduct an expedited 5 year review of the Hudson River, to determine what further actions will be necessary.

Can you please confirm that the EPA still plans on conducting an expedited 5 year review? If so, what is the anticipated timeline? I ask that you ensure that the review occurs in a manner that allows for a thorough, science-based approach. Successful completion of this review is vital to ensuring the long-term health of the Hudson River and its watershed.

I also ask that you meet with me and local stakeholders so we can speak with you about this issue and share with you our thoughts on how we can best cooperate on the shared goal of a clean, healthy Hudson River.

Answer. The second 5 year review for the site is underway and is being conducted in accordance with the EPA guidance. The EPA is working closely with all stakeholders to ensure a thorough and unbiased 5 year review. The stakeholders, including the Federal trustees, New York State Department of Environmental Conservation and Department of Health, and representatives of the Community Advisory Group (including non-governmental organizations) were invited by the EPA to participate on the Five Year Review team. Five Year Review team meetings are being held monthly through the fall.

[ATTACHMENT 1]

Federal Register

Vol. 79, No. 39

Thursday, February 27, 2014

Notices

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2013–0579; FRL–9906–98]

Draft Guidelines; Product Environmental Performance Standards and Ecolabels for Voluntary Use in Federal Procurement; Reopening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; reopening of comment period.

SUMMARY: EPA issued a notice in the *Federal Register* issue of November 27, 2013, concerning public review and comment on draft guidelines with a potential approach for using nongovernmental product environmental performance standards and ecolabels in Federal purchasing. This document reopens the comment period for two months, until April 25, 2014. The Agency received several requests to extend the comment period to allow more time for stakeholder review, collaboration, and response.

DATES: Comments, identified by docket identification (ID) number EPA–HQ–OPPT–2013–0579, must be received on or before April 25, 2014.

ADDRESSES: Follow the detailed instructions as provided under **ADDRESSES** in the *Federal Register* document of November 27, 2013.

FOR FURTHER INFORMATION CONTACT: Alison Kinn Bennett, Pollution Prevention Division (7409M), Office of Pollution Prevention and Toxics, Environmental Protection

Agency, 1200 Pennsylvania Ave. NW., Washington, D.C. 20460–0001; telephone number: (202) 564–8859; e-mail address: *kinn.alison@epa.gov*.

SUPPLEMENTARY INFORMATION: This document reopens the public comment period established in the *Federal Register* issue of November 27, 2013 (78 FR 70938) (FRL–9394–7). In that document, EPA announced for public review and comment draft guidelines intended to provide a transparent, fair, and consistent approach to using nongovernmental product environmental performance standards and ecolabels in Federal purchasing, consistent with Federal standards policy and sustainable acquisition mandates. These draft guidelines have been developed in response to requests via a wide variety of stakeholder engagement channels from suppliers, manufacturers, environmental organizations, Federal purchasers, and other stakeholders over the last several years. EPA is hereby reopening the comment period to April 25, 2014.

To submit comments, or access the docket, please follow the detailed instructions as provided under **ADDRESSES** in the November 27, 2013 *Federal Register* document. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

List of Subjects

Environmental protection, Ecolabels, Government procurement, Guidelines, Standards.

Dated: February 20, 2014.

WENDY C. HAMNETT, *Director,* Office of Pollution Prevention and Toxics.

[FR Doc. 2014–04329 Filed 2–26–14; 8:45 a.m.]

BILLING CODE 6560–50–P

[ATTACHMENT 2]

Federal Register

Vol. 80, No. 53

Thursday, March 19, 2015

Notices

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2014–0838; FRL–9923–58]

Agency Information Collection Activities; Proposed Collection and Comment Request; Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: *Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement,* and identified by EPA ICR No. 2516.01 and OMB Control No. 2070—new, represents a new request. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment. EPA is also announcing the testing of draft guidelines and a pilot project on an assessment approach for recognizing product environmental performance standards and ecolabels for Federal procurement in the following three categories: Furniture, building flooring, and building paints/coatings/removers. An additional purchase category may be piloted, depending on available resources and other considerations. EPA is seeking comment on the criteria/qualifications that will be used for the selection of the multi-stakeholder panel members, who will refine the draft guidelines for specific sectors. In addition, EPA is seeking volunteer standards development organizations and ecolabel programs to be assessed per the draft guidelines.

DATES: Comments on multi-stakeholder panel member criteria/qualifications must be received on or before April 20, 2015. Expressions of interest to participate in the pilot and comments on the ICR must be received on or before May 18, 2015.

ADDRESSES: Submit your expressions of interest to participate in the pilot and comments on the ICR and multi-stakeholder panel member criteria/qualifications, identified by docket identification (ID) number EPA–HQ–OPPT–2014–0838, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, D.C. 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Julie Shannon, Chemistry, Economics, and Sustainable Strategies Division (7409M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, D.C. 20460–0001; telephone number: (202) 564–8834; e-mail address: *shannon.julie@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Testing of Updated Draft Guidelines

In the *Federal Register* of November 27, 2013 (78 FR 70938) (FRL–9394–6), EPA issued for public comment draft guidelines for product environmental performance standards and ecolabels for voluntary use in Federal procurement. EPA's goal in developing these draft guidelines is to create a "transparent, fair, and consistent approach to selecting product environmental performance standards and ecolabels to support the Agency's mission and Federal sustainable acquisition mandates." The fundamental aim of the draft guidelines is to establish a cross-sector framework to be used in recognizing non-governmental environmental standards (and consequently, environmentally preferable products meeting these standards) for use in Federal procurement.

The draft guidelines include four sections:

1. Guidelines for the process for developing standards refers to the procedures used to develop, maintain, and update an environmental standard.
2. Guidelines for the environmental effectiveness of the standards refers to the criteria in the environmental standard or ecolabel that support the claim of environmental preferability.
3. Guidelines for conformity assessment refers to the procedures and practices by which products are assessed for conformity to the requirements specified by standards and ecolabeling programs.
4. Guidelines for Management of Ecolabeling Programs refers to the organizational and management practices of an ecolabeling program.

EPA has responded to public comments and released a new version of the "Guidelines for the Environmental Effectiveness of the Standards" at *http://www.epa.gov/draftGuidelines/responses.html.* The majority of public comments supported EPA undertaking—with key external entity and stakeholder participation—additional work to further refine the draft guidelines and test a potential approach to assessing standards and ecolabels. Therefore, in this next phase of work, EPA is contracting with an entity to convene a coordinating Governance Committee, product category-specific multi-stakeholder panels, and independent assessment entity(ies) to develop and pilot test an approach in three product categories: Furniture, building flooring, and building paints/coatings/removers. These sectors were chosen because they meet some or all of the following criteria:

- Potentially significant environmental and/or human health impact (based on lifecycle assessments and hazard and risk assessments).
- Opportunity for environmental and/or human health improvement through private sector standards/ecolabels.
- Significant volume of Federal purchases.
- Current Federal sustainable acquisition mandates in the category are limited, out-of-date, and/or could be augmented with private sector standards.

An additional to-be-determined purchase category may be piloted, depending upon available resources and other considerations. In addition, due to significant interest, EPA will explore the potential for the draft guidelines to apply to service sector standards and ecolabels (*e.g.,* services related to building maintenance, cafeterias, and professional consultants, among others). The potential pilot for this sector would not assess service sector standards; rather the analysis and recommendations could potentially position the draft guidelines to accommodate such assessments in 2016 and beyond.

II. Opportunity To Participate in a Pilot

Standards development organizations, ecolabel programs, and certification entities that have product environmental performance standards and/or ecolabels that cover one or more of the three product categories, and could be considered for use in Federal procurement per E.O. 13514, entitled: *Federal Leadership in Environmental, Energy, and Economic Performance* (74 FR 52117, October 8, 2009), the Federal Acquisition Regulation (FAR) (48 CFR 23.103), and Federal Government standards policy, should consider submitting those standards and ecolabels for assessment as a part of the pilot project.

Those standards and ecolabels assessed will provide information per product-category specific checklists (based on the draft guidelines), to be developed by multi-stakeholder panels, as described at *http://www.epa.gov/epp/draftGuidelines/pilot.html*. Each purchase category panel shall include a balanced group of relevant stakeholders in the environmental and human health performance standards and ecolabels space and ensure an objective, open, and consensus-driven process and credible results. The stakeholder types that may be represented on the multi-stakeholder panels include, but are not limited to:

- Standards development organizations.
- Ecolabel program managers/system owners.
- Conformity assessment bodies.
- Federal purchasers.
- Other large institutional purchasers such as state governments or universities.
- Manufacturers and/or vendors in the product categories targeted for assessment.
- Professional societies, users groups, and industry consortia.
- Research and development organizations and academia.
- Non-governmental organizations widely respected for their work on public health, environmental protection, and sustainability issues.
- Federal Government agencies knowledgeable in conformity assessment.

EPA is seeking input from the public regarding the multi-stakeholder panel member criteria/qualifications. EPA proposed the following:

- Knowledge of the environmental and/or human health impacts of the particular product category.
- Experience working with diverse stakeholders towards consensus.
- Familiarity with the draft Guidelines and Federal sustainable acquisition mandates.
- Familiarity with standards development and conformity assessment approaches.
- Ability to devote the necessary time to the panel (including one meeting and regular conference calls).
- Willingness to sign a conflict of interest disclosure form.

III. Information Collection Request (ICR)

A. What comments are sought on the ICR?

Pursuant to the PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

In particular, EPA is requesting comments from very small businesses and nonprofit organizations (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses and nonprofit organizations affected by this collection.

B. What information collection activity or ICR does this apply to?

Title: Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement.

ICR number: EPA ICR No. 2516.01.

OMB control number: OMB Control No. 2070—New.

ICR status: This ICR is for a new information collection activity. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the *Code of Federal Regulations* (CFR), after appearing in the *Federal Register* when approved, are listed in 40 CFR part 9, are displayed either by publication in the *Federal Register* or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: EPA is engaging in this collection pursuant to the authority in the Pollution Prevention Act (42 U.S.C. 13103(b)(11)), which requires EPA to "Identify opportunities to use Federal procurement to encourage source reduction" and section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note), which requires Federal agencies to "use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities." Federal agencies need this assessment per the draft guidelines to determine which, among sometimes dozens of private sector standards within a single purchase category, are appropriate and effective in meeting Federal procurement goals and mandates.

Federal agencies must comply with the following sustainability-related purchasing mandates: Section 2(h) of E.O. 13514; section 6002 of the Resource Conservation and Recovery Act (42 U.S.C. 6002); section 9002 of the Farm Security and Rural Investment Act (7 U.S.C. 8102); the Energy Policy Act (42 U.S.C. 13201 et seq.); section 2(d) of E.O. 13423, entitled: *Strengthening Federal Environmental, Energy, and Transportation Management* (72 FR 3919, January 26, 2007); and the FAR, including 48 CFR part 23, entitled: *Environment, Energy and Water Efficiency, Renewable Energy Technologies, Occupational Safety, and Drug-Free Workplace* (see *http://www.whitehouse.gov/omb/procurement_index_green*).

Via NTTAA, Federal agencies are required to "use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities," except when an agency determines that such use "is inconsistent with applicable law or otherwise impractical." OMB Circular A–119, entitled: *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,* reaffirms Federal agency use of non-governmental standards in procurement.

While Federal purchasing policy is clear for the several standards and ecolabels that are listed in statute, regulation, or Executive Order, the lack of independently assessed information about and Federal guidance on using other product environmental performance standards and ecolabels often results in an inconsistent approach by Federal purchasers and confusion and uncertainty for vendors and manufacturers.

Burden statement: The annual public reporting and record-keeping burden for this collection of information is estimated to average 8.5 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR are standards development organizations, ecolabeling programs, and environmental certification entities.

Estimated total number of potential respondents: 20.

Frequency of response: Once during 2015 pilot; and, a to-be-determined frequency depending upon learnings from the pilot.

Estimated total average number of responses for each respondent: 2.

Estimated total annual burden hours: 340 hours.

Estimated total annual costs: $24,711.20 for burden hours, and $0 estimated costs for capital investment or maintenance and operational costs.

C. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another *Federal Register* document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

Authority: 44 U.S.C. 3501 et seq.

Dated: March 11, 2015.

JAMES JONES, *Assistant Administrator,* Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2015–06275 Filed 3–18–15; 8:45 a.m.]

BILLING CODE 6560–50–P

[ATTACHMENT 3]

[*https://www.epa.gov/pesticide-reevaluation/registration-review-schedules*]

Registration Review Schedules

Through the Pesticide *Registration Review program* (*https://www.epa.gov/pesticide-reevaluation/registration-review-process*), EPA reviews all registered pesticides at least every 15 years, as mandated by the Federal Insecticide, Fungicide, and Rodenticide Act.

EPA always strives to base its decisions on the best available sound science. However, science is constantly evolving, and new scientific information can come to light at any time and change our understanding of potential risks from pesticides. The review of new data could potentially prolong the risk assessment and decision-making process and change this schedule.

Below is a schedule of the status of different pesticides undergoing the registration review process. This schedule is subject to change based on shifting priorities and is intended to be a rough timeline. The schedule will be updated regularly to reflect any timeline changes, and to include anticipated deliverables for later dates.

Explanation of List

The *registration review process* (*https://www.epa.gov/pesticide-reevaluation/registration-review-process#process%20components*) includes:

- *Docket Openings* (*https://www.epa.gov/pesticide-reevaluation/registration-review-docket-opening-schedule*).
- *Draft Risk Assessments* (*https://www.epa.gov/pesticide-reevaluation/registration-review-process#case%20development*).
- *Proposed Interim Decisions/Proposed Decisions* (*https://www.epa.gov/pesticide-reevaluation/registration-review-process#decision*).
- *Interim Decisions/Decisions* (*https://www.epa.gov/pesticide-reevaluation/registration-review-process#decision*).

EPA commits to an open and transparent process by accepting public comments at most stages of the process. These are collected in each chemical's docket at *www.regulations.gov* and all comments submitted will be accounted for in the Agency's regulatory decisions for each chemical.

The schedule is also categorized by the fiscal year's (FY) quarters. Please note the following timeframes:

- Quarter 1 (Q1): October–December
- Quarter 2 (Q2): January–March
- Quarter 3 (Q3): April–June
- Quarter 4 (Q4): July–September

Registration Review Schedules

Draft Risk Assessments

FY16 Quarter 3

- 2,4-D salts and esters
- Atrazine

- Carfentrazone-ethyl
- Chlorethoxyfos
- Copper salts
- Cymoxanil
- Diazinon
- Kresoxim-Methyl
- Linuron
- Malathion
- Mineral Acids
- Propazine
- Simazine
- Spinosad/Spinetoram

FY16 Quarter 4

- Acephate
- Cyclanilide
- Cyprodinil
- Dimethomorph
- Etofenprox
- Fenpropathrin
- Flumethrin
- Glycolic acid and salts
- Imiprothrin
- Mepiquat chloride
- Metalaxyl/mefenoxam
- MGK-264
- Momfluorothrin
- Oxytetracycline
- Phenothrin (Sumithrin)
- Phosmet
- Prallethrin
- Pyrethrins
- Tau-fluvalinate
- Tefluthrin
- Tetramethrin

Proposed Interim Decisions/Interim Decisions

FY16 Quarter 3

- Antimycin-A
- Clethodim
- Flufenacet
- Flurprimidol
- Fosamine ammonium
- Glufosinate
- Lithium hypochlorite
- Methoxyfenozide
- Sucrose octanoate
- Sulfonylurea (SU) herbicides
  - Bensulfuron-methyl
  - Chlorimuron-ethyl
  - Chlorsulfuron
  - Flazasulfuron
  - Foramsulfuron
  - Halosulfuron-methyl
  - Imazosulfuron
  - Iodosulfuron-methyl-Na
  - Mesosulfuron-methyl
  - Metsulfuron-methyl
  - Nicosulfuron
  - Orthosulfamuron
  - Primisulfuron-methyl

- Prosulfuron
- Rimsulfuron
- Sulfometuron-methyl
- Sulfosulfuron
- Thifensulfuron-methyl
- Triasulfuron
- Tribenuron-methyl
- Trifloxysulfuron-Na
- Triflusulfuron-methyl

- Tebufenozide

FY16 Quarter 4

- Azoxystrobin
- Boric Acid
- Diquat Dibromide
- Ethephon
- Hexazinone
- Hymexazol

Interim Decisions/Decisions

FY16 Quarter 3

- Alpha-chlorohydrin
- Chlorfenapyr
- Cyanamide

FY16 Quarter 4

- 2-(Decylthio)ethanamine hydrochloride (DTEA-HCl)
- Aliphatic alcohols, C1–C5
- Bentazon
- Propoxur
- Propoxycarbazone
- Sodium Acifluorofen
- Thidiazuron

Contact Us (https://www.epa.gov/pesticide-reevaluation/forms/contact-us-about-pesticide-reevaluation) to ask a question, provide feedback, or report a problem.

[Accessed September 8, 2016]

[ATTACHMENT 4]

[*https://www.epa.gov/pesticide-registration/understanding-science-behind-epas-pesticide-decisions*]

Understanding the Science behind EPA's Pesticide Decisions

Science is the backbone of the EPA's decision-making. The Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity and quality of the science on which it relies. The environmental policies, decisions, guidance, and regulations that impact the lives of all Americans must be grounded, at a most fundamental level, in sound, high quality science.

The EPA regulates pesticides to ensure that they do not pose unreasonable risks to human health or the environment. As part of that effort, the EPA requires extensive test data from pesticide producers that demonstrate pesticide products can be used without causing harm to human health and the environment.

We evaluate information from all kinds of sources—pesticide companies, other governments, academia, and the published scientific literature. EPA scientists and analysts carefully review these data to determine whether to register (license) a pesticide product or use and whether specific restrictions are necessary. EPA maintains a transparent, public process for assessing potential risks to human health when evaluating pesticide products.

On this page:

- Risk Assessment Process
  - Ecological Risk Assessment
  - Human Health Risk Assessment
  - Epidemiology Studies

- When EPA Receives New Studies
- Scientific Integrity and Transparency

Risk Assessment Process

The process EPA uses for evaluating the potential for health and ecological effects of a pesticide is referred to as a risk assessment. The risk assessment is crucial to the overall decision-making process for pesticides, both new and existing. New pesticides must be evaluated before they can enter the market. Existing pesticides must be re-evaluated periodically to ensure that they continue to meet the appropriate safety standard. EPA's decision-making relies on a risk management process, which is conducted in *registration for new pesticide chemicals* (*https://www.epa.gov/pesticide-registration*) or new uses of existing chemicals, or *reregistration or registration review in the case of a general review of an existing chemical* (*https://www.epa.gov/pesticide-reevaluation*).

There are two main components to the risk assessment:

- Ecological Risk Assessment
- Human Health Risk Assessment

Ecological Risk Assessment

EPA conducts ecological risk assessments to determine what risks are posed by a pesticide and whether changes to the use or proposed use are necessary to protect the environment. Many plant and wildlife species can be found near or in cities, agricultural fields, and recreational areas. Before allowing a pesticide product to be sold on the market, the EPA ensures that the pesticide will not pose any unreasonable risks to plants, wildlife, and the environment. This is done by evaluating data submitted in support of registration regarding the potential hazard that a pesticide may present to non-target plants, fish, and wildlife species. In addition, EPA reviews scientific studies available in the open literature.

Ecological risk assessments include three phases, and are generally conducted following the *Guidelines for Ecological Risk Assessment* (*https://www.epa.gov/osa/basic-information-about-risk-assessment-guidelines-development*).

Human Health Risk Assessment

A human health risk assessment process estimates the nature and probability of adverse health effects in people who may be exposed to chemicals in the food and water they consume or in the air they breathe; through their work; or as a result of activities that may lead to contact with pesticide residues on treated surfaces now or in the future.

EPA uses the National Research Council's process for human health risk assessments:

1. **Hazard Identification:** Examines whether a pesticide has the potential to cause harm to humans and/or ecological systems, and if so, under what circumstances.
2. **Dose Response Assessment:** Examines the numerical relationship between exposure and effects.
3. **Exposure Assessment:** Examines what is known about the frequency, timing, and levels of contact with a pesticide.
4. **Risk Characterization:** Examines how well the data support conclusions about the nature and extent of the risk from exposure to pesticides.

Epidemiology Studies

EPA considers epidemiology studies that are available as part of its human health risk assessment data and actively supports the *Agricultural Health Study* (*https://aghealth.nih.gov/*). EPA reviews the available epidemiological information using a peer reviewed framework with well-accepted evaluation factors that specifically consider links between pesticide exposure and health outcomes.

- **Epidemiology Framework:** EPA developed a framework to incorporate epidemiology into risk assessment as one component of our work in this area. Concepts in the framework are based on peer-reviewed, robust principles and tools, and incorporate improvements based on recommendations from the National Academies' National Research Council reports on *Toxicity Testing in the 21st Century* (*http://www.nap.edu/catalog/11970/toxicity-testing-in-the-21st-century-a-vision-and-a*) and *Advancing Risk Assessment* (*http://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment*). This methodology was reviewed in 2010 by the *Federal Insecticide, Fungicide, and*

Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) (*https://www.epa.gov/sap*), an advisory panel of outside experts.

EPA is beginning to implement systematic review procedures consistent with the recommendations of *EPA's Integrated Risk Information System (IRIS)* (*https://www.epa.gov/iris*) workshops, the *National Toxicology Program* (*http://ehp.niehs.nih.gov/1306711/*), and others. As this process proceeds, the EPA anticipates improved transparency of how scientific information across a broad spectrum of scientific disciplines are integrated into our risk assessment and decision-making process.

When EPA Receives New Studies

EPA actively seeks out and considers new studies, and accounts for this information in pesticide regulatory decisions. When compelling data make it clear that regulatory action must be taken, the Agency responds appropriately.

We look closely at every study to determine whether the results are scientifically sound. Our analysis gives greater weight to high quality and well documented studies and those findings confirmed by multiple sources. Ultimately, the Agency looks at all of the studies to decide what the preponderance of evidence shows.

EPA has practices in place and enforcement policies to help ensure that studies represent sound science. Once studies are submitted to the Agency, EPA scientists conduct extensive analysis of the data to ensure that the design of the study is appropriate and that the data are collected and analyzed accurately.

EPA uses its *peer-reviewed framework* (*https://www.epa.gov/pesticide-registration/understanding-science-behind-epas-pesticide-decisions#framework*) to incorporate additional epidemiological studies into the risk assessment. *Additional information on the risk assessment process for pesticides* (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program*).

EPA guidance on the review of open literature (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-selecting-and-evaluating-open*).

Transparency and Scientific Integrity

At the EPA, scientific integrity is closely linked to transparency. The Agency remains committed to transparency in its interactions with all members of the public and has released Agency-wide principles and policies to clarify the importance of scientific integrity:

- *EPA's Scientific Integrity Policy February 2012* (*https://www.epa.gov/risk/policy-epa-scientific-integrity*) builds on the EPA's long history of scientific safeguards and further ensures that sound science drives Agency decision making.
- *EPA's Principles of Scientific Integrity* (*https://www.epa.gov/osa/epas-principles-scientific-integrity-fact-sheet*) outlines foundational principles that promote a culture of scientific integrity, public involvement, the use of peer review and Federal Advisory Committees, and the development of Agency scientists. It also establishes a Scientific Integrity Committee to implement the Agency-wide Scientific Integrity policy.
- Annual Report on Scientific Integrity: The *2014 Annual Report* (*https://www.epa.gov/osa/2014-annual-report-scientific-integrity*) highlights EPA's scientific integrity successes.

Additional information on EPA's Scientific Integrity Policies (*https://www.epa.gov/osa/basic-information-about-scientific-integrity*).

Learn about EPA and the Open Government Initiative (*https://www.epa.gov/open*).

Contact Us (*https://www.epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration*) to ask a question, provide feedback, or report a problem.

[Accessed September 8, 2016]

[ATTACHMENT 5]

Excerpt of *Revised Chlorpyrifos Human Health Risk Assessment*

Appendix 6. Columbia Center for Children's Environmental Health (CCCEH) Epidemiology Data Acquisition "Raw Data" Request

I. Action Requested

To fulfill identified information needs for the purposes of incorporating the Columbia Center for Children's Environmental Health (CCCEH) epidemiology data into the Human Health Risk Assessment (HHRA) for chlorpyrifos, the agency sought to

obtain certain "raw data" from CCCEH researchers. Specifically, EPA requested the original analytic data file used to support analyses presented in the peer-reviewed, published epidemiology studies concerning *in utero* chlorpyrifos exposure (V. Rauh, *et al.,* 2011; V.A. Rauh, *et al.,* 2006; Whyatt, *et al.,* 2004). CCCEH researchers did not agree to provide these data, however, the researchers met with EPA and discussed the agency's questions about the data to help determine whether further review of the raw data might assist EPA in resolving uncertainties. As a result of new information gathered through an on-site meeting and other sources, EPA is no longer pursuing the request for the original analytic data file from CCCEH researchers. This memorandum details the new information gained that resolves or renders unobtainable the previously identified information needs.

II. Background

EPA considers many different types of scientific information when performing a human health risk assessment (HHRA) of pesticide exposure in the human population. Traditionally, EPA uses toxicology, product and residue chemistry, and industrial hygiene studies as well as measured and modeled human and environmental exposure information to support assessment of environmental risks. In its preparation of the HHRA for chlorpyrifos, the agency has evaluated environmental epidemiology studies of the potential risk of long-term neurodevelopmental effects such as delayed motor skill acquisition or reduced intelligence quotient (IQ) measures among children who experienced pesticide exposure during gestational development. There are three prospective birth cohort studies in the U.S. that examine pesticide exposure (as well as other environmental toxicants) to the pregnant mother and fetus, and then measure neurological and neurodevelopmental performance in children as they grow older. EPA has provided some of the funding support for each of these studies. Authors hypothesize that *in utero* and early life exposure may influence brain development and effect neurological functioning in children. These studies include the CHAMACOS study in the Salinas Valley, CA, the Mt. Sinai children's environmental health study (Mt. Sinai study), and the Columbia Center for Children's Environmental Health (CCCEH).

The CCCEH study is the only one of the three studies that measures maternal and fetal exposure to chlorpyrifos specifically; the other two cohorts measure exposure to organophosphate pesticides generally. Authors with the CCCEH study reported reduced birth weight and birth length among neonates more highly exposed to chlorpyrifos during gestation (as measured by cord blood concentration of chlorpyrifos) (Whyatt, *et al.,* 2004). Similarly, authors observed slower motor skill acquisition and reduced mental capacity among infants who were more highly exposed to the chemical *in utero* (V.A. Rauh, *et al.,* 2006). In 2011, authors from all three birth cohort studies concurrently reported evidence of reduced measures of intelligence (Wechslar intelligence scale scores) by increasing *in utero* chlorpyrifos and/or organophosphate exposure (M.F. Bouchard, *et al.,* 2011; Engel, *et al.,* 2011; V. Rauh, *et al.,* 2011).

Given the value of this information to the agency's HHRA for chlorpyrifos, EPA requested the FIFRA SAP to provide external peer review of the strengths and limitations of the epidemiology data for use in the chlorpyrifos HHRA (FIFRA SAP September 2008 and April 2012). The agency identified two major areas in which additional information was needed to fully incorporate these data into the HHRA: additional measures of environmental exposure to chlorpyrifos in the CCCEH cohort to discern whether acetyl cholinesterase inhibition was likely to have occurred in connection with reported adverse outcomes, and also the role of other environmental chemicals (lead, polycyclic aromatic hydrocarbon (PAH), other organophosphate pesticides) in the observed adverse neurological effects reported in relation to *in utero* chlorpyrifos exposure.

To fulfill these information needs for the purposes of incorporating the epidemiology data into the chlorpyrifos HHRA, the agency sought to obtain certain "raw data" from the Columbia Center for Children's Environmental Health (CCCEH) study. Specifically, EPA requested the original analytic data file used to support analyses presented in the peer-reviewed, published epidemiology studies concerning *in utero* chlorpyrifos exposure (V. Rauh, *et al.,* 2011; V.A. Rauh, *et al.,* 2006; Whyatt, *et al.,* 2004). CCCEH did not agree to provide the data based upon these initial inquiries and they asserted that because EPA did not fund the pesticide exposure component of their cohort study EPA was not legally entitled to review their underlying data. CCCEH did agree, however, to meet and discuss EPA's questions about the data to help determine whether further review of the raw data might assist EPA in resolving uncertainties. As a result on April 15, 2013, EPA scientists and CCCEH researchers held an all-day meeting at the CCCEH data center (Mailman School of Public Health, New York City, NY) to discuss EPA's information needs and whether

acquisition of the full analytic data would be necessary or valuable to EPA's assessment. *Addendum 1* delineates the questions EPA posed to CCCEH study staff at this all-day meeting.

III. Resolution of Information Needs

A. Epidemiology Study Exposure Characterization

The primary rationale supporting EPA's request for "raw data" from the CCCEH researchers relates to the agency's need to determine whether the levels of chlorpyrifos exposure in the environment (apartments, apartment building or other outdoor environment, or dietary exposure) of CCCEH study participants were above or below levels that may elicit a greater than 10% inhibition of acetylcholinesterase enzyme levels, the current regulatory endpoint. During the April 2013 meeting, EPA learned that this type of information is neither available nor obtainable. CCCEH researchers estimated relative pesticide exposure using several different exposure methods including 48-hour air sampling with personal monitor, 2-week integrated stationary air monitoring, maternal urinary concentration of TCPy (urinary metabolite of chlopryrifos) during the last trimester of pregnancy, maternal urinary concentration of TCPy at delivery, and umbilical cord blood and meconium at delivery. To determine whether a significant change in acetyl cholinesterase levels may have occurred as a result of actual environmental exposure, temporal concordance between pesticide use and the chlorpyrifos measurement is needed, *i.e.,* exposure estimation at the time of pesticide application is optimal. The CCCEH study design did not incorporate pre- and post-pesticide use/exposure measurement in the study protocol. Therefore, this information was not collected and is not retrospectively obtainable.

In addition, EPA requested any additional information obtained by researchers as to specific pesticide products used to better understand the pattern and frequency of organophosphate pesticide use among cohort participants. This information was solicited from participants in a written questionnaire administered during a follow-up period (unpublished copy of questionnaire obtained by EPA Oct. 2012). In response to the EPA inquiry, researchers recalled that the Whyatt (2002) publication described the challenges of collecting pesticide product information in etiologic epidemiology studies, and in the on-site meeting in April 2013 confirmed that the information quality in the CCCEH written questionnaire responses is very low. This information was deemed of such poor quality by CCCEH data analysts that the data were not coded or entered into the analytic data file. Therefore, EPA learned that this specific request for "raw data" concerning pesticide product use is not available.

As a surrogate for this information, CCCEH researchers suggested EPA contact the New York City Department of Health to obtain a linked dataset of CCCEH study participant residential address and public housing pesticide usage. The linked dataset provides aggregated pesticide usage data at the cohort participant building-level only. EPA has obtained and reviewed these data (June 2013) and determined that pursuing a data reconstruction exercise is the most appropriate way to estimate environmental pesticide exposure that would have to occur among CCCEH study participants. EPA has conducted such analysis and included it in the revised human health risk assessment.

B. Co-Exposure to Other Environmental Contamin[a]nts

A second major concern raised by EPA, FIFRA SAP peer reviewers, and public commenters is the ability of the CCCEH study authors to accurately measure and statistically model the relationship between other environmental chemicals (lead and PAH, specifically) or other pesticides (diazinon, propoxur) that may influence fetal brain development and childhood neurodevelopmental performance, and also be related to chlorpyrifos exposure (these are "potentially confounding" exposures). EPA's concern stems from the understanding that if these other exposures are not sufficiently considered in the epidemiological analysis, then an incorrect inference and conclusion may result (*i.e.,* a potential false positive association). For example, prenatal and early life exposure to lead in the environment has been causally linked to adverse neurodevelopmental outcomes similar to those measured in the CCCEH cohort study including intelligence measures. EPA was concerned about the potential error in the CCCEH study if lead levels were not appropriately considered, *i.e.,* the apparent chlorpyrifos effect on neurodevelopment observed in the study may have been due to the lead exposure.

However, EPA has confirmed with study authors that lead levels and chlorpyrifos levels in cord blood are not statistically associated in this population. Plotting blood lead levels against cord blood chlorpyrifos levels illustrates that the two exposures are extremely weakly (linearly) correlated in this cohort ($\rho<1\%$) (V.A. Rauh, *et al.,* 2006). Further, EPA learned from unpublished, supplemental analyses performed by

CCCEH researchers upon EPA request that postnatal blood lead levels and prenatal chlorpyrifos levels are also not strongly statistically associated (Andrews, January 21, 2013). This is plausible because of intensive lead abatement programs on-going in New York City during the time period of this study. According to the New York City Department of Health, the number of children with elevated blood lead levels declined 92% between 1995 and 2008.[75] Therefore, because the two exposures are not related, it is not likely that pre- or postnatal blood lead exposure could explain the observed association with chlorpyrifos.

Furthermore, during the April 2013 meeting CCCEH researchers pointed out that based upon available information it appears that lead and chlorpyrifos may affect the brain differently. It is well understood that lead affects the neurodevelopmental sub-domain leading to outward motivation and aggression; while research within the CCCEH cohort indicates chlorpyrifos may affect inward motivation, information processing and organization (V. Rauh, *et al.,* 2011; V.A. Rauh, *et al.,* 2006; Wright, *et al.,* 2008). Additionally, MRI imaging studies of lead affected persons and preliminary brain imaging studies of chlorpyrifos affected persons show different MRI patterns, grey matter as opposed to white matter compositional patterns, respectively (Brubaker, Dietrich, Lanphear, & Cecil, 2010; Brubaker, *et al.,* 2009; Cecil, *et al.,* 2008; Cecil, *et al.,* 2011; V.A. Rauh, *et al.,* 2012). Therefore, given that neither pre- nor postnatal lead levels and chlorpyrifos levels are not statistically associated with one another in the CCCEH study, and the different ways through which lead and chlorpyrifos appear to influence neurodevelopmental domains EPA concludes that lead exposure did not likely confound (bias or render incorrect) the observed association between chlorpyrifos exposure and neurodevelopment in this study population.

Peer review panelists participating on the April 2012 FIFRA SAP panel identified the concern that authors had not fully considered the long-term effects of polycyclic aromatic hydrocarbon (PAH) exposure, a ubiquitous air pollutant in inner-city areas such as NYC, in the observed association between chlorpyrifos and neurodevelopmental outcomes. Specifically, panelist argued that 'a shift in environmental exposures over time' such that postnatal PAH exposure may have combined with the measured *in utero* pesticide exposure to result in the observed ND outcomes. During the April 2013 meeting, authors clarified that the study design did not include a repeat measure of exposures over time, so an analysis of postnatal PAH exposures is not possible. In the published studies, authors were able to control for the effect of prenatal PAH through statistical adjustment. In addition, authors examined the possible modifying role of prenatal PAH in this epidemiological association and did not observe any evidence of a different risk estimate between chlorpyrifos and ND among those more highly exposed to PAH. Concerning the role of postnatal environmental exposures, CCCEH researchers also stated their belief that their overall study results illustrate that it is gestational exposure, and not early life exposure, that influences neurodevelopment in the study population. They state that the longitudinal analyses of infant and child neurodevelopment in relation to *in utero* chlorpyrifos exposure illustrates a persistent effect of the prenatal environment (M. Bouchard, *et al.,* 2003; M.F. Bouchard, *et al.,* 2011; Engel, *et al.,* 2007; Engel, *et al.,* 2011; Eskenazi, *et al.,* 2004; Eskenazi, *et al.,* 2007; V. Rauh, *et al.,* 2011; V.A. Rauh, *et al.,* 2006; Whyatt, *et al.,* 2004). EPA concluded that CCCEH researchers utilized best practices in statistical analysis of epidemiological data concerning the role of prenatal PAH in neurodevelopmental outcomes, and that a study of repeated, postnatal PAH exposure was beyond the scope of the current CCCEH study, and would require a follow-up study not yet undertaken.

EPA was also interested to learn more about the co-exposure to other organophosphate pesticides among CCCEH study participants. Specifically, EPA as well as external peer review panelists noted the uncertainty as to the degree to which exposure to multiple acetyl cholinesterase inhibiting pesticides exposures over time and/or concurrent in time may have influenced study results. CCCEH researchers agreed that a more clear understanding of the role of mixtures—exposure to multiple OP pesticides overall or concurrent in time—on these neurodevelopmental outcomes is desirable; however they also recognized that the current sample size is too small to perform this type of analysis. To better understand the role of exposure to a mixture of OP pesticides a new cohort study with a larger sample size and different design is required. Therefore, EPA concluded that co-exposure to multiple organophosphate mixtures is not currently obtainable.

For risk characterization purposes, EPA was also interested in understanding the relative contributions of various environmental exposures on ND outcomes, (*e.g.,* PAH, environmental tobacco smoke, chlorpyrifos). Researchers noted that a preliminary indication of the relative contribution of various risk factors for intelligence

[75] *http://www.nyc.gov/html/doh/html/data/stats-childlead.shtml.*

measures in these cohorts can be seen through examination of supplemental tables published by CCCEH researchers, *i.e.,* the beta-coefficients provided in published supplemental tables provide an indication of the relative contribution of each risk factor (V. Rauh, *et al.,* 2011). However, CCCEH researchers indicated that to gain a true reflection the causal model in the population a series of studies in other study populations is needed. EPA and CCCEH researchers agreed that these studies will likely accumulate over time, however they are not currently available.

IV. Conclusions

In the past, EPA sought to obtain the original analytic data file used to support certain epidemiological analysis of *in utero* exposure to chlorpyrifos and subsequent adverse neurodevelopmental health outcomes in children generated by the Columbia Center for Children's Environmental Health (CCCEH) to support the Human Health Risk Assessment (HHRA) of chlorpyrifos. EPA believed these data were important to both clarify the exposure-response relationship observed in the epidemiology study relative to the current regulatory endpoint (acetylcholinesterase inhibition), and also to resolve uncertainties regarding study participants co-exposure to other environmental contaminants, among other areas of uncertainties. CCCEH researchers did not agree to provide these data, however, the researchers met with EPA and discussed the agency's questions about the data to help determine whether further review of the raw data might assist EPA in resolving uncertainties. As a result of this meeting and additional discussions with CCCEH staff, EPA concluded that access to the raw data would either not provide answers to EPA's questions or that the information EPA sought could be obtained without analyzing the raw data. Indeed, based on discussions in that meeting as well as further work conducted by agency staff, EPA has gained additional information to better clarify and characterize the major issue areas identified as uncertainties. For these reasons, EPA decided that it would not further pursue its request for the analytic data file from the CCCEH researchers.

Works Cited

Andrews, H.F. (January 21, 2013). [Clarification of Relation between Blood Lead and Cord Blood Levels of Chlorpyrifos in the Columbia Center for Children's Environmental Health (CCCEH) Studies (Electronic mail communication)].

Bouchard, M., Gosselin, N.H., Brunet, R.C., Samuel, O., Dumoulin, M.J., & Carrier, G. (2003). *Atoxicokinetic model of malathion and its metabolites as a tool to assess human exposure and riskthrough measurements of urinary biomarkers.* TOXICOL. SCI., 73(1), 182–194. doi: 10.1093/toxsci/kfg061.

Bouchard, M.F., Chevrier, J., Harley, K.G., Kogut, K., Vedar, M., Calderon, N., . . . Eskenazi, B. (2011). *Prenatal exposure to organophosphate pesticides and IQ in 7-year-old children.* ENVIRON. HEALTH PERSPECT., 119(8), 1189–1195. doi: 10.1289/ehp.1003185.

Brubaker, C.J., Dietrich, K.N., Lanphear, B.P., & Cecil, K.M. (2010). *The influence of age of leadexposure on adult gray matter volume.* NEUROTOXICOLOGY, 31(3), 259–266. doi: 10.1016/j.neuro.2010.03.004.

Brubaker, C.J., Schmithorst, V.J., Haynes, E.N., Dietrich, K.N., Egelhoff, J.C., Lindquist, D.M., . . . Cecil, K.M. (2009). *Altered myelination and axonal integrity in adults with childhood lead exposure: a diffusion tensor imaging study.* NEUROTOXICOLOGY, 30(6), 867–875. doi: 10.1016/j.neuro.2009.07.007.

Cecil, K.M., Brubaker, C.J., Adler, C.M., Dietrich, K.N., Altaye, M., Egelhoff, J.C., . . . Lanphear, B.P. (2008). *Decreased brain volume in adults with childhood lead exposure.* PLOS MED., 5(5), e112. doi: 10.1371/journal.pmed.0050112.

Cecil, K.M., Dietrich, K.N., Altaye, M., Egelhoff, J.C., Lindquist, D.M., Brubaker, C.J., & Lanphear, B.P. (2011). *Proton magnetic resonance spectroscopy in adults with childhood lead exposure.* ENVIRON. HEALTH PERSPECT., 119(3), 403–408. doi: 10.1289/ehp.1002176.

Engel, S.M., Berkowitz, G.S., Barr, D.B., Teitelbaum, S.L., Siskind, J., Meisel, S.J., . . . Wolff, M.S. (2007). *Prenatal organophosphate metabolite and organochlorine levels and performance on the Brazelton Neonatal Behavioral Assessment Scale in a multiethnic pregnancy cohort.* AM. J. EPIDEMIOL., 165(12), 1397–1404. doi: 10.1093/aje/kwm029.

Engel, S.M., Wetmur, J., Chen, J., Zhu, C., Barr, D.B., Canfield, R.L., & Wolff, M. S. (2011). *Prenatal exposure to organophosphates, paraoxonase 1, and cognitive development in childhood.* ENVIRON. HEALTH PERSPECT., 119(8), 1182–1188. doi: 10.1289/ehp.1003183.

Eskenazi, B., Harley, K., Bradman, A., Weltzien, E., Jewell, N.A., Barr, D.B., . . . Holland, N.T. (2004). *Association of **in utero** organophosphate pesticide exposure and fetal growth and length of gestation in an agricultural population.* ENVIRONMENTAL HEALTH PERSPECTIVES, 112(10), 1116–1124. doi: 10.1289/ehp.6789.

Eskenazi, B., Marks, A.R., Bradman, A., Harley, K., Barr, D.B., Johnson, C., . . . Jewell, N.P. (2007). *Organophosphate pesticide exposure and neurodevelopment in young Mexican-American children.* ENVIRON. HEALTH PERSPECT., 115(5), 792–798. doi: 10.1289/ehp.9828.

Rauh, V., Arunajadai, S., Horton, M., Perera, F., Hoepner, L., Barr, D.B., & Whyatt, R. (2011). *Seven-year neurodevelopmental scores and prenatal exposure to chlorpyrifos, a common agricultural pesticide.* ENVIRON. HEALTH PERSPECT., 119(8), 1196–1201. doi: 10.1289/ehp.1003160.

Rauh, V.A., Garfinkel, R., Perera, F.P., Andrews, H.F., Hoepner, L., Barr, D.B., . . . Whyatt, R.W. (2006). *Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children.* PEDIATRICS, 118(6), e1845–1859. doi: 10.1542/peds.2006-0338.

Rauh, V.A., Perera, F.P., Horton, M.K., Whyatt, R.M., Bansal, R., Hao, X.J., . . . Peterson, B.S. (2012). *Brain anomalies in children exposed prenatally to a common organophosphate pesticide.* PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA, 109(20), 7871–7876. doi: 10.1073/pnas.1203396109.

Whyatt, R.M., Camann, D.E., Kinney, P.L., Reyes, A., Ramirez, J., Dietrich, J., . . . Perera, F.P. (2002). *Residential pesticide use during pregnancy among a cohort of urban minority women.* ENVIRON. HEALTH PERSPECT., 110(5), 507–514.

Whyatt, R.M., Rauh, V., Barr, D.B., Camann, D.E., Andrews, H.F., Garfinkel, R., . . . Perera, F.P. (2004). *Prenatal insecticide exposures and birth weight and length among an urban minority cohort.* ENVIRON. HEALTH PERSPECT., 112(10), 1125–1132.

Wright, J.P., Dietrich, K.N., Ris, M.D., Hornung, R.W., Wessel, S.D., Lanphear, B.P., . . . Rae, M.N. (2008). *Association of prenatal and childhood blood lead concentrations with criminal arrests in early adulthood.* PLOS MED., 5(5), e101. doi: 10.1371/journal.pmed.0050101.

Appendix 6. Addendum 1: Columbia University Epidemiology Studies

The agency is obligated to review and address peer review comments in support of regulatory decisions. The following is a list of key issues about the epidemiological studies carried out by researchers at Columbia University that were raised in peer review comments. These issues require EPA to have access to the raw data for additional analyses by the agency.

(1) **Further analysis of other chemical exposures (*e.g.*, lead, PAHs, other pesticides) to address, if possible, their impact or contribution as modulating factors on the measured outcomes.**

- **2012 SAP**—"it should be noted that it cannot be stated that chlorpyrifos is the sole contributor to the observed outcomes."
- **2012 SAP**—"In an earlier examination of the same cohort, Perera, *et al.* (2009) reported an association between a decrease in full-scale IQ and verbal IQ in 5-year-olds with prenatal polycyclic aromatic hydrocarbons (PAH) exposure rather than chlorpyrifos, thus, raising an issue of the shift in chemical exposure association with increase in age. In each of these analyses, statistical modeling showed that the exposures were independently associated with IQ, and no significant interaction was observed with the other chemical. While this is a statistically sound approach to determine independent responses, panel members noted that it is very difficult to identify the independent physiological effects of a single chemical in this type of multi-chemical exposure scenario."
- **2012 Federal Peer Review**—"even low levels of lead can impact neurodevelopment, and even that the observed neurobehavioral deficits are more pronounced at lower blood lead levels when compared with higher blood lead levels".
- **2008 SAP**—"In order to eliminate the possible causes of neurodevelopmental effects by other pesticides in the Columbia study, it is suggested that EPA should repeat the pre-post residential cancellation analysis done for chlorpyrifos using other pesticide measurements, such as malathion diacid (MDA), a specific metabolite of malathion. The outcomes from those additional analyses will either confirm or reject EPA's preliminary conclusion that chlorpyrifos is likely to play a role in the neurodevelopmental outcomes."
- **2008 SAP**—"It would be useful to examine the results of a statistical analysis that includes all three AChE-inhibiting insecticides in the analysis model as dichotomous variables (above or below LOD) in combination with continuous measurements for these variables. This type of analysis would likely not change the results, but it could be helpful in illustrating threshold or dose response effects."

(2) **Further analysis and information to address and, if possible, better characterize uncertainty around outcome measures on learning/memory/IQ.**

- **2012 SAP**—Alternative considerations for non-quantified samples: "little use was made of techniques to integrate non-quantified samples into the statistical test . . . . Various methods were reviewed by the July 2010 SAP that can be applied to either normally or lognormally distributed data that include a significant (even a majority) of non-detectable sample . . . . Specifically, the use of 'probability plots' was described that can yield an estimate of the geometric mean of the distribution [GM], the geometric standard deviation [GSD], and corresponding percentiles."
- **Federal Peer Review**—"There is a scatterplot showing the raw scores for overall IQ and for each of the subtests, but it is not possible to obtain the necessary information to compare the distributions of these scores with the norms for the test or with any other study sample. Ideally, the means and standard deviations for these scores should be presented for either a non-exposed or a non-exposed combined with low exposed group and these should be compared to a moderate or high-exposed group as was done for the BSID–II in the Rauh, *et al.,* 2006 paper. Here the uncertainties stem from the assumptions that are made when regression analyses are performed. The main issue here is that outliers can greatly influence the slope of the function."
  - **Federal Peer Review**—A between group analysis using inferential statistics, as was done for the Bayley Scales of Infant Development II in the Rauh, *et al.,* 2006 paper, should be performed on each variable in both studies (*i.e.,* the Child Behavior Checklist in Rauh, *et al.,* 2006, and the full

scale IQ and subscales for the WISC–IV in the Rauh, *et al.,* 2011 study). This would be the most direct and least problematic method for determining whether exposure to chlorpyrifos resulted in significant decreases in IQ or significant increases in behavioral problems ". . . no information was provided regarding the qualifications of the individuals who administered and scored the tests. "

(3) **Further analysis to assess, if possible, whether individual cohort members had the potential for exposure to chlorpyrifos and/or other acetylcholinesterase (AChE) inhibiting pesticides (*e.g.,* diazinon, propoxur), prenatally and/or postnatally, at levels leading to greater than 10% AChE inhibition (the level used to derive the regulatory point of departure).**

- **2012 SAP**—recommended conducting a dose reconstruction analysis—"data on the concentration of chlorpyrifos in various media (*i.e.,* house dust, air and water) while market basket data exists on the concentration of chlorpyrifos on food. These data provide the main tools for developing an effective exposure assessment and a subsequent reconstruction of potential dose." The agency has begun such analysis but the current draft analysis is limited without data on the exposure information relevant to individual women such that environmental chlorpyrifos exposure can then be linked to measures of blood chlorpyrifos.
- **2012 SAP**—recommended the agency consider issues related to multiple chemical exposure (*i.e.,* mixtures) to chlorpyrifos and other key AChE inhibiting pesticides identified by the Columbia University studies (diazinon, propoxur). Assumptions of co-exposure will likely be grossly over-estimated without access to the raw data; such raw data may enable the agency to evaluate actual co-exposure information for individuals from air monitoring samples and blood samples.

[ATTACHMENT 6]

[*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*]

About Water Exposure Models Used in Pesticide [Assessments]

On this Page

- General Information about Water Models
  - Model Names and Specific Uses
- Surface Water Models
  - GENEEC
  - FIRST
  - Surface Water Concentration Calculator
  - Tier 1 Rice Model
  - PFAM
  - KABAM
- Ground Water Models
  - SCI–GROW
  - PRZM–GW
- References

Water Models

When EPA's Office of Pesticide Programs (OPP) assesses the risk of a pesticide, it considers the exposure to the pesticide as well as the toxicity of the pesticide. For both drinking water and aquatic exposure assessments, reliable field monitoring data, when available, as well as mathematical models can be used to generate exposure estimates. Monitoring and modeling are both important tools for assessing pesticide concentrations in water and can provide different types of information. Monitoring tells the user what is happening under current use practices and under typical conditions. Although monitoring data can provide a direct estimate of the concentration of a pesticide in water at a particular time and at a particular location, it may not provide reliable estimates for exposure assessments because sampling may not occur where and when the highest concentrations of a pesticide are found.

For drinking water and aquatic exposures assessments, OPP typically relies on mathematical models to generate exposure estimates. These models calculate estimated environmental concentrations (EECs) using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment. The guidelines for these laboratory studies can be found at the following website: *Series 835—Fate, Transport and Transformation Test Guidelines* (*https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-835-fate-transport-and-transformation-test*). Although computer modeling provides an indirect estimate of pesticide concentrations, models can estimate concentrations continuously over long periods of time and for vulnerable areas of interest for a particular pesticide. Modeling can also be used to compare estimated concentrations with toxicity data to determine the risk a pesticide poses to both drinking water and aquatic systems. Another benefit of computer modeling is in determining how various mitigation practices affect the amount of the pesticide that can run off into water.

In estimating pesticide concentrations in aquatic environments, OPP uses a tiered approach. The intent of this approach is to estimate pesticide concentrations in water from sites that are highly vulnerable to runoff or leaching. With this approach, pesticides that pass Tier I will likely pose a low possibility of harming human health, wildlife, or the environment. Failing a tier, however, does not necessarily mean the chemical is likely to cause health or environmental problems, but rather that there is a need to move to a higher tier and conduct a more refined assessment. This tiered modeling system is designed to provide a thorough analysis of each pesticide, while at the same time focus OPP's efforts on those pesticides that pose the greatest potential risk. For more information on this approach, refer to the archives about Science Policy Issues and Guidance Documents related to Tolerance Reassessment Advisory Committee (TRAC). *Search EPA Archive* (*https://archive.epa.gov/*).

Model Names and Specific Uses

For estimating upper bound concentrations of pesticides in drinking water, OPP uses FIRST (FQPA Index Reservoir Screening Tool) as a Tier I model for surface water exposure assessments and PRZM–GW for groundwater exposure assessments. For estimating upper bound concentrations of pesticides in other aquatic environments, OPP uses the Tier I model GENEEC2 (GENeric Estimated Environmental Concentration) for surface water exposure assessments. *View these and other models* (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment*).

For Tier II surface water exposure assessments, OPP uses the Surface Water Concentration Calculator (SWCC), which accommodates the specific characteristics of the chemical and includes more site-specific information regarding the application method and impact of local daily weather on the treated field over a period of 30 years. At the Tier II level, the SWCC uses maximum application rates and frequencies for a vulnerable drinking water reservoir or vulnerable pond. Additional refinements in application rates may be considered if usage data indicate they are appropriate. Currently, scientists in the Environmental Fate and Effects Division (EFED) of the Office of Pesticide Programs (OPP) are exploring the use of the SWCC for Tier I level assessments. *View the SWCC and other models* (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment*).

For Tier II groundwater exposure assessments, refinement strategies for PRZM–GW can be used to estimate pesticide concentrations in groundwater. These refinement strategies include consideration of representative scenarios, additional fate parameters, annual application retreatment, well setbacks, and representative exposure durations of concern.

Although exposure models make it easy to evaluate the impacts of numerous variables in the environment, the results of these models are highly dependent on the accuracy of the chemical parameters that are used as inputs and the ability of the model to represent what occurs in the environment. In order to improve transparency and confidence in these models, EFED Scientists present new model developments at the *Environmental Modeling Public Meetings* (EMPM) (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/environmental-modeling-public-meeting-information*), which are held on a semiannual basis. In addition, the code and documentation for all EFED/OPP water models are posted on the web page for *models used in pesticide risk assessment* (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment*).

The following is a more detailed summary of OPP's current Tier I and Tier II aquatic exposure models along with links to user manuals that can be downloaded.

Surface Water Models

Pesticides can enter surface waters through runoff, spray drift, and deposition. Once pesticides have entered surface waters, they are exposed to a number of physical, chemical, and microbial processes that impact the fate of the pesticides. These processes include photodegradation, volatilization, biodegradation, absorption/adsorption, chemical degradation, leaching, and sedimentation. To better understand the fate of pesticides in surface waters, OPP has developed a number of models that capture these processes and predict the concentration of pesticides in surface waters. These models range from simple screening models that require few inputs to more complex models that reflect the dynamics of the surface water ecosystem. Below is a description of the surface water models that OPP uses in its pesticide exposure assessments.

GENEEC2

The GENeric Estimated Environmental Concentration (GENEEC 2.1) is a screening model to predict environmental concentrations of pesticides in surface water for aquatic exposure assessments. The model, which was recompiled to operate in the Microsoft® Windows 7® environment, is a legacy model for EPA and is currently available on the *Water Models—Previous Versions* (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-water-models-previous-versions#geneec2*) Web page. For the most part, the Surface Water Concentration Calculator (SWCC) has replaced GENEEC2 for estimating environmental concentrations of pesticides in surface water for aquatic exposure assessments. *View current models* (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment*).

In the past, OPP used GENEEC2 as a Tier I screening model for assessing exposure of aquatic organisms and the environment to pesticides. GENEEC2 provides a rapid screen to separate the low risk pesticides from those that need more refined assessments. The model estimates high level exposure values of pesticides in surface water from a few basic chemical characteristics and pesticide label use and application information.

GENEEC2 considers adsorption of the pesticide to soil or sediment, incorporation of the pesticide at application, direct deposition of spray drift into the water body, and degradation of the pesticide in soil before runoff and within the water body. It is a single-event model, meaning that it assumes one single large rainfall/runoff event, which occurs on a 10-hectare field and which removes a large quantity of pesticide at one time from the field to a pond. In this case, the pond has a 20,000 cubic water volume and is 2 meters deep. The GENEEC2 program is generic in that it does not consider differences in climate, soils, topography or crop in estimating potential pesticide exposure.

GENEEC2 is expected to overestimate pesticide concentrations in surface water for most sites and may be inappropriate for some chemicals, especially those that are persistent and/or have a high sorption coefficient, as well as frequently applied pesticides. In these cases, users should go directly to a higher tiered assessment using the more sophisticated Surface Water Concentration Calculator discussed below.

FIRST

OPP uses the Tier I model, FQPA Index Reservoir Screening Tool (FIRST), to assess exposure to pesticides in drinking water. Using a few basic chemical parameters (*e.g.,* half-life in soil) and pesticide label application information, FIRST estimates peak values (acute) and long-term (chronic) average concentrations of pesticides in water. Like GENEEC, it is based upon the linked PRZM and EXAMS models and is a single-event process. However, it is different from GENEEC in several aspects. As with the Tier II modeling for drinking water, FIRST uses an *Index Reservoir* (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/development-and-use-index-reservoir-drinking-water*) watershed based on the Shipman City Lake in Illinois.

FIRST also uses Percent Cropped Area (PCA) factors, which consider the percentage of the watershed that is cropped rather than assuming that the whole watershed is cropped. The program automatically adjusts the output in accordance with the user-specified maximum percent of crop area in any watershed. For more information, see the *FIRST User's Manual* (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/first-version-10-users-manual*) and Model Description.

Surface Water Concentration Calculator

Currently, OPP uses the Surface Water Concentration Calculator (SWCC) for higher level, refined (Tier II) estimations of pesticide concentrations in surface

waters for drinking water and aquatic exposure assessments. The SWCC is designed to simulate the environmental concentration of a pesticide in the water column and sediment and is used for regulatory purposes by the EPA's Office of Pesticide Programs (OPP). The SWCC uses the Pesticide Root Zone Model (PRZM) version 5.0+ (PRZM5) and the Variable Volume Water Body Model (VVWM), replacing the older PE5 shell (last updated November 2006), which used PRZM3 (Carousel, *et al.,* 2005) and EXAMS (Burns, 2004). This updated model was designed to improve users' interactions with the program and facilitate maintenance and operation of the software.

For aquatic assessments, the SWCC uses the standard pond scenario, and for drinking water assessments, the SWCC uses the index reservoir/percent crop area factors.

PRZM5 is a process or "simulation" model that calculates what happens to a pesticide in a farmer's field on a day-to-day basis. It considers factors such as rainfall and evapotranspiration as well as how and when the pesticide is applied. It has two major components: hydrology and chemical transport. The hydrologic component for calculating runoff and erosion of soil is based on the Soil Conservation Service curve number technique and the Universal Soil Loss Equation (NRCS, 2003; Wischmeier and Smith, 1978).

Evapotranspiration of water is estimated from pan evaporation data. Total evapotranspiration of water includes evaporation from crop interception, evaporation from soil, and transpiration by the crop. Water movement is simulated by the use of generalized soil parameters, including field capacity, wilting point, and curve number. The chemical transport component simulates pesticide application on the soil or on the plant foliage. Dissolved, sorbed, and vapor-phase concentrations in the soil are estimated by considering surface runoff, erosion, degradation, volatilization, foliar washoff, advection, dispersion, retardation, among others.

Each PRZM5 modeling scenario represents a unique combination of climatic conditions, crop specific management practices, soil specific properties, site specific hydrology, and pesticide specific application and dissipation processes. Each simulation is conducted using multiple years of rainfall data to cover year-to-year variability in runoff. Daily edge-of-field loadings of pesticides dissolved in runoff waters and sorbed to sediment, as predicted by PRZM5, are discharged into a standard water body (either the standard pond or the Index Reservoir) simulated by the VVWM model. *Additional information about the PRZM5 model can be found on our models page (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment).*

The VVWM simulates the processes that occur in the water body by using the runoff and spray drift loading generated by PRZM5 to estimate the fate, persistence, and concentration of a pesticide in a water body on a day-to-day basis. As such, the model accounts for volatilization, sorption, hydrolysis, biodegradation, and photolysis of the pesticide. The VVWM has the ability to vary its volume on a daily scale and to include sediment burial (unlike its predecessor EXAMS) although these feature are only used for higher tiered assessments.

Multiple year pesticide concentrations in the water column are calculated from the simulations as the annual daily peak, maximum annual 96-hour average, maximum annual 21-day average, maximum annual 60-day average, and annual average. The upper 10th percentile concentrations (except annual average) are compared against ecotoxicological and human health levels of concern (LOC). *For a more detailed description of the parameters, validations and assessments for VVWM, see our information on aquatic models (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment).*

Tier 1 Rice Model

The Tier 1 Rice Model (version 1.0) is used to estimate surface water exposure from the use of pesticides in rice paddies. This screening-level model provides short- and long-term concentrations that can be used for both aquatic ecological risk assessments and drinking water exposure assessments. *Guidance for using the Tier 1 Rice Model can be found on our models page (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment).*

Pesticide in Flooded Application Model (PFAM)

Compared to the Tier 1 Rice Model, PFAM allows for a more advanced estimate of surface water exposure from the use of pesticides in flooded fields such as rice paddies and cranberry bogs. Some of the advanced features incorporated into PFAM include specifications for water and pest management practices, degradation data for soil and aquatic environments and post-processing information of discharged paddy waters to a stream. *Additional information concerning PFAM can be found*

on our models page (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment).

Aquatic Bioaccumulation Model

EPA uses the model KABAM version 1.0 (Kow (based) Aquatic Bioaccumulation Model) to estimate potential bioaccumulation of hydrophobic organic pesticides in freshwater aquatic food webs and subsequent risks to mammals and birds via consumption of contaminated aquatic prey. The model can also be used to estimate pesticide concentrations in fish tissues consumed by humans. KABAM is composed of two parts: (1) a bioaccumulation model estimating pesticide concentrations in aquatic organisms and (2) a risk component that translates exposure and toxicological effects of a pesticide into risk estimates for mammals and birds consuming contaminated aquatic prey. *The users manual and executable file for KABAM can be found on our models page (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment).*

Ground Water Models

SCI–GROW

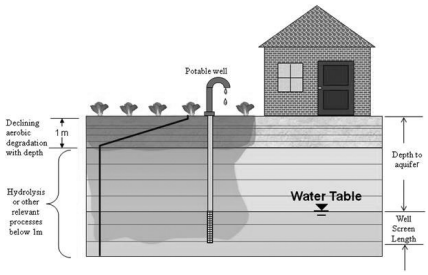
After the passage of the Food Quality Protection Act (FQPA) of 1996, the EPA developed SCI–GROW (Screening Concentration in Groundwater) as a screening-level tool to estimate drinking water exposure concentrations in groundwater resulting from pesticide use (Barrett, 1997). As a screening tool, SCI–GROW provides conservative estimates of pesticides in groundwater, but it does not have the capability to consider variability in leaching potential of different soils, weather (including rainfall), cumulative yearly applications or depth to aquifer. If SCI–GROW-based assessment results indicate that pesticide concentrations in drinking water exceed levels of concern, the ability to refine the assessment is limited. At the present time, SCI–GROW is considered a legacy model for EPA and has been largely replaced by PRZM–GW.

PRZM–GW

In 2004, the EPA and the Pest Management Regulatory Agency (PMRA)—Canada initiated a project to evaluate advanced methods for estimating pesticide concentrations in groundwater. The goals of this project were to identify a common computer model for estimating pesticide concentrations in groundwater and to develop common procedures for determining model input parameters from soil survey data, pesticide environmental fate studies, and pesticide use information. After evaluating 19 modeling programs, EPA and PMRA selected a modified version of PRZM as the North American Free Trade Agreement (NAFTA) regulatory tool for estimating concentrations of pesticides in ground water. Concurrently, EPA consulted with the FIFRA Scientific Advisory Panel (SAP) twice in 2005 on the development of a groundwater conceptual model and the use of PRZM–GW to implement the conceptual model.

Figure 2 depicts the general groundwater scenario concept for estimating pesticide concentrations in drinking water as implemented in PRZM–GW. This conceptual model is based on a rural drinking water well beneath an agricultural field (a high pesticide use area), which draws water from an unconfined, high water-table aquifer.

Figure 2: General Groundwater Scenario Concept for Estimating Pesticide Concentrations in Drinking Water As Implemented in PRZM–GW



The depth of the well is site-specific (*i.e.,* scenario specific). The well extends into a shallow unconfined aquifer and has a well-screen that starts at the top and continues down into the aquifer. The length of the well-screen represents the region of the aquifer where drinking water is collected. The well-screen length is well-spe-

cific and can be adjusted. Processes included in the conceptual model that influence pesticide transport through the soil profile include water flow, chemical specific dissipation and transportation parameters (*i.e.,* degradation and sorption), and crop specific factors, including transpiration, pesticide interception and management practices.

After developing the conceptual model for PRZM–GW, EPA compared its performance in estimating drinking water concentrations of pesticides with targeted and non-targeted groundwater monitoring data. Data from prospective ground water monitoring studies (detailed site investigations of pesticide leaching into vulnerable aquifers) were important in the development and evaluation of the PRZM–GW model. After an extensive evaluation, EPA determined that PRZM–GW was an effective tool for establishing upper bound pesticide concentrations in groundwater for national and site-specific assessments.

Initially, EPA implemented PRZM–GW using a Tier I procedure that involves simulation of 30 to 100 years of pesticide applications at labeled maximum application rates in defined scenarios that represent the most vulnerable types of aquifers utilized as drinking water sources. These studies showed that the primary pesticide-specific inputs affecting PRZM–GW exposure estimates are the application rate and timing, the aerobic soil degradation rate, the linear adsorption coefficient, and the hydrolysis rate. For volatile pesticides such as fumigants, a volatilization routine can also be incorporated in the model run.

After evaluating PRZM–GW as an effective tool for establishing Tier I screening assessments, EPA developed refinement strategies for using PRZM–GW for Tier II groundwater assessments. These refinement strategies can include consideration of representative scenarios, additional fate parameters, annual application retreatment, well setbacks, and representative exposure durations of concern. In the future, OPP may consider additional strategies to facilitate such refinements. For more information, refer to EPA's *Guidance for Using PRZM–GW in Drinking Water Exposure Assessments* (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/przm-gw-version-107-guidance-using-przm-gw-drinking*).

References

Barrett, M. 1997. *Initial Tier Screening of Pesticides for Groundwater Concentration Using the SCI–GROW Model.* U.S. Environmental Protection Agency. Washington, D.C.

Burns, L. 2004. *Exposure Analysis Modeling System (EXAMS)* (*https://www.epa.gov/exposure-assessment-models/exams-version-index*). *User's manual and system documentation.* Ecosystems Research Division. U.S. Environmental Protection Agency. Athens, GA. EPA/600/R–081. September 2000. Revision G.

Carousel, R.F., J.C. Imhoff, P.R. Hummel, J.M. Cheplick, A.S. Donigian, and L.A. Suarez. 2005. U.S. Environmental Protection Agency. Athens, GA. *Pesticide Root Zone Model (PRZM)–3. PRZM: a model for predicting pesticide and nitrogen fate in the crop root and unsaturated soil zones.* 3.12.2 ed.

NRCS, 2003. *National Engineering Handbook Section 4: Hydrology.* Natural Resources Conservation Service, U.S. Department of Agriculture, Washington D.C.

Wischmeier, W.H., and D.D. Smith. 1978. *Predicting rainfall erosion losses—a guide to conservation planning.* AGRICULTURE HANDBOOK 537, U.S. Department of Agriculture, Washington, D.C., USA.

Contact Us (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/forms/contact-us-about-pesticide-science-and*) to ask a question, provide feedback, or report a problem.

[Accessed September 8, 2016]

[ATTACHMENT 7]

[*http://www.ecfr.gov/cgi-bin/text-idx?SID=3f455fd5338126f4f8c99664dbbbe1b2&mc=true&node=ap40.24.127_127.a&rgn=div9*]

e-CFR data is current as of September 2, 2016.

Part 127—NPDES Electronic Reporting

Subpart C—Responsibilities of EPA and States, Tribes, and Territories Authorized to Implement the NPDES Program

Appendix A to Part 127—Minimum Set of NPDES Data

The following two tables identify the minimum set of NPDES data that authorized states, tribes, territories must enter or transfer to EPA's national NPDES data system as well as what NPDES-regulated entities must electronically report to the designated initial recipient (authorized NPDES program or EPA) [see 40 CFR 127.2(b)]. Authorized NPDES programs will be the data provider in the event the regulated entity is covered by a waiver from electronic reporting. Use of these two tables ensures that there is consistent and complete reporting nationwide, and expeditious collection and processing of the data, thereby making it more accurate and timely. Taken together, these data standardizations and the corresponding electronic reporting requirements in 40 CFR parts 3, 122, 123, 124, 125, 127, 403, and 503 are designed to save the NPDES authorized programs considerable resources, make reporting easier for NPDES-regulated entities, streamline permit renewals (as permit writers typically review previous noncompliance events during permit renewal), ensure full exchange of NPDES program data between states and EPA to the public, improve environmental decision-making, and protect human health and the environment.

Authorized NPDES programs may also require NPDES regulated entities to submit more data than what is listed in this appendix. The authorized NPDES program can require NPDES regulated entities to submit these "non-appendix A" data on paper, electronically, or attachments to electronic notices and reports filed in compliance with this part.

Instructions: *Table 1* of this appendix provides the list of data sources and minimum submission frequencies for the ten different NPDES Data Groups. *Table 2* of this appendix provides the data that must be electronically reported for each of these NPDES Data Groups. The use of each data element is determined by identifying the number(s) in the column labeled "NPDES Data Group Number" in *Table 2* and finding the corresponding "NPDES Data Group Number" in *Table 1.* For example, a value of "1" in *Table 2* means that this data element is required in the electronic transmission of data from the NPDES program to EPA (Core NPDES Permitting, Compliance, and Enforcement Data). Likewise, a value of "1 through 10" in *Table 2* means that this data element is required in all ten NPDES data groups. NPDES regulated entities that have no historical record (*e.g.,* "greenfield" facilities) do not need to provide data elements that rely on historical data elements. For the purposes of this appendix, the term 'sewage sludge' [see 40 CFR 503.9(w)] also refers to the material that is commonly referred to as 'biosolids.' EPA does not have a regulatory definition for biosolids but this material is commonly referred to as sewage sludge that is placed on, or applied to the land to use the beneficial properties of the material as a soil amendment, conditioner, or fertilizer. EPA's use of the term 'biosolids' in this appendix is to confirm that information about beneficially used sewage sludge (a.k.a. biosolids) is part of the data collected in this appendix.

Table 1—Data Sources and Regulatory Citations [1]

NPDES Data group No. [2]	NPDES data group	Program area	Data provider	Minimum frequency [3]
1	Core NPDES Permitting, Compliance, and Enforcement Data [40 CFR parts 122, 123, 403, 503]	All NPDES Program Sectors	Authorized NPDES Program	Within 40 days of the completed activity or within 40 days of receipt of a report from a regulated entity [see § 127.23(a)(1)]. However, the frequency associated with any particular permittee may be considerably less [*e.g.*, once every five years for most permit information].
2	General Permit Reports [Notices of Intent to discharge (NOIs); Notices of Termination (NOTs); No Exposure Certifications (NOEs); Low Erosivity Waivers and Other Waivers from Stormwater Controls (LEWs)] [40 CFR 122.26(b)(15), 122.28 and 124.5]	All NPDES Program Sectors	NPDES Permittee	Prior to obtaining coverage under a general permit or consideration for permit exclusion or waiver from permitting, and permit coverage termination. General permits are generally issued once every five years.
3	Discharge Monitoring Reports [40 CFR 122.41(l)(4)]	Most NPDES Program Sectors	NPDES Permittee	At least annual, more frequent submissions may be required by the permit.
4	Sewage Sludge/Biosolids Annual Program Reports [40 CFR part 503]	Sewage Sludge/Biosolids	NPDES Regulated Sewage Sludge/Biosolids Generator and Handler	Annual.
5	Concentrated Animal Feeding Operation (CAFO) Annual Program Reports [40 CFR 122.42(e)(4)]	CAFO	CAFO	Annual.
6	Municipal Separate Storm Sewer System (MS4) Program Reports [40 CFR 122.34(g)(3) and 122.42(c)]	MS4	NPDES Permittee	Year two and year four of permit coverage (Small MS4), Annual (Medium and Large MS4).
7	Pretreatment Program Reports [40 CFR 403.12(i)]	Pretreatment	POTW Pretreatment Control Authority, Approval Authority for SIUs in Municipalities Without Approved Pretreatment Programs	Annual.
8	Significant Industrial User Compliance Reports in Municipalities Without Approved Pretreatment Programs [40 CFR 403.12(e) and (h)]	Pretreatment	Significant Industrial User	Bi-Annual.
9	Sewer Overflow Event Reports [40 CFR 122.41(l)(6) and (7)]	Sewer Overflows	NPDES Permittee	Within 5 days of the time the permittee becomes aware of the sewer overflow event (health or environment endangerment), Monitoring report frequency specific in permit (all other sewer overflow events).
10	CWA section 316(b) Annual Reports [40 CFR part 125, subpart J]	CWA section 316(b)	NPDES Permittee	Annual.

[1] Entities regulated by a NPDES permit will comply with all reporting requirements in their respective NPDES permit.

[2] Use the "NPDES Data Group Number" in this table and the "NPDES Data Group Number" column in Table 2 of this appendix to identify the source of the required data entry. EPA notes that electronic systems may use additional data to facilitate electronic reporting as well as management and reporting of electronic data. For example, NPDES permittees may be required to enter their NPDES permit number ("NPDES ID"—NPDES Data Group 1 and 2) into the applicable electronic reporting system in order to identify their permit and submit a Discharge Monitoring Report (DMR–NPDES Data Group 3). Additionally, NPDES regulated entities may be required to enter and submit data to update or correct erroneous data. For example, NPDES permittees may be required to enter new data regarding the Facility Individual First Name and Last Name (NPDES Data Group 1 and 2) with their DMR submission when there is a facility personnel change.

[3] The applicable reporting frequency is specified in the NPDES permit or control mechanism, which may be more frequent than the minimum frequency specified in this table.

Table 2—Required NPDES Program Data

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Basic Facility Information			
[**Note:** As indicated in the "CWA, Regulatory, or Other Citation" column, some of these data elements apply to Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs and to regulated entities or locations that generate, process, or receive biosolids or sewage sludge.]			
Facility Type of Ownership	The unique code/description identifying the type of facility (*e.g.,* state government, municipal or water district, Federal facility, tribal facility). This data element is used by EPA's national NPDES data system to identify the facility type (*e.g.,* POTW, Non-POTW, and Federal)	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Site Name	The name of the facility	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 122.44(j), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Site Address	The address of the physical facility location	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 122.44(j), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Site City	The name of the city, town, village, or other locality, when identifiable, within which the boundaries (the majority of) the facility site is located. This is not always the same as the city used for USPS mail delivery	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 122.44(j), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Site State	The U.S. Postal Service (USPS) abbreviation for the state or state equivalent for the U.S. where the facility is located	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 122.44(j), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Site Zip Code	The combination of the 5-digit Zone Improvement Plan (ZIP) code and the 4-digit extension code (if available) where the facility is located. This zip code match the "Facility Site City" or the city used for USPS mail delivery	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 122.44(j), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Site Tribal Land Indicator	The EPA Tribal Internal Identifier for every unit of land trust allotment ("tribal land") within Indian Country (*i.e.,* Federally recognized American Indian and Alaska Native tribal entities). This unique identifier will identify whether the facility is on tribal land and the current name of the American Indian tribe or Alaskan Native entity. This unique identifier is different from the Bureau of Indian Affairs tribal code and does not change when a Tribe changes its name	122.21, 122.21(q), 122.28(b)(2)(ii), 503.18, 503.28, 503.48	1, 2, and 4.
Facility Site Longitude	The measure of the angular distance on a meridian east or west of the prime meridian for the facility. The format for this data element is decimal degrees (*e.g.,* −77.029289) and the WGS84 standard coordinate system. This data element will also be used to describe the two-dimensional area (polygon) regulated by a municipal storm sewer system (MS4) NPDES permit through use of multiple latitude and longitude coordinates. For MS4 the polygon data should provide a reasonable estimate of the MS4 boundaries. This data element can also be system generated when the Facility Site Address, Facility Site City, and Facility Site State data elements can be used to generate accurate longitude and latitude values. (Note: "Post Office Box" addresses and "Rural Route" addresses are generally not geocodable)	122.21, 122.21(q), 122.28(b)(2)(ii), 503.18, 503.28, 503.48	1, 2, and 4.

Facility Site Latitude	The measure of the angular distance on a meridian north or south of the equator for the facility. The format for this data element is decimal degrees (*e.g.,* 38.893829) and the WGS84 standard coordinate system. This data element will also be used to describe the two-dimensional area (polygon) regulated by a municipal storm sewer system (MS4) NPDES permit through use of multiple latitude and longitude coordinates. This data element can also be system generated when the Facility Site Address, Facility Site City, and Facility Site State data elements can be used to generate accurate longitude and latitude values. (Note: "Post Office Box" addresses and "Rural Route" addresses are generally not geocodable)	122.21, 122.21(q), 122.28(b)(2)(ii), 503.18, 503.28, 503.48	1, 2, and 4.
Facility Contact Affiliation Type	The affiliation of the contact with the facility (*e.g.,* "Owner," "Operator," or "Main Contact"). This is a unique code/description that identifies the nature of the individual's affiliation to the facility	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Contact First Name	The given name of an individual affiliated with this facility	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Contact Last Name	The surname of an individual affiliated with this facility	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Contact Title	The title held by an individual in an organization affiliated with this facility	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Contact E-Mail Address	The business e-mail address of the designated individual affiliated with this facility	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Facility Organization Formal Name	The legal name of the person, firm, public organization, or other entity that operates the facility. This name may or may not be the same name as the facility. The operator of the facility is the legal entity that controls the facility's operation rather than the facility or site manager. This data element should not use a colloquial name. This field is optional for MS4 permittees	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.8(f), 403.10, 403.12(i), 503.18, 503.28, 503.48	1, 2, 4, and 7.
Basic Permit Information			
[**Note:** As indicated in the "CWA, Regulatory, or Other Citation" column, some of these data elements also apply to Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs and to regulated entities or locations that generate, process, or receive biosolids or sewage sludge.]			
NPDES ID	This is the unique identifier for the NPDES permit or control mechanism for NPDES regulated entities or Unpermitted ID for an unpermitted facility. This data elements is used for compliance monitoring activities, violation determinations, and enforcement actions. This data element also applies to Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where the POTW is the Control Authority	122.2, 122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 122.34(g)(3), 122.41(l)(4)(i), 122.41(l)(6) and (7), 122.41(m)(3), 122.42(c), 122.42(e)(4), 123.26, 123.41(a), 125.96, 125.97(g), 125.98, 125.138(b), 401.14, 403.10, 403.12(e), 403.12(h), 403.12(i), 503.18, 503.28, 503.48	1, 2, 3, 4, 5, 6, 7, 8, 9, 10.
Master General Permit Number	The unique identifier of the master general permit, which is linked to a General Permit Covered Facility. This data element only applies to facilities regulated by a master general permit	122.2, 122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 122.34(g)(3), 122.41(l)(4)(i), 122.41(l)(6) and (7), 122.41(m)(3), 122.42(c), 122.42(e)(4), 123.26, 123.41(a), 403.10, 403.12(e), 403.12(h), 403.12(i), 503.18, 503.28, 503.48	1, 2.
Permit Type	The unique code/description identifying the type of permit [*e.g.,* NPDES Individual Permit, NPDES Master General Permit, General Permit Covered Facility, State Issued Non-NPDES General Permit, Individual IU Permit (Non-NPDES), Individual State Issued Permit (Non-NPDES)]	122.2, 122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.10	1, 2.
Permit Component	This will identify one or more applicable NPDES subprograms (*e.g.,* pretreatment, CAFO, CSO, POTW, biosolids/sewage sludge, stormwater) for the permit record. This field is only required when the permit includes one or more NPDES subprograms	122.2, 122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.10	1, 2.
Permit Issue Date	This is the date the permit was issued. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.46	1.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Permit Effective Date	This is the date on which the permit is effective. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.46, 122.21, 122.21(j)(6), 122.21(q), 403.10	1.
Permit Modification/Amendment Date	This is the date on which the permit was modified or amended. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.62, 122.63, 403.10	1.
Permit Expiration Date	This is the date the permit will expire. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.46, 122.21, 122.21(j)(6), 122.21(q), 403.10	1.
Permit Termination Date	This is the date the permit was terminated. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.64, 403.10	1.
Permit Major/Minor Status Indicator	This code/description identifies the permit status as "Major" or "Nonmajor" (a.k.a. "Minor"). This data element is initially system generated and defaults to "Minor". The most recent permit status is copied when the permit is reissued	122.2	1.
Permit Major/Minor Status Start Date	The date that the permit became its current Major/Minor status. Initially system-generated to match effective date. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.2	1.
Permit Application Total Design Flow	This is the design flow rate that a permitted facility was designed to accommodate, in millions of gallons per day (MGD). This is only required for wastewater treatment plants	122.21, 122.28(b)(2)(ii), 403.10(f)	1, 2.
Permit Application Total Actual Average Flow	This is the annual average daily flow rate that a permitted facility will likely accommodate at the start of its permit term, in MGD. This is only required for wastewater treatment plants	122.21,122.28(b)(2)(ii), 122.41, 403.10(f)	1, 2.
Complete Permit Application/NOI Received Date	This is the date on which the complete application for an individual NPDES permit was received or a complete Notice of Intent (NOI) for coverage under a master general permit was received. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. This data element can be system generated when the complete NOI is electronically received by the NPDES program	122.21, 122.28(b)(2)(ii), 403.10(f)	1.
Permit Application/NOI Received Date	This is the date on which the application for an individual NPDES permit was received or a Notice of Intent (NOI) for coverage under a master general permit was received. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. This data element can be system generated when the NPDES permit application or NOI is electronically received by the NPDES program	122.21, 122.28(b)(2)(ii), 403.10(f)	1.
Permit Status	This is a unique code/description that identifies the permit status (*e.g.,* Effective, Expired, Administratively Continued, Pending, Not Needed, Retired, Denied, and Terminated). This is system generated for all statuses except "Not Needed," which must be user entered	122.21, 122.21(j)(6), 122.21(q), 122.64, 122.46, 403.10(f)	1.
Master General Permit Industrial Category	These are the one or more unique codes/descriptions that identify the one or more industrial categories covered by the master general permit. This field is required for master general permits only	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.10(f)	1.
Permit Issuing Organization Type	This is the type of organization issuing a permit (*e.g.,* County, Federal, Local, Municipal, Regional, State, Tribal)	122.21, 122.21(j)(6), 122.21(q), 123.41, 403.10(f)	1.

DMR Non-Receipt	Turns non-receipt tracking for compliance monitoring submissions [*e.g.,* discharge monitoring reports (DMRs)] "on" or "off" for non-major permits (a.k.a. "minors"). This field is always "on" for major permits. This data element is initially system generated (defaults to "on") and the most recent value is copied when the permit is reissued. . . . This data element will also be used to track non-receipt tracking of periodic compliance monitoring data [40 CFR 403.12(e) and (h)] for Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where EPA or the State is the Control Authority)	123.45, 403.10(f)	1.
DMR Non-Receipt Start Date	This is the date on which the permit's "on" or "off" period for DMR Non-Receipt tracking status began. Initially system-generated to match effective date. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. This data element will also be used to track non-receipt tracking of periodic compliance monitoring data [40 CFR 403.12(e) and (h)] for Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where EPA or the State is the Control Authority)	123.45, 403.10(f)	1.
Reportable Noncompliance Tracking	Turns reportable noncompliance (RNC) tracking "on" or "off" for non-major permits (a.k.a. "minors"). This data element is initially system generated (defaults to "on") and the most recent value is copied when the permit is reissued	123.45, 403.10(f)	1.
Reportable Noncompliance Tracking Start Date	This is the date on which the permit's "on" or "off" period for Reportable Noncompliance Tracking status began. Initially system-generated to match effective date. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.45, 403.10(f)	1.
Applicable Effluent Limitations Guidelines	The applicable effluent limitations guidelines and new source performance standards in the NPDES permit (*e.g.,* part 414—Organic chemicals, plastics, and synthetic fibers point source category). This data element also applies to SIUs and CIUs that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where the POTW is the Control Authority	122.21, 122.21(j)(6), 122.21(q), 122.44, 403.10(f)	1.
Permit Compliance Tracking Status	This is a unique code/description that indicates whether the permit is currently "on" or "off" for compliance tracking purposes. This data element is initially system generated (defaults to "on") and the most recent value is copied when the permit is reissued	122.21, 122.21(j)(6), 122.21(q), 123.45, 403.10(f)	1.
Permit Compliance Tracking Status Start Date	This is the date on which the permit's "on" or "off" period for compliance tracking status began. Initially system-generated to match effective date. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.21, 122.21(j)(6), 122.21(q), 123.45, 403.10(f)	1.
RNC Status (Manual)	The status of reportable noncompliance (RNC) as it was entered by the regulatory authority for the official Quarterly Noncompliance Report (QNCR) or NPDES Noncompliance Report (NNCR). This data element can also be revised by the regulatory authority	122.21, 122.21(j)(6), 122.21(q), 123.45, 403.10(f)	1.
RNC Status (Manual) Year	The year associated with the RNC Status (Manual) being reported. This data element is used for the official Quarterly Noncompliance Report (QNCR) or NPDES Noncompliance Report (NNCR). This data element can also be revised by the regulatory authority	122.21, 122.21(j)(6), 122.21(q), 123.45, 403.10(f)	1.
RNC Status (Manual) Quarter	The quarter associated with the RNC Status (Manual) being reported. This data element is used for the official Quarterly Noncompliance Report (QNCR) or NPDES Noncompliance Report (NNCR). This data element can also be revised by the regulatory authority	122.21, 122.21(j)(6), 122.21(q), 123.45, 403.10(f)	1.
Associated NPDES ID Number	If applicable, the unique identifier for each NPDES Permit that is related to another NPDES Permit. For example, this data element identifies the recipient POTW's NPDES ID for each satellite collection system, the suppliers of biosolids and sewage sludge to a land application site, and the one or more NPDES IDs for other permitted operators at the same construction site or industrial facility. This data element does not apply to municipal storm sewer systems (MS4s) as other data elements create linkages between these entities	122.2, 122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 122.41(l)(4)(i), 122.41(l)(6) and (7), 122.41(m)(3), 122.42(e)(4), 123.26, 123.41(a), 503.18, 503.28, 503.48	1 through 5, 7, 8, and 9.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Associated NPDES ID Number Reason	The unique code/description that identifies the reason for the association between two NPDES IDs (*e.g.*, ETP = Effluent Trade Partner, APR = Associated Permit Record, SIP = Switched To An Individual Permit, SGP = Switched To A General Permit. This data element does not apply to municipal storm sewer systems (MS4s) as other data elements create linkages between these entities	122.2, 122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 122.41(l)(4)(i), 122.41(l)(6) and (7), 122.41(m)(3), 122.42(e)(4), 123.26, 123.41(a), 503.18, 503.28, 503.48	1 through 5, 7, 8, and 9.
Receiving POTW ID	This data element will identify for each Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) the unique identifier of the one or more POTWs receiving the discharge. This includes non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation to the one or more receiving POTWs. This data element only applies to SIUs and CIUs and will link the industrial discharger to the one or more receiving POTWs	122.21, 122.21(j)(6)[,]	1, 2, and 7.
SIC Code	The one or more four-digit Standard Industrial Classification (SIC) codes that represent the economic activities of the facility. This data element also applies to SIUs and CIUs that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where the POTW is the Control Authority. A value of "4952" can be system generated for POTWs and TWTDS	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.10(f), 403.12(e), 403.12(h), 403.12(i), 503.18, 503.28, 503.48	1, 2, and 7.
SIC Code Primary Indicator	This data element will identify the primary economic activity, SIC code, of the facility. This data element is required for electronic data transfer between state and EPA systems. This data element also applies to SIUs and CIUs that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where the POTW is the Control Authority122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.10(f), 403.12(e), 403.12(h), 403.12(i), 503.18, 503.28, 503.48	1, 2, and 7.	
NAICS Code	The six-digit North American Industry Classification System (NAICS) code/description that represents the economic activity of the facility. This field is optional if the "SIC Code" data element is provided for the facility	EPA SIC/NAICS Data Standard, Standard No. EX000022.2, 6 January 2006, Office of Management and Budget, Executive Office of the President, Final Decision on North American Industry Classification System (62 FR 17288), 403.10(f)	1, 2, and 7.
NAICS Code Primary Indicator	This data element will identify the primary economic activity, NAICS code, of the facility. This data element is required for electronic data transfer between state and EPA systems. This field is optional if the "SIC Code" data element is provided for the facility	EPA SIC/NAICS Data Standard, Standard No. EX000022.2, 6 January 2006, Office of Management and Budget, Executive Office of the President, Final Decision on North American Industry Classification System (62 FR 17288), 403.10(f)	1, 2, and 7.
Permittee Mailing Address	The mailing address of the permit holder	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.10(f)	1, 2.
Permittee Organization Formal Name	The legal, formal name of the organization that holds the permit	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.10(f)	1, 2.
Permittee City	The name of the city, town, or village where the mail is delivered for the permit holder	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.10(f)	1, 2.
Permittee State	The U.S. Postal Service abbreviation that represents the state or state equivalent for the U.S. for the permit holder	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.10(f)	1, 2.
Permittee Zip Code	The combination of the 5-digit Zone Improvement Plan (ZIP) code and the 4-digit extension code (if available) that represents the geographic segment that is a sub-unit of the ZIP Code assigned by the U.S. Postal Service to a geographic location for the permit holder	122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 403.10(f)	1, 2.

Residual Designation Determination Code	Under section 402(p)(2)(E) and (6) and 40 CFR 122.26(a)(9)(i)(C) and (D), the authorized NPDES program or the EPA Regional Administrator may specifically designate stormwater discharges as requiring an NPDES permit. In this 'residual designation' process the NPDES permitting authority regulates stormwater discharges based on: (1) Wasteload allocations that are part of "total maximum daily loads" (TMDLs) that address the pollutant(s) of concern in the stormwater discharges [see 40 CFR 122.26(a)(9)(i)(C)]; or (2) the determination that the stormwater discharge, or category of stormwater discharges within a geographic area, contributes to a violation of a water quality standard or is a significant contributor of pollutants to *waters of the United States* [see 40 CFR 122.26(a)(9)(i)(D)]. This data element is the unique code/description that identifies the main basis for this residual designation determination. This data element only applies to stormwater permits	122.26(a)(9)(i)(C) and (D) and CWA section 402(p)	1.
Electronic Reporting Waiver Type	The unique code/description that identifies whether the authorized NPDES program has granted the permittee a waiver from electronic reporting in compliance with this part (1 = temporary waiver; 2 = permanent waiver). This data element should be left blank if the permittee does not have a waiver from electronic reporting in compliance with this part	123.26, 123.41(a) and CWA section 308	1.
Electronic Reporting Waiver Expiration Date	This is the expiration date for a temporary waiver from electronic reporting in compliance with this part. This data element should be left blank if the permittee has a permanent waiver from electronic reporting or if the permittee does not have a waiver from electronic reporting in compliance with this part	123.26, 123.41(a) and CWA section 308	1.
Electronic Submission Type (General Permit Reports)	This is the unique code/description for each general permit report submitted by the facility or entity. Notices, certifications, and waiver requests covered by this data element are listed in *Table 1* in this appendix (*i.e.,* NPDES Data Group 2). This data element describes how each submission was electronically collected or processed by the initial recipient [see §127.2(b)]. For example, these unique codes/descriptions include: (1) NPDES regulated entity submits NPDES program data using an EPA electronic reporting system; (2) NPDES regulated entity submits NPDES program data using an authorized NPDES program electronic reporting system; (3) NPDES regulated entity has temporary waiver from electronic reporting and submits NPDES program data on paper to the authorized NPDES program who then electronically uses manual data entry to electronically process these data; (4) NPDES regulated entity has a permanent waiver from electronic reporting and submits NPDES program data on paper to the authorized NPDES program who then electronically uses manual data entry to electronically process these data; (5) NPDES regulated entity has an episodic waiver from electronic reporting and submits NPDES program data on paper to the authorized NPDES program who then electronically uses manual data entry to electronically process these data; (6) NPDES regulated entity submits NPDES program data on paper in a form that allows the authorized NPDES program to use of automatic identification and data capture technology to electronically process these data; (7) NPDES regulated entity submits NPDES program data using another electronic reporting system (*e.g.,* third-party). This data element can sometimes be system generated (*e.g.,* incorporated into an electronic reporting tool). This data element does not identify the electronic submission type of other reports (NPDES Data Groups = 3 through 10 in *Table 1*), which is tracked by the "Electronic Submission Type (Compliance Monitoring Activity)" data element	123.26, 123.41(a) and CWA section 308	1.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
NPDES Data Group Number	This is the unique code/description that identifies the types of NPDES program data that are required to be reported by the facility. This corresponds to *Table 1* in this appendix (*e.g.,* 3 = Discharge Monitoring Report [40 CFR 122.41(l)(4)]). This data element can be system generated. This data element will record each NPDES Data Group that the facility is required to submit. For example, when a POTW is required to submit a Discharge Monitoring Report, Sewage Sludge/Biosolids Annual Program Report, Pretreatment Program Report, and Sewer Overflow/Bypass Event Report, the values for this data element for this facility will be 3, 4, 7, and 9. The following general permit reports will have the following values for this data element: 2a = Notice of Intent to discharge (NOI); 2b = Notice of Termination (NOT); 2c = No Exposure Certification (NOE); and 2d = Low Erosivity Waiver or Other Waiver from stormwater Controls (LEW)	122.2, 122.21, 122.21(j)(6), 122.21(q), 122.28(b)(2)(ii), 122.34(g)(3), 122.41(l)(4)(i), 122.41(l)(6) and (7), 122.41(m)(3), 122.42(c), 122.42(e)(4), 123.26, 123.41(a), 403.10, 403.12(e), 403.12(h), 403.12(i), 503.18, 503.28, 503.48 and CWA section 308	1.
Narrative Conditions and Permit Schedules Information			
[**Note:** As indicated in the "CWA, Regulatory, or Other Citation" column, these data elements also apply to Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where EPA or the State is the Control Authority].			
Permit Narrative Condition Code	The unique code/description that identifies the type of narrative condition	122.47, 403.10(f)	1.
Permit Narrative Condition Number	This number uniquely identifies a narrative condition and its elements for a permit	122.47, 403.10(f)	1.
Permit Schedule Date	The date on which a permit schedule event is due to be completed and against which compliance will be measured. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.47, 403.10(f)	1.
Permit Schedule Actual Date	The date on which the permittee achieved the schedule event. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.47, 403.10(f)	1.
Required Report Received Date	The date on which the regulatory authority receives a report from the permittee indicating that a scheduled event was completed (*e.g.,* the start of construction) or the date on which the regulatory authority received the required report. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.47, 403.10(f)	1.
Permit Schedule Event Code	The unique code/description indicating the one or more events with which the permittee is scheduled to comply	122.47, 403.10(f)	1.
Permitted Feature Information			
[**Note:** These 'Permitted Feature' data elements are only required to be submitted for permits that require limits or outfall monitoring for stationary point sources. Additionally, as indicated in the "CWA, Regulatory, or Other Citation" column, some of these data elements apply to Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where EPA or the State is the Control Authority].			
Permitted Feature Application Actual Average Flow (MGD)	The average flow that a permitted feature will actually discharge or transmit, in MGD, at the start of its permit term. This data element does not apply to regulated entities that do not discharge (*e.g.,* some biosolids/sewage sludge generators) and entities that only discharge stormwater. This data element may also not apply to some intermittent dischargers	122.21, 122.28(b)(2)(ii), 403.10(f)	1, 2.

Permitted Feature Identifier (Permit)	The identifier assigned for each location at which conditions are being applied (*e.g.,* external outfall). This data element also identifies cooling water intake structures	122.21, 122.28(b)(2)(ii), 403.10(f)	1, 2.
Permitted Feature Type	The code/description that uniquely identifies the type of permitted feature (*e.g.*[,] external outfall, sum, intake structure, cooling water intake structure)	122.21, 122.28(b)(2)(ii), 403.10(f)	1, 2.
Receiving Waterbody Name for Permitted Feature	The name of the waterbody that is or will likely receive the discharge from each permitted feature	122.21, 122.28(b)(2)(ii)	1, 2.
Permitted Feature Longitude	The measure of the angular distance on a meridian east or west of the prime meridian for the permitted feature. The format for this data element is decimal degrees (*e.g.,* −77.029289) and the WGS84 standard coordinate system	122.21, 122.28(b)(2)(ii)	1, 2.
Permitted Feature Latitude	The measure of the angular distance on a meridian north or south of the equator for the permitted feature. The format for this data element is decimal degrees (*e.g.,* 38.893829) and the WGS84 standard coordinate system	122.21, 122.28(b)(2)(ii)	1, 2.
Limit Set Information			
[**Note:** These 'Limit Set' data elements are only required to be submitted for permits that require limits or outfall monitoring for stationary point sources. Additionally, as indicated in the "CWA, Regulatory, or Other Citation" column, these data elements apply to Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where EPA or the State is the Control Authority].			
Limit Set Designator	The alphanumeric field that is used to designate a particular grouping of parameters within a limit set	122.45, 403.10(f)	1.
Limit Set Type	The unique code/description identifying the type of limit set (*e.g.,* scheduled, unscheduled)	122.45, 403.10(f)	1.
Modification Effective Date (Limit Set)	The effective date of the permit modification that updated or created a limit set. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.45, 403.10(f)	1.
Modification Type (Limit Set)	The type of permit modification that updated or created this limit set (*e.g.,* major modification, minor modification, permit authorized change)	122.45, 403.10(f)	1.
Initial Monitoring Date	The date on which monitoring starts for the first monitoring period for the limit set. This date will be blank for unscheduled limit sets. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.45, 403.10(f)	1.
Initial DMR Due Date	The date that the first compliance monitoring submission (*e.g.,* DMR) for the limit set is due to the regulatory authority. This date will be blank for unscheduled limit sets. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. This data element will also be used to track non-receipt tracking of periodic compliance monitoring data [40 CFR 403.12(e) and (h)] for Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where EPA or the State is the Control Authority)	122.45, 403.10(f)	1.
Number of Report Units	The number of months covered in each compliance monitoring period (*e.g.,* monthly = 1, semi-annually = 6, quarterly = 3)	122.45, 403.10(f)	1.
Number of Submission Units	The number of months between compliance monitoring submissions (*e.g.,* monthly = 1, semi-annually = 6, quarterly = 3). This data element will be blank for unscheduled limit sets For example, if the permittee was required to submit monthly reports every quarter, the number of report units would be one (*i.e.,* monthly) and the number of submission units would be three (*i.e.,* three months of information in each submission).	122.45, 403.10(f)	1.
Limit Set Status	The status of the limit set (*e.g.,* active, inactive). Limit sets will not have violations generated when a limit set is inactive unless an enforcement action limit is present	subpart C of 122, 403.10(f)	1.
Limit Set Status Start Date	The date that the Limit Set Status started. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.45, 403.10(f)	1.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Limit Information			
[**Note:** These 'Limit' data elements are only required to be submitted for permits that require limits or outfall monitoring for stationary point sources. Additionally, as indicated in the "CWA, Regulatory, or Other Citation" column, some of these data elements apply to Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) that discharge (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) to one or more POTWs in states where EPA or the State is the Control Authority].			
Monitoring Location Code	The unique code/description of the monitoring location at which sampling should occur for a limit parameter	122.45, 403.10(f)	1.
Limit Season Number	Indicates the season of a limit and is used to enter different seasonal limits for the same parameter within a single limit start and end date	122.45, 403.10(f)	1.
Limit Start Date	The date on which a limit starts being in effect for a particular parameter in a limit set. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.45, 403.10(f)	1.
Limit End Date	The date on which a limit stops being in effect for a particular parameter in a limit set. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.45, 403.10(f)	1.
Change of Limit Status Indicator	The unique code/description that describes circumstances affecting limits, such as formal enforcement actions or permit modifications	subpart C of 122, 403.10(f)	1.
Limit Stay Type	The unique identifier of the type of stay applied to a limit (*e.g.,* X, Y, Z), which indicates whether the limits do not appear on the compliance monitoring report (*e.g.,* DMR) at all, are treated as monitor only, or have a stay value in effect during the period of the stay	122.45, 403.10(f)	1.
Limit Stay Start Date	The date on which a limit stay begins. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	124.19, 403.10(f)	1.
Limit Stay End Date	The date on which a limit stay is lifted. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	124.19, 403.10(f)	1.
Reason for Limit Stay	The text that represents the reason a stay was applied to a permit	124.19, 403.10(f)	1.
Stay Limit Value	The numeric limit value imposed during the period of the stay for the limit; if entered, during the stay period, the system will use this limit value for calculating compliance, rather than the actual limit value that was stayed	124.19, 403.10(f)	1.
Limit Type	The unique code/description that indicates whether a limit is an enforceable, or alert limit (*e.g.,* action level, benchmark) that does not receive effluent violations	122.45, 403.10(f)	1.
Enforcement Action ID	The unique identifier for the enforcement action that imposed the enforcement action limit; this data element helps uniquely tie the limit record to the final order record	122.45, 403.10(f)	1.
Final Order ID	The unique identifier for the Final Order that imposed the Enforcement Action limit; this data element ties the limit record to the Final Order record in the database	122.45, 403.10(f)	1.
Modification Effective Date	The effective date of the permit modification that created this limit. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.62, 403.10(f)	1.
Modification Type	The type of permit modification that created this limit (*e.g.,* major, minor, permit authorized change)	122.62, 403.10(f)	1.
Limit Parameter Code	The unique code/description identifying the parameter being limited and/or monitored	122.41(j), 403.10(f)	1.
Limit Months	The months that the limit applies	122.46, 403.10(f)	1.
Limit Value Type	The indication of the limit value type (*e.g.,* Quantity 1, Concentration 2)	122.45(f), 403.10(f)	1.

Limit Quantity or Concentration Units	The unique code/description representing the unit(s) of measure applicable to quantity or concentration limits as entered by the user	122.45(f), 403.10(f)	1.
Statistical Base Code	The unique code/description representing the unit of measure applicable to the limit and compliance monitoring activity (*e.g.,* DMR) values entered by the user (*e.g.,* 30-day average, daily maximum)	122.45(d), 403.10(f)	1.
Optional Monitoring Code	The code/description that indicates when monitoring is optional but not required (*e.g.,* DMR Non-Receipt violation generation will be suppressed for optional monitoring)	122.45, 403.10(f)	1.
Limit Value Qualifier	The unique code identifying the limit value operator (*e.g.,* "<", "=", ">")	122.45, 403.10(f)	1.
Limit Value	The actual limit value number from the Permit or Enforcement Action Final Order	122.45, 403.10(f)	1.
Sewage Sludge/Biosolids Information on NPDES Permit Application or Notice of Intent			
[**Note:** As indicated in the "CWA, Regulatory, or Other Citation" column, these data elements apply to Treatment Works Treating Domestic Sewage whose sewage sludge use or disposal practices are regulated by part 503.]			
Biosolids/Sewage Sludge Management Facility Type	The unique code/description that identifies whether the facility was issued a permit as a biosolids/sewage sludge generator, processor, or end user (*e.g.,* land application site, surface disposal site, incinerator). For the Sewage Sludge/Biosolids Annual Report this data element is also the unique code/description that identifies an off-site facility or location receives biosolids or sewage sludge from this facility. This data element is also required for the Sewage Sludge/Biosolids Annual Report	122.21(q), 122.28(b)(2)(ii), 503.18, 503.28, 503.48	1, 2, and 4.
Biosolids or Sewage Sludge Treatment Processes (Permit)	The one or more unique codes/descriptions that identifies the biosolids or sewage sludge treatment process or processes at the facility. For example, this may include treatment processes in the following categories: preliminary operations (*e.g.,* sludge grinding and degritting), thickening (concentration), stabilization, anaerobic digestion, aerobic digestion, composting, conditioning, disinfection (*e.g.,* beta ray irradiation, gamma ray irradiation, pasteurization), dewatering (*e.g.,* centrifugation, sludge drying beds, sludge lagoons), heat drying, thermal reduction, and methane or biogas capture and recovery	122.21(q)(6), 122.28(b)(2)(ii)	1, 2.
Biosolids or Sewage Sludge Form (Permit)	The one or more unique codes/descriptions that identify the nature of each biosolids and sewage sludge material generated by the facility in terms of whether the material is a biosolid or sewage sludge and whether the material is ultimately conveyed off-site in bulk or in bags. The facility will separately report the form for each biosolids or sewage sludge management practice and pathogen class	122.21(q)(6), 122.28(b)(2)(ii)	1, 2.
Biosolids or Sewage Sludge Management Practice (Permit)	The one or more unique codes/descriptions that identify the type of biosolids or sewage sludge management practice or practices (*e.g.,* land application, surface disposal, incineration) used by the facility. The facility will separately report the practice for each different form of biosolids and sewage sludge generated by the facility and pathogen class	122.21(q)(6), 122.28(b)(2)(ii)	1, 2.
Biosolids or Sewage Sludge Pathogen Class (Permit)	The one or more unique codes/descriptions that identify the pathogen class or classes (*e.g.,* Class A, Class B, Not Applicable) for biosolids or sewage sludge generated by the facility. The facility will separately report the pathogen class for each biosolids or sewage sludge management practice used by the facility and for each biosolids or sewage sludge form	122.21(q)(6), 122.28(b)(2)(ii)	1, 2.
Biosolids or Sewage Sludge Vector Attraction Reduction Options (Permit)	The one or more unique codes/descriptions that identify the option(s) used by the facility for vector attraction reduction. See a listing of these vector attraction reduction options at 40 CFR 503.33(b)(1) through (11). The facility will separately report the vector attraction reduction options for each biosolids or sewage sludge management practice used by the facility and for each biosolids or sewage sludge form as well as by each biosolids or sewage sludge pathogen class	122.21(q)(6), 122.28(b)(2)(ii)	1, 2.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Biosolids or Sewage Sludge Pathogen Reduction Options (Permit)	The one or more unique codes/descriptions that identify the option(s) used by the facility to control pathogens (*e.g.,* Class A—Alternative 1, Class A—Alternative 2, Class A—Alternative 3, Class A—Alternative 4, Class A—Alternative 5, Class A—Alternative 6, Class B—Alternative 1, Class B—Alternative 2, Class B—Alternative 3, or pH Adjustment (Domestic Septage). The facility will separately report the pathogen reduction options for each biosolids or sewage sludge management practice used by the facility and by each biosolids or sewage sludge form as well as by each biosolids or sewage sludge pathogen class	122.21(q)(6), 122.28(b)(2)(ii)	1, 2.
Biosolids or Sewage Sludge Amount (Permit)	This is the amount (in dry metric tons) of biosolids or sewage sludge applied to the land, prepared for sale or give-away in a bag or other container for application to the land, or placed on an active sewage sludge unit in the preceding 365-day period. This identification will be made for each biosolids or sewage sludge management practice used by the facility and by each biosolids or sewage sludge form as well as by each biosolids or sewage sludge pathogen class	122.21 (q), 122.28(b)(2)(ii)	1, 2.
Animal Feeding Operation Information on NPDES Permit Application or Notice of Intent			
Facility CAAP Designation	A unique code (*e.g.,* "Yes", "No") to indicate whether the facility includes Concentrated Aquatic Animal Production (CAAP)	122.21(i)(2), 122.24, 122.25, 122.28(b)(2)(ii)	1, 2.
Facility CAFO Type	The unique code/description that identifies whether the facility includes a small, medium or large Concentrated Animal Feeding Operation (CAFO)	122.21(i)(1), 122.23, 122.28(b)(2)(ii)	1, 2.
CAFO Designation Date	The date on which the facility is designated as a small or medium Concentrated Animal Feeding Operation (CAFO). The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.23	1.
CAFO Designation Reason	The reason(s) the State Director or the Regional Administrator used to designate an animal feeding operation as a small or medium CAFO. [Ed note: Large and medium CAFO definitions are in 40 CFR 122.23(b)]. This text field can include the following factors: (1) the size of the AFO and the amount of wastes reaching *waters of the United States;* (2) the location of the AFO relative to *waters of the United States*; (3) the means of conveyance of animal wastes and process waste waters into *waters of the United States;* (4) the slope, vegetation, rainfall, and other factors affecting the likelihood or frequency of discharge of animal wastes manure and process waste waters into *waters of the United States;* and (5) other relevant factors	122.23(c)	1.
CAFO Animal Types	The unique code/description that identifies the animal type(s) at the facility (*e.g.,* beef cattle, broilers, layers, swine weighing 55 pounds or more, swine weighing less than 55 pounds, mature dairy cows, dairy heifers, veal calves, sheep and lambs, horses, ducks, turkeys, other)	122.21(i)(1)(v), 122.28(b)(2)(ii)	1, 2.
CAFO Animal Maximum Numbers	The estimated maximum number of each type of animal in open confinement or housed under roof (either partially or totally) which are held at the facility for a total of 45 days or more in a 12 month period	122.21(i)(1)(v), 122.28(b)(2)(ii)	1, 2.
CAFO Animal Maximum Numbers in Open Confinement	The estimated maximum number of each type of animal in open confinement which are held at the facility for a total of 45 days or more in a 12 month period	122.21(i)(1)(v), 122.28(b)(2)(ii)	1, 2.
CAFO MLPW	The unique code/description that identifies the type of CAFO manure, litter, and process wastewater generated by the facility *i.e.,* in a 12 month period	122.21(i)(1)(viii), 122.28(b)(2)(ii)	1, 2.

CAFO MLPW Amounts	The estimated amount of CAFO manure, litter, and process wastewater generated by the facility *i.e.,* in a 12 month period	122.21(i)(1)(viii), 122.28(b)(2)(ii)	1, 2.
CAFO MLPW Amounts Units	The unit (*e.g.,* tons, gallons) for the estimated maximum amount of CAFO manure, litter, and process wastewater generated by the facility *i.e.,* in a 12 month period	122.21(i)(1)(viii), 122.28(b)(2)(ii)	1, 2.
CAFO MLPW Transferred	The estimated maximum amount of CAFO manure, litter, and process wastewater generated by the facility *i.e.,* in a 12 month period that is transferred to other persons. The units for this data element will be the same as the units for the "CAFO MLPW Amounts" data element	122.21(i)(1)(ix), 122.28(b)(2)(ii)	1, 2.
Total Number of Acres Available for Land Application	Total number of acres under the control of the applicant that are available for land application of CAFO manure, litter, and process wastewater	122.21(i)(1)(vii), 122.28(b)(2)(ii)	1, 2.
CAFO MLPW Containment and Storage Type	The unique code/description describing the one or more types of CAFO manure, litter, and process wastewater containment and storage (*e.g.,* lagoon, holding pond, evaporation pond, anaerobic lagoon, storage lagoon, evaporation pond, aboveground storage tanks, belowground storage tanks, roofed storage shed, concrete pad, impervious soil pad, other) at the facility	122.21(i)(1)(vi), 122.28(b)(2)(ii)	1, 2.
CAFO MLPW Containment and Storage Maximum Capacity Amounts	The estimated maximum capacity of each CAFO manure, litter, and process wastewater containment and storage type at the facility	122.21(i)(1)(vi), 122.28(b)(2)(ii)	1, 2.
CAFO MLPW Containment and Storage Maximum Capacity Amounts Unit	The unit for the estimated maximum capacity of each CAFO manure, litter, and process wastewater containment and storage type at the facility (*e.g.,* gallons)	122.21(i)(1)(vi), 122.28(b)(2)(ii)	1, 2.
Construction and Industrial Stormwater Information [from the permitting authority derived from the No Exposure Certification, Low Erosivity Waiver, and Other Waiver From Stormwater Controls (see Exhibit 1 to 40 CFR 122.26(b)(15)]			
No Exposure Certification Approval Date	This is the date on which the No Exposure Certification (NOE) was authorized by the NPDES permitting authority. Submission of a No Exposure Certification means that the facility does not require NPDES permit authorization for its stormwater discharges due to the existence of a condition of "no exposure." A condition of no exposure exists at an industrial facility when all industrial materials and activities are protected by a storm resistant shelter to prevent exposure to rain, snow, snowmelt, and/or runoff and the operator complies with all requirements at 40 CFR 122.26(g)(1) through (4). This date is provided by the permitting authority. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.26(g)	1.
Low Erosivity Waiver or Other Waiver From Stormwater Controls Approval Date	The NPDES Stormwater Phase II Rule allows NPDES permitting authorities to accept low erosivity waivers and other waivers from stormwater controls (LEWs) for small construction sites. The waiver process exempts small construction sites (disturbing under five acres) from NPDES permitting requirements when the rainfall erosivity factor is less than five during the period of construction activity as well as other criteria [see Exhibit 1 to 40 CFR 122.26(b)(15)]. This is the date when the NPDES permitting authority granted such waiver, based on information from the entity requesting the waiver; this date is provided by the permitting authority. The date must be provided in YYYY–MM–DD format, where YYYY is the year, MM is the month, and DD is the day	Exhibit 1 to 40 CFR 122.26(b)(15)	1.
Construction Stormwater Information on NPDES Permit Application, Notice of Intent, or Waiver Request [including construction activity requiring permit coverage under 40 CFR 122.26(b)(14)(x)]			
Total Area of the Site	This is an estimate of the total area of the construction site at the time of permit application (in acres). This data element is only required for individual construction stormwater permit applications. Values under 5 acres will be reported to the nearest 1/10 of an acre or nearest 1/4 acre. Authorized NPDES programs will have the discretion to choose whether permittees should report to the nearest 1/10 of an acre or nearest 1/4 acre for values under 5 acres	122.26(c)(1)(ii)(B)	1.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Total Activity Area (Construction)	This is the estimate of the total area of the construction activities at the time of permit application or filing of notice of intent to be covered under a general permit (in acres). Areas of construction activity include areas of clearing, grading, and/or excavation and areas of construction support activity (*e.g.,* concrete or asphalt batch plants, equipment staging yards, material storage areas, excavated materials disposal areas, borrow areas). Values under 5 acres will be reported to the nearest 1/10 of an acre or nearest 1/4 acre. Authorized NPDES programs will have the discretion to choose whether permittees should report to the nearest 1/10 of an acre or nearest 1/4 acre for values under 5 acres	122.26, 122.28(b)(2)(ii)	1, 2.
Post-Construction Total Impervious Area	This is the estimate of total impervious area of the site after the construction addressed in the permit application is completed (in acres). This estimate is made at the time of the permit application. This data element is only required for individual construction stormwater permit applications. Values under 5 acres will be reported to the nearest 1/10 of an acre or nearest 1/4 acre. Authorized NPDES programs will have the discretion to choose whether permittees should report to the nearest 1/10 of an acre or nearest 1/4 acre for values under 5 acres	122.26(c)(1)(ii)(E)	1.
Proposed Stormwater Best Management Practices for Construction Activities	This is the one or more unique codes that list the most important proposed measures, including best management practices, to control pollutants in stormwater discharges from construction activities. This data element includes temporary structural measures (*e.g.,* check dams, construction road stabilization, silt fences), vegetative measures (*e.g.,* mulching, seeding, sodding, straw/hay bale dikes), and permanent structures (*e.g.,* land grading, riprap slope protection, streambank protection). This data element field is only required for individual construction stormwater permit applications	122.26(c)(1)(ii)(C)	1.
Post-Construction Stormwater Best Management Practices for Construction Activities	This is the one or more unique codes that list the most important proposed long-term measures and permanent structures to control pollutants in stormwater discharges, which will occur after the completion of construction operations. The codes for this data element include long-term control measures (*e.g.,* cleaning and removal of debris after major storm events, harvesting vegetation when a 50 percent reduction in the original open water surface area occurs, sediment cleanout, repairing embankments, side slopes, and control structures) and permanent structures (*e.g.,* land grading, riprap slope protection, streambank protection, ponds, wetlands, infiltration basins, sand filters, filter strips). This data element is only required for individual construction stormwater permit applications	122.26(c)(1)(ii)(D)	1.
Soil and Fill Material Description	This is a text field describes the nature of fill material and existing data describing soils or the quality of the discharge. This data element is only required for individual construction stormwater permit applications	122.26(c)(1)(ii)(E)	1.
Runoff Coefficient of the Site (Post-Construction)	This is an estimate of the overall runoff coefficient of the site after the construction addressed in the permit application is completed. This data element is only required for individual construction stormwater permit applications	122.26(c)(1)(ii)(E)	1.
Estimated Construction Project Start Date	The estimated start date for the construction project covered by the NPDES permit. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.26, 122.28(b)(2)(ii)	1, 2.

Estimated Construction Project End Date	The estimated end date for the construction project covered by the NPDES permit. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.26, 122.28(b)(2)(ii)	1, 2.
Industrial Stormwater Information on NPDES Permit Application [excluding construction activity requiring permit coverage under 40 CFR 122.26(b)(14)(x)]			
Total Surface Area Drained (Industrial)	This is an estimate of the total surface area drained at the facility at the time of permit application (in acres). This data field is only required for individual industrial stormwater permit applications. Values under 5 acres will be reported to the nearest 1/10 of an acre or nearest 1/4 acre. Authorized NPDES programs will have the discretion to choose whether permittees should report to the nearest 1/10 of an acre or nearest 1/4 acre for values under 5 acres	122.26(c)(1)(i)(B)	1.
Total Impervious Surface Area (Industrial)	This is the estimate of the total impervious area at the facility at the time of permit application (in acres). This data element is only required for individual industrial stormwater permit applications. Values under 5 acres will be reported to the nearest 1/10 of an acre or nearest 1/4 acre. Authorized NPDES programs will have the discretion to choose whether permittees should report to the nearest 1/10 of an acre or nearest 1/4 acre for values under 5 acres	122.26(c)(1)(i)(B)	1.
Proposed Stormwater Best Management Practices (Industrial)	This is the one or more codes that identify the structural and non-structural control measures (including treatment) to control pollutants in stormwater discharges from industrial activities. This data element includes long-term measures (*e.g.,* good housekeeping of waste-handling and waste-storage areas, collecting debris and yard material, proper management of vehicle wash and equipment maintenance areas) and permanent structures (*e.g.,* covers, pads, diversion berms or channels, vegetative buffer strips, erosion prevention and sediment control such as land grading, riprap slope protection, streambank protection) to control pollutants in stormwater discharges. This data element is only required for individual industrial stormwater permit applications	122.26(c)(1)(i)(B)	1.
Municipal Separate Storm Sewer System (MS4) Information on NPDES Permit Application or Notice of Intent			
MS4 Permit Class	The unique code/description that identifies the size of the MS4 permit holder (*e.g.,* Phase I = large or medium MS4s, Phase II = small MS4s)	122.26, 122.28(b)(2)(ii)	1, 2.
Unique Identifier for Each Municipality Covered Under MS4 Permit	The unique identifier for each municipality covered under MS4 permit. Use of this identifier allows for greater geographic resolution for the MS4 components being tracked. This unique identifier does not change over time. Use of this unique identifier is similar to how the 'Permitted Feature Identifier (Permit)' data element is used to distinguish between permitted features	122.21(f), 122.26(d) 122.28(b)(2)(ii), 122.34(g)(3), and 122.42(c)	1, 2, 6.
MS4 Public Education Program	The one or more unique codes/descriptions that identifies the educational materials the permittee intends to distribute or equivalent outreach activities the permittee will implement to inform the target audience about the impacts of stormwater discharges and the steps the public can take to reduce stormwater pollutants	122.21(f), 122.26(d)(2)(iv)(A)(6), (B)(5) and (6), and (D)(4); 122.28(b)(2)(ii), 122.34(b)(1), 122.34(d)(1)(i)	1, 2.
MS4 Measurable Goals Associated With Public Education Program	The one or more unique codes/descriptions that identifies measurable goals associated with the public education programs including, as appropriate, the months and years in which the permittee will undertake required actions, including interim milestones and the frequency of the action. This data element only applies to Phase II MS4s	122.34(d)(1)(ii), 122.28(b)(2)(ii)	1, 2.
MS4 Public Involvement and Participation Program	The one or more unique codes/descriptions that identifies how the permittee intends to involve the public and at minimum comply with State, Tribal, and local public notice requirements to implement its public involvement and participation program	122.21(f), 122.26(d)(2)(iv), 122.28(b)(2)(ii), 122.34(b)(2), 122.34(d)(1)(i)	1, 2.
MS4 Measurable Goals for the Public Involvement and Participation Program	The one or more unique codes/descriptions that identifies the measurable goals associated with the public involvement and participation program including, as appropriate, the months and years in which the permittee will undertake required actions, including interim milestones and the frequency of the action. This data element only applies to Phase II MS4s	122.28(b)(2)(ii) 122.34(d)(1)(ii)	1, 2.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
MS4 Illicit Discharge Detection and Elimination	The one or more unique codes/descriptions that identify how the permittee will comply with Illicit Discharge Detection and Elimination requirements, including (at a minimum): (1) The status of the permittee's storm sewer system map showing the location of all outfalls and names and locations of all *waters of the U.S.* that receive discharges from those outfalls; (2) the status of the ordinance or other regulatory mechanism to prohibit non-stormwater discharges into the permittee's MS4; (3) the procedures and actions the permittee takes to enforce the prohibition of non-stormwater discharges to the permittee's MS4; (4) the status of the program that identifies the procedures and actions the permittee will take to detect and address non-stormwater discharges, including illegal dumping, to the permittee's MS4; and (5) the status of procedures and actions the permittee will take to inform public employees, businesses and the general public of hazards associated with illegal discharges and improper disposal of waste	122.21(f), 122.26(d)(1)(iii)(B), 122.26(d)(2)(i)(B) and (C), 122.26(d)(2)(iv)(B), 122.28(b)(2)(ii), 122.34(b)(3)(ii)(A)–(D), 122.34(d)(1)(i)	1, 2.
MS4 Measurable Goals Associated With Illicit Discharge Detection and Elimination Program	The one or more unique codes/descriptions that identifies the measurable goals associated with the illicit discharge detection and elimination program, including, as appropriate, the months and years in which the permittee will undertake required actions, including interim milestones and the frequency of the action. This data element only applies to Phase II MS4s	122.34(d)(1)(ii)	1, 2.
MS4 Construction Site Stormwater Runoff Control	The one or more unique codes/descriptions that identify how the permittee will comply with the Construction Site Runoff Control requirements, including (at a minimum): (1) status of the ordinance or other regulatory mechanism to require erosion and sediment controls, including sanctions to ensure compliance; (2) status of requirements for construction site operators to implement appropriate erosion and sediment control BMPs and control waste at the construction site that may cause adverse impacts to water quality; (3) status of procedures for site plan review that incorporate consideration of potential water quality impacts; (4) status of procedures for receipt and consideration of information submitted by the public; and (5) status of procedures for site inspection and enforcement of control measures	122.21(f), 122.26(d)(2)(iv)(D), 122.28(b)(2)(ii), 122.34(b)(4)(ii), 122.34(d)(1)(i)	1, 2.
MS4 Measurable Goals Associated with the Construction Site Stormwater Runoff Control Program	The one or more unique codes/descriptions that identify the measurable goals associated with the construction program, including, as appropriate, the months and years in which the permittee will undertake required actions, including interim milestones and the frequency of the action. This data element only applies to Phase II MS4s	122.34(d)(1)(ii)	1, 2.
MS4 Post-Construction Stormwater Management In New Development And Redevelopment	The one or more unique codes/descriptions that identify how the permittee will comply with the Post-Construction Stormwater Management in New Development and Redevelopment requirements, including (at a minimum): (1) Status of ordinance or other regulatory mechanism to address post-construction runoff from new development and redevelopment projects; (2) how the permittee plans to address stormwater runoff from new development and redevelopment projects that disturb a minimum of greater than or equal to one acre (including if the permittee requires on-site retention of stormwater; and (3) status of a plan to ensure adequate long-term operation and maintenance of BMPs for controlling runoff from new development and redevelopment projects	122.21(f), 122.26(d)(2)(iv)(A)(2), 122.28(b)(2)(ii), 122.34(b)(5), 122.34(d)(1)(i)	1, 2.

MS4 Measurable Goals Associated with the Post-Construction: Stormwater Management Program	The one or more unique codes/descriptions that identify the measurable goals associated with the post-construction program, including, as appropriate, the months and years in which the permittee will undertake required actions, including interim milestones and the frequency of the action. This data element only applies to Phase II MS4s	122.34(d)(1)(ii)	1, 2.
MS4 Pollution Prevention/Good Housekeeping for Municipal Operations Program	The one or more unique codes/descriptions that identify how the permittee will comply with the Pollution Prevention/Good Housekeeping requirements	122.21(f), 122.26(d)(2)(iv)(A)(1), (2) and (3), 122.28(b)(2)(ii), 122.34(b)(6)(i), 122.34(d)(1)(i)	1, 2.
MS4 Additional Measures	The one or more unique codes/descriptions that identify any other additional measures that are required by the permit such as controls to be consistent with the assumptions and requirements of any available wasteload allocation prepared by a state and approved by EPA. This data element is optional if there are no MS4 additional measures	122.28(b)(2)(ii), 122.34(b), 122.34(d) 122.44(d)(1)(vii)(B)	1, 2.
POTW Information on NPDES Permit Application or Notice of Intent			
Name of Collection System	This is the unique name of each collection system that provides flow to the permittee. This includes unincorporated connector districts and satellite collection systems, which are sanitary sewers owned or operated by another entity that conveys sewage or industrial wastewater to this permittee. This data element applies to POTWs	122.1(b) and 122.21(j)(1)(iv), 122.28(b)(2)(ii)	1, 2.
Owner Type of Collection System	The unique code/description that identifies the ownership type for each unique collection system that provides flow to the permittee (*e.g.,* municipality owned, privately owned). This includes unincorporated connector districts and satellite collection systems. This data element applies to POTWs	122.1(b) and 122.21(j)(1)(iv), 122.28(b)(2)(ii)	1, 2.
Collection System Identifier	This is the NPDES permit number ("NPDES ID") for each unique collection system that provides flow to the permittee. If there is no NPDES permit number for the collection system this data element will be a unique identifier for each collection system that provides flow to the permittee. This includes unincorporated connector districts and satellite collection systems. This data element applies to POTWs	122.1(b) and 122.21(j)(1)(iv), 122.28(b)(2)(ii)	1, 2.
Population of Collection System	This is the estimated population for each unique collection system that provides flow to the permittee. This includes unincorporated connector districts and satellite collection systems. This data element applies to POTWs	122.1(b) and 122.21(j)(1)(iv), 122.28(b)(2)(ii)	1, 2.
Percentage of Collection System That Is a Combined Sewer System	For each unique collection system that provides flow to the permittee, this is the estimated percentage of the collection system that is a combined sewer system. This includes unincorporated connector districts and satellite collection systems. This estimated percentage is calculated separately for each unique collection system that provides flow to the permittee and is based on the service population of each unique collection system. This data element applies to POTWs	122.1(b) and 122.21(j)(1)(iv) and (vii), 122.28(b)(2)(ii)	1, 2.
POTW Wastewater Treatment Technology Level Description	This data element describes the level of wastewater treatment technology [*e.g.,* raw discharge (no treatment), primary treatment, secondary wastewater treatment, advanced treatment] used at the facility. This data element only applies to POTWs	122.21(j)(3)(iii), 122.28(b)(2)(ii) and CWA section 516	1, 2.
POTW Wastewater Disinfection Technology	The one or more unique codes/descriptions that describe the types of disinfection technology that are used at the facility (*e.g.,* chlorination, ozonation, ultraviolet disinfection). This data element will also use a code/description to identify if this facility is using dechlorination, which may be required if the facility uses chlorination for disinfection. This data element only applies to POTWs	122.21(j)(3)(iii), 122.28(b)(2)(ii)	1, 2.
POTW Wastewater Treatment Technology Unit Operations	The one or more unique codes/descriptions that describe the wastewater treatment technology unit operations (*e.g.,* grit removal, flow equalization, complete mix activated sludge secondary treatment, trickling filter, facultative lagoon, biological nitrification) used at the facility. This data element is required for POTWs that have a design flow capacity equal to or above 10 million gallons per day (MGD) and is optional for POTWs with a design flow capacity below 10 MGD	122.21(j)(2)(ii)(A), 122.28(b)(2)(ii) and CWA section 516	1, 2.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Combined Sewer Overflow Information			
[**Note:** All Phase II and post-Phase II combined sewer system NPDES permittees are required to complete and implement a long-term CSO control plan (LTCP) as described in EPA's *Combined Sewer Overflow (CSO) Control Policy* (19 April 1994; 59 FEDERAL REGISTER 18688–18698). These data will be updated by the authorized NPDES program on a timely basis as changes occur with the combined sewer system and the LTCP as well as with the POTW's implementation and compliance with the LTCP.]			
Long-Term CSO Control Plan Permit Requirements and Compliance	This data element uses a unique code/description that identifies whether the permit requires the permit holder to complete and implement a LTCP and whether the permit holder is in compliance with these permit requirements	122.41(h), 122.43, 123.41(a) and CWA section 402(q)(1), Combined Sewer Overflow (CSO) Control Policy (59 FR 18688–18698, 19 April 1994)	1.
Nine Minimum CSO Controls Developed	This data element uses a unique code/description to identify by number each of the nine minimum control measures outlines in the CSO Control Policy that the permit holder has implemented in compliance with the applicable permit and/or enforcement mechanism. These unique codes are: (1) Proper operation and regular maintenance programs for the sewer system and the CSOs; (2) Maximum use of the collection system for storage; (3) Review and modification of pretreatment requirements to assure CSO impacts are minimized; (4) Maximization of flow to the publicly owned treatment works for treatment; (5) Prohibition of CSOs during dry weather; (6) Control of solid and floatable materials in CSOs; (7) Pollution prevention; (8) Public notification to ensure that the public receives adequate notification of CSO occurrences and CSO impacts; and (9) Monitoring to effectively characterize CSO impacts and the efficacy of CSO controls. For example, if the permit holder has only developed the "Maximum use of the collection system for storage" minimum control measure then the permitting authority will record "2" for this data element. Likewise, if the permit holder has developed all nine minimum control measures then permitting authority will record 1, 2, 3, 4, 5, 6, 7, 8, and 9 for this data element	122.41(h), 122.43, 123.41(a) and CWA section 402(q)(1), Combined Sewer Overflow (CSO) Control Policy (59 FR 18688–18698, 19 April 1994)	1.
Nine Minimum CSO Controls Implemented	This data element uses a unique code/description to identify by number each of nine minimum control measures outlined in the CSO Control Policy that the permit holder has implemented in compliance with the applicable permit and/or enforcement mechanism. These unique codes are: (1) Proper operation and regular maintenance programs for the sewer system and the CSOs; (2) Maximum use of the collection system for storage; (3) Review and modification of pretreatment requirements to assure CSO impacts are minimized; (4) Maximization of flow to the publicly owned treatment works for treatment; (5) Prohibition of CSOs during dry weather; (6) Control of solid and floatable materials in CSOs; (7) Pollution prevention; (8) Public notification to ensure that the public receives adequate notification of CSO occurrences and CSO impacts; and (9) Monitoring to effectively characterize CSO impacts and the efficacy of CSO controls. For example, if the permit holder has only developed the "Maximum use of the collection system for storage" minimum control measure then the permitting authority will record "2" for this data element. Likewise, if the permit holder has developed all nine minimum control measures then permitting authority will record 1, 2, 3, 4, 5, 6, 7, 8, and 9 for this data element	122.41(h), 122.43, 123.41(a) and CWA section 402(q)(1), Combined Sewer Overflow (CSO) Control Policy (59 FR 18688–18698, 19 April 1994)	1.

LTCP Submission and Approval Type	This data element uses a unique code/description to identify whether the most recent version of the LTCP was received and approved by the permitting authority (*e.g.,* most recent version of the LTCP was submitted by permit holder and was approved by the permitting authority, most recent version of the LTCP was submitted by permit holder but has not yet been approved by permitting authority, permit holder is required to submit a revised LTCP but the permitting authority has not yet received the revised LTCP from the permit holder, permit holder has not yet submitted a LTCP)	122.41(h), 122.43, 123.41(a) and CWA section 402(q)(1), Combined Sewer Overflow (CSO) Control Policy (59 FR 18688–18698, 19 April 1994)	1.
LTCP Approval Date	This data element identifies the date when the permitting authority approved the most current version of the LTCP. This data element will be updated for each revision to the LTCP. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.41(h), 122.43, 123.41(a) and CWA section 402(q)(1), Combined Sewer Overflow (CSO) Control Policy (59 FR 18688–18698, 19 April 1994)	1.
Enforceable Mechanism and Schedule to Complete LTCP and CSO Controls	This data element uses a unique code/description to identify whether the permit holder is on an enforceable schedule to complete all required LTCP and CSO controls and the type of enforcement mechanism	122.41(h), 122.43, 123.41(a) and CWA section 402(q)(1), Combined Sewer Overflow (CSO) Control Policy (59 FR 18688–18698, 19 April 1994)	1.
Actual Date Completed LTCP and CSO Controls	This data element identifies the date by which the permit holder completed construction and implementation of all currently required LTCP and CSO controls. This data element will be updated for each revision to the LTCP and CSO controls. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.41(h), 122.43, 123.41(a) and CWA section 402(q)(1), Combined Sewer Overflow (CSO) Control Policy (59 FR 18688–18698, 19 April 1994)	1.
Approved Post-Construction Compliance Monitoring Program	This data element uses a unique code/description to indicate whether the permit holder is currently implementing an approved post-construction compliance monitoring program	122.41(h), 122.43, 123.41(a) and CWA section 402(q)(1), Combined Sewer Overflow (CSO) Control Policy (59 FR 18688–18698, 19 April 1994)	1.
Other CSO Control Measures with Compliance Schedule	This data element uses a unique code/description to identify whether the permit holder has other CSO control measures specified in a compliance schedule, beyond those identified in the nine minimum controls, long-term CSO control plan (LTCP), or a plan for sewer system separation	122.41(h), 122.43, 123.41(a) and CWA section 402(q)(1), Combined Sewer Overflow (CSO) Control Policy (59 FR 18688–18698, 19 April 1994)	1.

Pretreatment Information on NPDES Permit Application or Notice of Intent (this includes permit application data required for all new and existing POTWs [40 CFR 122.21(j)(6)]

[**Note:** These data will be added or updated through the Annual Pretreatment Program Report, see 40 CFR 403.12(i), as needed. It is also important to note that the 'Associated NPDES ID Number' identifies the receiving POTW's NPDES permit number for each industrial user.]

Pretreatment Program Required Indicator	The unique code/description that describes whether the permitted municipality is required to develop or implement a pretreatment program (in accordance with 40 CFR 403)	122.28(b)(2)(ii), 122.44(j)	1.
Pretreatment Program Approval or Modification Date	The date the pretreatment program was approved or substantially modified. This data element can be system generated by carrying forward the most recent date (approval or modification). The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.28(b)(2)(ii), 403.8(a) and (b), 403.11	1.
Pretreatment Program Modification Type	The unique code describing the type of substantial modification to a POTW Pretreatment Program, which includes the initial start of a pretreatment program	122.28(b)(2)(ii), 403.8(a) and (b), 403.11, 403.18	1.
Industrial User Type	The unique code/description that identifies the type of each industrial user discharging to a POTW [*e.g.,* Significant Industrial User (SIU), Standard Categorical Industrial Users (CIU), Non-Significant Categorical Industrial User (NSCIU), and Middle Tier Categorical Industrial User (MTCIU)]. This data element is at the permit or control mechanism level and is required for each SIU, CIU, NSCIU, and MTCIU. This data element also applies to SIUs and CIUs that discharge non-domestic wastewater by truck, rail, and dedicated pipe or other means of transportation to one or more POTWs	122.21(j)(6), 122.28(b)(2)(ii), 122.44(j), 403.12(i)	1, 2, 7.
Significant Industrial User Subject to Local Limits	The unique code (*e.g.,* "Yes", "No") that identifies for each Significant Industrial User (SIU) or Categorical Industrial User (CIU) discharging to a POTW (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) whether the SIU is subject to local limits	122.21(j)(6), 122.28(b)(2)(ii), 122.44(j), 403.12(i)	1, 2, 7.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Significant Industrial User Subject to Local Limits More Stringent Than Categorical Standards	The unique code (*e.g.,* "Yes", "No") that identifies for each Categorical Industrial User (CIU) discharging to a POTW (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) whether the CIU is subject to one or more local limits that are more stringent than the applicable categorical standards	122.21(j)(6), 122.28(b)(2)(ii), 122.44(j), 403.12(i)	1, 2, 7.
Applicable Categorical Standards	This data element will identify for each Categorical Industrial User (CIU) discharging to a POTW (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) the applicable categorical standard(s) by its 40 CFR part number (*e.g., Metal Finishing*—part 433, *Electrical and Electronic Components*—Part 469). This data element will track the one or more applicable categorical standards even when the CIU is subject to one or more local limits that are more stringent than the applicable categorical standards	122.21(j)(6), 122.28(b)(2)(ii), 122.44(j), 403.12(i)	1, 2, 7.
Significant Industrial User Wastewater Flow Rate	This data element will identify for each Significant Industrial User (SIU) or Categorical Industrial User (CIU) that is discharging to a POTW (including non-domestic wastewater delivered by truck, rail, and dedicated pipe or other means of transportation) the estimated maximum monthly average wastewater flow rate (in gallons per day)	122.21(j)(6), 122.28(b)(2)(ii), 122.44(j)	1, 2.
Industrial User Causing Problems at POTW	The unique code/description that identifies for each Significant Industrial User (SIU) or Categorical Industrial User (CIU) whether it caused or contributed to any problems (including upset, bypass, interference, pass-through) at a POTW within the past four and one-half calendar years. EPA regulations require the Control Authority to develop and enforce local limits when the discharge from an IU causes or contributes to any problems (including upset, interference, and bypass) at the receiving POTW's effluent discharge or biosolids/sewage sludge management. This data element also applies to SIUs and CIUs that discharge non-domestic wastewater by truck, rail, and dedicated pipe or other means of transportation to one or more POTWs	122.21(j)(6), 122.28(b)(2)(ii), 122.44(j)(2)(ii), 403.5(c)	1, 2.
Receiving RCRA Waste	The unique code/description that identifies whether a POTW has received RCRA hazardous waste by truck, rail, or dedicated pipe within the last three calendar years	122.21(j)(7), 122.28(b)(2)(ii), 122.44(j)	1, 2.
Receiving Remediation Waste	The unique code/description that identifies whether the POTW has received RCRA or CERLCA waste from off-site remedial activities within the last three calendar years	122.21(j)(7), 122.44(j)	1, 2.
Control Authority Identifier	This data element identifies the one or more Control Authorities for each Significant Industrial User (SIU) or Categorical Industrial User (CIU). When the Control Authority is a POTW this data element will use the POTW's NPDES ID. There will also be a unique identifier for each state and EPA Region for SIUs and CIUs when they are the Control Authority	122.28(b)(2)(ii), 122.44(j)	1, 2.
Cooling Water Intake Information on NPDES Permit Application or Notice of Intent			
Cooling Water Intake Applicable Subpart	The unique code/description that identifies the regulatory subpart the facility is subject to [*e.g.,* 1 = New Facility under 40 CFR part 125, subpart I, 2 = New Offshore Oil and Gas Facility under 40 CFR part 125, subpart N, 3 = Existing Facility under 40 CFR part 125, subpart J, 4 = BPJ Facility under 40 CFR 125.80(c), 40 CFR 125.90(b), 40 CFR 125.130(c), or 40 CFR 401.14]	122.21(r), 122.28(b)(2)(ii), subparts I, J, and N of 125, 401.14, and CWA section 316(b)	1, 2.

Design Intake Flow for Cooling Water Intake Structure(s)	Design Intake Flow (DIF) means the value, in units of million gallons per day (MGD), assigned to each cooling water intake structure design that corresponds to the maximum instantaneous rate of flow of water the cooling water intake system is capable of withdrawing from a source waterbody. The facility's DIF may be adjusted to reflect permanent changes to the maximum flow capability of the cooling water intake system to withdraw cooling water, including pumps permanently removed from service, flow limit devices, and physical limitations of the piping. DIF does not include values associated with emergency and fire suppression capacity or redundant pumps (*i.e.,* back-up pumps). For new facilities this is the design maximum flow capacity of the cooling water intake structure. See 40 CFR 125.83 and 125.92. This data element will be reported for each cooling water intake structure, which will have a "Permitted Feature ID." Specific monitoring protocols and frequency of monitoring will be determined by the Director	122.21(r), 122.28(b)(2)(ii), 125.80, 125.86, 125.90, 125.92, 125.95, 125.131, 125.136, 401.14, and CWA section 316(b)	1, 2.
Actual Intake Flow for Cooling Water Intake Structure(s)	This actual flow value, in units of MGD, is intended to represent on-the-ground intake flow for each cooling water intake structure at the facility, as opposed to the DIF, which is based on maximum design flow intake. For existing facility, Actual Intake Flow (AIF) means the average flow rate of water withdrawn on an annual basis by each cooling water intake structure over the past three years. After October 14, 2019, AIF means the average flow rate of water withdrawn on an annual basis by each cooling water intake structure over the previous five years. Actual intake flow is measured at a location within the cooling water intake structure that the Director deems appropriate. The calculation of actual intake flow includes days of zero flow. AIF does not include flows associated with emergency and fire suppression capacity. See 40 CFR 125.92. This data element will be reported for each cooling water intake structure, which will have a "Permitted Feature ID." Specific monitoring protocols and frequency of monitoring will be determined by the Director	122.21(r), 122.28(b)(2)(ii), 125.86,125.92(a), 125.95, 125.136, 401.14, and CWA section 316(b)	1, 2.
Location Type for Cooling Water Intake Structure	The unique code/description that identifies the location and description for each cooling water intake structure [*e.g.,* 1 = shoreline intake description (flushed, recessed), 2 = intake canal, 3 = embayment, bank, or cove, 4 = submerged offshore intake, 5 = near-shore submerged intake, 6 = shoreline submerged intake, 7 = Offshore Velocity Cap (800 foot minimum distance from shoreline), 8 = other]. Each cooling water intake structure will have its own "Permitted Feature ID"	122.21(r), 122.28(b)(2)(ii), 125.86, 125.95, 125.136, 401.14 and CWA section 316(b)	1, 2.
Actual Through-Screen Velocity	This is the actual through-screen velocity (in feet/second) of the water intake through the screen for each cooling water intake structure at an existing facility. This is the measured average intake velocity as water passes through the structural components of a screen measured perpendicular to the screen mesh during normal operations. See 40 CFR 125.94. This data element will be reported for each cooling water intake structure, which will have a "Permitted Feature ID." Specific monitoring protocols and frequency of monitoring will be determined by the Director	122.21(r), 122.28(b)(2), 125.86, 125.94, 125.95, 125.136, 401.14 and CWA section 316(b)	1, 2.
Source Water for Cooling Purposes	The unique code/description that describes the one or more source water for cooling purpose for each cooling water intake structure [*e.g.,* 1 = Ocean, 2 = Estuary, 3 = Great Lake, 4 = Fresh River, 5 = Lake/Reservoir, 6 = contract or arrangement with an independent supplier (or multiple suppliers)]. Each cooling water intake structure will have its own "Permitted Feature ID"	122.21(r), 122.28(b)(2)(ii), 125.86, 125.95, 125.136, 401.14 and CWA section 316(b)	1, 2.
Cooling Water Intake Structure Chosen Compliance Method	The unique code/description to indicate the one or more compliance method selected for each cooling water intake structure based on EPA's CWA section 316(b) regulations or based on BPJ. For new facilities for example, Track I, Track II, alternative requirements, *etc.* For existing facilities, which of the 40 CFR 125.94(c) compliance options were chosen and reported as part of 40 CFR 122.21(r)(6), whether the facility has chosen to comply on an intake basis or facility wide, or whether alternative requirements were requested. Facilities have the option to comply on a facility wide or on an intake basis. Each cooling water intake structure will have its own "Permitted Feature ID"	122.21(r)(6), 122.28(b)(2)(ii), 125.84, 125.85, 125.94, 125.134, 125.135, 401.14 and CWA section 316(b)	1, 2.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Source Water Baseline Biological Characterization Data: Threatened or Endangered Status	For new and existing facilities, a unique code/description that identifies whether there are Federally-listed threatened or endangered species (or relevant taxa) that might be susceptible to impingement and entrainment at the facility's cooling water intake structures. This unique code/description will also identify whether designated critical habitat is in the vicinity of facility's cooling water intake structure	122.21(r)(4), 122.28(b)(2), 125.86, 125.95, 125.136, 401.14 and CWA section 316(b)	1, 2.
CWA section 316(a) Thermal Variance Information on NPDES Permit Application or Notice of Intent			
Thermal Variance Request Type	The unique code/description that describes the thermal variance request submitted by the discharger (*e.g.,* 1 = new request, 2 = renewal request)	125, subpart H and CWA section 316(a)	1.
Public Notice of Section 316(a) Requests	This is the unique code that describes whether the NPDES permitting authority included the information required under 40 CFR 124.57(a) in the public notice regarding the CWA section 316(a) request	124.57, 125, subpart H and CWA section 316(a)	1.
Thermal Variance Granted Date	This is the most recent date when the NPDES permitting authority granted or renewed a CWA section 316(a) variance for the controlling NPDES permit. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day122.28(b)(2)(ii), subpart H of 125 and CWA section 316(a)	1.	
Compliance Monitoring Activity Information (General)			
Compliance Monitoring Identifier	The unique identifier for the compliance monitoring activity performed by the authorized NPDES program and EPA (*e.g.,* inspections). This data element can be system generated	123.26, 123.41(a) and CWA section 308	1.
Permitted Feature Identifier (Compliance Monitoring Activity)	The unique identifier for the permitted feature number(s) entered by the user for the inspected or monitored permitted feature(s). This data element will use the same number used by 'Permitted Feature Identifier (Permit)' data element for each compliance monitoring activity permitted feature. This will provide a unique link between each compliance monitoring activity permitted feature and the corresponding NPDES permitted feature. This data element can be left blank if the compliance monitoring activity does not involve a permitted feature. For Sewer Overflow/Bypass Event Reports this data element will identify the permitted feature(s), if any, for each Sewer Overflow/Bypass Identifier. The POTW can leave this data element blank on the Sewer Overflow/Bypass Event Report if the sewer overflows are caused by an extreme weather event (*e.g.,* hurricane) that floods the entire sewer system and are too numerous to count. This data element applies to compliance monitoring activities performed by the authorized NPDES program and EPA (*e.g.,* inspections) as well as compliance monitoring reports submitted by the NPDES regulated entity (*e.g.,* DMRs, program reports)	122.34(g)(3), 122.41(l)(4)(i), 122.41(l)(6) and (7), 122.41(m)(3), 123.26, 123.41(a), 122.42(c), 403.12(e), 403.12(h) and CWA section 308	1, 3, 4, 6, 8, and 9.

Electronic Submission Type (Compliance Monitoring Activity)	This is the unique code/description for each report submitted by the NPDES regulated entity. Report submissions covered by the data element are listed in *Table 1* in this appendix (*i.e.,* NPDES Data Groups 3 through 10). This data element describes how each submission was electronically collected or processed by the initial recipient [see §127.2(b)]. For example, these unique codes/descriptions include: (1) NPDES regulated entity submits NPDES program data using an EPA electronic reporting system; (2) NPDES regulated entity submits NPDES program data using an authorized NPDES program electronic reporting system; (3) NPDES regulated entity has temporary waiver from electronic reporting and submits NPDES program data on paper to the authorized NPDES program who then electronically uses manual data entry to electronically process these data; (4) NPDES regulated entity has a permanent waiver from electronic reporting and submits NPDES program data on paper to the authorized NPDES program who then electronically uses manual data entry to electronically process these data; (5) NPDES regulated entity has an episodic waiver from electronic reporting and submits NPDES program data on paper to the authorized NPDES program who then electronically uses manual data entry to electronically process these data; (6) NPDES regulated entity submits NPDES program data on paper in a form that allows the authorized NPDES program to use of automatic identification and data capture technology to electronically process these data; (7) NPDES regulated entity submits NPDES program data using another electronic reporting system (*e.g.,* third-party). This data element can sometimes be system generated (*e.g.,* incorporated into an electronic reporting tool). This data element does not identify the electronic submission type of general permit reports (NPDES Data Group = 2 in *Table 1*), which is tracked by the "Electronic Submission Type (General Permit Reports)" data element. This data element applies to information submitted by NPDES regulated entities and does not apply to compliance monitoring information generated by authorized NPDES programs and EPA (*e.g.,* inspection data)	123.26, 123.41(a) and CWA section 308	1.
Compliance Monitoring Activity Information (General Data Generated from Authorized NPDES Programs and EPA)			
Compliance Monitoring Activity Actual End Date	The actual date on which the compliance monitoring activity ended. For example, the date of an authorized NPDES program inspection of a facility can be used for this data element. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.26, 123.41(a) and CWA section 308	1.
Compliance Monitoring Activity	The unique code/description that identifies each compliance monitoring activity taken by the authorized NPDES program (*e.g.,* inspection, investigation, information request, offsite records review)	123.26, 123.41(a) and CWA section 308	1.
Compliance Monitoring Type	The unique code/description that identifies each compliance monitoring activity type taken by a regulatory Agency (*e.g.,* audit, biomonitoring, case development, diagnostic, evaluation, reconnaissance with sampling, reconnaissance without sampling, sampling)	123.26, 123.41(a) and CWA section 308	1.
Biomonitoring Test Type	The unique code/description that identifies the type of biomonitoring inspection method (*e.g.,* acute, chronic, or flow through) and sample type (*e.g.,* grab, composite). This data element supplements the Compliance Monitoring Type data element. This data element only applies to compliance monitoring activities that involve biomonitoring	123.26, 123.41(a) and CWA section 308	1.
Compliance Monitoring Action Reason	The unique code/description that identifies the reason for the initiation of the compliance monitoring activity (*e.g.,* Agency Priority, Citizen Complaint/Tip, Core Program)	123.26, 123.41(a) and CWA section 308	1.
Was this a State, Federal or Joint (State/Federal) Inspection?	This data element identifies if the inspection is a joint inspection by [F]ederal, [S]tate, [T]ribal, or territorial personnel. Only one value for this data element may be used for each compliance monitoring activity [*e.g.,* State, Federal, Joint (State/Federal)]	123.26, 123.41(a) and CWA section 308	1.
Programs Evaluated	The unique code/description for the one or more programs evaluated or related to the compliance monitoring activity (*e.g.,* NPDES Base Program, Biosolids/Sewage Sludge, Pretreatment, and MS4)	123.26, 123.41(a) and CWA section 308	1.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Compliance Monitoring Activity Information (Program Data Generated from Authorized NPDES Programs and EPA)			
Deficiencies Identified Through the Biosolids/Sewage Sludge Compliance Monitoring	This is the unique code/description that that identifies each deficiency in the facility's biosolids and sewage sludge program (40 CFR part 503) for each compliance monitoring activity (*e.g.,* inspections, audits) by the regulatory authority. This data element includes unique codes to identify when the facility failed to comply with any applicable permit requirements or enforcement actions. The values for this data element will distinguish between noncompliance and significant noncompliance (SNC)	123.26, 123.41(a), 123.45 and CWA section 308	1.
Deficiencies Identified Through the MS4 Compliance Monitoring	This is the unique code/description that that identifies each deficiency in the MS4's program to control stormwater pollution for each compliance monitoring activity (*e.g.,* inspections, audits) by the regulatory authority. This data element includes unique codes to identify when the MS4 failed to comply with any applicable permit requirements or enforcement actions. The values for this data element will distinguish between noncompliance and significant noncompliance (SNC)	123.26, 123.41(a), 123.45 and CWA section 308	1.
Deficiencies Identified Through the Pretreatment Compliance Monitoring	This is the unique code/description that that identifies each deficiency in the POTW's authorized pretreatment program for each pretreatment compliance monitoring activity (*e.g.,* inspections, audits) by the regulatory authority. The values for this data element will distinguish between noncompliance and significant noncompliance (SNC). These unique codes include: (1) Failure to enforce against pass through and/or interference; (2) failure to submit required reports within 30 days; (3) failure to meet compliance schedule milestones within 90 days; (4) failure to issue/reissue control mechanisms to 90% of SIUs within 6 months; (5) failure to inspect or sample 80% of SIUs within the past 12 months; and (6) failure to enforce standards and reporting requirements	123.26, 123.41(a), 123.45, 403.10, and CWA section 308	1.
Deficiencies Identified Through the Sewer Overflow/Bypass Compliance Monitoring	This is the unique code/description that that identifies each deficiency in the POTW's control of combined sewer overflows, sanitary sewer overflows, or bypass events for each compliance monitoring activity (*e.g.,* inspections, audits) by the regulatory authority. This data element includes unique codes to identify when a POTW has failed to provide 24-hour notification to the NPDES permitting authority or failed to submit the Sewer Overflow/Bypass Event Report within the required 5-day period. This data element also includes unique codes to identify when the POTW failed to comply with any applicable long-term CSO control plan, permit requirements, or enforcement actions. The values for data element will distinguish between noncompliance and significant noncompliance (SNC)	122.41(h), 122.41(l)(6) and (7), 122.43, 123.26, 123.41(a), and CWA sections 308 and 402(q)(1)	1.
Compliance Monitoring Activity Information (AFO/CAFO Program Data Generated from Authorized NPDES Programs and EPA)			
Animal Types (Inspection)	The unique code/description that identifies the animal type(s) at the facility at the time of inspection (*e.g.,* beef cattle, broilers, layers, swine weighing 55 pounds or more, swine weighing less than 55 pounds, mature dairy cows, dairy heifers, veal calves, sheep and lambs, horses, ducks, turkeys, other)	122.23, 123.26, 123.41(a), and CWA section 308	1.
Animal Numbers (Inspection)	The number of each type of animal in open confinement or housed under roof (either partially or totally) which are held at the facility at the time of inspection	122.23, 123.26, 123.41(a) and CWA section 308	1.
Animal Numbers in Open Confinement (Inspection)	The number of each type of animal in open confinement which are held at the facility at the time of inspection	122.23, 123.26, 123.41(a) and CWA section 308	1.

MLPW Containment and Storage Type (Inspection)	The one or more types of containment and storage (*e.g.,* anaerobic lagoon, roofed storage shed, storage ponds, underfloor pits, above ground storage tanks, below ground storage tanks, concrete pad, impervious soil pad, other) at the facility at the time of inspection	122.23, 123.26, 123.41(a) and CWA section 308	1.
MLPW Containment and Storage Type Within Design Capacity (Inspection)	The one or more unique codes/descriptions that identifies whether or not the facility is operating within the design capacity for each type of containment and storage used by the facility for MLPW at the time of inspection	122.23, 123.26, 123.41(a) and CWA section 308	1.
AFO/CAFO Unauthorized Discharges (Inspection)	A unique code (*e.g.,* "Yes", "No") that indicates whether there evidence of unauthorized discharge(s) of pollutants from the facility's production area and/or land application area(s) to a water of the U.S.	122.23, 123.26, 123.41(a) and CWA section 308	1.
Permit Requirements Implementation (Inspection)	The unique code/description that identifies whether or not the facility is properly implementing its NPDES permit requirements, including the applicable Nutrient Management Plan (NMP) or other nutrient management planning, at the time of inspection	122.23, 123.26, 123.41(a) and CWA section 308	1.
Compliance Monitoring Activity Information (Discharge Monitoring Report, and Pretreatment Periodic Compliance Reports for Significant Industrial Users (SIUs) and Categorical Industrial Users (CIUs) when EPA or the State is the Control Authority)			
[**Note:** Authorized NPDES programs will identify in the applicable NPDES permits will identify whether MS4 regulated entities are required to submit DMRs.]			
Limit Set Designator (Compliance Monitoring Activity)	The unique identifier tying the compliance monitoring activity (*e.g.,* DMR submission) to the corresponding Limit Set record	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	3, 6, 8.
Parameter Code (Compliance Monitoring Activity)	The unique code/description identifying the parameter reported on the compliance monitoring activity (*e.g.,* DMR submission)	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	3, 6, 8.
Monitoring Location Code (Compliance Monitoring Activity)	The unique code/description that identifies the monitoring location at which the sampling occurred for a compliance monitoring activity parameter (*e.g.,* DMR submission)	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	3, 6, 8.
Limit Season Number (Compliance Monitoring Activity)	The unique identifier tying the compliance monitoring activity (*e.g.,* DMR submission) to the Limit Season Number of the corresponding limit. This data element is necessary as a parameter can have different seasonal limits within a single limit start and end date	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	3, 6, 8.
Monitoring Period End Date (Compliance Monitoring Activity)	The monitoring period end date for the values covered by the compliance monitoring activity (*e.g.,* DMR submission). The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	3, 6, 8.
No Data Indicator (NODI) (Compliance Monitoring Activity)	The unique code/description that indicates the reason that "No Discharge" or "No Data" was reported on the compliance monitoring activity (*e.g.,* DMR submission) (*e.g.,* B = Below Detection Limit, C = No Discharge)	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	3, 6, 8.
Value (Compliance Monitoring Activity)	The number value reported on the compliance monitoring activity (*e.g.,* DMR form)	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	3, 6, 8.
Quantity or Concentration Units (Compliance Monitoring Activity)	The unique code/description that identifies the one or more units of measure that are applicable to quantity or concentration limits and measurements as entered on the compliance monitoring activity (*e.g.,* DMR submission). This field is optional if the units are the same as the limit units	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	3, 6, 8.
Value Received Date (Compliance Monitoring Activity)	The date the compliance monitoring value was received by the regulatory authority (*e.g.,* DMR submission). The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	1.
Value Type (Compliance Monitoring Activity)	The unique code/description identifying a value type (*e.g.,* Quantity 1, Quantity 2, Concentration 1, Concentration 2, Concentration 3) on a compliance monitoring activity (*e.g.,* DMR submission)	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	3, 6, 8.
Value Qualifier (Compliance Monitoring Activity)	The unique code identifying the qualifier for the reported value (*e.g.,* "<", "=", ">") on a compliance monitoring activity (*e.g.,* DMR submission). This field is optional if the qualifier is "="	122.41(l)(4)(i), 123.26, 123.41(a), 403.12(e), 403.12(h)	3, 6, 8.
Compliance Monitoring Activity Information (Periodic Program Reports)			
Program Report Received Date	The date the program report was received. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	These are data elements that are common to reports required in parts 122, 123, 403, and 503	1.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Program Report Event ID	The unique identifier for each program report submission. This will provide for unique tracking of program report submissions. This data element can be system generated	These are data elements that are common to reports required in parts 122, 123, 403, and 503	1.
Start Date of Reporting Period (Program Report)	The start date of the reporting period for the program report. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. For the Sewer Overflow/Bypass Event Report this is the start or best estimate of the start date for each Sewer Overflow/Bypass Identifier	These are data elements that are common to reports required in parts 122, 123, 403, and 503	4, 5, 6, 7, 9, 10.
End Date of Reporting Period (Program Report)	The end date of the reporting period for the program report. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. For the Sewer Overflow/Bypass Event Report this is the end or best estimate of the end date for each Sewer Overflow/Bypass Identifier	These are data elements that are common to reports required in parts 122, 123, 403, and 503	4, 5, 6, 7, 9, 10.
NPDES Data Group Number (Program Report)	This data element identifies the NPDES Data Group for each program report submission. This corresponds to *Table 1* in this appendix [*e.g.,* 7 = Pretreatment Program Reports [40 CFR 403.12(i)]].This data element also applies to Significant Industrial User Compliance Reports in Municipalities Without Approved Pretreatment Programs [40 CFR 403.12(e) and (h)], which is NPDES Data Group Number 8 (*Table 1* in this appendix). This can be a system generated data element	These are data elements that are common to reports required in parts 122, 123, 403, and 503	4 through 10.
Compliance Monitoring Activity Information (Data Elements Specific to Sewage Sludge/Biosolids Annual Program Reports)			
Biosolids or Sewage Sludge Treatment Processes	The one or more unique codes/descriptions that identify the biosolids or sewage sludge treatment process or processes at the facility. For example, this data element uses codes to identify treatment processes in the following categories: preliminary operations (*e.g.,* sludge grinding and degritting), thickening (concentration), stabilization, anaerobic digestion, aerobic digestion, composting, conditioning, disinfection (*e.g.,* beta ray irradiation, gamma ray irradiation, pasteurization), dewatering (*e.g.,* centrifugation, sludge drying beds, sludge lagoons), heat drying, thermal reduction, and methane or biogas capture and recovery	503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge Analytical Methods	The one or more unique codes/descriptions that identify each of the analytic methods used by the facility to analyze enteric viruses, fecal coliforms, *helminth ova, Salmonella* sp., and other regulated parameters. For example, EPA requires facilities to monitor for the certain parameters, which are listed in *Tables 1, 2, 3,* and *4* at 40 CFR 503. 13 and *Tables 1* and *2* at 40 CFR 503.23. This data element stores each analytic methods used by the facility only once for each annual report (not for each parameter measurement)	503.8(b), 503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge Form	The one or more unique codes/descriptions that identify the nature of each biosolids and sewage sludge material generated by the facility in terms of whether the material is a biosolid or sewage sludge and whether the material is ultimately conveyed off-site in bulk or in bags. The facility will separately report the form for each biosolids or sewage sludge management practice or practices used by the facility and pathogen class	503.18, 503.28, 503.48	4.

Biosolids or Sewage Sludge Management Practice	The one or more unique codes/descriptions that identify the type of biosolids or sewage sludge management practice or practices (*e.g.,* land application, surface disposal, incineration) used by the facility. The facility will separately report the management practice for each biosolids or sewage sludge form and pathogen class. This data element will also identify the management practices used by surface disposal site owners/operators (see 40 CFR 503.24)	503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge Pathogen Class	The one or more unique codes/descriptions that identify the pathogen class or classes [*e.g.,* Class A, Class B, Not Applicable (Incineration)] for biosolids or sewage sludge generated by the facility. The facility will separately report the pathogen class for each biosolids or sewage sludge management practice used by the facility and by each biosolids or sewage sludge form	503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge Amount (Program Report)	This is the amount (in dry metric tons) of biosolids or sewage sludge applied to the land, prepared for sale or give-away in a bag or other container for application to the land, or placed on an active sewage sludge unit. This identification will be made for each biosolids or sewage sludge management practice used by the facility and by each biosolids or sewage sludge form as well as by each biosolids or sewage sludge pathogen class	503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge Pathogen Reduction Options	The one or more unique codes/descriptions that identify the options used by the facility to control pathogens (*e.g.,* Class A—Alternative 1, Class A—Alternative 2, Class A—Alternative 3, Class A—Alternative 4, Class A—Alternative 5, Class A—Alternative 6, Class B—Alternative 1, Class B—Alternative 2, Class B—Alternative 3, or pH Adjustment (Domestic Septage). The facility will separately report the pathogen reduction options for each biosolids or sewage sludge management practice used by the facility and by each biosolids or sewage sludge form as well as by each biosolids or sewage sludge pathogen class	503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge Vector Attraction Reduction Options	The one or more unique codes/descriptions that identify the options used by the facility for vector attraction reduction. See a listing of these vector attraction reduction options at 40 CFR 503.33(b)(1) through (11). The facility will separately report the vector attraction reduction options for each biosolids or sewage sludge management practice used by the facility and by each biosolids or sewage sludge form as well as by each biosolids or sewage sludge pathogen class	503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge Monitored Parameter	This is the biosolids or sewage sludge parameter that is monitored by the facility. If there is more than one class, then the facility will separately report each monitored parameter for each biosolids or sewage sludge management practice used by the facility and by each biosolids or sewage sludge form. EPA requires facilities to monitor for the certain parameters, which are listed in Tables 1, 2, 3, and 4 at 40 CFR 503. 13 and Tables 1 and 2 at 40 CFR 503.23, pathogens (*e.g.,* fecal coliform, *Salmonella* sp., enteric viruses, *helminth ova*), and vector attraction reduction parameters (*e.g.,* specific oxygen uptake rate, and total, fixed, and volatile solids)	503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge Monitored Parameter Value	This is the value of the Biosolids or Sewage Sludge Monitored Parameter	503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge Monitored Parameter Units	This is the measurement unit (*e.g.,* mg/kg) associated with the Biosolids or Sewage Sludge Monitored Parameter Value	503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge Monitored Parameter End Date	This is the end date of the monthly monitoring period for the biosolids or sewage sludge sampling (*e.g.,* 1/31/2015 for biosolids or sewage sludge monitoring data in January 2015). This data element is used to track the frequency of biosolids or sewage sludge monitoring in the reporting period (*e.g.,* annual, quarterly, bi-monthly, or monthly). For example, see *Table 1* of 40 CFR 503.16 (Land Application), *Table 1* of 40 CFR 503.26 (Surface Disposal)	503.18, 503.28, 503.48	4.
Biosolids or Sewage Sludge—Surface Disposal Maximum Allowable Pollutant Concentration	This data element is applicable to facilities that use an active surface disposal sites (*e.g.,* monofills, surface impoundments, lagoons, waste piles, dedicated disposal sites, and dedicated beneficial use sites) without a liner. This data element identifies the maximum allowable pollutant concentration for each of the three pollutants: Arsenic, chromium, and nickel (in units of mg/kg). This data element will use Tables 1 and 2 of 40 CFR 503.23 or the procedures identified in 40 CFR 503.23(b)	503.23, 503.28	4.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Biosolids or Sewage Sludge—Land Application or Surface Disposal Deficiencies	This data element is applicable to facilities that use land application and/or an active surface disposal site (*e.g.,* monofills, surface impoundments, lagoons, waste piles, dedicated disposal sites, and dedicated beneficial use sites). This data element uses one or more unique codes/descriptions to identify all deficiencies in the biosolids or sewage sludge program within the reporting period. For example, this data element uses a unique code/description to identify when a biosolids or sewage sludge pollutant concentration exceed a ceiling concentration (*e.g., Table 1* of 40 CFR 503.13 for facilities utilizing land application). This data element also uses a unique code/description to identify when the facility failed to properly collect and analyze its biosolids or sewage sludge in accordance with the approved analytical methods (including appropriate method holding times). This data element also uses a unique code/description to identify deficiencies with pathogen reduction and/or vector attraction reduction. For facilities that use an active surface disposal site this data element will use a unique code/description to identify any deficiencies in meeting the applicable surface disposal requirements [see 40 CFR 503.24(a) through (n)]	503.18, 503.28	4.
Compliance Monitoring Activity Information (Data Elements Specific to CAFO Annual Program Reports)			
CAFO Animal Types (Program Report)	The unique code/description that identifies the permittee's applicable animal sector(s) in the previous 12 months. This includes (but not limited to) beef cattle, broilers, layers, swine weighing 55 pounds or more, swine weighing less than 55 pounds, mature dairy cows, dairy heifers, veal calves, sheep and lambs, horses, ducks, and turkeys	122.42(e)(4)(i)	5.
CAFO Animal Maximum Number (Program Report)	The estimated maximum number of each type of animal in open confinement or housed under roof (either partially or totally) which are held at the facility for a total of 45 days or more in the previous 12 months	122.42(e)(4)(i)	5.
CAFO Animal Maximum Number in Open Confinement (Program Report)	The estimated maximum number of each type of animal in open confinement which are held at the facility for a total of 45 days or more in the previous 12 months	122.42(e)(4)(i)	5.
CAFO MLPW (Program Report)	The unique code/description that identifies the type of CAFO manure, litter, and process wastewater generated by the facility *i.e.,* in the previous 12 months	122.42(e)(4)(ii)	5.
CAFO MLPW Amounts (Program Report)	The estimated total amount of CAFO manure, litter, and process wastewater generated by the facility in the previous 12 months	122.42(e)(4)(ii)	5.
CAFO MLPW Amounts Units (Program Report)	The unit (*e.g.,* tons, gallons) for the estimated total amount of CAFO manure, litter, and process wastewater generated by the facility *i.e.,* in the previous 12 months	122.42(e)(4)(ii)	5.
CAFO MLPW Transferred (Program Report)	The estimated total amount of CAFO manure, litter, and process wastewater generated by the facility *i.e.,* in the previous 12 months that is transferred to other persons. The units for this data element will be the same as the units for the "CAFO MLPW Amounts (Program Report)" data element	122.42(e)(4)(iii)	5.
Total Number of Acres for Land Application Covered by the Nutrient Management Plan (Program Report)	Total number of acres for land application covered by the current nutrient management plan	122.42(e)(4)(iv)	5.
Total Number of Acres Used for Land Application (Program Report)	The total number of acres under control of the CAFO and used for land application in the previous 12 months	122.42(e)(4)(v)	5.

Discharge Type (Program Report)	The unique code/description that identifies for each discharge from the permittee's production area in the previous 12 month whether a 25-year, 24-hour rainfall event was the cause for the discharge. These data are optional if permittee uses a Discharge Monitoring Report (DMR) to provide the permitting authority with information on their discharges	122.42(e)(4)(vi), 412	5.
Discovery Dates of Discharges from Production Area (Program Report)	The date of each discharge from the permittee's production area in the previous 12 months. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. These data are optional if permittee uses a Discharge Monitoring Report (DMR) to provide the permitting authority with information on their discharges	122.42(e)(4)(vi)	5.
Duration of Discharges from Production Area (Program Report)	The estimated duration time (in hours) of each discharge from the permittee's production area in the previous 12 months. These data are optional if permittee uses a Discharge Monitoring Report (DMR) to provide the permitting authority with information on their discharges	122.42(e)(4)(vi)	5.
Approximate Volume of Discharge from Production Area (Program Report)	The approximate volume (in gallons) of each discharge from the permittee's production area in the previous 12 months. These data are optional if permittee uses a Discharge Monitoring Report (DMR) to provide the permitting authority with information on their discharges	122.42(e)(4)(vi)	5.
Whether NMP Approved or Developed by Certified Planner (Program Report)	The unique code/description that identifies whether the current version of the NMP was approved or developed by a certified nutrient management planner	122.42(e)(4)(vii)	5.
CAFO MLPW Nitrogen Content (Program Report)	The nitrogen content of CAFO manure, litter, and process wastewater used or generated by the facility *i.e.,* in the previous 12 months	122.42(e)(4)(viii)	5.
CAFO MLPW Phosphorus Content (Program Report)	The phosphorus content of CAFO manure, litter, and process wastewater used or generated by the facility *i.e.,* in the previous 12 months	122.42(e)(4)(viii)	5.
CAFO MLPW Nitrogen or Phosphorus Units (Program Report)	The unit(s) (*e.g.,* lbs/tons, lbs/1,000-gallons) for the nitrogen and phosphorus content of CAFO manure, litter, and process wastewater used or generated by the facility *i.e.,* in the previous 12 months	122.42(e)(4)(viii)	5.
CAFO MLPW Nitrogen or Phosphorus Form (Program Report)	The form (*e.g.,* total nitrogen, ammonium-nitrogen, total phosphorus) for the nitrogen and phosphorus content of CAFO manure, litter, and process wastewater used or generated by the facility *i.e.,* in the previous 12 months	122.42(e)(4)(viii)	5.
Field Identification Number (Program Report)	A unique field number to which CAFO MLPW was applied in the previous 12 months. This data element will be used when the term "for each field" is used in the CAFO Annual Program Report	122.42(e)(4)(viii)	5.
Actual Crop(s) Planted for Each Field (Program Report)	Actual crop(s) planted for each field	122.42(e)(4)(viii)	5.
Actual Crop Yield(s) for Each Field (Program Report)	Actual crop yield(s) for each field	122.42(e)(4)(viii)	5.
Actual Crop Yield(s) for Each Field Units (Program Report)	The unit(s) for the actual crop yield(s) for each field (*e.g.,* bushels per acre)	122.42(e)(4)(viii)	5.
Method for Calculating Maximum Amounts of Manure, Litter, and Process Wastewater (Program Report)	The unique code/description that identifies whether the CAFO used the Linear Approach [40 CFR 122.42(e)(5)(i)] or the Narrative Rate Approach [40 CFR 122.42(e)(5)(ii)]	122.42(e)(4)(viii)	5.
CAFO MLPW Land Application For Each Field (Program Report)	The unique code/description that identifies for each field the type of CAFO manure, litter, and process wastewater *i.e.,* in the previous 12 months and used for land application	122.42(e)(4)(viii)	5.
CAFO MLPW Land Application Maximum Amount For Each Field (Program Report)	The maximum amount of CAFO manure, litter, and process wastewater for each field in the previous 12 months and used for land application. The maximum amounts of CAFO manure, litter, and process wastewater is calculated in accordance with procedures in the Linear Approach [40 CFR 122.42(e)(5)(i)(B)] or the Narrative Rate Approach [40 CFR 122.42(e)(5)(ii)(D)]	122.42(e)(4)(viii)	5.
CAFO MLPW Land Application Actual Amount For Each Field (Program Report)	The actual amount of CAFO manure, litter, and process wastewater for each field in the previous 12 months and used for land application	122.42(e)(4)(viii)	5.
CAFO MLPW Land Application For Each Field Unit (Program Report)	The unit (*e.g.,* tons, gallons) for the maximum and actual amount of CAFO manure, litter, and process wastewater for each field in the previous 12 months and used for land application	122.42(e)(4)(viii)	5.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Nitrogen Soil Test Measurement (Narrative Rate Approach) (Program Report)	For each field used for land application, the results of the most recent soil nitrogen analysis for any soil test taken in the preceding 12 months (*i.e.,* amount of nitrogen in the soil). This data element is only applicable to facilities using the Narrative Rate Approach as described in 40 CFR 122.42(e)(5)(ii)	122.42(e)(4)(viii)	5.
Phosphorus Soil Test Measurement (Narrative Rate Approach) (Program Report)	For each field used for land application, the results of the most recent soil phosphorus analysis for any soil test taken in the preceding 12 months (*i.e.,* amount of phosphorus in the soil). This data element is only applicable to facilities using the Narrative Rate Approach as described in 40 CFR 122.42(e)(5)(ii)	122.42(e)(4)(viii)	5.
Soil Test Measurement Form (Narrative Rate Approach) (Program Report)	The form (*e.g.,* total nitrogen, ammonium-nitrogen, total phosphorus) for each soil test measurement. This data element is only applicable to facilities using the Narrative Rate Approach as described in 40 CFR 122.42(e)(5)(ii)	122.42(e)(4)(viii)	5.
Soil Test Measurement Unit(s) (Narrative Rate Approach) (Program Report)	The unit(s) for the amounts of nitrogen and/or phosphorus for any soil test results. This data element is only applicable to facilities using the Narrative Rate Approach, as described in 40 CFR 122.42(e)(5)(ii)	122.42(e)(4)(viii)	5.
Nitrogen Amount of Any Supplemental Fertilizer Applied (Program Report)	For each field used for land application, provide the amount of nitrogen in supplemental fertilizer applied in the previous 12 months. This data element is only applicable to facilities using the Narrative Rate Approach as described in 40 CFR 122.42(e)(5)(ii)	122.42(e)(4)(viii)	5.
Phosphorus Amount of Any Supplemental Fertilizer Applied (Program Report)	For each field used for land application, provide the amount of phosphorus in supplemental fertilizer applied in the previous 12 months. This data element is only applicable to facilities that are using the Narrative Rate Approach as described in 40 CFR 122.42(e)(5)(ii)	122.42(e)(4)(viii)	5.
Supplemental Fertilizer Applied Units (Program Report)	The unit(s) for the amount(s) of nitrogen and/or phosphorus in any supplemental fertilizer applied in the previous 12 months (*e.g.,* ppm, pounds per acre). This data element is only applicable to facilities using the Narrative Rate Approach, as described in 40 CFR 122.42(e)(5)(ii)	122.42(e)(4)(viii)	5.
Compliance Monitoring Activity Information (Data Elements Specific to Municipal Separate Storm Sewer System Program Reports)			
[**Note:** The MS4 permit may require one report for each unique governmental entity or one report per permit].			
MS4 Reliance on Other Government Entities Status	This is a unique code (*e.g.,* "Yes", "No") that identifies whether the permittee relies on another unique governmental entity to satisfy any of the permit requirements	122.26(d)(2)(vii), 122.34(g)(3)(v)	6.
MS4 Reliance on Other Government Entities: Permit Component Status	For each MS4 permit component this data element identifies the responsible government entity. This data element uses the 'Unique Identifier for Each Municipality Covered Under MS4 Permit' data element. Use of this identifier allows for greater geographic resolution for the MS4 components being tracked. This unique identifier does not change over time. The number identifies the entity taking responsibility for complying with each MS4 permit component	122.34(g)(3)(i) and (v), 122.35(a) and 122.42(c)	6.

MS4 Permit Components Descriptions and Measurable Goals	The one or more codes/descriptions that identify for each unique municipality all of the permitted components and measurable goals that are included in the MS4 permit. For Phase II MS4s, these components will be pre-populated from the BMPs each Phase II MS4 permittee indicated it will implement in its NOI or permit application. The groupings of these MS4 components will include public education and outreach on stormwater impacts; public involvement/participation; illicit discharge detection and elimination; construction site stormwater runoff; post-construction stormwater management in new development and redevelopment; and pollution prevention/good housekeeping for municipal operations	122.34(g)(3) and 122.42(c)	6.
Changes to MS4 Permit Components and Measurable Goals	The one or more codes/descriptions that describe for each unique municipality any changes made to MS4 permit components (*e.g.,* BMPs) during the reporting period	122.34(g)(3)(iv) and 122.42(c)	6.
Status of Compliance with each Minimum Control Measure	The unique code (*e.g.,* "Yes", "No") that identifies if the permittee has completed each measureable goal associated with each MS4 permit component	122.34(g)(3) and 122.42(c)	6.
Progress and Summary of Results with Each Minimum Control Measure	This is a text summary describing the permittee's compliance and progress toward meeting each measurable goal including a summary of results for each unique municipality	122.34(g)(3) and 122.42(c)	6.
MS4 Enforcement Action Type	For each unique municipality covered under a Phase I MS4 permit, this data element identifies the one or more types of enforcement actions taken during the past reporting period (*e.g.,* notice of violations, stop work orders, administration orders, administrative fines, civil penalties, criminal actions). The unique municipality covered under the MS4 permit will identify "No Authority" for this data element if the municipality does not have the authority to conduct enforcement actions. This data element is optional for Phase II MS4s	122.34(g)(3) and 122.42(c)	6.
MS4 Enforcement Action Number	For each unique municipality covered under a Phase II MS4 permit and for each MS4 Enforcement Action Type, this data element identifies the number of enforcement actions taken by responsible MS4 Municipal Enforcement Agency. The unique municipality covered under the MS4 permit will identify "No Authority" for this data element if the municipality does not have the authority to conduct enforcement actions. For Phase II MS4s this data element will be the total number of enforcement actions taken during the reporting period	122.34(g)(3) and 122.42(c)	6.
MS4 Municipality Enforcement Agency	For each unique municipality covered under the MS4 permit and for each MS4 Enforcement Action Type, this data element identifies the corresponding MS4 Municipal Enforcement Agency by its unique municipality number ("Unique Identifier for Each Municipality Covered Under MS4 Permit"). This data element is only required for permittees that have co-permittees under their unique MS4 permit	122.34(g)(3) and 122.42(c)	6.
MS4 Industrial Stormwater Control	The one or more unique codes/descriptions that identify how the MS4 permittee will comply with industrial stormwater control requirements, including (at a minimum): (1) Status of the ordinance or other regulatory mechanism to control the contribution of pollutants by stormwater discharges associated with industrial activity, including authority to carry out all inspection, surveillance and monitoring procedures necessary to determine compliance and noncompliance, and including sanctions to ensure compliance; (2) status of the MS4 permittee industrial stormwater inventory, which identifies facilities with industrial activities and assesses the quality of the stormwater discharged from each facility with an industrial activity; (3) status of program to monitor and control pollutants in stormwater discharges from municipal landfills, hazardous waste treatment, disposal and recovery facilities, industrial facilities that are subject to Toxics Release Inventory (TRI) reporting requirements (Emergency Planning and Community Right-To-Know Act Section 313), and industrial facilities that are contributing a substantial pollutant loading to the MS4; and (4) status of monitoring program for discharges associated with industrial facilities. This data element is optional for Phase II MS4s	40 CFR 122.26(d)(2)(i)(A, B, C, E, and F) and 40 CFR 122.26(d)(2)(ii) and (iv)(A)(5) and (iv)(C), 122.42(c)	6.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Compliance Monitoring Activity Information (Data Elements Specific to Pretreatment Program Reports, SIU Periodic Compliance Reports in Municipalities without an Approved Pretreatment Program)			
[**Note:** These data elements do not apply to the development, evaluation, or compliance monitoring activities supporting wastewater surcharge rates.]			
SNC Published	A unique code (*e.g.,* "Yes", "No") that identifies for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial Users (NSCIU) in SNC whether the Control Authority published a public notice within the reporting period	403.8(f)(2)(viii), 403.12(i)(2)	7.
SNC with Pretreatment Enforceable Compliance Schedule Status	The unique code/description that identifies for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) in SNC whether the industrial user in SNC is subject to one or more enforceable compliance schedules within the reporting period	403.8(f)(2)(viii), 403.12(i)(2)	7.
Local Limits Adoption Date	This is the most recent date on which the Control Authority adopted new local limits within the reporting period. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. The Control Authority can leave this data element blank on the Pretreatment Program Report if the Control Authority did not adopt any new local limits within the reporting period	122.44(j)(2)(ii), 403.5(c), 403.8(f)(4) and (5), 403.12(i)(4)	7.
Local Limits Evaluation Date	This is the most recent date on which the Control Authority completed an evaluation on the potential need for local limits within the reporting period. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. The Control Authority can leave this data element blank on the Pretreatment Program Report if the Control Authority did not evaluate any local limits within the reporting period	122.44(j)(2)(ii), 403.5(c), 403.8(f)(4) and (5), 403.12(i)(4), 403.8(f)(4)	7.
Local Limits Pollutants	This is the list of the pollutants for which the Control Authority adopted local limits. The Control Authority will only need to enter each pollutant once no matter how many treatment works are managed by the Control Authority. The Control Authority can leave this data element blank on the Pretreatment Program Reports if the Control Authority did not change the pollutants for which the Control Authority derived local limits	403.5(c), 403.12(i)(4)	7.
POTW Discharge Contamination Indicator (Program Report)	The one or more unique codes/descriptions that identify any problems (*e.g.,* pass-through, interference, violation of NPDES permit limits) with the receiving POTW's effluent discharge within the reporting period. See 40 CFR 403.3(k) and (p). EPA regulations require the Control Authority to develop and enforce local limits when the discharge from an IU causes or contributes to any problems at the receiving POTW	403.8(f), 403.12(i)	7.
POTW Biosolids or Sewage Sludge Contamination Indicator (Program Report)	The one or more unique codes/descriptions that identify any problems (*e.g.,* interference with the use or disposal of biosolids or sewage sludge, violation of NPDES permit requirements or EPA's regulations at 40 CFR part 503) with the receiving POTW's biosolids or sewage sludge within the reporting period. See 40 CFR 403.3(k). EPA regulations require any Control Authority that must develop a Pretreatment Program also to develop and enforce local limits to ensure that the discharge from an IU does not cause or contribute a disruption of biosolids' use or disposal at the receiving POTW	403.8(f), 403.12(i)	7.
Industrial User Control Mechanism Status	A unique code/description that identifies whether the Industrial User is subject to an effective Control Mechanism within the reporting period	403.3(k), 403.5(c), 403.8(f), 403.12(i)	7.

Industrial User Control Mechanism Effective Date	The date when the active Control Mechanism for the Industrial User became effective. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	403.8(f)(1)(iii)(B)(1), 403.12(i)	7.
Industrial User Control Mechanism Expiration Date	The date when the active Control Mechanism for the Industrial User will expire. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	403.8(f), 403.12(i)	7.
SNC With Pretreatment Standards or Limits (Program Report)	This data element will identify for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) whether the IU was in Significant Non-Compliance (SNC) with any pretreatment standard or local limits applicable to the industrial user's discharge within the reporting period	403.8(f), 403.12(i)	7.
SNC With Pretreatment Standards or Limits Pollutants (Program Report)	This data element will identify for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) the pollutants that related to the industrial user's Significant Non-Compliance (SNC) status with any applicable pretreatment standard or local limits within the reporting period	403.8(f), 403.12(i)	7.
SNC With Reporting Requirements (Program Report)	This data element will identify for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) whether the IU was in Significant Non-Compliance (SNC) with reporting requirements (including baseline monitoring reports, notice of potential problems, periodic self-monitoring reports, notice of change in Industrial User discharge, hazardous waste notification and BMP certification) within the reporting period	123.26, 123.41(a), 123.45, 403.8(f), 403.10, 403.12(i)	1, 7.
SNC with Other Control Mechanism Requirements (Program Report)	This data element will identify for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) whether the IU was in Significant Non-Compliance (SNC) with any other control mechanism requirements within the reporting period. This data element does not include instances of SNC that relate to the industrial user's applicable discharge standards or local limits or reporting requirements	123.26, 123.41(a), 123.45, 403.8(f), 403.10, 403.12(i)	1, 7.
Listing of Months in SNC	This data element will identify for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) the month or months the IU is in SNC within the reporting period. These data must be provided in YYYY–MM format where YYYY is the year and MM is the month	123.26, 123.41(a), 123.45, 403.8(f), 403.10, 403.12(i)	1, 7.
Number of Industrial User Inspections by Control Authority	This data element will identify for each Significant Industrial User (SIU) the number of inspections conducted by the Control Authority within the reporting period	403.8(f), 403.12(i)	7.
Number of Industrial User Sampling Events by Control Authority	This data element will identify for each Significant Industrial User (SIU) the number of complete sampling events conducted by the Control Authority within the reporting period	403.8(f), 403.12(i)	7.
Number of Required Industrial User Self-Monitoring Events	This data element will identify for each Significant Industrial User (SIU) the number of required self-monitoring sampling events within the reporting period that must be reported to the Control Authority	403.8(f), 403.12(i)	7.
Actual Number of Industrial User Self-Monitoring Events	This data element will identify for each Significant Industrial User (SIU) the actual number of self-monitoring sampling events within the reporting period submitted to the Control Authority	403.8(f), 403.12(i)	7.
Types of Industrial User Enforcement Action	This data element will identify for each Significant Industrial User (SIU) the type(s) of formal enforcement action(s) (*e.g.*, formal notices of violation or equivalent actions, administrative orders, civil suits, criminal suits) issued by the Control Authority within the reporting period. The Control Authority can also optionally use this data element to track informal actions that they issued within the reporting period	403.8(f), 403.12(i)	7.
Number of Industrial User Enforcement Actions	This data element will identify for each Significant Industrial User (SIU) and for each type of enforcement action the total number of formal enforcement actions issued by the Control Authority within the reporting period. The Control Authority can also optionally use this data element to track informal actions that they issued within the reporting period	403.8(f), 403.12(i)	7.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Industrial User Cash Civil Penalty Amount Assessed	For civil judicial Enforcement Actions, the dollar amount of the penalty assessed against each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) within the reporting period as specified in the final entered Consent Decree or Court Order. For Administrative Enforcement Actions, it is the dollar amount of the penalty assessed in the Consent/Final Order	CWA section 309	7.
Industrial User Cash Civil Penalty Amount Collected	For civil judicial Enforcement Actions, the dollar amount of the penalty collected from each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) within the reporting period. For Administrative Enforcement Actions, it is the dollar amount collected of the penalty assessed in the Consent/Final Order	CWA section 309	7.
Industrial User POTW Discharge Contamination Indicator (Program Report)	The one or more unique codes/descriptions that identify for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) whether the Industrial User caused or contributed to any problems (*e.g.,* pass-through, interference, violation of NPDES permit limits) with the receiving POTW's effluent discharge in the previous reporting period. See 40 CFR 403.3(k) and (p). EPA regulations require the Control Authority to develop and enforce local limits when the discharge from an IU causes or contributes to any problems *e.g.,* at the receiving POTW	123.26, 123.41(a), 123.45, 403.5(c), 403.8(f), 403.10, 403.12(i)	1, 7.
Industrial User Biosolids or Sewage Sludge Contamination Indicator (Program Report)	The one or more unique codes/descriptions that identify for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) whether the Industrial User caused or contributed to any problems (*e.g.,* interference with the use or disposal of biosolids or sewage sludge, violation of NPDES permit requirements or EPA's regulations at 40 CFR part 503) with the receiving POTW's biosolids or sewage sludge in the previous reporting period. See 40 CFR 403.3(k). EPA regulations require the Control Authority to develop and enforce local limits when the discharge from an IU causes or contributes to any problems e.g., at the receiving POTW	123.26, 123.41(a), 123.45, 403.5(c), 403.8(f), 403.10, 403.12(i)	1, 7.
Industrial User Wastewater Flow Rate (Program Report)	This data element will identify for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) the maximum monthly average wastewater flow rate (in gallons per day) in the previous reporting period	403.8(f), 403.12(e), 403.12(h), 403.12(i)	7, 8.
Middle-Tier Significant Industrial User Reduced Reporting Status	The unique code/description that identifies for each Middle-Tier Significant Industrial User (MTSIU) whether the Control Authority has granted reduced reporting requirements in accordance with 40 CFR 403.12(e)(3)	123.26, 123.41(a), 123.45, 403.10, 403.12(e)(3), 403.12(i)(2)	1, 7.
Non-Significant Categorical Industrial User (NSCIU) Certification Submitted to Control Authority	The unique code/description that identifies for each Non-Significant Categorical Industrial User (NSCIU) whether the facility has reported its required annual compliance certification to the Control Authority within the reporting period	123.26, 123.41(a), 123.45, 403.10, 403.12(i)(2), 403.12(q)	1, 7.
Notification of Changed Discharge Submission	The unique code (*e.g.,* "Yes", "No") that identifies for each Significant Industrial User (SIU) and Non-Significant Categorical Industrial User (NSCIU) whether the Industrial User submitted a notification within the reporting period to the Control Authority of a substantial change in the volume or character of pollutants in their discharge, including the listing or characteristic hazardous wastes for which the Industrial User previously submitted notice	403.8(f), 403.12 (i), 403.12(j)	1, 7.

Compliance Monitoring Activity Information (Data Elements Specific to Sewer Overflow/Bypass Event Reports)

[**Note:** These data elements apply to sewer overflows and bypass events at POTWs. These data elements do not apply to industrial facilities. This report uses the 'Permitted Feature Identifier (Compliance Monitoring Activity)' data element to identify the location of each sewer overflow or bypass at a permitted feature. Each bypass location should be permitted and have an identifier in the 'Permitted Feature Identifier (Permit)' data element. This report will also identify the location of each sewer overflow at an unpermitted feature.]

Sewer Overflow/Bypass Identifier	This data element will allow the reporting of multiple sewer overflows or bypasses on one report. Each individualized sewer overflow or bypass will be given a unique identifier (*e.g.,* 1, 2, 3, and so on) for each Sewer Overflow/Bypass Event Report. This field can be system generated to accommodate one or more individual sewer overflows or bypasses. If the sewer overflows are caused by an extreme weather event (*e.g.,* hurricane) that floods the entire sewer system the POTW can use this data element to indicate that the number of sewer overflows cannot be tabulated as they are too numerous to count	122.41(l)(4), (6), and (7) and 122.41(m)(3)	3, 9.
Sewer Overflow Longitude for Unpermitted Feature (Sewer Overflow/Bypass Event Report)	This data element is required for each Sewer Overflow/Bypass Identifier without a corresponding identifier in the 'Permitted Feature Identifier (Permit)' data element, which is reported on the NPDES permit application or Notice of Intent for NPDES permit coverage. This data element is the measure of the angular distance on a meridian east or west of the prime meridian for the sewer overflow location. The format for this data element is decimal degrees (*e.g.,* −77.029289) and the WGS84 standard coordinate system. The 'Permitted Feature Identifier (Compliance Monitoring Activity)' data element is used to identify the location of each sewer overflow at a permitted feature. If the sewer overflow is associated with a private residence the longitude of the nearest collection system structure (*e.g.,* manhole) can be used for this data element to the extent that reporting is required. The POTW can leave this data element blank on the Sewer Overflow/Bypass Event Report if the sewer overflows are caused by an extreme weather event (*e.g.,* hurricane) that floods the entire sewer system and are too numerous to count. This data element can also be system generated if the Sewer Overflow/Bypass Event Report collects the street location of the sewer overflow and the street location can be used to generate an accurate longitude value. (Note: "Post Office Box" addresses and "Rural Route" addresses are generally not geocodable)	122.41(l)(4), (6), and (7)	3, 9.
Sewer Overflow Latitude for Unpermitted Feature (Sewer Overflow/Bypass Event Report)	This data element is required for each Sewer Overflow/Bypass Identifier without a corresponding identifier in the 'Permitted Feature Identifier (Permit)' data element, which is reported on the NPDES permit application or Notice of Intent for NPDES permit coverage. This data element is the measure of the angular distance on a meridian north or south of the equator for the sewer overflow location. The format for this data element is decimal degrees (*e.g.,* −77.029289) and the WGS84 standard coordinate system. The Permitted Feature Identifier (Compliance Monitoring Activity) data element is used to identify the location of each sewer overflow at a permitted feature. If the sewer overflow is associated with a private residence the latitude of the nearest collection system structure (*e.g.,* manhole) can be used for this data element to the extent that reporting is required. The POTW can leave this data element blank on the Sewer Overflow/Bypass Event Report if the sewer overflows are caused by an extreme weather event (*e.g.,* hurricane) that floods the entire sewer system and are too numerous to count. This data element can also be system generated if the Sewer Overflow/Bypass Event Report collects the street location of the sewer overflow and the street location can be used to generate an accurate longitude value. (Note: "Post Office Box" addresses and "Rural Route" addresses are generally not geocodable)	122.41(l)(4), (6), and (7)	3, 9.
Type of Sewer Overflow/Bypass (Sewer Overflow/Bypass Event Report)	A unique code/description that identifies the type of sewer overflow or bypass (*e.g.,* CSO or SSO from the POTW's collection system, anticipated bypass from the treatment works, unanticipated bypass from the treatment works) for each Sewer Overflow/Bypass Identifier. For bypass events the permittee will also use this data element to identify if any NPDES effluent limitations were violated as a result of the bypass	122.41(l)(4), (6), and (7) and 122.41(m)(3)	3, 9.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Type of Sewer Overflow/Bypass Structure	A unique code/description that identifies the type of sewer overflow or bypass structure (*e.g.,* manhole, CSO outfall) for each Sewer Overflow/Bypass Identifier. The POTW can leave this data element blank on the Sewer Overflow/Bypass Event Report if the sewer overflows are caused by an extreme weather event (*e.g.,* hurricane) that floods the entire sewer system and are too numerous to count	122.41(l)(4), (6), and (7) and 122.41(m)(3)	3, 9.
Sewer Overflow/Bypass Cause	The one or more unique codes/descriptions that best represent the likely cause of the sewer overflow or bypass (*e.g.,* broken pipe, fats/oil/grease, mechanical failure, pump station electrical failure, wet weather, vandalism) for each Sewer Overflow/Bypass Identifier.	122.41(l)(4), (6), and (7) and 122.41(m)(3)	3, 9
Duration of Sewer Overflow/Bypass (hours) (Sewer Overflow/Bypass Event Report)	Estimated duration of the sewer overflow or bypass (in hours) for each Sewer Overflow/Bypass Identifier. If the discharge has not been corrected, this is the best professional judgment from the sewer owner or in the case of a bypass, the treatment plant owner, of the time the sewer overflow or bypass is expected to continue. The POTW can leave this data element blank on the Sewer Overflow/Bypass Event Report if the sewer overflows are caused by an extreme weather event (*e.g.,* hurricane) that floods the entire sewer system and are too numerous to count	122.41(l)(4), (6), and (7) and 122.41(m)(3)	3, 9.
Sewer Overflow/Bypass Discharge Volume (gallons) (Sewer Overflow/Bypass Event Report)	Best professional judgment from the sewer owner on the estimated number of gallons of sewer overflow or bypass for each Sewer Overflow/Bypass Identifier. If the discharge has not been corrected, this is the best professional judgment from the sewer owner or in the case of a bypass, the treatment plant owner, of the volume of overflow or bypass prior to cessation. The POTW can leave this data element blank on the Sewer Overflow/Bypass Event Report if the sewer overflows are caused by an extreme weather event (*e.g.,* hurricane) that floods the entire sewer system and are too numerous to count	122.41(l)(4), (6), and (7) and 122.41(m)(3)	3, 9.
Receiving Waterbody Name for Unpermitted Feature (Sewer Overflow/Bypass Event Report)	This data element identifies the receiving waterbody name for each Sewer Overflow/Bypass Identifier that does not have a corresponding value in the 'Permitted Feature Identifier (Permit)' data element. This data element will use the best professional judgment of the sewer owner to identify the name of the waterbody that is or will likely receive the discharge from each Sewer Overflow/Bypass Identifier. The POTW can leave this data element blank on the Sewer Overflow/Bypass Event Report if the sewer overflows are caused by an extreme weather event (*e.g.,* hurricane) that floods the entire sewer system and are too numerous to count	122.41(l)(4), (6), and (7)	3, 9.
Wet Weather Occurrence for Sewer Overflow/Bypass Status	The unique code (*e.g.,* "Yes", "No") that represents the best professional judgment of the sewer owner, or in the case of a bypass, the treatment plant owner, regarding whether the sewer overflow or bypass, by Sewer Overflow/Bypass Identifier, occurred during wet weather	122.41(l)(4), (6), and (7) and 122.41(m)(3)	3, 9.

Corrective Actions Taken or Planned for Sewer Overflow/Bypass (Sewer Overflow/Bypass Event Report)	The unique code/description that describes the steps taken or planned to reduce, eliminate, and prevent reoccurrence of future sewer overflows or bypasses for each Sewer Overflow/Bypass Identifier and the related impacts to health and the environment. This data element can be used to identify the portion of the sewer overflow or bypass that was contained and recovered prior to any discharge to *waters of the U.S.* This data element will also identify if any monitoring of the receiving waterbody was done during and/or after the sewer overflow or bypass to gauge the potential impact to health and the environment. The POTW can leave this data element blank on the Sewer Overflow/Bypass Event Report if the sewer overflows are caused by an extreme weather event (*e.g.,* hurricane) that floods the entire sewer system and are too numerous to count	122.41(l)(4), (6), and (7) and 122.41(m)(3)	3, 9.
Type of Potential Impact of Sewer Overflow/Bypass (Sewer Overflow/Bypass Event Report)	The unique code/description that describes the type of potential health or environmental impact(s) (*e.g.,* beach closure) for each Sewer Overflow/Bypass Identifier. Under 40 CFR 122.41(l)(6), "the permittee shall report any noncompliance which may endanger health or the environment." This data element provides information regarding the nature of such potential endangerment. The POTW can leave this data element blank on the Sewer Overflow/Bypass Event Report if the sewer overflows are caused by an extreme weather event (*e.g.,* hurricane) that floods the entire sewer system and are too numerous to count	122.41(l)(4), (6), and (7) and 122.41(m)(3)	3, 9.
Compliance Monitoring Activity Information (Data Elements Specific to CWA section 316(b) Annual Reports)			
[**Note:** Where the Director requires additional measures to protect Federally-listed threatened or endangered species or critical habitat pursuant to 40 CFR 125.94(g), the Director shall require reporting associated with those measures [see 40 CFR 125.97(g)]. The following data elements correspond to this reporting requirement. These data elements are only required for facilities that are required to report on their additional measures to protect Federally-listed threatened or endangered species or critical habitat.]			
CWA Section 316(b) Biological Monitoring—Species Name (Program Report)	For existing facilities, a listing of each Federally-listed threatened or endangered species (or relevant taxa) for all life stages that might be susceptible to impingement and entrainment at the facility's cooling water intake structure(s). Specific monitoring protocols and frequency of monitoring will be determined by the Director	125.96, 125.97(g), 125.98, 125.138(b), 401.14 and CWA section 316(b)	10.
CWA Section 316(b) Biological Monitoring—Species Number (Program Report)	For existing facilities, the number of each Federally-listed threatened or endangered species (or relevant taxa) that might be susceptible to impingement and entrainment at the facility's cooling water intake structure(s). Specific monitoring protocols and frequency of monitoring will be determined by the Director	125.96, 125.97(g), 125.98, 125.138(b), 401.14 and CWA section 316(b)	10.
CWA Section 316(b) Biological Monitoring—Threatened or Endangered Status (Program Report)	For existing facilities, a unique code/description that identifies for each Federally-listed threatened or endangered species (or relevant taxa) whether the species is threatened, endangered, or is an otherwise protected species that might be susceptible to impingement and entrainment at the facility's cooling water intake structure(s). Specific monitoring protocols and frequency of monitoring will be determined by the Director	125.96, 125.97(g), 125.98, 125.138(b), 401.14 and CWA section 316(b)	10.
CWA Section 316(b) Biological Monitoring—Species Impinged and Entrained (Program Report)	For existing facilities, the number of each Federally-listed threatened or endangered species (or relevant taxa) impinged and entrained per year by the facility's cooling water intake structure(s). Specific monitoring protocols and frequency of monitoring will be determined by the Director	125.96, 125.97(g), 125.98, 125.138(b), 401.14 and CWA section 316(b)	10.
CWA Section 316(b) Biological Monitoring—Applicable Measures to Protect Designated Critical Habitat (Program Report)	For existing facilities, a text summary of the measures taken by the permittee to protect designated critical habitat in the vicinity of impingement and entrainment at the facility's cooling water intake structure(s)	125.96, 125.97(g), 125.98, 125.138(b), 401.14 and CWA section 316(b)	10.
Information Common to Violations, Enforcement Actions, and Final Orders			
[**Note:** Single Event Violation (SEV) data elements are mandatory for construction stormwater inspections that identify CWA violations that result in a regulatory authority taking a formal enforcement action. SEV data elements are optional for other construction stormwater inspections.]			

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Violation Code	The unique code/description that identifies each type of violation that has occurred at the facility (*e.g.,* D80 = Required Monitoring DMR Value Non-Receipt, E90 = Effluent Violation, C20 = Schedule Event Achieved Late). This includes single event violations (SEVs) and violations that are system generated based upon DMRs, schedules, *etc.*	123.45 and CWA section 309	1.
Violation Date	This is the date of the violation, which varies depending on the type of violation. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. This data element may be system generated and does not apply to single event violation dates	123.45 and CWA section 309	1.
Violation Information			
Agency Identifying the Single Event Violation (SEV)	The unique code/description that identifies the agency that identified the single event violation (SEV)	123.26, 123.41(a), 123.45	1.
Single Event Violation Start Date	The date the single event violation (SEV) began. If the SEV occurred on one date, this data element is optional as this date can be system generated to equal "Single Event Violation End Date" when left blank. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.26, 123.41(a), 123.45	1.
Single Event Violation End Date	The date the single event violation (SEV) ended. This field will be left blank to denote an ongoing or unresolved SEV. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.26, 123.41(a), 123.45	1.
RNC Detection Code	The unique code/description that identifies the type of reportable noncompliance (RNC) detected by the regulatory authority	123.26, 123.41(a), 123.45	1.
RNC Detection Date	The date that reportable noncompliance (RNC) was detected. This date may vary according to the type of violation detected. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.26, 123.41(a), 123.45	1.
RNC Resolution Code	The unique code/description that identifies the reportable noncompliance (RNC) status (*e.g.,* noncompliant, resolved pending, waiting resolution, resolved) for each violation. This data element can be entered manually or system generated	123.26, 123.41(a), 123.45	1.
RNC Resolution Date	The date reportable noncompliance (RNC) was marked to its current resolution status. This data element is entered manually. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.26, 123.41(a), 123.45	1.
Enforcement Action Information			
[**Note:** NPDES authorized programs will only need to share criminal action information with EPA when the criminal case is concluded.]			
Enforcement Action Identifier	The unique identifier for each enforcement action. For EPA enforcement actions, this field will be have three components, each separated by a hyphen (*e.g.,* 04–2014–4509). These three components are: (1) the EPA Region responsible for the enforcement action as identified by the EPA Region code (*e.g.,* 04); (2) the four-digit fiscal year during which the enforcement action is initiated (*e.g.,* 2014); and (3) a four-digit, user-assigned sequence number between 0001 and 9999 (*e.g.,* 4509). States will be able to use this same structure, or they will be able to use a different structure of their choosing provided that the first two characters of the identifier constitute the state code (*e.g.,* Alabama = "AL")	123.27, 123.41(a), and CWA section 309	1.

Enforcement Action Forum	This identifies the forum of the formal enforcement action (*e.g.,* administrative formal, judicial). This can be system generated	123.27, 123.41(a), and CWA section 309	1.
Enforcement Action Type	The unique code/description that identifies the type for each formal or informal enforcement action. This code/description identifies, for example, whether the enforcement action is a civil judicial referral, a notice of violation, an administrative penalty order, administrative order, or criminal prosecution	123.27, 123.41(a), and CWA section 309	1.
Programs Violated (Enforcement Action)	The unique code/description that identifies each program (*e.g.,* pretreatment, biosolids/sewage sludge, MS4s, Core NPDES program) associated with each enforcement activity	123.27, 123.41(a), and CWA section 309	1.
Enforcement Action Sub-activity Type	A unique code/description that identifies the type for each sub-activity associated with each enforcement activity (*e.g.,* COMPS = compliance achieved, MECDJ = motion to enforce consent agreement, AHRG = administrative hearing, AMNCA = amended complaint). Some of these sub-activities are system required and some can be system generated. Data on sub-activities that are not milestones are optional	123.27, 123.41(a), and CWA section 309	1.
Enforcement Action Sub-activity Completion Date	The date on which the sub-activity was completed. This data element is required for each sub-activity provided. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day. Some of these dates can be system generated	123.27, 123.41(a), and CWA section 309	1.
Final Order Information			
[**Note:** These data elements are linked to the "Enforcement Action Identifier". NPDES authorized programs will only need to share criminal action information with EPA when the criminal case is concluded.]			
Final Order Identifier	The unique identifier for each final order. This data element can be system generated	123.27, 123.41(a), and CWA section 309	1.
Final Order Type	A unique code that identifies the legal process used by the authorized NPDES program to settle the enforcement action (*e.g.,* administrative compliance order, an administrative penalty order, consent decree, Federal facility agreement, criminal conviction or plea agreement)	123.27, 123.41(a), and CWA section 309	1.
Final Order Issued/Entered Date	For a judicial enforcement action this is the date the Clerk of the Court stamps the document after it is signed by the presiding Judge. For an administrative formal enforcement action this is the date the Final Order was issued. For a criminal enforcement action, this is the date the sentence was imposed. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.27, 123.41(a), and CWA section 309	1.
NPDES Closed Date	The date of closure for each NPDES final order. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.27, 123.41(a), and CWA section 309	1.
Penalty Information			
[**Note:** These data elements are linked to the "Enforcement Action Identifier". NPDES authorized programs will only need to share criminal action information with EPA when the criminal case is concluded.]			
Penalty Amount Assessed	For civil judicial enforcement actions, the dollar amount of the penalty assessed against the defendant(s) as specified in the final entered Consent Decree or Court Order. For administrative enforcement actions, it is the dollar amount of the penalty assessed in the Consent Decree or Final Order. For criminal enforcement actions, it is the dollar amount of the fine agreed to by the defendant or sentenced by the Court and should include fields for prison time, probation, home confinement or monitoring periods, restitution, and special assessments	123.27, 123.41(a), and CWA section 309	1.
Penalty Amount Collected	For civil judicial enforcement actions, the dollar amount of the penalty collected from the defendant(s). For administrative enforcement actions, it is the dollar amount collected of the penalty assessed in the Consent Decree or Final Order. For criminal enforcement actions, it is the dollar amount of the fine paid by the defendant as well as restitution and special assessments	123.27, 123.41(a), and CWA section 309	1.
Supplemental Environmental Project Identifier	The unique identifier for each supplemental environmental project. This data element can be system generated	123.27, 123.41(a), and CWA section 309	1.

Table 2—Required NPDES Program Data—Continued

Data name	Data description	CWA, regulatory (40 CFR), or other citation	NPDES data group No. (*see Table 1*)
Supplemental Environmental Project Amount	The assessed cost, in dollars, of the one or more of the defendant's Supplemental Environmental Projects (SEPs). This is the dollar amount that is assessed either in addition to civil penalties or *in lieu of* civil penalties. This data element is only required if there is a SEP and may be entered at a later date when the data is available	123.27, 123.41(a), and CWA section 309	1.
Supplemental Environmental Project Description	This text field summarizes the Supplemental Environmental Projects (SEPs) that the respondent has completed in response to an enforcement action. This data element is only required if there is a SEP and may be entered at a later date when the data is available	123.27, 123.41(a), and CWA section 309	1.
Compliance Schedule Information			
[**Note:** These data elements are linked to the "Enforcement Action Identifier".]			
Compliance Schedule Number	This number that in combination with the Compliance Schedule Type and NPDES ID uniquely identifies a compliance schedule	123.27, 123.41(a), and CWA section 309	1.
Compliance Schedule Type	The unique code/description that identifies the type of compliance schedule (*e.g.,* an administrative formal action = "A", a judicial action = "J")	123.27, 123.41(a), and CWA section 309	1.
Compliance Schedule Description	The unique code/description that identifies each type of condition or requirement (*e.g.,* best management practices plan development) for the compliance schedule	123.27, 123.41(a), and CWA section 309	1.
Compliance Schedule Event Code	The unique code/description that identifies each event that is added within a compliance schedule	123.27, 123.41(a), and CWA section 309	1.
Compliance Schedule Due Date	The date the compliance schedule event is scheduled to be completed (*i.e.,* the due date). The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.27, 123.41(a), and CWA section 309	1.
Compliance Schedule Actual Date	The actual date on which the compliance schedule event was completed or achieved. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.27, 123.41(a), and CWA section 309	1.
Compliance Schedule Report Received Date	The date the regulatory agency received the report required by the compliance schedule report. The date must be provided in YYYY–MM–DD format where YYYY is the year, MM is the month, and DD is the day	123.27, 123.41(a), and CWA section 309	1.

Notes:

(1) The NPDES program authority may pre-populate these data elements and other data elements (*e.g.,* Federal Registry System ID) in the NPDES electronic reporting systems in order to create efficiencies and standardization. For example, the NPDES program authority may configure their electronic reporting system to automatically generate NPDES IDs for control mechanisms for new facilities reported on a Pretreatment Program Report [40 CFR 403.12(i)]. Additionally, the NPDES program authority can decide whether to allow NPDES regulated entities to override these pre-populated data.

(2) The data elements in this table conform to EPA's policy regarding the application requirements for renewal or reissuance of NPDES permits for discharges from municipal separate storm sewer systems (see 61 FR 41698; 6 August 1996).

(3) The data elements in this table are also supported by the Office Management and Budget approved permit applications and forms for the NPDES program.

(4) These data will allow EPA and the NPDES program authority to link facilities, compliance monitoring activities, compliance determinations, and enforcement actions. For example, these data will provide several ways to make the following linkages: linking violations to enforcement actions and final orders; linking single event violations and compliance monitoring activities; linking program reports to DMRs; linking program reports to compliance monitoring activities; and linking enforcement activities and compliance monitoring activities.

[ATTACHMENT 8]

USDA Comments on Draft Final WPS Rule

Submitted July 8, 2015

USDA Background

A healthy and strong agricultural workforce is one of the key factors in the success of American agriculture. The labor force, whether employed in greenhouses, fields, orchards, nurseries, or other productive agricultural enterprises, like employees in other industries, should be aware of all activities in their workplace, particularly when there is potential occupational exposure directly to pesticides or their residues, so that they can take appropriate measures to minimize those risks. Agricultural employers have a responsibility to ensure that people working at an agricultural enterprise have the protections of a safe workplace. The accountability of worker protection is not one-sided. To be successful, the labor force and the employer share equally in the responsibility. USDA supports strong agricultural worker protection standards as they are essential to successful, modern agriculture.

Comments on EPA Worker Protection Standard Final Rule

USDA did not reference its comments by page number and line, because changing the display settings for the tracked changes in the draft final rule USDA received from EPA resulted in varying page and line number alignments. To prevent confusion, USDA is referencing its comments by unit and subunit number for the preamble, and by section and subsection for the draft final rule.

Comments on the Preamble

1. USDA. The draft final rule has an overall weakness in a number of places in the document in the manner in which EPA justifies positions it takes in the document. This weakness is a lack of evidenced-based scientific data. In these cases, the positions presented by EPA could have be greatly strengthened to make the draft final rule more compelling in its justification for their proposed changes to the 1992 Worker Protection Standards. With the lack of evidenced-based scientific data, some of EPA's positions tend to appear as opinions rather than factual determinations. Examples of language in the draft final rule that demonstrate this lack of evidenced-based scientific data are listed below:

(a) II.D.: "Even if the lack of quantitative data impairs the reliability of estimates of the total number of chronic illnesses avoided, it is reasonable to expect that the proposed changes to the WPS will reduce pesticide exposure, and thereby reduce the incidence of chronic disease resulting from pesticide exposure."

(b) IV.B.2.: "Although EPA cannot quantify the specific reduction in incidents from any single change to the regulation, taken together, EPA estimates that the final rule will result in an annual reduction of between 540 and 1,620 acute, health-related incidents."

(c) V.H.2.: "2. *Benefits.* While EPA can estimate the costs of the changes to pesticide safety training for workers and handlers, quantifying the benefits is more difficult. Nonetheless, as explained in the NPRM, it is reasonable to expect that more frequent training would lead to better retention of information by workers and handlers, ultimately resulting in fewer incidents of pesticide exposure and illness in workers and handlers, improved decontamination procedures, reduced take-home exposure, and better protection of children."

EPA Response. The preamble discusses the best evidence and data that are available, including a detailed analysis of occupational pesticide incidents for the four most recent years in the SENSOR-Pesticides database. EPA believes the statements in the preamble—including the ones USDA cited—are accurate, and that the evidence and data adequately support these revisions to the WPS. EPA is not aware of any additional data sources that address the specific scenarios covered by the regulations and is interested in learning about any evidence-based scientific data that USDA has seen. EPA's decisions on training were based partially on the widely accepted idea that training people on worker safety decreases the number of incidents even though there is little research in how the training quantitatively translates to fewer incidents. As stated in Unit IV.B.2 of the preamble, EPA has seen a significant reduction in the number of estimated incidents since the 1992 rule even though EPA cannot determine the impact of each individual requirement in the rule, as well as other changes in agriculture, on that reduction in incidents.

2. Unit IV.B.2. ("Surveillance data")

USDA. Consider rewriting to improve clarity. The original statement is "Another example of potentially avoidable exposure is spray drift; labeling prohibits applica-

tion that contacts other persons and handlers should be instructed to apply pesticides in a manner that does not contact other persons, but incidents continue to occur." Consider revising to say: "Another example of potentially avoidable exposure is spray drift. Labeling instructs handlers to apply pesticides in a manner that does not contact other persons, but incidents continue to occur."

EPA Response. EPA has made this change to the preamble by revising it as follows: ". . . Another example of potentially avoidable exposure is spray drift. **l** Labeling **prohibits application that contacts other persons and** instructs handlers **must** to apply pesticides in a manner that does not contact other persons, but pesticide drift continues to cause exposure incidents."

3. Unit V.D. ("Expand the Content of Worker and Handler Pesticide Safety Training")

USDA. USDA is concerned that the draft final rule does not include any estimate for how much additional time, if any, will be required to teach the expanded content of Worker and Handler Pesticide Safety Training. Without these time estimates, one cannot compare the training times for the expanded content for workers or handlers versus the typical time needed to teach the current pesticide safety training covering specific content. The time required for training is a significant driver of costs to effectively implement the draft final rule. This apparent increase in training time needed to provide the expanded content appears to put in question EPA's marginal costs estimates of Impact on Jobs (page 10) of a typical farmworker to increase only $5/year and the marginal cost for a more skilled pesticide handler to increase only $50 per year. The "Economic Analysis of the Agricultural Worker Protection Standard Revisions" did not dispel this concern, because the analysis was based on the current training time of 30 minutes per sessions without an analysis of how long the "expanded" training sessions will require. This would also put into question EPA's estimate (Costs and Benefits of Revisions to Pesticide Safety Training, page 53) of $62 to $80 per agricultural establishment per year.

EPA Response. In the Economic Assessment, Unit 3.3.1 Pesticide Safety Training, Step 1 Calculate Baseline Costs, EPA provides an estimate of 30 minutes for a full training session for workers under the current rule. In the second paragraph on page 57, and under Table 3.3–7 on page 57, EPA provides the estimate of 45 minutes for worker safety training with the expanded content, an increase of 15 minutes of training time.

For the handler training baseline, please refer to Table 3.3–3 for the estimate of 45 minutes. Handler safety training covers more material than worker safety training. EPA estimated that the additional content in the final rule will result in an additional 15 minutes for handler training, and EPA includes that estimate in the narrative in the economic analysis.

The 15 minute estimate for the increases in worker and handler training time is based on the length and content of current training videos.

4. Unit V.H.1. ("Costs and Benefits of Revisions to Pesticide Safety Training: Costs")

The expanded training is good from a safety standpoint and is necessary. However, it does not appear that the economic analysis addresses the impact of the time spent for training on worker/handler income particularly if the training is performed at the field prior to a work day. For many laborers, wages are earn based on their volume of work and not on the hours worked. Are they paid for the time spent training or does the time spent training significantly impact their earned wages for that day?

EPA Response. EPA does not require employers to pay workers for their time spent in training, although some employers do pay workers for that time. This is addressed in the EA as follows:

> Training, Step 1 Calculate Baseline Costs: "Action is required by two actors, the WPS farm, which provides or arranges the training, and the workers, who take the training. We consider these actors separately, although we assume the WPS farm incurs the training costs and implicitly pays the worker to take the training at the same wage he or she earns doing field work. However, some workers may bear the opportunity cost of taking the training. Workers who are hired to harvest fruits and vegetables are often paid by the quantity harvested; thus, time spent in training is time they are not earning pay."

Because EPA estimates that under the final rule worker training will last 45 minutes, workers who are not paid for by the hour would incur an average opportunity cost of less than $10 annually due to the training requirement.

5. Unit VII.A.2. ("Hazard Information—Location and Accessibility: Final rule")

USDA. Please define the term "valid" in this context and describe how an employer will be able to determine that the request and employee's signature is authentic. [In regards to the following sentence: "When the employer is presented a valid request, the employer must provide a copy of, or access to, all of the requested information that is applicable within 15 working days from the receipt of the request."]

EPA Response. In this context, the term "valid" was used to mean the request contains all of the required information. The agricultural employer is required to provide the information only when the designated representative presents a complete request. However, for clarity, EPA will replace "valid" with more descriptive language. Specifically, the sentence in Unit VII.A.2 has been revised as follows: "When the employer is presented a ~~valid~~ request that contains all of the necessary information specified in the regulations, the employer must provide a copy of, or access to, all of the requested information that is applicable within 15 working days from the receipt of the request."

The employer will have access to the employee's signature in training records. The pesticide use information is not confidential Personally Identifiable Information, and it should be readily provided to anyone with a plausible claim to be a designated representative. See § 170.401(d)(1) for details.

6. Unit VII.B.3. (Paragraph on "Comments on inconsistencies in information between labels and SDSs")

It is surprising that EPA is not acknowledging that it is common for SDSs to show PPE requirements that are different from the pesticide labels, since the two documents are intended for different audiences. EPA states here that since the label is not required to be posted, they do not "expect issues with a perception of conflict between labeling and SDSs." USDA questions whether this is correct. Many Forest Service employees have reported finding differences between the PPE listed in the SDSs compared to the label. At a minimum, EPA should address this issue in the preamble.

EPA Response. EPA's intention with requiring agricultural employers to display the Safety Data Sheets (SDSs) is to provide farmworkers and handlers with information regarding chronic, developmental and reproductive toxicity that is usually found on SDSs and not the label. Much of the technical information on SDSs, such as the chemical and physical properties of the pesticide, is designed for use by multiple professionals such as manufacturers, transporters, medical personnel and firefighters.

EPA maintains our position that we do not anticipate issues with a perception of conflict between labeling and SDSs. First, many SDSs include a reference to the pesticide label in the section on exposure controls and personal protection. Second, the persons who would wear PPE are handlers who are trained that they must follow labeling instructions, including those regarding PPE. However, EPA has amended the preamble to clarify that pesticide applicators and handlers must always follow the instructions on the labeling regardless of any differences between information on the labeling and the SDS, and will make a point of including in future training materials warnings against reliance on SDS provisions regarding PPE.

EPA has adjusted the response to this comment in Unit VII.B.3 of the preamble as follows: ". . . The SDS provides succinct information about the known health hazards of the product that typically is not presented as part of the product label or labeling. Such information can be invaluable to medical professionals for the diagnosis and treatment of certain pesticide-related illnesses and injuries. Because EPA is not requiring the employer to display the labeling, EPA does not expect issues with a perception of conflict between labeling and SDSs. The persons who would wear PPE are handlers who receive more thorough training than ordinary workers. If pesticide handlers encounter conflicting information on labeling and SDSs, such as the PPE identified, they should know that they must follow the instructions on the pesticide labeling, as they are trained to do. For information on OSHA's adoption of the Globally Harmonized System of Classification and Labeling of Chemicals for SDSs and the pesticide product labeling . . ."

7. Unit XVIII.E. ("Equivalency provisions" and "Clarifications")

There are two subsections labeled "E." The second one, "E. Clarifications" should be relabeled "F. Clarifications".

EPA Response. The correction has been made.

Comments on the Rule 8. § 170.305

a. USDA. The definition for "agricultural plant" depends on the definition for "commercial production," and the definition for "commercial production" depends on the definition for "agricultural plant." Similar issues exist in the definitions of "agri-

cultural establishment" and "farm," "forest operation," and "nursery." USDA recommends resolving these circular dependencies by defining at least one of the terms in each pair independently.

EPA Response. EPA agrees that these definitions are somewhat circular, and while EPA is not convinced that serious confusion would result, EPA has eliminated some definitions and revised others to address USDA's concern. The terms "commercial production," "farm," "nursery," and "forest operation" appear only in the definition section and are not used elsewhere in the regulation. Accordingly, EPA will delete these definitions and merge their substantive content into the definitions of "agricultural establishment" and "agricultural plant," as follows:

> "Agricultural establishment" means any farm, forest operation, or nursery engaged in the outdoor or enclosed space production of agricultural plants. An establishment that is not primarily agricultural is an agricultural establishment if it produces agricultural plants for transplant or use (in part or their entirety) in another location instead of purchasing the agricultural plants. "Agricultural plant" means any plant, or part thereof, grown, maintained, or otherwise produced for commercial purposes, including growing, maintaining or otherwise producing plants for sale or trade, for research or experimental purposes, or for use in part or their entirety in another location. "Agricultural plant" includes, but is not limited to, grains, fruits and vegetables; wood fiber or timber products; flowering and foliage plants and trees; seedlings and transplants; and turf grass produced for sod. "Agricultural plant" does not include pasture or rangeland used for grazing.

b. USDA. The definition of "handler employer" is very broad, because it includes *both* agricultural employers and commercial pesticide handler employers (CPHEs), even in a situation where both are simultaneously present on the agricultural establishment. This causes significant concerns and confusion as to who is ultimately responsible for providing the protections in Subpart F (see additional comments on Subpart F below).

As currently written, a "handler employer" is anyone who employs any handler, as well as self-employed handlers. The definition of "handler employer" uses the verb "to employ," which is also defined in § 170.305, as "to obtain, *directly or through a labor contractor,* the services of a person in exchange for a salary or wages . . . without regard to who may pay or who may receive the salary or wages" (emphasis added). This definition in turn uses the term "labor contractor," whose definition would include any CPHE hired by an agricultural employer to provide handlers. Reading these definitions together, it becomes clear that agricultural employers can be "handler employers" even when they do not *directly* employ a single handler, because they are employing handlers through a labor contractor/CPHE.

In a situation where an agricultural employer hires a CPHE, who in turn hires handlers, both the agricultural employer and the CPHE meet the definition of "handler employer," since both employ handlers under the WPS definition of "employ": the CPHE does so "directly," while the agricultural employer does so "through a labor contractor" (*i.e.,* the CPHE). In other words, a handler that is *directly* employed by a commercial pesticide employer handler is simultaneously "employed" by both the CPHE and the agricultural employer, leading to confusion over who has ultimate responsibility.

A solution to this problem would be to change the definition of "labor contractor" to explicitly exclude CPHEs: "*Labor contractor* means a person, other than a commercial pesticide handler employer, who employs workers **and handlers** to perform tasks . . . " [The reference to handlers in the definition for "labor contractor" could then be eliminated, since any person employing handlers is a CPHE, and no longer a labor contractor.] For handlers, this change would have the practical effect of limiting the meaning of the word "employ" to just a direct employment relationship. As a result, each handler would only have a single handler employer (*i.e.,* his or her direct employer). For workers who are not handlers, agricultural employers would still "employ" anyone engaged directly or through a labor contractor.

EPA Response. EPA agrees that the current definitions of labor contractor and commercial pesticide handler employer contain some problematic language that could result in potential confusion and/or conflict regarding agricultural employer and commercial pesticide handler employer duties under the rule. EPA has made the suggested changes to the final rule with minor modifications to address the fact that some labor contractors do bring handlers on to agricultural establishments. EPA believes the revised text below clarifies that CPHEs are responsible for the handlers they employ and agricultural employers would no longer be considered employers of CPHE handlers for the purposes of the WPS, without overlooking the fact

that some handlers are hired by agricultural employers through labor contractors and not CPHEs.

Commercial pesticide handler employer means any person, other than an agricultural employer, who employs any handler to perform handler activities on an agricultural establishment. A labor contractor who does not provide pesticide application services or supervise the performance of handler activities, but merely employs laborers who perform handler activities at the direction of an agricultural or handler employer, is not a commercial pesticide handler employer.

Employ means to obtain, directly or through a labor contractor, the services of a person in exchange for a salary or wages, including piece-rate wages, without regard to who may pay or who may receive the salary or wages. It includes obtaining the services of a self-employed person, an independent contractor, or a person compensated by a third party, except that it does not include an agricultural employer obtaining the services of a handler through a commercial pesticide handler employer or a commercial pesticide handling establishment.

Labor contractor means a person, other than a commercial pesticide handler employer, who employs workers or handlers to perform tasks on an agricultural establishment for an agricultural employer.

c. USDA. USDA is further concerned that EPA's definitions of "employ" and "agricultural employer" are not consistent with common legal definitions of these terms. Common law, tax law, and certain court decisions interpreting related statutes such as the Fair Labor Standards Act and the Seasonal Agricultural Worker protection Act, *Aimable* v. *Long and Scott Farms,* 20 F.3d 434 (1994), make a clear distinction between an employer/employee relationship and other, less direct working arrangements, such as independent contractors. USDA encourages EPA to assign WPS responsibilities in accordance with these more traditional and accepted definitions of "employer" and "to employ".

EPA Response. EPA disagrees. EPA acknowledges that its use of the term "employ" in the WPS is more aligned with popular usage than with the common law and tax law uses of the term, but notes that the definition of "agricultural employer" in the existing WPS has been used since 1992 without significant conflict or confusion with similar terms. USDA's objection pertains to the existing WPS definition of "agricultural employer" to the same degree as it does to the draft final rule's definitions of "employ" and "agricultural employer," and EPA declines to change this fundamental and longstanding WPS principle.

d. USDA. EPA included in the definition of "outdoor production" the phrase ". . . or in the case of forest operations, a natural forest". Ignoring the question of what an "unnatural" forest would be, USDA is unsure why this phrase is needed at all. As this is written one could say that any planted forest is then not subject to WPS. There are other occurrences in the preamble (pages 202, 204, and perhaps others).

EPA Response. EPA agrees that the inclusion of the term "natural forest" in the definition of "outdoor production" creates confusion and is not needed. EPA has made the following change to the definition of "outdoor production" to address USDA's comments:

Outdoor production means production of an agricultural plant in an outside area that is not enclosed or covered in any way that would obstruct the natural air flow.

e. USDA. In addition, most golf courses have nursery greens located next to, or near, the golf course. Posting agricultural exclusion zones, *etc.* could disrupt golfing activities. USDA requests clarification of how nursery greens are considered. If they are covered by this rule, did EPA consider the costs to golf courses which may have nurseries?

EPA Response. Golf courses that have operations considered nurseries on their establishment (*e.g.,* they are growing turf/greens in a nursery area for use in replacing turf on the playing areas of the golf course, or they are growing ornamentals in a greenhouse for planting on the golf course) have always been covered by the WPS, and compared to the existing WPS, the coverage of golf courses that have nurseries on their establishment is not changed by the amendments in this final rule. EPA has included an excerpt from the 1995 WPS guidance which clarifies this coverage below. Since there are no posting requirements associated with application exclusion zones, EPA does not see this as an issue. Additionally, EPA understands that most golf course pesticide applications are conducted when the public is not using the course, and this should be similar with applications to a nursery operation on the golf course. EPA expects this practice should minimize any potential impact to golf course operations due to WPS requirements. EPA considered the cost to golf courses that operate nurseries; the costs would be accounted for under the costs of the WPS revisions on nursery operations.

14–24 Production of agricultural plants for other than direct sale

IGW Question: What is the scope of the WPS with respect to establishments producing agricultural plants for other than direct sale, *i.e.,* in-house use?

IGW Answer: There is no exception for agricultural plants produced for other than direct sale, *i.e.,* in-house use. The WPS covers an agricultural establishment if (1) a WPS-labeled agricultural pesticide is used on the establishment, (2) workers or handlers are employed by or on the agricultural establishment, (3) the establishment is a farm, forest, nursery, or greenhouse, as defined in the WPS, and (4) the establishment or the activity is not covered by one of the exceptions specifically described in the rule, Section 170.102 (b).

For instance, the following operations are covered by the WPS: Production of hay or feed grown for livestock on dairy farms, cattle ranches, or other livestock operations; sod farms, greenhouses, or nurseries operated by golf courses; and greenhouses and nurseries operated by theme parks, hotel chains, botanical gardens, and state and local governments. (Note: Pasture and rangeland used for grazing are excluded.) (March 15, 1995)

f. USDA. Including "arranging for the application of the pesticide" in the definition of "use, as in 'to use a pesticide'" is superfluous and gives the impression of expanding the WPS—and the related state enforcement actions—far beyond the actual agricultural establishment to reach off-site administrators involved only in pre-application tasks. USDA recommends removing the reference to "arranging for the application of the pesticide."

EPA Response. EPA also received several similar comments from states, growers, agricultural associations and pesticide manufacturer associations objecting to the proposed definition of "use." Most commenters objected to the definition of use because they did not support inclusion of "arranging for application of the pesticide" as part of the definition of "use," and they said they believed that this language would greatly expand the scope of the WPS and would be unreasonable and unnecessary. EPA disagrees with comments that say the proposed definition for the term "use" could or will expand the scope of the WPS because this language has been in § 170.9(a) of the WPS since the rule first became effective in 1992. Moreover, EPA has not been made aware of any instances where this definition of "use" has resulted in an unreasonable or inappropriate outcome. EPA believes that "arranging for application of the pesticide" is appropriately part of the definition of "use" for the purposes of the WPS because in production agriculture, the individual who physically "uses" a pesticide almost always does so at the direction of another person who has substantially greater control over the circumstances of the use. Thus the WPS is designed so that when an agricultural or handler employer arranges for the application of a pesticide by a handler employee, it triggers certain WPS duties that are properly the responsibility of the agricultural or handler employer. For instance, once the agricultural employer arranges for a pesticide application by a commercial pesticide handling establishment, the commercial pesticide handler employer must provide the agricultural employer with certain information about the intended application before the application takes place (so the employer will be able to fulfill WPS notification requirements and protect workers during application, *etc.*). In such circumstances, it is reasonable and appropriate that the handler employer should be held responsible for the pre-application information exchange even though the application has not commenced and even though the handler employer personally never physically applies the pesticide. Therefore, since EPA has not been made aware of any instances where the existing interpretation of the term "use" has resulted in unreasonable difficulties for growers, states or the agricultural industry, EPA has moved the definition for the term "use" into the definitions section of the rule without any changes from the proposal.

8.1 "Administration of Conservation Programs" was not included in the proposed rule. This NAICS code includes the administration of recreational areas and weather forecasting administration, geologic survey program administration, preservation of natural resources, recreational areas, erosion control, *etc.* USDA would like an expansion on the rationale for their inclusion into the worker protection standard. Furthermore, the entirety of this NAICS code's government population, appears not to be addressed in the Economic Analysis and, therefore, the impact on this sector may not have been included.

EPA Response. EPA did not receive comments from the entities listed under this NAICS code, and does not believe that the WPS applies to them. EPA has removed the reference from the preamble, per USDA's request.

9. § 170.309(c) and § 170.313(c) minimum age

USDA. As in previous reviews, USDA opposes changing the minimum age for handlers and early-entry workers proposed by EPA and defer this decision to the States.

U.S. agricultural workers operate under a variety of Federal requirements, including those of the Environmental Protection Agency and the U.S. Department of Labor. States also have minimum age requirements for users of pesticides. The U.S. Department of Labor has already set Federal minimum age limits for people who are 18 years old or younger when working with pesticides. The current regulatory system allows for States to increase age requirements and most states have already exercised this right based on their unique circumstances. USDA believes the current Federal-state system is working in this regard. The need for added regulation is not apparent and should be weighed against state discretion and current state and Federal laws.

Please see the following as posted by the Department of Labor at *http://www.dol.gov/elaws/esa/flsa/docs/hazag.asp*. (Italics added for emphasis.)

Prohibited Occupations for Agricultural Employees

The child labor rules that apply to agricultural employment depend on the age of the young worker and the kind of job to be performed. The rules are the same for all youth, migrant children as well as local resident children. In addition to restrictions on hours, the Secretary of Labor has found that *certain jobs in agriculture are too hazardous for anyone under 16 to perform.*

- *Once a young person turns 16 years old, he or she can do any job in agriculture.*
- A youth 14 or 15 years old can work in agriculture, on any farm, but only in non-hazardous jobs. ? A youth 12 or 13 years of age can only work in agriculture on a farm if a parent has given written permission or if a parent is working on the same farm as his or her child, and only in non-hazardous jobs.
- If the youth is younger than 12, he or she can only work in agriculture on a farm if the farm is not required to pay the Federal minimum wage. Under the FLSA, "small" farms are exempt from the minimum wage requirements. "Small" farm means any farm that did not use more than 500 "man-days" of agricultural labor in any calendar quarter (3-month period) during the preceding calendar year. "Man-day" means any day during which an employee works at least one hour. If the farm is "small," workers under 12 years of age can only be employed with a parent's permission and only in non-hazardous jobs.

Hazardous Occupations

- The Secretary of Labor has found that the *following agricultural occupations are hazardous for youths under 16 years of age. No youth under 16 years of age may be employed at any time in any of these hazardous occupations in agriculture* (HO/A) unless specifically exempt. Exemptions (*) will apply to HO/A #1 through #6 under limited circumstances. (None of the exemptions apply to pesticides.)
  - HO/A #9 *Handling or applying agricultural chemicals if the chemicals are classified under the Federal Insecticide, Fungicide and Rodenticide Act as Toxicity Category I—identified by the word "Danger" and/or "Poison" with skull and crossbones; or Toxicity Category II—identified by the word "Warning" on the label.* (Handling includes cleaning or decontaminating equipment, disposing of or returning empty containers, or serving as a flagman for aircraft applying agricultural chemicals.)

USDA requests that EPA work with DOL to unify their regulations so that those working in agriculture have clear guidance as to Federal minimum age requirements for agricultural workers. The States have regulations in place that are consistent with DOL—or more restrictive—based on the needs of individual States.

EPA Response. EPA notes that a majority of the comments received encouraged the Agency to implement a minimum age of 18 for handlers and early-entry workers.

EPA welcomes input from DOL to ensure no avoidable conflict between the WPS and FLSA. However, the statutory criteria for regulating under FIFRA and the child labor provisions of FLSA are different. While EPA will defer to DOL regarding the scope of its authority under FLSA, it does not appear that DOL has the discretion to use the FLSA section 12 child labor provisions to protect children 16 or older working in agriculture. FIFRA does not contain such a limitation, and EPA believes that pesticide handling in agriculture and entry to a treated area when a restricted-entry interval (REI) is in effect ("early-entry workers") by persons under the age of 18 is inconsistent with the FIFRA statutory standard.

Moreover, where DOL exercises its FLSA child labor authorities in regard to children employed in agriculture, its focus is on protecting the child worker (see 29 U.S.C. 213(c)(4)). EPA's mandate under FIFRA is significantly broader, requiring EPA to prevent unreasonable adverse effects of pesticides to workers, other persons, and the environment, and these are put at risk when agricultural pesticides are applied by persons with immature judgment and risk-taking behaviors. Inasmuch as FLSA and FIFRA have different purposes and different scopes, it is not surprising that they should produce different regulatory outcomes.

DOL's standard and the WPS differ in the types of pesticides covered. DOL's restrictions on pesticide use in agricultural employment applies only to pesticides with high acute toxicity (toxicity categories I and II). The WPS applies to all agricultural use pesticides, some of which may pose a variety of other risks. Pesticides that are extremely toxic to other species, or that are powerful carcinogens or mutagens, may nevertheless have low acute human toxicity, and therefore be classified in toxicity categories III and IV. Such pesticides can pose significant risks to the handler, bystanders, and the environment if not used properly.

To the extent that DOL's standard does protect children from agricultural pesticides, it only protects children as pesticide applicators. DOL's standard does not cover early-entry workers at all, though they face increased risks from entering an area treated with pesticides before the residue levels have fallen to a level unlikely to cause unreasonable adverse effects.

In sum, EPA disagrees with USDA's request that EPA should defer to the states or the FLSA and not establish any age-related restrictions on pesticide handling or early-entry activities. EPA has the responsibility under FIFRA to regulate the use of pesticides to avoid unreasonable adverse effects, apart from any requirements established by other Federal or state laws.

10. § 170.311(b)(6)

a. USDA: The new requirement to maintain application information and SDSs for 2 years is onerous and without foreseeable benefit. Acute toxic effects would be the most likely triggering need to get this information to a worker. EPA should have considered a longer application information posting time (45 days, 60 days) rather than a 2-year record retention.

EPA Response. EPA believes that workers in agriculture and pesticide regulatory agencies should have access to application and exposure information, and believes that two years is a reasonable compromise between access and the burdens of record retention. Acute pesticide illnesses are the most common triggering effects; however, chronic illnesses are potentially linked to pesticide exposure, and workers and handlers may present such illnesses and should have access to the exposure or hazard information. Under OSHA, records of exposure to hazardous chemicals are required to be retained for 30 years, and access to those must be provided to workers, even if they are no longer employed by the employer. Once the record is created and filed, there is little cost to maintaining it. In addition, employers may choose to keep the information at the central posting display for the required retention period of two years from the date of application, providing that the information remains legible and all other requirements are met.

b. USDA: USDA expresses concern over the increased burden placed on agricultural employers due to a significant expansion and complexity of record-keeping requirements. As written, agricultural employers will bear the sole responsibility in providing records and responses to workers, their designated representatives, plus states and Federal enforcement. Agricultural employers already must keep records under OSHA, including The Migrant and Seasonal Agricultural Worker Protection Act (MSPA), Field Sanitation Standards under the Occupational Safety and Health Act, and Agricultural Employers under the Fair Labor Standards Act (FLSA). USDA is further concerned over agricultural employers' liability resulting from small procedural mistakes stemming from the added recording-keeping requirements under FIFRA.

EPA Response. EPA responded to comments from agricultural interests opposing the proposed record-keeping on the basis of burden by examining the purpose and need for the records. As a result, EPA eliminated from the final rule the requirement for documenting oral notification to workers for early-entry. The review found that collection of the application information and the SDS are necessary for hazard communications. The remaining records were found to be necessary for employers to demonstrate compliance with aspects of the regulation.

USDA expresses concern for employers' liability from small procedural mistakes. Small procedural mistakes are typically addressed with a warning notice, rather than monetary penalties. After implementation, there will be a period of compliance assistance. During this period, EPA and state regulatory agencies will work with

agricultural interests to ensure understanding of the rule requirements and how to comply with them, thereby minimizing "small procedural mistakes."

c. USDA. Under OSHA, there are already considerations for "designated representatives" for farm accidents, farm chemical hazards, wages, *etc.* which can be confusing if there is a separate "designated representative" under FIFRA for pesticide hazard communication records. OSHA provides a process for expiration, revocation of "designated representatives," and whether the designated representative can be a union representative, worker group representative, *etc.* for records and in what circumstances the designated representative can accompany an inspection. The WPS language does not specify how many authorized representatives a worker may have. The time to process multiple authorizations, confirm signatures and make changes will incur added costs to agricultural employers and should be included in the Economic Analysis.

EPA Response. EPA believes the WPS final rule is clear regarding the identification and function of the designated representative. The representative must provide, in writing, the designation from the worker or handler. The information that the employer must provide is limited to the application records and the SDS that were displayed while the worker or handler was on the establishment. EPA's designated representative requirement is modeled on OSHA's rule at 29 CFR 1910.1020. EPA is aware that California and Texas regulations include employee representatives' access to information for farmworkers. Comments from the Texas Department of Agriculture encouraged EPA to require the designation in writing and to limit access to records to the timeframe of 2 years.

Under the final rule, while a worker may have multiple authorized representatives, EPA expects a single individual could be the designated representative under both sets of regulations, thereby minimizing confusion and burden for the employer. The final rule does not provide access to inspections for the designated representative.

The Economic Analysis has been updated to provide an estimate of the costs of processing requests on a per-request basis, and includes the cost of verifying the validity of the request. Please refer to comment #30 for details.

d. USDA. USDA believes the total costs for record-keeping should include the following: set-up costs to establish a record-keeping system (if one has not already been established; costs to develop internal record forms; printing costs for paper records); computer software/system costs (for electronic records); storage costs; disposal costs of records with sensitive information; maintenance costs for records beyond the two-year minimum for longer-term employees. Did EPA consider all these in its cost estimates for record-keeping, especially for small businesses and government agencies?

EPA Response. As USDA noted previously in this comment (10.b.), agricultural employers must comply with record-keeping under requirements from other Federal agencies. Therefore, EPA believes that establishments will have record-keeping systems in place as a result of complying with the cited requirements. EPA estimates the following costs: paper, time to collect information and signatures, and storage. The records required by EPA do not include information that would ordinarily be considered private or sensitive (note that the draft final rule does not require employers to record workers' birthdates), therefore, there is no need to dispose of those in any particular manner. Finally, as there is not a requirement to retain records beyond the two year timeframe regardless of a worker or handler's continued employment, such cost is not necessary to assess.

11. § 170.311(b)(7)–(9)

a. USDA. Compared to the proposed rule's "authorized representative," EPA has now coined and defined the term "designated representative" and added additional language. Regardless of terms, EPA's definition of "designated representative" still raises serious concerns for USDA. We also remind EPA of the concerns expressed by key stakeholders that are detailed below in response to reading the proposed rule. USDA is concerned that EPA has not seriously considered their concerns. We also note that there was only one public comment in support of this concept during the proposed rule period which was far outnumbered by those written in opposition.

Minor Crop Farmer Alliance (MCFA)

"The current proposed definition of 'authorized representative' is overly broad and would be very difficult to manage to ensure information that is worker specific is protected. The information necessary to provide support for workers who seek treatment for potential health related impacts is already provided in the current WPS regulations. The proposed definition is open-ended and subject to serious abuse. The representative of a worker seeking information under the provision of the WPS

should be limited to family members or medical personnel with a legitimate need for information."

National Association of State Departments of Agriculture (NASDA)

"Authorized representative: We request EPA remove 'Authorized representative' from the proposed rule. We recognize at least one state has this provision included in its state regulations, and we understand the inclusion has led to a range of complications and on-going litigation that does nothing to forward the purpose of the WPS or facilitate a sound regulatory framework. If mandated in the *Code of Federal Regulations,* the new provision will lead to numerous complications for both the state regulatory agency and the regulated community in trying to comply with the proposed WPS rule, even if the designation is required in writing, while protecting against liability in responding to fraudulent claims or interests seeking to utilize this provision for non-WPS purposes. We oppose this proposal."

Association of American Pesticide Control Officials (AAPCO)

"Authorized employee representative—A person designated by the worker or handler, orally or in writing, to request and obtain any information that the employer is required to provide upon request to the worker or handler.

AAPCO does not support the definition as proposed. An authorized representative should be designated in writing for a specific worker or handler and for a specific event or time period within the last 2 years from the date of request (due to record retention requirements). The information required to be provided to the authorized representative, and the purpose of the request or intended use of the information, should be clearly specified as noted in the above comments."

EPA [R]esponse. In response to the many comments concerning the identification of the designated (authorized) representative, EPA has clarified the requirements for the designation: it must be in writing, include the name and signature of the requesting employee, describe the specific information being requested, the date of the designation, and directions for sending the information if so desired. These requirements largely meet the AAPCO recommendation. In addition, the employer has 15 days to provide the information. EPA believes requiring the identification of the designated representative in writing addresses the concerns raised for the legitimacy of the designated representative and clarity of the request, while continuing to allow access to important pesticide exposure information for workers and handlers that they may be reluctant to request of their employer.

One public comment states that the emergency provisions of the current rule provide adequate support for workers. However, under the rule, only employees seeking emergency assistance while on the establishment are so protected. Additionally, employees should have access to the information if they are concerned for their exposure but do not show symptoms.

USDA states that only a single public comment supports the authorized representative concept; however, EPA has found several comments in support of the authorized representative, stating that the requirement would enable a worker or handler access to important information for medical purposes.

b. USDA has the following additional comments on this section

These requirements for providing application data to the worker or handler, treating medical personnel, or a designated representative do not spell out the timeframe for which records can be produced based on § 170.311(b)(6) (two year application information retention requirement). Each of subsections should include the phrase "within the last two years" to clarify that after two years there is no expectation that such records would have been retained.

EPA should be clear on the differences between a "designated representative" and a person acting under the direction of medical personnel. Who are those "persons"? While the two could be the same person, it is possible that in an emergency situation, the requirements for requesting the information as outlined may not be expedient.

EPA Response. EPA has clarified in those sections that the information is accessible for only that period of time after it is collected and retained.

USDA has also expressed concern that it is not clear who may access the information as a person acting under the direction of treating medical personnel. In consultation with USDA, EPA has revised the language to clarify that treating medical personnel and persons working under their supervision are to be given access to the information.

c. USDA. Allowing oral requests to the employer by workers and handlers for pesticide application information and safety data sheets is not consistent with the EPA's new posting requirements that prohibit oral notification to workers of pesticide applications due to difficulty in recalling oral information, difficulty commu-

nicating orally if language barriers exist and the lack of verification of an oral notification. For these same reasons, oral notification to employers should be replaced with written notification. USDA encourages EPA to meet with stakeholders representing employers and farmworkers to best balance the oral *versus* written requests and the mechanism for collecting the written statement to designate the representative.

EPA Response. USDA finds inconsistency between (1) the option for workers and handlers to orally request hazard information from their employer and (2) the requirement for the employer to post areas treated with a pesticide with an REI of greater than 48 hours. EPA does not agree that these requirements need to be consistent with each other. While it would be more convenient for employers to get a written request for the hazard communication information, in the interest of promoting access to workers and handlers who may not be literate and could not provide a written request, allowing oral requests facilitates the flow of information and outweighs the convenience for the employer. Posting a treated area under an REI as a visual warning is intended to provide an ongoing reminder to workers not to enter the area, because they may forget the oral notification given, or there may be confusion about which field is treated.

Regarding USDA's comment about the mechanism for collecting the written request to designate the representative, the written information can be hand delivered, mailed, provided to the employer as an attachment to an e-mail, or any other way seen as appropriate. Oral identification of the designated representative is not sufficient.

12. § 170.313

USDA. This section creates responsibilities for commercial pesticide handler employers (CPHEs) toward "each handler" or "any handler," without limiting the CPHE's responsibility to only the handlers employed by the given CPHE. This may lead to difficulties and unintended consequences when multiple CPHEs are operating on the same agricultural establishment, or when an agricultural employer chooses to employ some handlers directly while contracting for additional handlers through a CPHE.

Regarding subsection (b), how is a CPHE supposed to ensure that handlers employed by a different CPHE or handlers employed directly by the agricultural employer receive the protections required by the WPS?

Regarding subsection (c), how is a CPHE supposed to ensure that handlers employed by a different CPHE or handlers employed directly by the agricultural employer are at least 18 years old?

The same line of questioning also applies to subsections (d), (e), (f), (g), (h), and (k). A CPHE will not likely be able to follow these requirements with regards to handlers that are not employed by him or her and thus are not within his or her supervisory control. USDA recommends clarifying that for purposes of § 170.313, the term "handler" is limited to handlers employed by the CPHE (*i.e.,* the CPHE's "own" handlers).

In addition, if EPA makes the changes to the definition of "labor contractor" in § 170.305 suggested above, EPA should remove references to labor contractors in this section. This is because any contractor who employs handlers will no longer be both a "labor contractor" and a CPHE, but only a CPHE instead.

EPA Response. EPA does not believe that a CPHE has responsibilities for handlers other than its own handler employees because the required employer-employee relationship that triggers WPS responsibilities does not exist for handlers that are not employed by the CPHE. However, in the interest of providing greater clarity in the, EPA has clarified in the rule in 170.313 that the commercial pesticide handler employer duties are only applicable for handlers they directly employ. The revised reg text is included below:

§ 170.313 Commercial pesticide handler employer duties.

"Commercial pesticide handler employers must:

(a) Ensure that any pesticide is used in a manner consistent with the pesticide product labeling, including the requirements of this part, when applied on an agricultural establishment by a handler employed by the commercial pesticide handling establishment.

(b) Ensure each handler employed by the commercial pesticide handling establishment and subject to this part receives the protections required by this part.

(c) Ensure that any handler employed by the commercial pesticide handling establishment is at least 18 years old.

(d) Provide to each person, including labor contractors, who supervises any handlers employed by the commercial pesticide handling establishment, information and directions sufficient to ensure that each handler receives the protections required by this part. Such information and directions must specify the tasks for which the supervisor is responsible in order to comply with the provisions of this part.

(e) Require each person, including labor contractors, who supervises any handlers employed by the commercial pesticide handling establishment, to provide sufficient information and directions to each handler to ensure that the handler can comply with the provisions of this part.

(f) Ensure that before any handler employed by the commercial pesticide handling establishment uses any equipment for mixing, loading, transferring, or applying pesticides, the handler is instructed in the safe operation of such equipment.

(g) Ensure that, before each day of use, equipment used by their employees for mixing, loading, transferring, or applying pesticides is inspected for leaks, obstructions, and worn or damaged parts, and any damaged equipment is repaired or is replaced.

(h) Ensure that whenever a handler who is employed by the commercial pesticide handling establishment will be on an agricultural establishment, the handler is provided information about, or is aware of, the specific location and description of any treated areas where a restricted-entry interval is in effect, and the restrictions on entering those areas.

(i) Provide the agricultural employer all of the following information before the application of any pesticide on an agricultural establishment:

(1) Specific location(s) and description of the area(s) to be treated.

(2) The date(s) and start and estimated end times of application.

(3) Product name, EPA registration number, and active ingredient(s).

(4) The labeling-specified restricted-entry interval applicable for the application.

(5) Whether posting, oral notification or both are required under § 170.409.

(6) Any restrictions or use directions on the pesticide product labeling that must be followed for protection of workers, handlers, or other persons during or after application.

(j) If there are any changes to the information provided in § 170.313(i)(1), § 170.313(i)(4), § 170.313(i)(5), § 170.313(i)(6) or if the start time for the application will be earlier than originally forecasted or scheduled, ensure that the agricultural employer is provided updated information prior to the application. If there are any changes to any other information provided pursuant to § 170.313(i), the commercial pesticide handler employer must provide updated information to the agricultural employer within two hours after completing the application. Changes to the estimated application end time of less than one hour need not be reported to the agricultural employer.

(k) Provide emergency assistance in accordance with this paragraph. If there is reason to believe that a handler has experienced a potential pesticide exposure during his or her employment by the commercial pesticide handling establishment or shows symptoms similar to those associated with acute exposure to pesticides during or within 72 hours after his or her employment by the commercial pesticide handling establishment, and needs emergency medical treatment, the commercial pesticide handler employer must do all of the following promptly after learning of the possible poisoning or injury:

(1) Make available to that person transportation from the commercial pesticide handling establishment, or any agricultural establishment on which that handler may be working on behalf of the commercial pesticide handling establishment, to an operating medical care facility capable of providing emergency medical treatment to a person exposed to pesticides.

(2) Provide all of the following information to the treating medical personnel:

(i) Copies of the applicable safety data sheet(s) and the product name(s), EPA registration number(s) and active ingredient(s) for each pesticide product to which the person may have been exposed.

(ii) The circumstances of application or use of the pesticide.

(iii) The circumstances that could have resulted in exposure to the pesticide.

(l) Ensure that persons directly employed by the commercial pesticide handling establishment do not clean, repair, or adjust pesticide application equipment, unless trained as a handler under § 170.501. Before allowing any person not directly employed by the commercial pesticide handling establishment to clean, repair, or adjust equipment that has been used to mix, load, transfer, or apply pesticides, the commercial pesticide handler employer must provide all of the following information to such persons:

(1) Notice that the pesticide application equipment may be contaminated with pesticides.

(2) The potentially harmful effects of exposure to pesticides.

(3) Procedures for handling pesticide application equipment and for limiting exposure to pesticide residues.

(4) Personal hygiene practices and decontamination procedures for preventing pesticide exposures and removing pesticide residues.

(m) Provide any records or other information required by this part for inspection and copying upon request by an employee of EPA or any duly authorized representative of a Federal, State or Tribal government agency responsible for pesticide enforcement."

Please note that EPA has not removed the references to labor contractors in this section. This is because the rule must still address the possibility that a CPHE could hire handler labor through a labor contractor and the CPHE must be responsible for providing handler protections to individuals hired through a contractor. The final rule has been revised so that a CPHE is no longer considered a labor contractor under the WPS, and therefore the CPHE handlers will not be considered employees of the agricultural establishment when hired through the CPHE, but it recognizes that a CPHE may use labor contractors.

13. § 170.315 Whistleblower

General comment: Because agricultural employers must already comply with OSHA regulations on health and safety, USDA seeks a broad inter-agency discussion on whistleblower rights of workers. OSHA already investigates whistleblower complaints under seven environmental statutes, and established procedures are already in place for OSHA investigations. Is there a way to take advantage of existing OSHA investigative standards, regulatory processes and whistleblower investigative procedures for farm accidents, labor, chemical hazards, dust, wages, migrant housing, sanitation, drinking water, *etc.?* This would also take advantage of existing state whistleblower laws and regulations. Both growers and workers would benefit as there will be one Federal body to place whistleblower complaints and an existing regulatory process and infrastructure. One can therefore expect farmworkers, agricultural employers and labor contractors to experience reduced regulatory confusion.

EPA Response. EPA is interested in meeting with OSHA regarding their whistleblower procedures and standards. The final WPS has adopted language consistent with OSHA's approach to providing whistleblower protections, and it makes sense to have similar processes for investigations. However, as it is not clear that OSHA can adequately enforce the WPS whistleblower provisions, EPA is not prepared to cede that responsibility to OSHA. Although OSHA jurisdiction covers most areas of agriculture, they do not cover pesticide use or establishments with fewer than 11 workers, i.e., the majority of the farms subject to the WPS.

14. § 170.401(a) and § 170.501(a) Annual Training

USDA. After reviewing the public comments and conferring with state Departments of Agriculture, USDA finds that annual training for workers and handlers will place an excessive burden on states and growers, without any evidence of increased protections for workers. USDA recommends that training should be required at most every two years.

Moreover, USDA urges that EPA confer with their state regulatory partners regarding the feasibility of annual training with respect to the ability of state and extension service personnel at local universities to enforce or provide training on an annual basis. USDA has noted letters of concern dated August 15, 2014, in the docket from the Association of American Pest Control Officials (AAPCO) and the National Association of State Departments of Agriculture (NASDA). Federalism and resource issues were raised by NASDA. Also, per the Louisiana AgCenter August 18, 2014, Docket Letter to EPA, "In Louisiana, we already retrain workers and handlers every three years. This is a dramatic change requiring annual training rather than every five years. This would increase the cost of the program and limit opportunities

to attend training sessions. What is the funding source to support this increase in the frequency of training events?"

Finally, the Forest Service's experience with mandatory annual training is that such training becomes robotic and less useful over time. USDA is concerned that an annual training requirement will add costs without any appreciable benefit or increase in safety. Annual training for handlers is required in California, but probably not too many other places.

EPA Response. EPA is sensitive to the concerns of agricultural employers regarding the potential burden of annual training. Many comments linked the concern for burden with EPA's proposal to eliminate one segment of trainers, certified applicators, from qualifying as trainers of workers. Based on the comments in support of allowing certified applicators to train workers, EPA reassessed the ability of certified applicators to provide worker training and has retained certified applicators as trainers in the final rule. EPA believes that, with the addition of certified applicators as trainers, there are adequate resources to provide worker safety training. Please refer to the USDA comment 18 from this document:

> "USDA is very supportive of expanding the class of persons qualified to train workers and handlers compared to the proposed rule, and is especially in favor of allowing certified applicators to train workers (170.401) and handlers (170.501). This is particularly important to provide adequate numbers of trainers without severely straining cooperative extension trainer resources required to meet the annual training requirement in the draft final rule. USDA also supports that EPA retained the ability to use as trainers those who are so identified at the state level as qualified trainers. That allows the Forest Service in California to utilize registered professional foresters as trainers; something that was fought for in the past in state regulations."

Safety training is well recognized as an important factor to reduce workplace incidents. Despite the absence of studies on this subject, it is reasonable to attribute to the 1992 WPS the significant reduction in agricultural pesticide exposure incidents dating from the implementation of rule. Although EPA cannot attribute the reduction in incidents to particular provisions in the WPS, we think the rule has contributed significantly to this reduction, and EPA expects the number of incidents to be further reduced upon implementation of the amendments contained in this rule.

15. § 170.401(c)(1) [comment cross-referenced from EA]

USDA. Due to the added training topics and other requirements, USDA does not believe that the estimated 45 minutes of training include ample time to thoroughly cover added topics and take questions. To allow for at least 5 minutes per training topic (11 for workers and 13 for handlers) and at least 15 minutes for questions the estimated training time should be adjusted to 1.5 hours. This is still a conservative estimate and does not take into account the added time required when a translator is used.

EPA Response. Many of the topics listed for training content are self-explanatory and do not require substantial elaboration. Current EPA training videos take about 30 minutes per session, including questions. While questions and answers from workers can be unpredictable in quantity and length, based on past experience EPA estimates that the training with added content will not take longer (on average) than 45 minutes.

EPA recognizes there are many different languages in the workforce. The EA considers only new burdens that would result from the amendments to the existing WPS. Sections 170.130(c) and 170.230(c) of the existing WPS include the same requirement that training be conducted "in a manner workers can understand."

16. § 170.401(c)(3)

USDA. EPA states that after the effective date, "training programs required under this section must include, at a minimum, all of the topics listed in § 170.401(c)(i)–(xvi) . . ." This is followed by a list of 23 points numbered from (i) to (xxiii). If only the first 16, up to (xvi), should be included in future training, there is no reason to include the remaining 7 points in the rule. Alternatively, if all 23 points should be included in future training, then the language should be corrected to include "all of the topics listed in § 170.401(c)(i)–(xxiii) . . ."

Most of the points listed in § 170.401(c)(3), including (ii)–(xv) and (xix)–(xxii), sound like topics for training, as they should. However, there are a few points, notably (i), (xvi)–(xviii), and (xxiii), that sound like restated or new requirements placed on agricultural employers. Unlike the other points, these five points include "agricultural employer" as the subject together with commanding verbs such as "are required," "must not," "must," and "are prohibited." This could easily lead to confusion

if these points are misinterpreted as binding requirements, rather than training topics.

In addition to being generally misleading, two of these five points include statements that are incorrect. First, (i) states that agricultural employers are required to "*provide* pesticide safety training," (emphasis added) when in fact agricultural employers are merely required to "*ensure* that each worker has been trained" (§ 170.401(a), emphasis added), meaning that workers can be trained by a third party. Second, (xvi) states that agricultural employers are required to "provide workers information about the location of safety data sheets," when in fact agricultural employers must display the safety data sheets "at a place on the agricultural establishment where workers and handlers are likely to pass by or congregate" and must allow workers "access to the location of the information" (§ 170.311(b)), but there is no express requirement to provide workers information about this location.

USDA recommends that at a minimum, the language in (i) and (xvi) be corrected to properly reflect the requirements placed on agricultural employers in the WPS. EPA should also consider rewording all of the five points in question—(i), (xvi)–(xviii), and (xxiii)—to make it clear that these are merely topics for training, and not new requirements.

EPA Response. EPA appreciates the correction, and has included all the points in the citation at 170.401(c)(3). EPA will revise the language at § 170.401(c)(3)(i), (xvi)–(xviii), and (xxiii) to clarify their intent as training points.

Regarding § 170.401(c)(3)(i), USDA's comment is correct; the employer is required only to ensure that the worker or handler has been trained. Therefore, EPA has adjusted the language to reflect that distinction. However, the comment stating that there is not a requirement for employers to inform workers and handlers of the location of the safety data sheets that reflects the training point at 170.401(c)(3)(xvi) is incorrect; please refer to 170.403(a) and 170.503(b)(1) that instruct the employer to inform their employees of the location(s) of the safety data sheets.

17. § 170.401(c)(3)(i)

USDA. Add the phrase "in writing" after "designate" to make it clear to workers that such designation must be in writing.

EPA Response. This change has been made. The rule text at § 170.401(c)(3)(i) has been revised as follows:

> (i) Agricultural employers are required to provide workers with information and protections designed to reduce work-related pesticide exposures and illnesses . . . A worker may designate in writing a representative to request access to pesticide application and hazard information.

18. § 170.401(c)(4) and § 170.501(c)(4) certified applicators

USDA. USDA is very supportive of expanding the class of persons qualified to train workers and handlers compared to the proposed rule, and is especially in favor of allowing certified applicators to train workers (170.401) and handlers (170.501). This is particularly important to provide adequate numbers of trainers without severely straining cooperative extension trainer resources required to meet the annual training requirement in the draft final rule. USDA also supports that EPA retained the ability to use as trainers those who are so identified at the state level as qualified trainers. That allows the Forest Service in California to utilize registered professional foresters as trainers; something that was fought for in the past in state regulations.

EPA Response. None required.

19. § 170.401(d) National Data Base for trained workers and handlers

USDA. USDA reminds EPA of the comments submitted by key stakeholder groups that have responsibilities for record-keeping:

a. Association of American Pest [sic] Control Officials (AAPCO)

AAPCO supports record-keeping of employee training. We recommend that the date of birth be removed as a requirement from the record, as this will complicate use of the record, since the birth date can be considered confidential information. The employer must verify age by other means (license, immigration documentation, *etc.*) for personnel purposes that are maintained separately. We recommend that the Agency provide a template for record-keeping that can be provided as a convenience for employers, but not make use of the template a requirement. The records should be kept by the agricultural employer.

EPA Response. EPA was convinced by concerns raised by states regarding the confidentiality issues with personally identifiable information, and has removed the requirement for a record of the birthdate in the training record.

EPA plans to develop an optional form that employers may use to collect training records.

USDA.

b. Association of American Pest [sic] Control Officials (AAPCO)

AAPCO has serious concerns about the requirement in § 170.101(d)(2). The possibility for use of fraudulent records is real, and verification of the training record could require significant resources by state lead agency personnel, or may be impossible if the record is provided by an out of state trainer. AAPCO recommends that EPA develop a national data base that can be used by certified trainers to enter information, coupled with a national card with a scannable bar code. State lead agencies can access the data base to verify the training record. State lead agencies should not be expected to rely on the employee-provided record to verify training.

National Association of State Departments of Agriculture (NASDA)

We encourage EPA to consult with NASDA, SFIREG, AAPCO, and the regulated community to discuss and review the benefits and drawbacks of developing a central repository for basic training information submitted to and retained by EPA.

EPA Response. Please refer to the notice of proposed rulemaking Unit VII B, 79 FR 15444, page 15463, for a discussion of the advantages and disadvantages of a centralized database for training records. EPA declined to propose requirements that would centralize the recorded information because it would burden employers to enter the data, and the requirement for on-site records for inspection purposes would remain. EPA continues to believe that the costs of such a scheme would outweigh its expected benefits. Although there are potential uses for a centralized database of trained workers and handlers, EPA believes that it would require significant resources committed to ensure data quality. Giving workers and handlers a copy of their training records on their request should provide workers and handlers a simple way to demonstrate prior training to a new employer.

20. § 170.405(a)

USDA. USDA is concerned how helicopter or fixed wing applications can possibly meet this standard without *de facto* buffers. A pilot would otherwise have to be constantly scanning a distance of 100′ from the aircraft in all directions looking for some errant person; which is a huge safety issue in itself. This essentially means that a 100′ buffer remains with aerial applications.

EPA Response. The provision in § 170.405(a) establishes a requirement on the agricultural employer, not the applicator (handler). Specifically, an agricultural employer must not allow or direct a worker or other person to remain in the treated area or application exclusion zone within the boundaries of the establishment until application is complete. This is a relatively small extension of the current requirement in § 170.110(a) for agricultural employers to keep workers and others out of a treated area during application on farms and forests. The final rule will cover a slightly larger area from which the agricultural employer must exclude workers and other persons but only while the application equipment is treating that specific section of the treated area. For the example of an aerial application, there would be an additional 100′ area along the side of the treated area from which people must be excluded, but only while the helicopter or airplane is treating that edge of the field. Once the aircraft has left the edge of the field, workers and other persons must be excluded of only the treated area, as is currently required.

As explained in Unit IX.B.2, EPA notes that the application exclusion zone is *not* a "buffer," a term that typically is used to describe an area that cannot be sprayed. The application exclusion zone is simply an area around active application equipment that moves with the application equipment as the application progresses. Under the final rule, a pesticide can be applied in an application exclusion zone, and the requirement for agricultural employers is to keep workers and other people out of this zone (which is a specified distance from the application equipment, not the edge of the treated area) during the pesticide application.

For additional information, see the response to question 26.

21. § 170.409(b)(3)(ii)—forestry signs

USDA. The requirement to post outdoor production areas at all normal access points, or roads, or trails, or if no access points, at corners of the units can be problematic in forestry. Is a skid trail or a landing considered a road or access point? What if no roads or trails access the unit? Posting the corners makes no sense in such a case, as those would be essentially invisible anyway. EPA may want to reconsider posting requirements related to forestry regulations.

EPA Response. The requirement in the final rule is that "the signs must be visible from all reasonably expected points of worker entry to the treated area, including at least each access road, each border with any worker housing area within 100′ of

the treated area and each footpath and other walking route that enters the treated area." EPA does not believe the application of this proposal to forestry operations is unique or substantially from its application to large fields or orchards that may not have definitive points of entry. In the situation described above, the draft final rule would require the employer to consider whether the "skid trail" or landing is a reasonably expected point of worker entry; if so, then it must be posted. Where there are no reasonably expected points of worker entry, the draft final rule provides that "signs must be posted in the corners of the treated area or in any other location affording maximum visibility." If as USDA suggests, the geography of a particular treated area makes posting the corners irrelevant, then the employer should post the locations providing maximum visibility for workers entering the treated area.

EPA intends that the final rule should apply to these situations in the same manner as described in the existing WPS IGW guidance that addresses this topic (a copy of the WPS IGW guidance applicable to this issue is included below). It is worth noting that EPA intends to revisit all the existing WPS IGW guidance Q&As and will retain those that are still applicable, and will revise any guidance that is still necessary but needs to be updated to reflect changes in the final rule. EPA would be glad to work with USDA to revise the existing WPS IGW guidance related to posting such types of fields/forests to make sure it adequately addresses forestry concerns.

13–10 Posting areas with unlimited entry points

Question: If a treated area has unlimited entry points, how often should treated-area warning signs be posted to be "visible from all usual points of entry?" Every 100′?

Answer: The rule requires that signs be visible at all usual points of worker entry, including at least each access road, each border with any labor camp adjacent to the treated area, and each footpath and other walking route that enters the treated area. If there are many usual points of entry, then signs must be visible from all usual points of entry. When there are no usual points of worker entry, signs must be posted in the corners of the treated area or a location affording maximum visibility. In areas where there are unlimited points of entry, the agricultural employer must determine the usual points of entry and make signs visible from those points of entry. (March 7, 1995)

22. § 170.411(b) Decon water—1 gallon/worker

USDA. Requiring a gallon of water at the beginning of the work shift for every worker entering a treated unit for a period lasting 30 days after the REI could be problematic in forestry applications. If the water is always located in the worker's vehicle, it is probably not a major issue, although carrying extra canteens in the vehicle will be a change in procedures.

EPA Response. Since the WPS requirement for the quantity of decontamination water for workers in the final rule is merely a codification of an existing WPS IGW policy that clarified what a "sufficient" amount of water per worker was, EPA does not believe this change should represent a significant burden compared to the existing rule. Since this is water that only has to be available at the area where decontamination supplies are provided, or at the nearest point of vehicular access, the provision will not result in workers having to carry any water on their persons. It will only necessitate that the required amount of water per worker be available at the area where decontamination supplies are provided, or at the nearest point of vehicular access. Additionally, EPA believes the current exceptions in the rule for the location of decontamination supplies provide adequate flexibility to agriculture and forestry to accommodate the range of situations.

23. § 170.411(d) and § 170.509(c)—define nearest place of vehicular access

USDA. The term "nearest place of vehicular access," which is where decontamination supplies must be stored when workers or handlers are working in remote areas, is not defined in the WPS. This location depends on whether one considers just regular automobiles that travel on paved or well-maintained unpaved roads; or also tractors and all-terrain vehicles that can travel where regular automobiles cannot; or even helicopters, drones, and other aircraft. Is there a general standard for what "nearest place of vehicular access" means, or does it depend on which vehicles the agricultural employer or handler employer happens to have available at the time? USDA recommends the EPA include a definition of "nearest place of vehicular access" in § 170.305.

EPA Response. EPA does not believe it is necessary to define the phrase "nearest place of vehicular access" because the term is sufficiently clear in its meaning without further explanation. USDA is correct that the nearest place of vehicular access

would be dependent on the type of vehicle in use for the situation, and because it is not practical to describe all situations, EPA believes it is appropriate to use a general term that can be easily interpreted. In the 20 years of WPS implementation and taking questions from regulators and the regulated community, EPA is not aware of any serious disagreement related to the meaning of the phrase "nearest place of vehicular access", and feels that trying to define the term may reduce the existing flexibility in the rule afforded by the current approach.

24. Subpart F, § 170.501–170.509 Conflict between "handler employer" and "CPHE employer"

USDA. Subpart F assigns a host of responsibilities regarding handlers to the "handler employer." As noted in the comments on § 170.305, the definition of "handler employer" is currently so broad, that at any given moment there could be two or more "handler employers" responsible for the same handler (*i.e.,* the agricultural employer and one or more commercial pesticide handler employers).

This dual responsibility is very problematic. Is each requirement in Subpart F supposed to be carried out in duplicate? This would mean that both the agricultural employer and the commercial pesticide handler employer would have to independently check the handler's training status (and keep the corresponding records), age, and knowledge of relevant information; both would have to ensure that handlers using highly toxic pesticides or fumigants within enclosed spaces are monitored regularly; and both would have to provide PPE and decontamination supplies to the handler. This approach would be ridiculously wasteful. At the same time, it is questionable whether splitting responsibility between the agricultural employer and the commercial pesticide handler employer would lead to better results, since the two parties would have to coordinate extensively to determine who will cover each requirement.

USDA recommends that EPA address this problem by making the changes to the definition of "labor contractor" in § 170.305 suggested above, which would have the practical effect of changing the definition of "handler employer" to mean only the handler's *direct* employer, whether that is an agricultural employer or a commercial pesticide handler employer.

EPA Response. EPA believes it has made the revisions to the rule text necessary to address USDA's concerns in this area. Please see EPA's responses to comments 8b and 12.

25. § 170.501(c)(3)(xiv) training for handlers—error in reg text

USDA. This section requires that the training for handlers include the following point: "Handler employers must post treated areas as required by this rule." However, under § 170.309(h) and § 170.409, it is the agricultural employer—not the handler employer—who is required to display information and signs related to pesticide applications and worker entry restrictions. USDA recommends that EPA resolve this discrepancy.

EPA [R]esponse. EPA corrected the text of the final rule to refer to the agricultural employer.

26. § 170.505(b)—AEZ—handler suspend application if person in zone, even when outside the property

USDA. This section requires that handlers suspend pesticide application when individuals are present in the application exclusion zone. Unlike in § 170.405(a)(2), there is no exception if the individuals are outside the boundaries of the agricultural establishment, for example on a neighboring property or on a public right-of-way. USDA recommends that the language in § 170.505(b) should be adjusted to match § 170.405(a)(2): ". . . the handler performing the application must immediately suspend a pesticide application if any worker or other person [other than another handler] is in the application exclusion zone described in § 170.405(a)(1) *that is within the boundaries of the establishment* . . ." The agricultural employer has no control over individuals outside of the agricultural establishment, and this should be recognized by not requiring automatic suspension of application in situations where individuals beyond the boundaries of the establishment might peripherally encroach on an application exclusion zone. It should be noted that § 170.505(a) already requires the handler to "ensure that no pesticide is applied so as to contact, directly or through drift, any worker or other person [other than another handler]." This renders superfluous the additional restriction in § 170.505(b) requiring suspension when the application exclusion zone is encroached outside the establishment.

EPA Response. EPA disagrees that the application exclusion zone should be limited to the boundaries of the agricultural establishment for the requirement in § 170.505(b) for a handler to suspend application if a worker or other person is in the application exclusion zone.

EPA agrees with USDA that labels and § 170.210(a) already require handlers to apply in a way so pesticides do not contact a worker or another person. However, these provisions appear inadequate because drift from pesticide applications continues to cause human exposure incidents. EPA also agrees that an agricultural employer has no control over individuals outside the establishment, which is why the requirement for agricultural employers in § 170.405(a) is limited to the boundaries of the agricultural establishment. However, the handler who is applying the pesticide does have the ability to temporarily suspend an application and restart it after the worker or person leaves the area. Handlers who are applying should already be doing this so they do not contact a worker or other person during application. As stated by the National Agricultural Aviation Association in their comments on the proposed rule, "It is standard operating procedure for aerial applicators to temporarily avoid making passes adjacent to such [rural] roads if workers happen to be passing by in vehicles or on foot."

27. § 170.507 [comment cross-referenced from EA] Respirator Requirement costs and update terminology

USDA. The discussion of costs associated with respirator fit tests could be clarified by providing additional information on the types of pesticides that are assumed to require respirators, the frequency those pesticides are applied (every year or less frequently), and the number of farms likely to apply those pesticides.

Consistent use of terminology: USDA commends the change of terminology from dust/mist filtering respirator to filtering facepiece respirator. Use of the OSHA terminology prevents confusion and contributes to more cohesive standards across agencies. USDA suggests the addition of this term to § 170.205 to reflect the definition provided by OSHA in 29 CFR 1910.134 (b) (quoted below) for further clarity.

> "*Filtering facepiece respirator* means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium."

EPA Response. EPA disagrees that a detailed discussion of the respirator cost analysis is needed in the *Federal Register.* Those details are included in the economic analysis.

EPA appreciates USDA's comments on changing terminology from dust/mist respirators to filtering facepiece respirators. The final WPS rule only uses the term filtering facepiece respirator in the preamble; it does not appear in the reg text itself. Therefore, EPA has added OSHA's definition of filtering facepiece respirator to Unit XV.A.3 of the preamble as follows: ". . . Many farmworker advocacy organizations and some PPE manufacturers asserted that EPA should also apply the proposed standards for fit testing, training, and medical monitoring to users of filtering facepiece respirators in addition to the other respirator types (*e.g.,* tight fitting elastomeric facepieces). Commenters suggested that filtering facepiece respirators are widely used and covered by OSHA's respirator requirements, and that their exclusion would result in inadequate protection for many pesticide handlers. *OSHA defines a filtering facepiece as 'a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium' in 29 CFR 1910.134(b)."*

28. § 170.509(b) and (d) decon water in forestry

a. USDA. Requiring 3 gallons of water per handler at the beginning of the work shift will be problematic, especially if added to the eye wash requirement of 6 gallons of water for mixer/loaders using pesticides requiring protective eyewear. When using backpack applicators, each handler is at some point a mixer/loader (loading from a batch tank into the backpack, most commonly). A crew of 8 applicators could then potentially need 72 gallons of water to be carried each day. This seems excessive. It is clear that each handler requires 3 gallons of water at the start of the shift for decontamination, but in such a circumstance as described, would a crew of 8 each need 6 gallons for eye flushing, or would one quantity of 6 gallons meet the requirement? This could be clarified.

EPA Response. Section 170.509(d) requires an emergency eye wash system at the mixing/loading site immediately available to the handler when a handler is mixing or loading a product whose labeling requires protective eyewear for handlers. Only one emergency eye wash system (that meets the WPS requirements) is required at a mixing/loading site regardless of how many handlers are mixing or loading at that site. EPA has revised Unit XII.C.3 of the preamble as follows to clarify this: ". . . The final rule allows employers to provide either at least 6 gallons of water in containers suitable for providing a gentle eye flush for about 15 minutes, or a system capable of delivering gently running water at a rate of 0.4 gallons per minute for at least 15 minutes to satisfy the requirement. *One emergency eye wash system is*

required at a mixing/loading site when a handler is mixing or loading a product whose labeling requires protective eyewear to handlers, regardless of how many handlers are mixing or loading at that site." The final rule retains the existing requirement for water to be of "a quality and temperature that will not cause illness or injury."

b. USDA. May this water be drafted from local natural surface waters (woodland stream)? May the requirement be met by pre-positioning 6 gallons at the nearest place of vehicular access outside any treated area or area subject to a restricted-entry interval? Clarification invited.

EPA Response. The water in an emergency eye wash system can be drawn from local natural surface waters if the handler employer has determined the water meets the standard of being "of a quality and temperature that will not cause illness or injury when it contacts the skin or eyes or if it is swallowed" as required in § 170.509(b)(1). An emergency eye wash system at the nearest place of vehicular access would not satisfy the requirement of § 170.509(d)(1) unless it is "at the mixing/loading site immediately available to the handler."

29. § 170.601(a)(1)(xii)—mistake in numbering in reg text

USDA. This point references § 170.605(a) through (c) and (e) through (k). However, the rule as currently written does not include a § 170.605(k), only (a) through (j). EPA likely meant to write § 170.605(a) through (c) and (e) through (j).

EPA Response. This change has been made to the rule text.

USDA Comments on EPA Worker Protection Standard Economic Analysis

30. § 170.311 Display Requirements for Pesticide Application and Hazard Information

a. USDA. The economic analysis does not account for provision of safety data sheet and information about the application to the worker or a designated representative within 15 days of request for such material. In addition, there is no cost assumed for mailing this material to the designated representative. There is no estimate of the expected number of requests for this information by workers or their representatives. These costs should be included.

EPA Response. These costs have now been included in the EA (Section 3.3.2) and Appendix B (Section 2, Tables B.2.a–2 and B.2.a–5). EPA calculates that the cost of responding to a request from a current employee to be about $3.50 and the cost of responding to a request from a former employee to be about $14, including mailing costs. It does not seem likely that costs would vary substantially whether the request comes directly from an employee or from a designated representative.

The number of requests is subject to a great deal of uncertainty; however, California and Texas have similar provisions and have not suggested that the issue arises frequently. For purposes of the EA, EPA has assumed that current employees may request hazard information once for every 20 applications made while one in 100 former employees may make a request.

b. USDA. The economic analysis assumes all farms have double-sided copies when it estimates 3.3 pages are required to store the Safety Data Sheet, reported to be 6.7 pages on average (Table B.2.b.1 Cost per Final Rule, WPS Farms, Information on Pesticide Applications, p. 17, Appendix B).

EPA Response. That is correct.

c. USDA. The period over which these records must be made available to the worker is unclear. The cost of retaining these records over time should be included and as well as the period over which they must be retained.

EPA Response. Records must be retained for two years (170.311(b)(6)). Retention costs are the cost of the folder used to store the documents, and are included in the EA.

31. § 170.401 Training Requirements for Workers

a. USDA. Due to the added training topics and other requirements, USDA does not believe that the estimated 45 minutes of training include ample time to thoroughly cover added topics and take questions. To allow for at least 5 minutes per training topic (11 for workers and 13 for handlers) and at least 15 minutes for questions the estimated training time should be adjusted to 1.5 hours. This is still a conservative estimate and does not take into account the added time required when a translator is used.

EPA Response. EPA's experience with the training material, as well as information provided in comments, suggest that current training sessions are about 30 minutes in length. One respondent to a questionnaire by the National Council of Agricultural Employers indicated that in the past year they spent about 2,100 hours training 4,400 workers, or slightly less than 30 minutes per worker. See EPA's response to Comment 15, above.

b. USDA. The Economic Analysis does not take into consideration the cost of a translator for training. Though a translator is not required by the regulation, it does suggest the use of a translator in order to ensure that training is carried out "in a manner workers understand" (citation). These costs could be incorporated by estimating a reasonable probability of the number of trainings that will require a translator. Since EPA plans to develop training materials in several languages, the probability of requiring a translator could be estimated based on which languages and dialects would not be covered by those materials.

EPA Response. The EA considers only new burdens that would result from the amendments to the existing WPS. Sections 170.130(c) and 170.230(c) of the existing WPS include the same requirement that training be conducted "in a manner workers can understand".

c. USDA. Small farms bear a disproportionately larger cost for the new training requirements than large farms. The economic analysis Appendix B states that worker training costs will result in an increase of 85% over baseline costs for small-small WPS farms, and increase by 75% for medium-small WPS farms and large-small WPS farms with less than 10 employees, 48% for large-small farms with 10 or more employees, and 42% for large WPS farms. It would be clearer if costs were summarized for each of these farm size categories for each of the rule provisions throughout the economic analysis.

EPA Response. USDA appears to have misunderstood the information in Appendix B. The percentage changes reported do not refer to increases in overall costs, only the change in the number of trainings needed. For example, the Appendix states that "Small-small farms (revenue/year less than $10,000) are assumed to hold an average of 1.2 training sessions per year, an increase of 85% over the baseline." That is, the number of training sessions increases from an average of 0.65 sessions to 1.2 sessions, an absolute increase of 0.55 sessions. EPA assumes a large farm (revenue ≥$750,000) with more than 10 workers will increase the average number of training sessions from 4.5 sessions to 6.4, an absolute increase of 1.9 sessions.

EPA has provided a summary of costs by farm size throughout the analysis and provided an analysis of overall impacts to small farms, defined by the Small Business Administration as entities with revenue less than $750,000. Because this definition implies that 95% of all U.S. farms, and almost 80% of farms affected by the WPS, are small, EPA also provides a more detailed analysis to examine the impacts across the distribution of small farms.

d. USDA. The cost per farm of training workers or handlers appears to assume that only 1 training record per training needs to be retained by the farm (Table B.1.b.3. Cost under Final Rule, cost per WPS farm by size, Worker Training). For both large and small WPS farms, the economic analysis assumes retention of only one copy per training event. If a worker requests a copy, USDA assumes that only the worker's information will be provided and not the records of other workers who also attended the training. If EPA assumes the employer will provide records for all workers attending training (for example on the same sign-in sheet) when one worker requests their training record, the impact of this provision on privacy requirements should be included in the analysis. If privacy constraints prevent sharing records of other workers, the cost of record retention at the farm level should reflect the cost of providing individual records.

EPA Response. EPA's goal is to make the process of confirming training as easy as possible. The record of the training can be as simple as a paper with the following information:

(i) The trained worker's printed name and signature.

(ii) The date of the training.

(iii) Information identifying which EPA-approved training materials were used.

(iv) The trainer's name and documentation showing that the trainer met the requirements of § 170.401(c)(4) at the time of training.

(v) The agricultural employer's name.

As the draft final rule does not require the collection of any personally identifiable information, no personally identifiable information would be included in the record. For a worker to confirm to a subsequent employer that he or she has recently completed the pesticide safety training, a copy of the training record would have the information needed for the subsequent employer's records.

e. USDA. As part of their preliminary research, EPA conducted a Small Business Administration Review Panel (SBAR Panel or Panel). In almost every written comment they received, small business owners urged them to keep a grace period for employee training. Since EPA conducted a SBAR Panel, USDA would like to see an

acknowledgment that these issues were taken into consideration. Though most of the commenters did not see many real cost added with removing (or decreasing) the grace period, they did indicate that workers would have to be hired sooner and thus paid for days where the employer received no work. If the time lost from work is considered in the benefits section regarding healthcare, then time lost from work due to training and paperwork must be considered in the costs.

EPA Response. EPA thinks the elimination of the grace period is not likely to lead employers to hire workers and pay them for no work. Rather, EPA anticipates that employers may have to provide additional training sessions (see response 31.c.). The opportunity cost of time for the worker to attend a safety training is included in the estimated cost of the revisions.

f. USDA. The elimination of the grace period and the requirement that all workers be trained "in manner workers understand" creates the potential for discrimination on the basis of language and literacy. Economic analysis should discuss the probability that workers who speak the language used by the employer or by on-site trainers will be used more frequently when training is required by temporary or seasonal workers immediately prior to performing a field or handler task. If a farm must train workers immediately before any allowable exposure to pesticides, the most easily trained workers will be more likely to be used in job situations where exposure could occur, at least initially.

EPA Response: EPA notes that the requirement for training to be provided in a manner that the worker can understand is not new. EPA has not received comment regarding discriminatory practices related to language as a result of the WPS.

32. § 170.507 Personal Protective Equipment

a. USDA. Consistent use of terminology: USDA commends the change of terminology from dust/mist filtering respirator to filtering facepiece respirator. Use of the OSHA terminology prevents confusion and contributes to more cohesive standards across agencies. USDA suggests the addition of this term to § 170.205 to reflect the definition provided by OSHA in 29 CFR 1910.134 (b) (quoted below) for further clarity.

> "***Filtering facepiece respirator*** means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium."

Costs and benefits: In the cost estimate for the addition of filtering facepiece respirators the Agency assumes that all employers will use the suggested online medical evaluation (introduced in lines 3388–3394 of the rule preamble) from the outset. While the use of online medical evaluations would be the most cost-effective option for employers, assuming that employers will be able to use this method of evaluation in the first years of implementation does not seem likely. This is especially true for rural areas where broadband access is not available on every farm operation. Though online medical evaluations will likely be used by some employers, the estimated probability seems high for the first year. The probability of using an off-site medical evaluation is much more likely in the first year with a decreasing probability within the first five years as employers learn more about their available options.

EPA Response. EPA does not agree with USDA's reasoning. Employers are unlikely to forego cost-effective options, even initially. EPA plans significant outreach and is confident that private interests, including crop advisors and pesticide dealers, will engage in similar programs. According to the 2012 Census of Agriculture almost 70% of U.S. farms have Internet access and most have high-quality service, including broadband or DSL. Less than 10% of farms rely on dial-up connections.

b. USDA. Additionally, the time estimate for an off-site medical evaluation (Table 3.3–34) should use the same estimate as the follow-up medical exam ($72.12). The analysis must also take into consideration the lost wages and travel time associated with visiting a medical professional considering that most farm operations are located in rural areas where access to a licensed medical professional may increase time and travel. The time should at least reflect the time allotted to the evaluation, but should also include at least 30 minutes of travel time. Please see table below for an example of suggested edits.

Table 3.3–34. Costs under Final Rule, Large WPS Farm, Respirator Fit Test

Action/Material (j)	wage/price $_{wj}$	unit time/quantity $H_{r,i,j}/M_{r,i,j}$	annual frequency Prob (ji)	cost
Time for medical evaluation	$20.04/hr	1.5 hour	0.535	$16.08
Off-site evaluation	$72.17	1	0.535	$38.61

Table 3.3–34. Costs under Final Rule, Large WPS Farm, Respirator Fit Test—Continued

Action/Material (j)	wage/price $_{wj}$	unit time/quantity $H_{r,i,j}/M_{r,i,j}$	annual frequency Prob (ji)	cost
On-line evaluation	$27.00	1	0.134	$3.62
Time for follow-up exam [1]	$20.04/hr	2 hour	0.134	$5.36
Follow-up medical exam [1]	$72.17	1	0.134	$9.66
Time for fit test, with travel	$20.04/hr	1.5 hour	0.535	$16.09
Fit test and training	$50.00	1	0.535	$26.76
Employer management	$33.44/hr	1 hour	0.535	$17.90
Collect/Store documentation	$33.44/hr	4 min	0.535	$1.19
$cost_{r,i,a}{}^{P}$				**$135.27**

Source: EPA estimation. See text for data sources. Numbers may not sum due to rounding. 1 EPA assumes approximately 25 percent of handlers taking the medical evaluation will be referred for a more complete medical examination.

EPA Response. EPA does not agree with USDA's reasoning that employers will select a more costly response to the regulatory burden. Further, if they choose to skip the screening evaluation for a complete medical evaluation *e.g.,* because of a previously scheduled physical examination, there would be no need for an on-line (screening) evaluation or subsequent follow-up evaluation.

c. USDA. In the Economic Analysis for the rule, EPA explains that it derives costs for respirator fit tests from the assumption that each farm will only have one handler that will need to be fit tested and that only 40 percent of farms will likely use pesticides that require respirators.

> "Accounting for the fact that not all farms will use pesticides every year, EPA estimates about 40 percent of large farms and large-small farms will use a product requiring a respirator. A farm is unlikely to need more than one handler when using these products, so for ease we calculate costs at the farm level. Further, some handlers will undergo fit testing because the requirement has been incorporated onto some product labels, for example, various soil fumigants." (Economic Analysis § 3.3.6)

With the addition of filtering facepiece respirators, USDA does not believe this estimate is accurate. First, though only one handler may be involved in pesticide use at a time, this does not imply that there is only one handler on the farm that will need to be fit tested. The number of handlers per farm that need fit tests should be estimated based on small *versus* large WPS farms.

Second, the assumption that only 40 percent of farms will use pesticides that require respirators seems low considering the addition of filtering facepiece respirators (which are required for a much larger number of pesticides than chemical cartridge respirators (NIOSH 23–C)). USDA urges EPA to gather further data on the number of pesticide labels that require respirators (including filtering facepiece respirators) and use that data to re-estimate the cost of respirator fit tests.

EPA Response. EPA notes that USDA is quoting the baseline estimation of cost, where about 40% of the larger farms ultimately use a product requiring a respirator and the employer provides the handler with instruction on fit and use. Under the final rule, EPA assumes that over half of the larger farms will arrange for a handler to be tested.

d. USDA. The discussion of costs associated with respirator fit tests could be clarified by providing additional information on the types of pesticides that are assumed to require respirators, the frequency those pesticides are applied (every year or less frequently), and the number of farms likely to apply those pesticides. The economic analysis could be strengthened by providing a more detailed explanation for the assumption that under the baseline and final rule, 60% of crop-producing farms use pesticides requiring respirators with an annual use at 40% of these farms. In Appendix A, 76% of crop-producing WPS farms are estimated to use pesticides. It is unclear whether the 60% estimate requiring respirators includes pesticides requiring only the filtering facepiece respirators as well as pesticides requiring other types of respirators. The baseline calculation for the cost of fit tests at WPS farms assumes 40.4% of these farms will have a handler undergo a fit test with 3% of these baseline fit tests consistent with OSHA requirements. The final rule calculations assume 53.5% of large and 13.4% of large-small WPS farms have handlers undergoing

fit tests. EPA should present the baseline percentage of WPS farms where handlers undergo fit tests in terms of large and large-small WPS farms to allow direct comparison between the two scenarios.

EPA Response. EPA does not think further discussion is warranted. As noted in the EA, "Pesticides bearing label requirements for respirators are not common, but there are a few commonly used pesticides with the requirement." The requirement is product-specific and may apply to the mixer/loader and/or to the applicator. In the end, EPA assumes that 75% of large and large-small primarily crop farms (farms with annual revenue of $750,000 or more and farms with annual revenue between $100,000 and $750,000, respectively) will account for virtually all respirator use subject to the WPS. According to data from the 2012 Census of Agriculture, farms primarily producing crops (NAICS 111) in these size ranges account for about 67% of all crop acreage in the U.S., but about 80% of all herbicide and insecticide treated acreage and over 90% of all acres treated with fungicides or plant growth regulators.

e. USDA. The family farms fit test calculation needs further clarification. The economic analysis references Appendix A for the number of family farms by category (large, large-small, *etc.*). Appendix A does not discuss family farms explicitly—by back-calculating from the existing tables you could derive the number of family farms but this adds some uncertainty and the values do not match those reported in the economic analysis (18,949 large family farm and 141,753 large-small family farms). Further explanation or support is needed for the assumption that 40% of family farms producing crops use a pesticide requiring a respirator.

EPA Response. EPA acknowledges that *Appendix A* does not contain information on so-called family farms, *i.e.,* those farms that do not report hired labor. However, EPA has provided the exact numbers used within the analysis.

f. USDA. The values used in the baseline analysis for respirator fit tests at WPS farms are not consistent between the main economic analysis and its explanatory [A]ppendix B (See Table 3.3.32. Baseline Costs, per Large and Large-Small WPS Farm, Respirator Fit, Economic Analysis *versus* Table B–6.a.3. Baseline Cost, per WPS Farm, Respirator Fit, Appendix B). Likewise, the values reported in Appendix B for the number of large (79,434) and small-large (141,753) WPS farms do not appear in Appendix A where the reader is referred for further information. Since the population of WPS farms affected by the rule is assumed to only include crop-producing farms, it is assumed that these values represent crop-producing farms hiring labor (shown in Table A.1.10 of Appendix A). Further explanation would strengthen the economic analysis.

EPA Response. EPA acknowledges that Appendix B was in error and revised the tables and explanations.

g. USDA. In the cost estimate (p. 90, Economic Analysis) for the addition of filtering facepiece respirators the Agency assumes that all employers will use the suggested online medical evaluation (introduced in lines 3388–3394 of the rule preamble) from the outset. While the use of online medical evaluations would be the most cost-effective option for employers, assuming that employers will be able to use this method of evaluation in the first years of implementation does not seem likely. This is especially true for rural areas where broadband access is not available on every farm operation. Though online medical evaluations will likely be used by some employers, the estimated probability seems high for the first year. On-line medical evaluations are currently offered only in Spanish and English. Workers speaking other languages will need off-site medical evaluations. The probability of using an off-site medical evaluation is much more likely in the first year with a decreasing probability within the first five years as employers learn more about their available options.

EPA Response. EPA does not agree with USDA's reasoning. Employers are unlikely to forego cost-effective options, even initially. EPA plans significant outreach and is confident that private interests, including crop advisors and pesticide dealers, will engage in similar programs. According to the 2012 Census of Agriculture almost 70% of U.S. farms have Internet access and most have high-quality service, including broadband or DSL. Less than 10% of farms rely on dial-up connections. EPA does not see language as a significant barrier for employers and handlers.

h. USDA. The cost of the off-site medical evaluation used in the economic analysis is based on a single provider—Affordable Safety Training, offered in English and Spanish. A quick review of on-line medical evaluations for fit testing shows a range of products from the $25 for McHaney and Associates to $27 for Affordable Safety Training to $28 for a 3M on-line medical evaluation. These products are only offered in English and Spanish. If these medical evaluation materials need to be provided in other languages, there is no cost considered for this in the economic analysis. The Affordable Safety Training web site offers a fit test kit for $140 using Bitrex and

$139.95 using saccharin. The economic analysis cites the cost for a fit test as ranging between $80 and $140 for an employer administered test.

EPA Response. EPA agrees that there are multiple options of similar price. Fit test kits come in a range of prices with smoke tests typically costing less than other options. EPA does not see language as a significant barrier for employers and handlers.

i. USDA. The economic analysis does not include costs accounting for circumstances requiring the same person to repeat the fit test for a different class of respirator which may involve additional measurements. The medical evaluation questionnaire required by OSHA lists two separate categories of respirators. A worker/handler would need an additional fit test and evaluation if required to use another class of respirator. The analysis also does not consider agricultural establishments where the same person is not the handler for all pesticides or for the entire year. Seasonal workers may not remain at an establishment for the entire period where pesticides requiring respirators may be applied.

EPA Response. EPA does not think the cost of a medical screen would be significantly increased if the handler seeks testing for different classes of respirators. Multiple respirators could be tested at an off-farm site or tested using the same test kit.

33. § 170.601 Exemptions—family farms

a. USDA. Family farm exemption is too narrow: The exemption for family farms applies to any agricultural establishment that is wholly owned by an individual, or where **all** of the owners of the establishment are members of the same immediate family. This definition is narrower than the definition used by ERS in the Agricultural Resource Management Survey (ARMS). The ERS definition is more flexible and requires only that the majority of the business is owned by the operator and individuals related to the operator by blood, marriage, or adoption, including relatives that do not live in the operator's household. Using this definition, ERS finds around 97% of all farms are family farms based on data from ARMS.

Findings from the 2013 ARMS survey indicate that 97.6 farm are family farms, using the ERS definition. Family farms are organized as individually owned, partnerships, corporations and other types of legal status (trust, estate, cooperative). The largest category of ownership in family farms is individual ownership (91.5%). Partnerships account for 4.4 %, corporations for 3.3 % and other types of legal status for 0.8 %. Family farms that are not individually owned account for 173,434 farms.

It is unclear how many of the farms considered family farms in the economic analysis would meet the definition required in the agricultural establishment exemption. The EPA should estimate how many of the crop producing family farms would be not be eligible for the exemption and thus should be counted in population of farms that must comply with the WPS standard. If ownership type is distributed similarly between crop producing family farms and all family farms, as many as 8% of crop producing farms may not be eligible for the exemption.

EPA Response. To determine the number of farms that would be impacted by revisions to the WPS, EPA considered all farms hiring labor as reported in the 2012 Census of Agriculture. Since farms may describe in their Census report as hired labor persons who would qualify for the WPS immediate family exemption, EPA has probably overestimated of the number of farms and workers/handlers affected by the WPS.

b. USDA. The definition of immediate family is too narrow. In regard to establishing a minimum age for handlers and workers performing early-entry tasks, the final rule requires that handlers and workers performing early-entry tasks be at least 18 years old, rather than the proposed minimum age of 16 years old. This minimum age does not apply to an adolescent working on an establishment owned by an immediate family member. (EPA WPS FR page. 7). EPA has finalized the definition of "immediate family" as limited to the owner's spouse, parents, stepparents, foster parents, father-in-law, mother-in-law, children, stepchildren, foster children, sons-in-law, daughters-in-law, grandparents, grandchildren, brothers, sisters, brothers-in-law, and sisters-in-law (EPA WPS FR page 169).

The EPA should reconsider the definition of immediate family. The proposed definition would not allow the exemption to youth who would work for a more distant family member such as an uncle. This definition would also not allow the exemption to youth whose parents are farm operators, but not owners. The Department of Labor (DOL) has exemptions for youth in the child labor requirements in agricultural occupations under the Fair Labor Standards Act. The Act states: "A child of any age may be employed by his or her parent or person standing in place of the parent at any time in any occupation on a farm owned or operated by that parent

or person standing in place of that parent" (*http://www.dol.gov/whd/regs/compliance/childlabor102.pdf*). EPA should revise their definition of immediate family, or the exemption itself to be more consistent with rules enforced by DOL.

EPA Response. Under the owner and immediate family exemption in the existing WPS, establishments that qualify must be either wholly owned by the individual, or all owners of the establishment must be members of the same immediate family. While EPA is proposing to expand the types of familial relationships that would be considered "immediate family" under the WPS, EPA did not consider and does not plan to further expand the exemption to allow farms that are majority owned by family members to qualify. EPA did not propose such a change to the requirement and has not received comments from the public indicating that the current requirement for the establishment to be wholly owned by an individual or persons who are all members of the same immediate family is too restrictive.

[ATTACHMENT 9]

August 18, 2014

Hon. GINA MCCARTHY,
Administrator,
U.S. Environmental Protection Agency,
Washington, D.C.

Re: Agricultural Worker Protection Standard Revisions; Docket ID #EPA–HQ–OPP–2011–0184

Dear Administrator McCarthy:

Migrant Clinicians Network (MCN) welcomes this important opportunity to comment on the proposed revisions to the Agricultural Worker Protection Standard (WPS). MCN is a national clinical organization with over 10,000 health care provider constituents dedicated to health justice for the mobile under-served, including migrant and immigrant farmworkers and their families. MCN states unequivocally that farmworker occupational safety and health is a critical health priority. Since our inception in 1984 we have worked to eliminate health disparities among farmworkers. In particular we have focused on occupational health disparities, as the work and lifestyle that accompanies this vulnerable population places migrants at higher risk for injuries and other health problems. We have worked to address pesticide exposure on a number of levels, including our national program to improve clinical practices regarding the recognition and management of pesticide poisonings, in partnership with the U.S. Environmental Protection Agency (EPA).

We write to support many aspects of the proposed WPS that foster worker health and safety for an estimated 2 million workers across the United States who harvest our food. Additionally, we highlight areas of the proposed regulation that need to be strengthened to better protect farmworkers from pesticide exposure. These vulnerable workers, the majority of whom are immigrants from Mexico and other Latin American countries, have limited English proficiency, low educational attainment, and poverty-level incomes. They are also the most overexposed population to pesticides.

Economic analysis of the proposed rule: In its economic analysis in support of the proposed rule, EPA acknowledges that many acute pesticide incidents are underreported and adjusts its calculation regarding costs and benefits to account for the unreported costs of acute pesticide incidents. (79 *Fed. Reg.* No. 53 at 15449). MCN supports EPA's acknowledgement of underreported pesticide incidents. MCN provides training to clinicians to recognize the signs and symptoms of pesticide exposures and underscores the importance of reporting pesticide poisonings to the appropriate state agencies. Once trained, clinicians have repeatedly acknowledged that they likely have misdiagnosed and/or failed to report pesticide exposures. In 2014, over ½ the clinicians participating in MCN trainings stated they were unfamiliar with the pesticide reporting requirements in their state and did not know which agency to contact to report pesticide poisonings. MCN's Chief Medical Officer, Ed Zuroweste, M.D., has worked in the field of migrant health for over 30 years as a frontline physician, medical director of a migrant health center and a clinical consultant assessing health center performance. He has trained and provided technical assistance to thousands of clinicians. He states, "I have yet to meet an experienced clinician who has not admitted that he or she misdiagnosed or failed to report a pesticide exposure." A survey of environmental medicine content in U.S. medical schools found that 75 percent of schools require only about seven hours of study in

environmental medicine over four years.[1] Of the clinicians MCN trained in 2014, 45 percent had less than one hour of training in environmental and occupational health. It is not surprising that clinicians are unprepared to accurately recognize and manage (including report) pesticide exposure. Clinicians are also challenged in making an accurate diagnosis and reporting exposures as there are few readily accessible confirmatory clinical tests for pesticide poisoning.[2] Clinicians undoubtedly resist reporting to public health agencies unless diagnosis is certain and reporting is mandated. Although 30 states have rules requiring some form of clinician reporting of pesticide exposure and illness, only 12 states have a surveillance program to act on these reports.[3–4] Underreporting is also due to many workers not seeking medical attention for overexposures as they do not understand their rights and fear losing their jobs.

MCN agrees with EPA that the full costs of occupational illness related to pesticide exposure include not only costs in medical care and lost productivity to workers and handlers in acute incidents, but also the long-term costs from the health effects of chronic exposure to pesticides. There is an extraordinary cost to workers, farmers and our society for occupational illness and injury both in the short term and long term in terms of medical care, lost work days, lost wages, and potential workers' compensation insurance premiums for an occupational injury or illness. While the cost of illness and injury as a result of work-related pesticide exposure is challenging to determine, when occupational illness and injury are assessed across industries, the cost is more than $250 billion a year. In fact, occupational injuries and illnesses are the second costliest medical condition behind cardiovascular disease and ahead of cancer.[5] In addition, EPA is correct to consider the costs of illness related to exposures to farmworkers' families due to the pesticides that are brought home on workers' clothes, skin and hair.

Preparing and Equipping Clinicians to Protect Workers: MCN applauds EPA's recognition that clinicians play an important role in worker protection. We urge EPA to help clinicians to improve their recognition and management of pesticide exposure by supporting the development of clinical diagnostic tools, and providing training and technical assistance for clinicians. This need is underscored in recommendations outlined in the 2011 Agency for Toxic Substances and Disease Registry's National Conversation on Public Health and Chemical Exposures Action Agenda. It states: "Clinicians need a set of skills and tools for (1) diagnosing, treating, and intervening to prevent chemical exposures, (2) providing information about chemical exposures to their patients and communities, and (3) participating in surveillance for chemical exposures and health effects."[6] The National Strategies for Health Care Providers: Pesticide Initiative, established in 1998 by EPA and the U.S. Departments of Health and Human Service, Agriculture, and Labor, also aims to improve the training of health care providers in the recognition, diagnosis, treatment, and prevention of pesticide poisonings among those who work with pesticides.[7]

EPA relies on data from surveillance systems such as the SENSOR Pesticide Program in order to make decisions about pesticides once they are on the market. These systems rely in large part on reports submitted by healthcare providers. A well trained clinician, who receives education to recognize the signs and symptoms of pesticide exposures as well as information about where to report, is the first step

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[1] Schenk M., Popp S.M., Neale A.V., Demers R.Y. *Environmental medicine content in medical school curricula.* ACAD. MED. 1996 May; 71(5): 499–501.

[2] American Public Health Association. *APHA Policy Statement 20108: Requiring Clinical Diagnostic Tools and Biomonitoring of Exposures to Pesticides.* Washington, D.C.: American Public Health Association. 2010. Available at: *http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1400*. Accessed August 4, 2014.

[3] National Institute for Occupational Health and Safety. *Pesticide-related illness and injury surveillance: a how-to guide for state-based programs.* DHHS (NIOSH) Publication Number 2006–102. Washington, D.C.: National Institute for Occupational Health and Safety; 2005. Available at: *http://www.cdc.gov/niosh/docs/2006-102/pdfs/2006-102.pdf*. Accessed August 15, 2014.

[4] Centers for Disease Control and Prevention. *Pesticide Injury Surveillance: Sentinel Event Notification System for Occupational Risk (SENSOR) Program.* July 2014. Available at *http://www.cdc.gov/niosh/topics/pesticides/overview.html*. Accessed on August 16, 2014.

[5] Leigh J.P. *Economic burden of occupational injury and illness in the United States.* MILBANK Q. 2011; 89(4): 728–72.

[6] Agency for Toxic Substances and Disease Registry, *National Conversation on Public Health and Chemical Exposures Action Agenda.* 2011. Available at: *http://www.atsdr.cdc.gov/nationalconversation/action_agenda.html*. Accessed August 5, 2014.

[7] US Environmental Protection Agency, *National Strategies for Health Care Providers: Pesticide Initiative.* Available from *http://www.epa.gov/oppfead1/safety/healthcare/healthcare.htm#Cooperative*. Accessed August 18, 2014.

to improve reporting. As important are clinical diagnostic tools to confirm a clinical impression and to help provide the objective confirmation of the work relatedness of an illness. Confirmatory diagnostic tests are essential to providing the information clinicians need to treat overexposed workers and handlers and to ultimately provide EPA with the data necessary to understand the health effects of registered pesticides. The Agency for Toxic Substances and Disease Registry, National Conversation on Public Health and Chemical Exposures Action Agenda also calls for clinical diagnostic tools and states: "To more fully prepare healthcare providers to address chemical exposures, validated clinical diagnostic tools similar to blood lead testing are needed."[8] The American Public Health Association echoes this recommendation as well.[9] MCN calls for clinical diagnostic tools to monitor pesticide exposure. Providing clinicians with the clinical diagnostic tools they need to make the most accurate diagnosis possible should be a central part of worker protection and it is glaringly absent in the proposed rule.

Hierarchy of Controls for Occupational Health and Safety: MCN urges EPA to apply the standard and universally accepted public health best practice for control of worker exposure to chemicals—the industrial hygiene "hierarchy of controls." Under the hierarchy of controls, risk reduction is based on the following preferred order of controls: elimination, substitution with less hazardous materials, engineering controls (such as closed systems), warnings, administrative control, and personal protective equipment.[10] MCN is concerned that the revised WPS largely relies on the least protective measures for workers—PPE and administrative controls such as training and record keeping.

Annual Training and Record Keeping: MCN supports annual pesticide safety training for farmworkers and pesticide handlers as well as a record-keeping system to document when these trainings take place. An informed workforce is an important first step in worker protection. Annual training will reinforce important pesticide safety practices and information to help workers better protect themselves and their families from pesticide overexposure. Studies indicate that workers who have been trained in the preceding year retain more information from new training than those whose previous training is more than two years old; that workers maintain information but begin to show some drop-off at five months; and that knowledge gains are correlated with improved self-reported use of PPE.[11–13] Pedagogically, it is unreasonable to expect a workforce characterized by limited formal education and low levels of literacy to retain training content beyond one year. Training requirements to protect agricultural workers and handlers should be comparable to those required by OSHA regulations that require employers to provide annual training to protect employees from chemical hazardsin the workplace.

Training Content: MCN supports expanding the content of the required training for workers and handlers, underscoring the importance of including the proposed topics of worker rights, emergency assistance and ways to minimize paraoccupational exposures or pesticide "take home" exposures. Additionally, we call for EPA to emphasize training regarding the possible reproductive health effects of pesticide exposure. We also recommend that EPA be mindful of the needs of workers and some handlers due to low literacy and limited English language when revising the training standards. The training should be provided in meaningful interactive formats that include training in a language that the individual understands.

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[8] Agency for Toxic Substances and Disease Registry, *National Conversation on Public Health and Chemical Exposures Action Agenda.* 2011. Available at: *http://www.atsdr.cdc.gov/nationalconversation/action_agenda.html*. Accessed August 5, 2014.

[9] American Public Health Association. *APHA Policy Statement 20108: Requiring Clinical Diagnostic Tools and Biomonitoring of Exposures to Pesticides.* Washington, D.C.: American Public Health Association; 2010. Available at: *http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1400*. Accessed August 4, 2014.

[10] American National Standards Institute—American Industrial Hygiene Association Z10–2005 Occupational Health and Safety Management Systems. 2005; as described in Manuele, F. ANSI/AIHA Z10–2005: The new benchmark for safety management systems. February 2006. Available from: *http://www.asse.org/publications/standards/z10/docs/25-33Feb2006.pdf*. Accessed August 5, 2014.

[11] Anger W.K., Patterson L., Fuchs M., Will L.L., Rohlman D.S. *Learning and recall of Worker Protection Standard (WPS) training in vineyard workers.* J. AGROMEDICINE. 2009; 14(3): 336–44. doi: 10.1080/10599240903042057.

[12] LePrevost C.E., Storm J.F., Asuaje C.R., Arellano C., Cope W.G. *Assessing the effectiveness of the Pesticides and Farmworker Health Toolkit: A curriculum for enhancing farmworkers' understanding of pesticide safety concepts.* J. AGROMEDICINE. 2014; 19(2): 96–102. doi: 10.1080/1059924X.2014.886538.

[13] Levesque D.L., Arif A.A., Shen J. *Effectiveness of pesticide safety training and knowledge about pesticide exposure among Hispanic farmworkers.* J. OCCUP. ENVIRON. MED. 2012 Dec.; 54(12): 1550–6. doi: 10.1097/JOM.0b013e3182677d96.

Training Grace Period: MCN supports the elimination of a grace period for worker training. Any training grace period severely undermines the intent of the WPS. An untrained worker is more vulnerable to pesticide overexposure and should not be put at risk. OSHA standards require employers in almost all industries to notify their workers of the hazards that may be encountered in the workplace before the work begins. Agriculture should be held to the same standard when it comes to exposure to hazardous chemicals.

Minimum Age—MCN supports the establishment of a minimum age of 18 rather than the proposed minimum age limit of 16 for pesticide handlers and early-entry workers. Children younger than 18 are still developing both physically and mentally and high levels of exposure to pesticides could have life-long health effects. Furthermore, most minors do not have the maturity to follow all label instructions or take the necessary precautions to ensure their safety and the safety of other workers.[14–15] Children working in other industries are prohibited from engaging in high hazard tasks.[16] Children employed in agriculture should be afforded the same protections as children working in other hazardous industries.

Hazard Communication—MCN does not support the EPA's proposal to eliminate the current requirement for a central posting location for pesticide application information. We do support EPA's clarification that this information, in addition to the Safety Data Sheets (SDSs) and labeling for pesticide applications, must be made available to workers' representatives such as clinicians, attorneys and union representatives. Particularly in the case of workers injured by pesticides, it is critical for workers' representatives to be able to obtain accurate, timely information about the pesticides to which workers may have been exposed. However, specific information about the pesticides applied and the hazards they pose must be made available to workers universally, in advance of pesticide applications. Such information should be available in nonemergency situations and it should not require any type of request from the worker or worker representative. Workers may not understand that they have the right to request such information. If workers do understand, many will be reluctant (for fear of job loss) or unable due to language barriers to ask their employer for the information.

Additionally, we recommend requiring availability of SDSs in Spanish as well as English both in a central location and electronically using a smart phone scan code. SDSs in Spanish and other written languages should now be readily available, because format and basic content of SDSs has been harmonized internationally to comply with Globally Harmonized System requirements. Labels should also be made available electronically, as well as at a central location and provided in Spanish and other languages when available.

Monitoring Handler Exposure to Cholinesterase Inhibiting Pesticides: We support medical monitoring of pesticide handlers who mix, load or apply Toxicity Category I or II organophosphates or N-methyl carbamates. Monitoring programs have been successfully implemented for 40 years in California and over 10 years in Washington State, substantially helping to prevent overexposure of handlers. These biomonitoring programs have been critical in reducing overexposure by removing workers from ongoing exposure and identifying flaws in the system of worker protection.[17–18]

We strongly disagree with EPA's decision not to implement such a program nationwide based on its determination that these programs are "reactive, catching incidents after they occur rather than working to stop them from happening." This analysis contradicts some of the very basic tenets of public health. Medical monitoring programs are essential preventive measures, which successfully stop handlers from being overexposed by identifying subclinical evidence of exposure, prompting

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[14] Salazar M.K., Napolitano M., Scherer J.A., and McCauley L.A. *Hispanic adolescent farmworkers' perceptions associated with pesticide exposure.* WEST J. NURSE RES. 2004; 26(2): 146–166.

[15] Steinberg L. *Cognitive and affective development in adolescence.* TRENDS IN COGNITIVE SCIENCE. 2005; 9(2): 69–74.

[16] US Department of Labor. Labor Regulations, Orders and Statements of Interpretation. § 29 CFR 570. Available from *http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&sid=48d6ee3b99d3b3a97b1bf189e1757786&rgn=div5&view=text&node=29:3.1.1.1.31&idno=29Accessed* August 4, 2014.

[17] Ames R.G., Brown S.K., Mengle D.C., *et al. Cholinesterase activity depression among California agricultural pesticide applicators.* AM. J. IND. MED. 1989; 15(2): 143–150.

[18] Hofmann J.N., Keifer M.C., De Roos A.J., *et al. Occupational determinants of serum cholinesterase inhibition among organophosphate-exposed agricultural pesticide handlers in Washington state.* OCCUP. ENVIRON. MED. 2010;67:375–386.

[19] Occupational Safety and Health Administration. *General Industry. Medical Screening and Surveillance.* § 29 CFR 1910. Available from *https://www.osha.gov/SLTC/medicalsurveillance/*. Accessed August 5, 2014.

review of primary prevention practices. Medical monitoring is common in other industries and OSHA has promulgated over 25 specific standards for medical screening of workers exposed to hazardous substances.[19] Pesticide handlers deserve the same protections that are afforded to workers in other industries. MCN recommends that EPA expeditiously explore a national requirement for cholinesterase monitoring for pesticide handlers mixing, loading or applying Category I or II organophosphates or N-methyl carbamates, and that the Washington State requirements provide a model.

Emergency Assistance: MCN supports the EPA's proposal to clarify when employers must make transportation to a medical facility available to workers and handlers. However, transportation should be made available within 3–4 minutes if the injury is life-threatening or 15 minutes if it is not life-threatening upon learning of an exposure, and not within 30 minutes. We support the proposal to require employers to provide to the worker, handler or the treating medical personnel the relevant SDS and pesticide label, or all of the pertinent information in an alternate form (as opposed to waiting for it to be requested). In certain circumstances, employers should be required to document the time and length of the exposure and report it to the worker and clinician.

Respirator Training and Fitting: We support requiring employers of pesticide handlers to comply with OSHA-equivalent training on respirator use, fit-testing of respirators, and medical evaluation requirements whenever a respirator is required by the labeling. However, the rule should also include the OSHA requirement for each employer to adopt a worksite-specific respiratory protection program to address in detail how respirators are properly selected, cleaned, stored, repaired, and replaced. Furthermore, we disagree with EPA's decision to exclude dust or mist filtering masks, since a majority of pesticides with label requirements for handlers to wear respirators only require dust/mist filtering respirators. Medical evaluation, fit-testing and training should be required for all types of dust/mist filtering respirators.

Decontamination Supplies: We support the EPA recommendation to require employers to provide decontamination supplies that include one gallon of water per worker for routine washing and emergency eye flushing, soap, and single use towels and at least three gallons of water per worker for decontamination for workers performing tasks in an entry-restricted area. We also recommend that EPA require further decontamination supplies including shower facilities onsite. We recommend following the American National Standards Institute standard (Z358.1–2009) for emergency eyewash and shower equipment and require an emergency shower that can deliver water at 20 gallons per minute for 15 minutes.[20]

Contaminated Personal Protective Equipment: MCN supports the EPA proposal to require employers to render contaminated PPE unusable before properly disposing of PPE that cannot be decontaminated according to the manufacturer's instructions. Such measures will prevent adverse health effects resulting from the wearing of contaminated garments.

Closed Systems for Mixing and Loading: MCN supports the EPA proposal to clarify the criteria for closed systems by adopting the California standards for system design. However, EPA should go further and adopt, at a minimum, the California standards requiring the use of closed systems for highly-toxic categories of pesticides. As noted above, under the industrial hygiene hierarchy of controls, engineering controls are preferred over PPE. It therefore is appropriate for EPA to require the engineering control of a closed system rather than PPE as the primary protection for pesticide handlers. Closed systems are already used extensively in California, and for some pesticides and certain types of uses across the country. The proper use of closed transfer systems for mixing and loading pesticides reduces the potential for human exposure from spills, splashes and blowing, and this type of engineering control—rather than PPE—should be the first line of defense against pesticide exposure.

Drift Protections: MCN supports the EPA proposal to require handlers to cease application if someone other than a trained and properly equipped handler enters treated or surrounding areas. We also support the establishment of entry-restricted

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[19] Occupational Safety and Health Administration. *General Industry. Medical Screening and Surveillance.* §29 CFR 1910. Available from *https://www.osha.gov/SLTC/medicalsurveillance/*. Accessed August 5, 2014.

[20] American National Standards Institute. *American National Standard Z358.1–2009 for Emergency Eyewashes and Shower Equipment.* Available at: *http://webstore.ansi.org/RecordDetail.aspx?sku=ANSI%2fISEA+Z358.1-2009.* Accessed August 6, 2015. Described in Bradley Corporation. *A Guide to the ANSI Z358.1–2009 Standard for Emergency Eyewashes and Shower Equipment.* 2012. Available from *https://www.bradleycorp.com/download/2081/4002.pdf.* Accessed August 6, 2014.

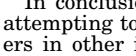
areas adjacent to the treated areas in farms and forests. But, as proposed, these protections apply only to fields on the farm that was sprayed. This safeguard should extend to workers in harm's way who work at a neighboring establishment. Though modest in scope, the proposed entry-restricted areas are a step in the right direction to protect workers and others in the immediate vicinity of pesticideapplications.

Early Entry Restrictions: MCN believes that early reentry for fieldwork should only be allowed in true agricultural emergencies. Worker protection during early reentry is largely dependent upon proper use of PPE. Many of the tasks involved with early reentry, such as moving irrigation pipes and performing hand labor tasks, may be cumbersome with required PPE. Given the nature of the tasks as well as the potential for escalating heat stress with PPE, there is potential for improper use or no use of PPE. The proposed improvements in training and age restriction cannot adequately mitigate these risks. In addition, we oppose the relaxing of the early reentry restriction for irrigators, allowing early reentry even if the need for irrigation could have been foreseen before the pesticide application. Irrigators are at high risk of pesticide poisoning because they tend to work long hours. They also often work alone with no coworker to assist in calling for help in case of pesticide or heat illness.

Notification about Restricted Entry Intervals (REIs): MCN recommends that EPA continue to require on the sign the wording "Keep Out" and not change it to "Entry Restricted." While this semantic change may be technically more accurate, it is far more difficult for most people to understand. According to a standard readability program, "Entry Restricted" tests at a Grade 13 reading level. By contrast, "Keep Out" tests at Grade 0, meaning that it should be easily understood by most six-year-olds.[21]

In conclusion, MCN applauds EPA for proposing to strengthen the WPS and for attempting to bring the WPS more closely into line with protections offered to workers in other industries. EPA can better protect the health and well-being of farmworkers MCN strongly urges EPA to act affirmatively on our recommendations to further strengthen the WPS.

Sincerely,



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KAREN MOUNTAIN, M.B.A., M.S.N., R.N.,
Chief Executive Officer.

[ATTACHMENT 10]

August 17, 2014

Hon. GINA MCCARTHY,
Administrator,
U.S. Environmental Protection Agency,
Washington, D.C.

Re: Agricultural Worker Protection Standard Revisions; Proposed Rule Docket ID # EPA–HQ–OPP–2011–0184

Dear Administrator McCarthy,

Thank you for the opportunity to comment on the proposed revisions to the Worker Protection Standard. The Farmworker Advocacy Network is a statewide network of organizations that work to improve living and working conditions of farmworkers and poultry workers in North Carolina.

Farmworker Advocacy Network is pleased that the U.S. EPA has proposed many improvements to the WPS, which we believe will improve pesticide safety on the job for the 2+ million workers across the U.S. who harvest our food. There are several areas in which we believe that improvements that would strengthen the rule's effectiveness in preventing unnecessary pesticide exposure for migrant and seasonal farmworkers in North Carolina and across the U.S.

[21] Tested using The Readability Test Tool on August 16, 2014 available from *http://readable.com/*.

We are concerned that the proposed rules fall short in several key areas:

- The proposed **Minimum Age** of 16 to work as a pesticide handler, or as an early re-entry worker, is inappropriate and unsupported by the scientific literature. We urge you most strongly to adopt a minimum age of 18.
- The proposal to eliminate **Central Posting** does not solve the need for better hazard communication. We recommend retaining central posting, particularly for greenhouse and nursery workers, as well as implementing more robust field posting to address gaps in Hazard Communications.

Our comments and rationale on these items and several others are included below. You will find citations on the last page.

Minimum Age

The proposed minimum age of 16 to work as a pesticide handler, or as an early re-entry worker [§§ 170.9(c), 170.13(c) and 170.303)], is inappropriate and unsupported by the scientific literature. It is widely opposed by farmworkers, health care providers, and public health advocates. *We strongly recommend a minimum age of 18.*

Pesticide handlers and early re-entry workers are at high risk of pesticide exposure. Working with pesticides is not appropriate work for youth because:

- Teens' bodies are still developing. The brain and reproductive system in particular undergo significant development during the teen years.[i–ii] Many pesticides are highly toxic to the brain and to the reproductive system.[iii] Exposing immature, developing systems to pesticides can do long-term harm.
- Exposure to pesticides can increase the risk of chronic diseases such as cancer[iv] and Parkinson's Disease.[v] The likelihood of developing such diseases later in life increases with additional years of exposure.
- Teens are capable of many jobs, but they are not yet mature enough to handle highly-hazardous chemicals like pesticides. Studies have shown that teens perceive themselves as less vulnerable to harm, and therefore do not follow the same safety precautions as adults—even when they have received the same trainings.[vi–vii]
- Pesticide poisoning surveillance data show that youth are more likely than adults to be injured by pesticides on the job.[viii]
- In every other industry, 16 and 17 year-olds are not allowed to work with hazardous chemicals.[ix] There is no compelling reason to treat farmworker youth differently or afford them a lesser level of protection on the job.

EPA proposed a minimum age of 16, based on the higher cost of increasing the minimum age to 18. For a cost differential of only *$10* per year for an average farm, EPA has proposed to promulgate a standard that would put over 89,000 16- and 17-year-old farmworker teens at elevated risk of pesticide exposure, affording them a lesser level of protection from chemical hazards than they would receive at any other job.

There is simply no viable reason to afford farmworker children a lesser degree of protection, as the U.S. Department of Labor does through its Hazardous Orders. FIFRA allows EPA to regulate child labor in agriculture more broadly than DOL can under the FLSA, and thus EPA can reach different results about when children ages 16 to 18 can do agricultural work involving the handling of pesticides. For DOL to regulate child labor, it must make a finding of particular hazard or detriment to health [29 U.S.C. § 203(l)]; whereas EPA can regulate the use of pesticides to avoid "unreasonable risk," broadly understood [7 U.S.C. § 136(bb)]. Because allowing children ages 16 and 17 to work as pesticide handlers would pose "unreasonable risks," EPA is mandated by FIFRA to prohibit this practice as part of the Worker Protection Standard. The FLSA does not preempt more protective standards in other Federal laws. Regulations adopted by DOL under the authority of the FLSA provide that "Nothing in this subpart shall authorize non-compliance with any Federal or State law, regulation, or municipal ordinance establishing a higher standard. If more than one standard within this subpart applies to a single activity the higher standard shall be applicable" [29 CFR § 570.50].

Since the founding of EPA's Office of Children's Health Protection in 1997, EPA has repeatedly restated its commitment to protect children as "fundamental to EPA's core mission."[x] Advancing a rule that explicitly allows adolescents to work with high-risk materials is at odds with that mission, and out of step with protections for youth working in every other industry nationwide.

Hazard Communications

EPA has proposed doing away with the current requirement for a central posting location for pesticide application information, while requiring that employers make the SDS and labeling for pesticide applications available to workers or their representatives upon request [§ 170.11(b)]. We support EPA's clarification that this information must be made available to workers' representatives (whether medical providers, attorneys, union representatives, *etc.*). Particularly in the case of workers injured by pesticides, it is critical for workers' representatives to be able to obtain accurate, timely information about the pesticides to which workers may have been exposed. However, specific information about the pesticides applied and the hazards they pose must be made available to workers universally, in advance of pesticide applications. Anything less is a step backward in Hazard Communications.

The proposal to maintain pesticide use records for 2 years is a significant improvement over the current 30-day requirement. North Carolina adopted a 2-year record retention requirement in 2009 in the wake of the Ag-Mart case [02 NCAC § 9L.1402]. *However, we urge the Agency to go further in adopting a 5-year interval, which would coincide with the statute of limitations for civil violations* (28 U.S.C. § 2462). The cost difference for growers in maintaining records for five years *vs.* two years would be negligible.

However, the proposal omits any record-keeping of worker re-entry into treated areas. In the 2006 Ag-Mart case in North Carolina, one of the major points at issue was whether workers were sent into fields before the re-entry interval (REI) had expired. *EPA should require that employers record the date, time and field location of worker re-entry into treated areas, and should require that those records be maintained for five years* (coinciding with the statute of limitations for civil violations). The act of recording worker re-entry into recently-treated fields could also serve as a deterrent that makes employers more aware of REIs and less likely to endanger workers' health by sending them into recently-treated areas too soon.

Notification to Workers and Handlers

EPA is proposing requiring employers to post warning signs regarding the application of a pesticide that has an REI greater than 48 hours (for outdoor production), or 4 hours (for enclosed space production) [§§ 170.109(a)(1)(i) and 170.109(a)(1)(ii)]. We believe that this change could reduce occupational pesticide illnesses. However, the 48-hour limit seems excessive, since as EPA notes in its proposal, people have difficulty remembering what they have been told orally. *We recommend requiring both posting signs* ***and*** *oral warnings for* ***all*** *pesticide applications,* or at a minimum for those pesticides with an REI of 12 hours or more. The most effective way to convey important information is through multiple routes, *i.e.,* oral *and* written.

Training

We strongly support the proposal to require annual training of workers and handlers [§§ 170.101(a) and 170.201(a)]. This is the current practice in California, and anecdotally many growers in North Carolina report using annual training as well. Annual training will decrease the likelihood that workers fail to receive critical pesticide safety training on the job. We also support the record-keeping and verification proposals [§§ 170.101(d) and 170.201(d)] to help employers and workers track compliance with the training requirement.

However, the training grace period of two days [§ 170.309], while an improvement over the current rule, still puts workers at serious risk when they begin at a new workplace. *We recommend eliminating the grace period and requiring that pesticide safety training take place* ***before*** *any worker is put at risk of exposure on the job.* There is currently no grace period in California, and in most other industries OSHA requires that employers provide safety training *before* employees begin work with potentially hazardous materials, as EPA notes in the proposal package [29 CFR 1910.1200(h)]. There is no compelling reason that the standard should be different for farmworkers.

We strongly support the proposal that qualified trainers should provide WPS training to workers. However, the standard should be the same for pesticide handlers. [§§ 170.101(c)(4) and 170.201(c)(4)]. We question the agency's logic in deciding that for trainers of handlers, simple Certified Applicator status is adequate to provide an effective training, when that status is not adequate for trainers of workers—especially because handlers are arguably at higher risk of exposure. *All trainings—whether for workers or handlers—should be provided by someone who has proven competency in adult education techniques, in the language of the trainees, and cultural competence to convey the information effectively to the target audience.* A high-quality nationwide train-the-trainer program can ensure these competencies.

It is absolutely critical that workers be well-trained in pesticide safety. However, it is at least as important to ensure that the employer understand clearly the hazards of the pesticides being used and her/his obligations to protect workers. The WPS places a lopsided emphasis on training and information provision to workers, who have no control over the circumstances in which pesticides are used. The employer is the one responsible for compliance with the rule, and in control of whether the conditions for compliance exist, such as adequate PPE, decontamination supplies, *etc. The rule needs a specific mandate for Employers and labor contractors/crew leaders to receive regular training on pesticide hazards and their obligations under the WPS.* A proactive approach to training employers and crew leaders could help improve compliance rates, ease the transition to the changes in the WPS, create safer work conditions, and place the emphasis on compliance where it belongs—with the employer.

Prevention of Take-Home Exposure

Training workers in preventing take-home exposure is key for better protecting the health and safety of workers' children and other family members [§§ 170.101(c)(2) through (3)]. However, workers will be severely challenged to actually carry out prevention of take-home exposure, since employers do not have to provide a place for workers to change and store clean clothes, wash clothes or take a shower before leaving the workplace. EPA must do more to ensure that workers can actually act [and] carry out the precautions and behavior changes in which they are trained.

For example, EPA did not choose to propose that employers provide a place to shower before leaving work. How can workers be reasonably expected to shower before returning home if no shower is provided? On the [E]ast [C]oast, many migrant workers are housed in barracks or trailers provided by their employers. The current migrant housing standard in North Carolina requires employers to provide only 1 working shower head per 10 workers, meaning that after work many workers are forced to wait in long lines to remove pesticide residues. The North Carolina migrant housing standard does not require washing machines, or a ride to the local laundromat—only one "laundry tub" per 30 people for washing work clothes [NCGS § 95–222:229]. Workers cannot be reasonably expected to wash work clothes regularly and separately from other laundry under such conditions. *We recommend that EPA require employers to provide such facilities at the worksite that would enable compliance with safety training:*

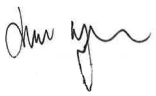
- Showers with separate stalls or privacy screens;
- A changing area with lockers to store clean clothes; and
- Washing machines designated for work clothes, or regular access to a nearby laundromat or other similarly-equipped facility.

Training workers on these safety topics is futile without the facilities to actually comply.

As EPA moves forward with this new rule and begins to consider implementation and training, we hope that you will reach out to us for assistance. Developing *and* field-testing strong new training and compliance materials will be key to this rule's success in both preventing hazardous pesticide exposure for workers and their families, and minimizing the challenges of compliance for growers. Farmworker Advocacy Network's members stand ready to assist you.

Thank you for the opportunity to provide comments on the proposal to revise the agricultural Worker Protection Standard. We congratulate EPA for taking this major step forward, and look forward to working with you to ensure pesticide safety in the workplace.

Sincerely,



MELINDA WIGGINS, *Executive Director,* Student Action with Farmworkers.
On behalf of Farmworker Advocacy Network.

[References]

[i] Lebel and Beaulieu. "Longitudinal Development of Human Brain Wiring Continues from Childhood into Adulthood." *The Journal of Neuroscience,* July 27, 2011. 31(30): 10937–10947.

[ii] *Medline Plus,* "Adolescent Development." U.S. National Library of Medicine, National Institutes of Health. *http://www.nlm.nih.gov/medlineplus/ency/article/002003.htm* (accessed 3/17/2014).

[iii] Roberts and Reigart. "Chapter 21: Chronic Effects" in *Recognition and Management of Pesticide Poisonings,* Sixth Edition. 2013. U.S. EPA Publication number 735K13001.

[iv] Bassil, *et al.* "Cancer health effects of pesticides: Systematic review" *Canadian Family Physician.* October 2007 vol. 53 no. 10 1704–1711.

[v] Kamel, *et al.* "Pesticide Exposure and Self-reported Parkinson's Disease in the Agricultural Health Study" *Am. J. Epidemiol.* 2007; 165: 364–374.

[vi] Salazar, *et al.* 2004. "Hispanic Adolescent Farmworkers' perceptions associated with pesticide exposure." *West J. Nurse Res.* 26(2): 146–166.

[vii] Steinberg, 2005. "Cognitive and affective development in adolescents." *Trends in Cognitive Sciences,* February 2005 vol. 9 no. 2 69–74.

[viii] Calvert, *et al.* 2003. "Acute pesticide poisoning among agricultural workers in the United States 1998–2005." *Am. J. Ind. Med.* 51(12): 883–898.

[ix] "Youth & Labor: Hazardous Jobs" United States Department of Labor. *http://www.dol.gov/dol/topic/youthlabor/harzardousjobs.htm* (accessed 3/17/2014).

[x] U.S. EPA Office of Children's Health Protection website. *http://www.yosemite.epa.gov/ochp/ochpweb.nsf/content/homepage.htm* (accessed 4/25/2014).

[ATTACHMENT 11]

August 14, 2014

Hon. GINA MCCARTHY,
Administrator,
U.S. Environmental Protection Agency,
Washington, D.C.

Re: Agricultural Worker Protection Standard Revisions; Docket ID # EPA–HQ–OPP–2011–0184

Dear Administrator McCarthy:

Thank you for the opportunity to comment on the proposed revisions to the Worker Protection Standard. I write on behalf of the American Public Health Association, a diverse community of public health professionals who champion the health of all people and communities. APHA and its 53 affiliated state and regional public health associations represent 50,000 public health professionals. APHA brings a 140+ year perspective from all fields of public health, including occupational health and safety, environmental health, children's health and immigrant health. APHA firmly believes that the occupational health and safety of workers is a public health priority, and we have a long history of supporting measures to protect workers and improve occupational health and safety.

We write to support many aspects of the proposed WPS that foster worker health and safety for an estimated 2 million workers across the United States who harvest our food. These workers, the majority of whom are immigrants from Mexico and other Central American countries, are the most overexposed population to pesticides.

Prevention of occupational disease, injury and exposure is fundamental to worker health and safety. APHA believes the protection of agricultural workers and their families, immigrant workers, including farmworkers, and workers exposed to pes-

ticides is a critical public health concern and believes stronger, protective measures are urgently needed.[1–5]

More importantly, we wish to underscore the standard and universally accepted public health best practice for control of worker exposure to chemicals—the industrial hygiene "hierarchy of controls." Under the hierarchy of controls, risk reduction is based on the following preferred order of controls: elimination, substitution with less hazardous materials, engineering controls (such as closed systems), warnings, administrative control, and personal protective equipment.[6] While we commend the U.S. Environmental Protection Agency for proposing to strengthen the WPS, we are concerned that the revised WPS largely relies on the least protective measures for workers—PPE and administrative controls. We therefore urge EPA to apply the hierarchy of controls principle to strengthen protections for farmworkers.

We also emphasize the public health benefit of preventing injury, illness and exposure. While there are costs associated with the protection of this important and vulnerable workforce, there is also an extraordinary cost to workers, farmers and our society for occupational illness and injury in terms of medical care, lost work days, lost wages, and potential workers' compensation insurance premiums for an occupational injury or illness. At the price of more than $250 billion a year, occupational conditions are the second costliest medical condition behind cardiovascular disease and ahead of cancer.[7] The cost of illness and injury as a result of work-related pesticide exposure is challenging to assess. This is largely due to the current weaknesses in our regulations, formal and informal exclusions from the workers' compensation systems, challenges in clinically confirming the diagnosis of pesticide poisonings, lack of understanding regarding incident reporting as well as patchwork surveillance systems. Additionally, many workers do not report overexposures as they do not understand their rights and fear losing their jobs. Prevention policies and programs are cost-effective, reduce health care costs, and can improve productivity.

Detailed below are the areas of the rule that we strongly support, and those areas in need of strengthening in order to better protect farmworkers.

Training Frequency—APHA supports annual pesticide safety training for farmworkers and pesticide handlers. An informed workforce is an important first step in worker protection. Annual training will reinforce important pesticide safety practices and information to help workers better protect themselves and their families from pesticide overexposure. Studies indicate that workers who have been trained in the preceding year retain more information from new training than those whose previous training is more than two years old; that workers maintain information but begin to show some drop-off at five months; and that knowledge gains are correlated

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[1] American Public Health Association. APHA Policy Statement 96–06: *The Precautionary Principle and Chemical Exposure Standards for the Workplace.* 1996. Available at: *www.apha.org/advocacy/policy/policysearch/default.htm?id=124*. Accessed August 4, 2014.

[2] American Public Health Association. APHA Policy Statement 2005–4: *Occupational Health and Safety Protections for Immigrant Workers*. 2005. Available at: *http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1318*. Accessed August 4, 2014.

[3] American Public Health Association. APHA Policy Statement 20108: *Requiring Clinical Diagnostic Tools and Biomonitoring of Exposures to Pesticides.* Washington, D.C.: American Public Health Association; 2010. Available at: *http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1400*. Accessed August 4, 2014.

[4] American Public Health Association. APHA Policy Statement 201110: *Ending Agricultural Exceptionalism: Strengthening Worker Protection in Agriculture through Regulation, Enforcement, Training, and Improved Worksite Health and Safety.* American Public Health Association; 2011. Available at: *http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1420*. Accessed August 4, 2014.

[5] American Public Health Association. APHA Policy Statement 2005–06: *Reducing occupational exposure to benzene in workers and their offspring.* Available at: *http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1322*. Accessed August 4, 2014.

[6] American National Standards Institute—American Industrial Hygiene Association Z10–2005 Occupational Health and Safety Management Systems. 2005; as described in Manuele, F. ANSI/AIHA Z10–2005: *The new benchmark for safety management systems.* February 2006. Available from: *http://www.asse.org/publications/standards/z10/docs/25-33Feb2006.pdf*. Accessed on August 5, 2014.

[7] Leigh J.P. *Economic burden of occupational injury and illness in the United States.* MILBANK Q. 2011; 89(4): 728–72.

with improved self-reported use of PPE.[8–10] Pedagogically, it is unreasonable to expect a workforce characterized by limited formal education and low levels of literacy to retain training content beyond one year. Moreover, workers in most other industries receive annual safety training and farmworkers deserve the same protection.

Training Content—APHA supports expanding the content of the required training for workers and handlers, underscoring the importance of including the proposed topics of worker rights, emergency assistance and ways to minimize paraoccupational exposures or pesticide "take home" exposures. Additionally, we call for the EPA to emphasize training regarding the possible reproductive health effects of pesticide exposure. We also recommend that EPA be mindful of the needs of workers and some handlers due to low income, low literacy and limited English language when revising the training standards. The training should be provided in meaningful interactive formats that include training in a language that the individual understands.

Training Grace Period—APHA supports the elimination of a grace period for worker training. Any training grace period severely undermines the intent of the WPS. An untrained worker is more vulnerable to pesticide overexposure and should not be put at risk.

Minimum Age—APHA supports the establishment of a minimum age of 18 rather than the proposed minimum age limit of 16 for pesticide handlers and early-entry workers. Children younger than 18 are still developing both physically and mentally, and high levels of exposure to pesticides could have life-long health effects. Furthermore, most minors do not have the maturity to follow all label instructions or take the necessary precautions to ensure their safety and the safety of other workers.[11–12] Children working in other industries are prohibited from engaging in high hazard tasks.[13] Children employed in agriculture should be afforded the same protections as children working in other hazardous industries.

Hazard Communication—APHA does not support EPA's proposal to eliminate the current requirement for a central posting location for pesticide application information. We support EPA's clarification that this information, in addition to the Safety Data Sheets and labeling for pesticide applications, must be made available to workers' representatives such as clinicians, attorneys and union representatives. Particularly in the case of workers injured by pesticides, it is critical for workers' representatives to be able to obtain accurate, timely information about the pesticides to which workers may have been exposed. However, specific information about the pesticides applied and the hazards they pose must be made available to workers universally, in advance of pesticide applications. Such information should be available in nonemergency situations and it should not require any type of request from the worker or worker representative. Workers may not understand that they have the right to request such information. If workers do understand, many will be reluctant (for fear of job loss) or unable due to language barriers to ask their employer for the information.

Additionally, we recommend requiring availability of SDSs in Spanish as well as English both in a central location and electronically using a smart phone scan code. SDSs in Spanish and other written languages should now be readily available, because format and basic content of SDSs has been harmonized internationally to comply with Globally Harmonized System requirements. Labels should also be made available electronically, as well as at a central location and provided in Spanish and other languages when available.

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[8] Anger W.K., Patterson L., Fuchs M., Will L.L., Rohlman D.S. *Learning and recall of Worker Protection Standard (WPS) training in vineyard workers.* J. AGROMEDICINE. 2009; 14(3): 336–44. doi: 10.1080/10599240903042057.

[9] LePrevost C.E., Storm J.F., Asuaje C.R., Arellano C., Cope W.G. *Assessing the effectiveness of the Pesticides and Farmworker Health Toolkit: a curriculum for enhancing farmworkers' understanding of pesticide safety concepts.* J. AGROMEDICINE. 2014; 19(2): 96–102. doi: 10.1080/1059924X.2014.886538.

[10] Levesque D.L., Arif A.A., Shen J. *Effectiveness of pesticide safety training and knowledge about pesticide exposure among Hispanic farmworkers.* J. OCCUP. ENVIRON. MED. 2012 Dec.; 54(12): 1550–6. doi: 10.1097/JOM.0b013e3182677d96.

[11] Salazar M.K., Napolitano M., Scherer J.A., and McCauley L.A. *Hispanic adolescent farmworkers' perceptions associated with pesticide exposure.* WEST J. NURSE RES. 2004; 26(2): 146–166.

[12] Steinberg L. *Cognitive and affective development in adolescence.* TRENDS IN COGNITIVE SCIENCE. 2005; 9(2): 69–74.

[13] U.S. Department of Labor. Labor Regulations, Orders and Statements of Interpretation. § 29 CFR 570. Available from *http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=48d6ee3b99d3b3a97b1bf189e1757786&rgn=div5&view=text&node=29:3.1.1.1.31&idno=29*. Accessed August 4, 2014.

Monitoring Handler Exposure to Cholinesterase Inhibiting Pesticides—APHA supports medical monitoring of pesticide handlers who mix, load or apply Toxicity Category I or II organophosphates or N-methyl carbamates. Monitoring programs have been successfully implemented for 40 years in California and over 10 years in Washington State, substantially helping to prevent overexposure of handlers. We strongly disagree with EPA's decision not to implement such a program nationwide based on its determination that these programs are "reactive, catching incidents after they occur rather than working to stop them from happening." This analysis contradicts some of the very basic tenets of public health. Medical monitoring programs are essential preventive measures, which successfully stop handlers from being overexposed by identifying subclinical evidence of exposure, prompting review of primary prevention practices. Medical monitoring is common in other industries and OSHA has promulgated over 25 specific standards for medical screening of workers exposed to hazardous substances.[14] Pesticide handlers deserve the same protections that are afforded to workers in other industries.

Clinical Diagnostic Tools and Monitoring Workers for Pesticide Exposure—APHA believes biomonitoring is critical to protecting agriculture workers from over exposure to pesticides.[15] Health care providers have few clinical diagnostic tools readily available to help to better recognize and manage pesticide exposures. Additional information offered by a confirmatory diagnostic test is essential in providing information clinicians need to treat overexposed workers and handlers and to ultimately provide EPA with frontline data necessary to understand the health effects of registered pesticides. Providing clinicians with the clinical diagnostic tools they need to make the most accurate diagnosis possible should be a central part of worker protection, a feature that is glaringly absent in the proposed rule. The Agency for Toxic Substance and Disease Registry, National Conversation on Public Health and Chemical Exposures Action Agenda, also calls for clinical diagnostic tools and states: "To more fully prepare healthcare providers to address chemical exposures, validated clinical diagnostic tools similar to blood lead testing are needed." [16]

Emergency Assistance—APHA supports EPA's proposal to clarify when employers must make transportation to a medical facility available to workers and handlers. However, transportation should be made available within 3–4 minutes if the injury is life-threatening or 15 minutes if it is not life-threatening upon learning of an exposure, and not within 30 minutes. We support the proposal to require employers to provide to the worker, handler or the treating medical personnel the relevant SDS and pesticide label, or all of the pertinent information in an alternate form (as opposed to waiting for it to be requested). In certain circumstances, employers should be required to document the time and length of the exposure and report it to the worker and clinician.

Informed and Prepared Clinicians—APHA applauds EPA's recognition that clinicians play an important role in worker protection. In addition to requiring employers to provide treating medical personnel with pertinent pesticide exposure information, we urge EPA to consider further measures. EPA should help clinicians to improve their recognition and management of pesticide overexposure by (1) supporting the development of clinical diagnostic tools, and (2) providing training and technical assistance for clinicians. A survey of environmental medicine content in U.S. medical schools found that 75 percent of schools require only about seven hours of study in environmental medicine over four years.[17] Not surprisingly, clinicians are often unprepared to recognize, manage, or help prevent exposure-related illness. APHA echoes the recommendation outlined in the ATSDR National Conversation on Public Health and Chemical Exposures Action Agenda that "Clinicians need a set of skills and tools for (1) diagnosing, treating, and intervening to prevent chemical exposures, (2) providing information about chemical exposures to their patients and

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[14] Occupational Safety and Health Administration. General Industry. Medical Screening and Surveillance. § 29 CFR 1910. Available from *https://www.osha.gov/SLTC/medicalsurveillance/*. Accessed on August 5, 2014.

[15] American Public Health Association. APHA Policy Statement 20108: *Requiring Clinical Diagnostic Tools and Biomonitoring of Exposures to Pesticides.* Washington, D.C.: American Public Health Association; 2010. Available at: *http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1400*. Accessed August 4, 2014.

[16] Agency for Toxic Substance and Disease Registry, *National Conversation on Public Health and Chemical Exposures Action Agenda.* 2011. Available at: *http://www.atsdr.cdc.gov/nationalconversation/action_agenda.html*. Accessed August 5, 2014.

[17] Schenk M., Popp S.M., Neale A.V., Demers R.Y. *Environmental medicine content in medical school curricula.* ACAD. MED. 1996 May; 71(5): 499–501.

communities, and (3) participating in surveillance for chemical exposures and health effects." [18]

Respirator Training and Fitting—APHA supports requiring employers of pesticide handlers to comply with OSHA-equivalent training on respirator use, fit-testing of respirators, and medical evaluation requirements whenever a respirator is required by the labeling. However, the rule should also include the OSHA requirement for each employer to adopt a worksite-specific respiratory protection program to address in detail how respirators are properly selected, cleaned, stored, repaired, and replaced. Furthermore, we disagree with EPA's decision to exclude dust or mist filtering masks, since a majority of pesticides with label requirements for handlers to wear respirators only require dust/mist filtering respirators. Medical evaluation, fit-testing and training should be required for all types of dust/mist filtering respirators.

Decontamination Supplies—APHA supports the EPA recommendation to require employers to provide decontamination supplies that include one gallon of water per worker for routine washing and emergency eye flushing, soap, and single use towels and at least three gallons of water per worker for decontamination for workers performing tasks in an entry-restricted area. We also recommend that EPA require further decontamination supplies including shower facilities onsite. We recommend following the American National Standard Institute standard (Z358.1–2009) for emergency eyewash and shower equipment and require an emergency shower that can deliver water at 20 gallons per minute for 15 minutes.[19]

Contaminated Personal Protective Equipment—APHA supports the EPA proposal to require employers to render contaminated PPE unusable before properly disposing of PPE that cannot be decontaminated according to the manufacturer's instructions. Such measures will prevent adverse health effects resulting from the wearing of contaminated garments.

Closed Systems for Mixing and Loading—APHA supports the EPA proposal to clarify the criteria for closed systems by adopting the California standards for system design. However, EPA should go further and adopt, at a minimum, the California standards requiring the use of closed systems for highly-toxic categories of pesticides. As noted above, under the industrial hygiene hierarchy of controls, engineering controls are preferred over PPE. It therefore is appropriate for EPA to require the engineering control of closed system as the primary protection for pesticide handlers rather than PPE. Closed systems are already used extensively in California, and for some pesticides and certain types of uses across the country. The proper use of closed transfer systems for mixing and loading pesticides reduces the potential for human exposure from spills, splashes and blowing, and this type of engineering control—rather than PPE—should be the first line of defense against pesticide exposure.

Drift Protections—APHA supports the EPA proposal to require handlers to cease application if someone other than a trained and properly equipped handler enters treated or surrounding areas. We also support the establishment of entry-restricted areas adjacent to the treated areas in farms and forests. But, as proposed, these protections apply only to fields on the farm that was sprayed. This safeguard should extend to workers in harm's way who work at a neighboring establishment. Though modest in scope, the proposed entry-restricted areas are a step in the right direction to protect workers and others in the immediate vicinity of pesticide applications.

Early Entry Restrictions—APHA believes that early reentry for fieldwork should only be allowed in true agricultural emergencies. Worker protection during early reentry is largely dependent upon proper use of PPE. Many of the tasks involved with early reentry such as moving irrigation pipes and performing hand labor tasks may be cumbersome with required PPE. Given the nature of the tasks as well as the potential for escalating heat stress with PPE, there is potential for improper use or no use of PPE. The proposed improvements in training and age restriction cannot adequately mitigate these risks. In addition, we oppose the relaxing of the early reentry restriction for irrigators, allowing early reentry even if the need for irrigation could have been foreseen before the pesticide application. Irrigators

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[18] Agency for Toxic Substance and Disease Registry, *National Conversation on Public Health and Chemical Exposures Action Agenda.* 2011. Available at: *http://www.atsdr.cdc.gov/nationalconversation/action_agenda.html*. Accessed August 5, 2014.

[19] American National Standards Institute . American National Standard Z358.1–2009 for Emergency Eyewashes and Shower Equipment. Available at: *http://webstore.ansi.org/RecordDetail.aspx?sku=ANSI%2fISEA+Z358.1-2009*. Accessed August 6, 2014. Described in Bradley Corporation. *A Guide to the ANSI Z358.1–2009 Standard for Emergency Eyewashes and Shower Equipment.* 2012. Available from *https://www.bradleycorp.com/download/2081/4002.pdf*. Accessed August 6, 2014.

are at high risk of pesticide poisoning because they tend to work long hours. They also often work alone with no coworker to assist in calling for help in case of pesticide or heat illness.

In conclusion, APHA strongly urges you to adopt these recommendations to strengthen the WPS. EPA can better protect the health and well-being of farmworkers by bringing the WPS more closely into line with protections offered to workers in other economic sectors.

Sincerely,

GEORGES C. BENJAMIN, M.D.,
Executive Director.

[ATTACHMENT 12]

August 15, 2014

Hon. GINA MCCARTHY,
Administrator,
U.S. Environmental Protection Agency,
Washington, D.C.

Re: Docket ID No. EPA–HQ–OPP–2011–0184, Agricultural Worker Protection Standard Revisions

Dear Administrator McCarthy:

Our firm represents and submits these comments on behalf of the Coalition of Florida Farmworker Organizations (CoFFO) of Florida City, Florida. CoFFO is a statewide organization whose main objective is to enhance the living and working conditions of migrant and seasonal farmworkers and the rural poor in Florida.

These comments are submitted in response to the Environmental Protection Agency's ("EPA") proposed regulatory changes to the *Worker Protection Standard Revisions*, 79 FED. REG. 15444, 15449 (proposed Mar. 19, 2014) While the proposed rule makes important improvements to the outdated and inadequate current version of the worker protection standards, it falls short in a number of respects in providing maximum feasible protection to farmworkers and their families. Notably, the proposed rule leaves farmworkers with considerably fewer protections against exposure to dangerous chemicals and toxic substances in the workplace than those enjoyed by nonagricultural workers.

The EPA worker protection standards are of great importance to the estimated 250,000 workers employed in Florida's fields, groves, greenhouses, nurseries and forests. Because of its hot, humid subtropical climate, Florida uses a greater quantity of pesticides per acre than any other state. The use of pesticides, herbicides and fungicides is greatest in the state's nurseries, which employ an estimated 100,000 workers, a disproportionate number of whom are women of child-bearing age, and where the risks of exposure are increased by the contained or enclosed work areas.

Worker surveys indicate that pesticide misuse is widespread in Florida. Nearly ½ (48.3%) of over 400 crop workers in south Florida surveyed in 1980 reported that they had been directly sprayed with agricultural chemicals at least once while working. *See Danger in the Field: The Myth of Pesticide Safety,* Florida Rural Legal Services, Inc. (May 1980), at 1.[1] However, relatively few pesticide incidents are reported to the state Department of Agriculture and Consumer Services, and those that are reported rarely result in meaningful sanctions to employers who misuse pesticides. *See Indifference to Safety: Florida's Investigations into Pesticide Poisoning of Farmworkers,* Farmworker Justice Fund and Florida Legal Services (February 1998). Enhanced protections and increased worker training are important in addressing these longstanding problems.

The proposed rules should be based on several fundamental principles:

Federal WPS standards should not be less than state standards.

[1] There is evidence that these problems have not abated since the adoption of the Worker Protection Standards. In 2005, 84 employees of Ag-Mart Produce, Inc., one of the nation's largest grape tomato producers, were interviewed following the widely-reported incidence of three of its employees bearing children with severe birth defects. Nearly ¼ (22%) of the respondents reported being sprayed directly during the prior month, with 40% claiming during that same period that they were exposed to pesticides through drift. *See* Ag-Mart worker survey, Florida Legal Services (June 2005).

At a minimum, the Worker Protection Standards should be at least as stringent as state law. In the past, variances between the WPS and Florida law have led to confusion among both farmworkers and their employers. The proposed rule should adopt as an absolute floor state requirements regarding pesticide use. For example, Florida law prohibits minors (under 18) from handling pesticides. *See* § 450.061(2)(c), Fla. Stat. ("No minor under 18 years of age . . . shall be employed or permitted to suffer to work in any of the following places of employment . . . [i]n and around toxic substances or corrosives, including pesticides or herbicides . . .")

Protections against exposure to pesticides [for] farmworkers should be no less than corresponding OSHA provisions regarding use of toxic substances in nonagricultural workplaces.

Based on years of studies and its regulatory experience, the Occupational Safety and Health Administration (OSHA) has established detailed standards regarding the use of toxic substances in the workplace. No principled reason exists for the WPS to provide farmworkers with lower level of protection than required for nonagricultural workers under the OSHA regulations.[2] Unfortunately, the proposed regulations fall short of the OSHA minimums in a number of important respects. Among other things:

- Mandated closed systems are required by OSHA in many situations and similar requirements should be required for the mixing of pesticides.
- The protections in the proposed regulations are noticeably less than those required under OSHA'[s] respiratory protection program for dust- and mist-filtering respirators.
- Emergency showers should be available in the work area when there is bodily contact with pesticides, as is required by the OSHA.
- In instances of suspected pesticide exposures, the proposed regulations provide employers with a 30 minute grace period before arranging for medical care. OSHA requires that workers be immediately transported to a health care facility in such situations, and the same protocol should be followed with respect to farmworkers displaying symptoms of pesticide poisoning.
- OSHA requires that workers be provided training regarding hazardous chemicals in the workplace before employment begins. The proposed regulations provide a grace period of several days during which a farmworker can be employed prior to receiving training regarding pesticides. There is no principled basis for denying farmworkers the same right to pre-employment training that is extended to nonagricultural workers.
- Farmworkers who seek to assert or enforce their rights under the WPS are not afforded the same protections against retaliation as workers have under the Occupational Safety and Health Act.
- While proposed rule represents a marked improvement over the current regulations regarding record-keeping and record retention, it stops stop well short of the obligations imposed by the OSHA regulations. As part of its effort to "detect[], treat[] and prevent[] . . . occupational disease," *see* 29 CFR § 1910.1020(a), OSHA requires that records of employee exposure be maintained for at least 30 years. *See* 29 CFR § 1910.1020(d)(ii). There is no reason that pesticide application records should be retained for any shorter period, especially given that many of the long-term effects of pesticide poisoning do not manifest themselves for many years after the exposure. Furthermore, the proposed regulation is silent as to charges for providing the information available to workers. Consistent with the OSHA regulations, the proposed regulation should expressly provide that this information will be provided to the farmworker or his representative free of charge, as is the case under the OSHA regulations. *See* 29 CFR § 1910.1020(e)(1)(iii).

[2] We commend the agency for those portions of the proposed regulations that bring the protection of farmworkers into conformity with those extended to other workers. For example, the proposed regulation requires annual retraining of workers, similar to the mandates of OSHA with respect to nonagricultural workers regularly exposed to chemical hazards. Similarly, the proposed rule allowing for the authorized representatives of farmworkers to obtain pesticide information is consistent with the rights workers have to obtain information regarding occupational hazards under the OSHA. *See* 29 CFR 1910.1020(e)(1) (allowing access to a worker or his "designated representative," defined as "any individual or organization to whom an employee gives written authorization to exercise a right of access," and providing that a collective bargaining agent may obtain such records without written authorization).

Information must be made available in a manner that is accessible to and easily understood by farmworkers.

While the proposed regulations increase workers' access to information regarding pesticide applications, they omit provisions that would greatly enhance the usefulness of this information to farmworkers. Notably, the proposed regulation does not require the basic application information be provided in any foreign language. For the enhanced disclosures to be meaningful, it is imperative that the information be conveyed in a fashion that is comprehensible to the workers. The vast majority of farmworkers in both Florida and nationwide speak little or no English. *See* Daniel Carroll, *et al., Changing Characteristics of U.S. Farm Workers: 21 Years of Findings from the National Agricultural Workers Survey* (May 12, 2011), at 10 (finding that 62% of current farmworkers speak little or no English). Other farmworker protective laws require that essential information be provided in the worker's native language. *See* Migrant and Seasonal Agricultural Worker Protection Act, 29 U.S.C. § 1821(g) and 29 CFR § 500.78 (requiring information regarding job terms and housing conditions to be disclosed in writing in a language in which the worker is fluent). There is no reason to require an employer to disclose the wages and job terms to a worker in his native tongue while not also requiring vital health information regarding pesticide applications to be provided in the vernacular.

The proposed regulation removes the current requirement that mandates posting of pesticide application information in a central location. Posting in this fashion eliminates the need for a farmworker to confront his employer with a request for data, greatly reducing the chances of retaliation. We urge that the current posting requirements be retained. Farmworkers are reluctant to approach their employers to request information because of the widespread practice of retaliation against farmworkers perceived as potential troublemakers. *See, e.g., Fanette* v. *Steven Davis Farms,* LLC, 2014 WL 2961239, at *16 (N.D. Fla., July 1, 2014); *Castillo* v. *Case Farms of Ohio, Inc.,* 96 F. Supp. 2d 578, 631 (W.D. Tex. 1999), *Bertrand* v. *Jorden,* 672 F. Supp. 1417, 1425 (M.D. Fla. 1987).

Thank you for your consideration of our views.

GREGORY S. SCHELL,
Attorney at Law.

[ATTACHMENT 13]

Received May 5, 2014
April 29, 2014

Hon. GINA MCCARTHY,
Administrator,
U.S. Environmental Protection Agency,
Washington, D.C.

RE: Docket Number: EPA–HQ–OPP–2011–0184 (Pesticides; Agricultural Worker Protection Standard Revisions)

Dear Administrator McCarthy:

On behalf of Telamon Corporation I am writing to express our organization's strong support for the proposed revisions to the Worker Protection Standard for Agricultural Pesticides (WPS). We deeply appreciate your consideration of our comments.

With the support of a grant from the United States Department of Labor through the National Farmworker Jobs Program (NFJP), we provide critical job training to migrant and seasonal farmworkers to help them secure more stable and self- and family-sustaining employment. In doing so, our organization actively seeks to engage eligible members of this population by going into communities, often before and after working hours and on weekends, to make them aware of the opportunities we provide. We then work closely with program participants to help them complete training and find gainful employment that provides for them a more stable future. We are proud of the success we have had in this work and that of the program in its entirety. Nationally, NFJP continues to be one of the highest performing training programs at the Labor Department.

Because of our extensive, close work with farmworkers, we believe that we know better than most about just how important these WPS revisions are to farmworkers. Our organization fully supports these changes because of the greater protections

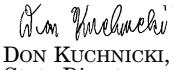
they will bring to the vulnerable migrant and seasonal farmworker population. In particular, we are especially happy to see the following changes proposed:

- *Yearly trainings for farmworkers.* As you know, current regulations require training only every five years. Again, because of our work with farmworkers, we see firsthand the turnover in this population. As a result, we consistently find farmworkers who have received little, if any, pesticide-safety training.
- *Added emphasis on take-home exposure for farmworker families.* Several years ago, our member organization, the Association of Farmworker Opportunity Programs (AFOP), developed a curriculum to educate farmworkers about the dangers of pesticide residue on clothing and equipment returned to the home at the end of each work day. Using excellent low-literacy materials to communicate this message, AFOP members have trained thousands of farmworkers on limiting this take-home exposure, greatly benefitting workers' families. While AFOP is pleased with that impact, it knows that many tens of thousands more suffer in ignorance of this threat to their homes and families.
- *Actions to reduce spray drift, especially near farmworker housing, schools, and playgrounds.* Spray drift is also a danger farmworkers face routinely. While we acknowledge the common use of pesticides, we also recognize the simple precautions proposed by this new rule will better protect farmworkers from overspray and fumes.
- *More stringent requirements for treated areas and improved notification for early-entry workers.* Again, we see these as common sense precautions that will help preserve the health and safety of laborers.
- *Making available to farmworkers or their advocates (including medical personnel) information specific to the pesticide application, including the pesticide label and Safety Data Sheets.* Working with farmworkers firsthand, we see consistently the barriers they face in working in the United States agricultural sector. Oftentimes, an inability to speak or understand the English language makes it difficult for these workers to communicate effectively with employers and understand sufficiently the information provided them. Accordingly, making this critical information available to advocates, including medical personnel, will allow these laborers to call on a family friend to communicate and better explain matters on their behalf. Importantly, it will also allow doctors, nurses and first-responders to better understand the nature of injuries through ready access to pesticide information.

On the topic of minimum age for pesticide handling, we understand the revisions would allow for a person as young as 16 years of age to handle pesticides. AFOP believes that 18 years of age would be a more appropriate age for that kind of work, and will state so in its comments. AFOP will also work with its collegial advocacy groups and the medical community to better demonstrate why the age change is warranted.

In closing, we would like to thank you for putting forward these important changes, and look forward to their quick adoption.

Sincerely,



DON KUCHNICKI,
State Director.

[ATTACHMENT 14]

[*http://www.statutes.legis.state.tx.us/Docs/AG/htm/AG.125.htm*]

Texas Agriculture Code

Title 5. Production, Processing, and Sale of Horticultural Products

Subtitle G. Workplace Chemicals

Chapter 125. Agricultural Hazard Communication Act

Sec. 125.001. DECLARATION OF PURPOSE. The legislature finds that the health and safety of persons living and working in agricultural areas in the state may be improved by providing access to information regarding certain hazardous chemicals to which they may be exposed either during their normal employment activities, during emergency situations, or as a result of proximity to the use of those chemicals. The legislature also finds that, because of the conditions of agricultural employment, there is a unique situation regarding certain agricultural laborers that makes it nec-

essary to establish formal procedures to provide access to information regarding certain hazardous chemicals and to assure those laborers that there will be no retaliation by the employer for the exercise of rights under this chapter. This chapter is intended to assure that accessibility to information regarding chemicals covered by this chapter be provided to agricultural laborers who may be exposed to those chemicals in agricultural workplaces, to certain emergency service organizations responsible for dealing with chemical hazards during emergency situations when those chemicals are in close proximity to residential areas, and to the department to make the information available to the general public through specific procedures.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.002. DEFINITIONS. In this chapter:

(1) "Agricultural laborer" means a person who plants, cultivates, harvests, or handles an agricultural or horticultural commodity in its unmanufactured state as determined by rule of the department, and includes an agricultural laborer who handles a chemical covered by this chapter. Office workers, cooks, maintenance workers, security personnel, and nonresident management are not agricultural laborers, except for purposes of a gross annual payroll determination, unless their job performance routinely involves potential exposure to chemicals covered under this chapter. Farm and ranch laborers working solely with livestock and persons working solely in the retail sales component of a business are not agricultural laborers for purposes of this chapter.

(2) "Chemical name" means the scientific designation of a chemical in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) rules of nomenclature, or a name that will clearly identify the chemical for the purpose of conducting a hazard evaluation.

(3) "Common name" means any designation of identification such as code name, code number, trade name, brand name, or generic name used to identify a chemical other than by its chemical name.

(4) "Chemical manufacturer" means an employer in Standard Industrial Classification (SIC) Codes 20 through 39.

(5) "Designated representative" means the individual or organization to whom an agricultural laborer gives written authorization to exercise the laborer's rights under this chapter. A designated representative is not required to reveal the name of the agricultural laborer he represents if the department has reviewed the laborer's written authorization, certifies that the representative has that authorization, and determines that the agricultural laborer would be entitled to the information the designated representative is seeking to obtain. A recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written authorization from a laborer.

(6) "Distributor" means any business, other than a chemical manufacturer or importer, that supplies chemicals covered by this chapter to other distributors or to purchasers.

(7) "Expose" or "exposure" means that an agricultural laborer is subjected to a chemical covered by this chapter in the course of employment through any route of entry, including inhalation, ingestion, skin contact, or absorption, and includes potential, possible, or accidental exposure.

(8) "Fire chief" means the elected or paid administrative head of a fire department as defined in Chapter *125* (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=AG&Value=125*), Acts of the 45th Legislature, Regular Session, 1937 (Article *6243e* (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=CV&Value=6243e*), Vernon's Texas Civil Statutes).

(9) "Label" means any written, printed, or graphic material displayed on or affixed to containers of chemicals covered by this chapter.

(10) "Material safety data sheet" ("MSDS") means a document containing chemical hazard and safe handling information that is prepared in accordance with the requirements of the Occupational Safety and Health Administration (OSHA) standard for that document or, in the case of a chemical labeled under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Section 136 et seq.) for which an MSDS is both unavailable and not required under the Federal OSHA's hazard communication standard, a product label or other equivalent document with precautionary statements, such as hazards to humans and domestic animals, and environmental, physical, or chemical hazards, including warning statements.

(11) "Work area" means a room, defined space, or field where chemicals covered by this chapter are stored or used and where agricultural laborers may be present.

(12) "Workplace" means a geographical location containing one or more work areas.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.003. APPLICATION. (a) This chapter applies only to the following employers who annually use or store any one of the chemicals covered by this chapter in excess of 55 gallons or 500 pounds or an amount that the department determines by rule for certain highly toxic or dangerous chemicals covered by this chapter:

(1) employers who themselves or through labor agents hire agricultural laborers to perform seasonal or migrant work and whose gross annual payroll for those laborers is $15,000 or more; and

(2) employers who themselves or through labor agents hire agricultural laborers for purposes other than seasonal or migrant work and whose gross annual payroll for those laborers is $50,000 or more.

(b) This chapter applies only to the following chemicals:

(1) chemicals labeled under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Section 136 et seq.); and

(2) fertilizers with chemicals that are listed or defined as hazardous chemicals in 29 CFR Section 1910.1200(c) or 1910.1200(d)(3), including those listed or defined in subsequent comparable regulations.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.004. WORKPLACE CHEMICAL LIST. (a) An employer covered by this chapter shall compile and maintain a workplace chemical list on a form prescribed by the department that contains the following information by crop for each chemical covered by this chapter that is actually used or stored annually in the workplace in excess of 55 gallons or 500 pounds or an amount that the department determines by rule for certain highly toxic or dangerous chemicals covered by this chapter:

(1) the product name used on the MSDS and container label and the Environmental Protection Agency registration number, if applicable;

(2) the date and crop on which the chemical was applied or used; and

(3) the work area in which the chemical is actually stored or used.

(b) The employer shall update the workplace chemical list as necessary but not less frequently than annually.

(c) The workplace chemical list may be prepared for the workplace as a whole or for each work area and must be readily available to agricultural laborers and their designated representatives. New or newly assigned agricultural laborers shall be made aware of the workplace chemical list before working with chemicals covered by this chapter or in a work area containing those chemicals.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.005. WORKPLACE CHEMICAL LIST FORM, MAINTENANCE, AND ACCESS. (a) The department shall prescribe forms for workplace chemical lists required by this chapter with places to indicate the crop, the product name of the chemical that is applied to the crop or that is stored, and the location and date of its application, use, or storage, as appropriate.

(b) An employer covered by this chapter shall maintain one form for each crop, work area, or workplace as a whole, as appropriate, and shall add information to the form as different chemicals are applied, used, or stored.

(c) The employer shall attach relevant information to the form, including MSDSs.

(d) The employer shall keep the forms and attachments accessible and available for copying and shall store them in a location suitable to preserve their physical integrity.

(e) The employer shall keep the forms and attachments under this chapter for 30 years. However, the department shall provide by rule that an employer may file with the department annually the forms and attachments, including an estimate of the total amount of each chemical listed on the form that was used. The department shall categorize and cross-reference the data on the forms in a manner to preserve the data for future medical use. An employer who files the forms and attachments with the department under rules adopted under this section is not required to preserve the forms.

(f) If it is determined after a hearing conducted under Section *12.032* (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=AG&Value=12.032*) that an employer has repeatedly failed to maintain the forms and attachments as required, the department may require the employer to file the documents with the department. In addition, the person may be subject to any applicable penalties provided by this chapter.

(g) If agricultural activities for which forms and attachments are maintained cease at a workplace, the forms and attachments shall be filed with the department, and the department shall retain the information for 30 years. If an employer covered by this chapter is succeeded or replaced in that function by another person, the person who succeeds or replaces the employer shall retain the forms as provided by Subsection (e) of this section but is not liable for violations committed by the former employer under this chapter or rules adopted under this chapter, including violations relating to the retention and preservation of forms and attachments.

(h) Except as otherwise provided by this section, the employer shall show the forms and attachments, on request, to an employee, designated representative, treating medical personnel, or a member of the community. The designated representative or treating medical personnel are not required to identify the employee represented or treated. If the employer has filed the forms and attachments with the department, the employer shall inform the requestor of that fact.

(i) If a designated representative or member of the community desires a copy of a form and attachments and the employer refuses to provide a copy, that person shall notify the department of the request and the employer's refusal. Within two working days, the department shall request that the employer provide the department with all pertinent copies. The employer shall provide copies of the form and attachments to the department within 24 hours after the department's request if a designated representative desires the copies, and within 14 days after the department's request if a member of the community desires the copies.

(j) The employer may not refuse to provide the forms and attachments to an employee or treating medical personnel.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988. Amended by Acts 1995, 74th Leg., ch. 419, Sec. 3.25, eff. Sept. 1, 1995.

Sec. 125.006. MATERIAL SAFETY DATA SHEETS. (a) Chemical manufacturers and distributors shall provide appropriate MSDSs to purchasers in this state of chemicals covered by this chapter.

(b) Employers covered by this chapter shall maintain the most current MSDS received from manufacturers or distributors for each purchased chemical covered by this chapter. If an MSDS has not been provided by the manufacturer or distributor for chemicals on the workplace chemical list at the time the chemicals are received at the workplace, the employer shall request one in writing from the manufacturer or distributor in a timely manner. This chapter does not require an employer who is not a chemical manufacturer to create an MSDS.

(c) The department may require any person who has or obtains a registration for a pesticide under Sections 76.041–76.048 of this code to provide with the registration a copy of the most current and complete MSDS for that pesticide.

(d) The department by rule may require chemical manufacturers to submit MSDSs for chemicals covered by this chapter, excluding chemicals covered by Subsection (c) of this section.

(e) All MSDSs in the files of the department are public records.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1.

Sec. 125.007. LABELS. (a) Existing labels on incoming containers of chemicals covered by this chapter may not be removed or defaced.

(b) Agricultural laborers may not be required to work with a chemical covered by this chapter from an unlabeled container except for a portable container intended for the immediate use of the laborer who performs the transfer.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.008. EMERGENCY INFORMATION. (a) Employers covered by this chapter and other entities who normally store products labeled under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Section 136 et seq.) in an amount in excess of 55 gallons or 500 pounds or an amount the department determines by rule for certain highly toxic or dangerous chemicals covered by this chapter within ¼ mile of a residential area composed of three or more private dwellings shall provide to the fire chief of the fire department having jurisdiction over the storage place, in writing, the names and telephone numbers of knowledgeable representatives of

the employer or other entity storing the product who can be contacted for further information or contacted in case of an emergency.

(b) Each employer, on request, shall provide a copy of the workplace chemical list to the fire chief having jurisdiction over the storage place. The employer shall notify the fire chief of any significant changes that occur in the workplace chemical list.

(c) The fire chief having jurisdiction over the storage place or his representative, on request, shall be permitted to conduct on-site inspections of the chemicals on the workplace chemical list for the sole purpose of preparing fire department activities in case of an emergency.

(d) Employers shall provide to the fire chief having jurisdiction over the storage place, on request, a copy of the MSDS for any chemical on the workplace chemical list.

(e) On request, the fire chief having jurisdiction over the storage place shall make the workplace chemical list and MSDSs available to members of the fire department having jurisdiction over the workplace and to other personnel outside the fire department who are responsible for preplanning emergency activities, but may not otherwise distribute the information without approval of the employer.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.009. TRAINING PROGRAM PROVIDED BY DEPARTMENT. (a) The department in conjunction with the Texas Agricultural Extension Service shall develop an ongoing training program for agricultural laborers. The program must provide information the department considers appropriate, and must include:

(1) information on interpreting labels and MSDSs and the relationship between those two methods of hazard communication;

(2) information on the proper storage, acute and chronic effects, and safe handling of chemicals covered by this chapter;

(3) information on protective clothing and equipment and first aid treatment to be used with respect to the chemicals covered by this chapter; and

(4) general safety instructions on the handling, cleanup procedures, and disposal of chemicals covered by this chapter.

(b) The department shall provide the training program in counties with a hired farm labor work force of 2,000 or more, according to the most recent United States Census of Agriculture. The department by rule may determine to provide the training program in additional counties with a significant farm labor work force or based on other relevant factors. In all other counties, the county office of the Texas Agricultural Extension Service shall provide the training program.

(c) The department or the county office of the Texas Agricultural Extension Service, as appropriate, shall notify agricultural laborers on a regular basis of the training program by public service announcements given by the media and shall contact in writing charitable, public, religious, and health care provider organizations to announce the training program to agricultural laborers in the county served by the organization.

(d) In addition to the Texas Agricultural Extension Service, the department may develop the training program in conjunction with the Texas Department of Health, other appropriate state agencies, clinics, hospitals, and other health care providers in counties in which the training program will be conducted, and organizations representing employers, organizations representing employees, and organizations representing manufacturers of chemicals covered by this chapter.

(e) The department shall prepare and make available to employers appropriate training materials for employers covered by this chapter and their managers and labor contractors.

(f) To help cover production costs, the department may charge not more than $10 plus the cost of a blank videotape from a person desiring to purchase the videotaped training program.

(g) The department or the county office of the Texas Agricultural Extension Service, as appropriate, shall provide to each agricultural laborer who completes the training program a card evidencing participation in the program. An employer may not refuse to hire an agricultural laborer solely because the laborer does not have a card issued under this subsection. An employer who refuses to hire an agricultural laborer for that reason is not entitled to the 14 days' written notice provided by Section *125.016*(d) (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=AG&Value=125.016*) of this code.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.010. CROP SHEET DEVELOPED BY DEPARTMENT. (a) The department shall develop crop sheets that contain the following information:

(1) the kinds of chemicals typically used on a particular crop;

(2) the typical time a chemical is applied to a particular crop;

(3) general safety information, including information on general hygiene, clothing, contact with chemicals, medical symptoms, pregnancy, and other relevant safety data;

(4) a notice of the training programs and the counties in which the programs will be conducted;

(5) the availability of MSDSs for chemicals used on a particular crop;

(6) the means of locating emergency medical information;

(7) agricultural laborers' rights under this chapter;

(8) the name and telephone number of the person to contact for information under this chapter;

(9) the appropriate telephone number for emergency information; and

(10) any other safety or health-related information the department considers relevant.

(b) The information on the crop sheet must be printed in English and Spanish, except that the information required by Subsections (a)(1) and (a)(2) of this section is required to be printed only in English. The department may provide crop sheets printed in other languages commonly used by agricultural laborers who work with a particular crop.

(c) The department shall develop the crop sheets in conjunction with the Texas Department of Health, the Texas Agricultural Extension Service, other appropriate state agencies, and clinics, hospitals, and other health care providers in counties in which training programs are provided by the department under Section *125.009* (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=AG&Value=125.009*) of this code.

(d) Annually, the department shall:

(1) provide appropriate crop sheets to clinics, hospitals, and other health care providers that serve agricultural laborers and that are located in counties in which the training program is provided; and

(2) provide to an employer covered by this chapter one crop sheet for each crop grown by that employer.

(e) The director of the Texas Feed and Fertilizer Control Service under Section *63.003* (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=AG&Value=63.003*) of this code shall provide to the department the information that is needed by the department under Subsection (a) of this section for the fertilizers that are covered by this chapter.

(f) For purposes of developing crop sheets under this chapter and complying with other provisions of this chapter, nursery stock, stored grain, and other logical groupings may be considered a single crop as determined by rules adopted by the department.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.011. CROP SHEET PROVIDED BY EMPLOYER. (a) An employer covered by this chapter shall provide crop sheets to each agricultural laborer pertaining to the crops that laborer will be working with if:

(1) the laborer does not have a card issued under Section *125.009*(g) (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=AG&Value=125.009*) of this code; or

(2) the laborer requests the crop sheets.

(b) An employer who is required under Subsection (a) of this section to provide crop sheets to an agricultural laborer shall ensure that the information on a crop sheet required by Sections *125.010*(a)(3), (a)(4), and (a)(10) (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=AG&Value=125.010*) of this code that pertains to the crops with which the laborer will be working is read to the laborer at least once each work season. When the crop sheet is read, the employer or the employer's agent shall inform the laborer of the date on which chemicals covered by this chapter were last applied or are scheduled to be applied to the field or to other areas in which the laborer will be working and shall inform the laborer of the time on which the reentry period, if any, expired for chemicals covered by this chapter that have been applied.

(c) If an employer is required under Subsection (b) of this section to read a crop sheet to an agricultural laborer, the employer or a person designated by the employer shall read the appropriate crop sheets on the first day of each work season or on the day the laborer begins employment with that employer, whichever is later.

(d) In addition to the crop sheet, the department shall require an employer to offer to the agricultural laborer, on the day on which the laborer is given his first pay for that work season, basic safety and health-related information approved by the department. That information shall be available to the employers free of charge.

(e) An employer who does not provide or read the crop sheets as required by this section is not entitled to the 14 days' written notice provided by Section *125.016*(d) (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=AG&Value=125.016*) of this code.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.012. PROTECTIVE CLOTHING. An employer covered by this chapter shall provide any protective clothing or device that is recommended by the MSDS, crop sheet, or department rule and that is in addition to the standard long-sleeved shirt, long pants, boots or shoes, and socks normally provided by the agricultural laborer.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.013. RIGHTS OF AGRICULTURAL LABORERS. (a) Agricultural laborers employed by employers covered by this chapter who may be exposed to chemicals covered by this chapter shall be informed of the exposure and shall have access to the workplace chemical list and MSDSs for those chemicals. Laborers, on request, shall be provided a copy of a specific MSDS. In addition, laborers shall receive training on the hazards of the chemicals and on measures they can take to protect themselves from those hazards and shall be provided with appropriate personal protective equipment as required by this chapter. These rights are guaranteed on January 1, 1988.

(b) An employer covered by this chapter may not discharge, cause to be discharged, otherwise discipline, or in any manner discriminate against an agricultural laborer because the laborer has made an inquiry, filed a complaint, assisted an inspector of the department who may make or is making an inspection under Section *125.016* (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=AG&Value=125.016*) of this code, instituted or caused to be instituted any proceeding under or related to this chapter, testified or is about to testify in such a proceeding, or exercised any rights afforded under this chapter on behalf of the laborer or on behalf of others. Pay, position, seniority, or other benefits may not be lost as the result of the exercise of any right provided by this chapter.

(c) Any waiver by an agricultural laborer of the benefits or requirements of this chapter is against public policy and is void. Any employer's request or requirement that a laborer waive any rights under this chapter as a condition of employment is a violation of this chapter.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.014. DEPARTMENT RULES; OUTREACH PROGRAM. (a) The department may adopt rules and administrative procedures reasonably necessary to carry out the purposes of this chapter.

(b) The department shall develop and provide to each employer covered by this chapter a suitable form of notice providing agricultural laborers with information regarding their rights under this chapter.

(c) As part of an outreach program, the department shall develop and distribute a supply of informational leaflets on employers' duties, agricultural laborers' rights, the public's ability to obtain information under this chapter, the outreach program, and the effects of chemicals covered by this chapter.

(d) The department may contract with a public institution of higher education or other public or private organizations to develop and implement the outreach program.

(e) The department shall publicize the availability of information to answer inquiries from agricultural laborers, employers, or the public in this state concerning the effects of chemicals covered by this chapter.

(f) In cooperation with the department, an employer covered by this chapter may provide an outreach program in the community.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.015. LIABILITY UNDER OTHER LAWS. (a) The provision of information to an agricultural laborer does not in any way affect the liability of an employer with regard to the health and safety of a laborer or other person exposed to chemicals, nor does it affect the employer's responsibility to take any action to prevent the occurrence of occupational disease as required under any other provision of law.

(b) The provision of information to an agricultural laborer does not affect any other duty or responsibility of a manufacturer, producer, or formulator to warn ultimate users of a chemical under any other provision of law.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988.

Sec. 125.016. COMPLAINTS, INVESTIGATIONS, AND PENALTIES. (a) Complaints received in writing from agricultural laborers or their designated representatives relating to alleged violations of this chapter by employers covered by this chapter shall be investigated in a timely manner by the department as provided by this section.

(b) Officers or representatives of the department, on presentation of appropriate credentials, have the right of entry into any workplace at reasonable times to inspect and investigate complaints for purposes of determining compliance with this chapter.

(c) The department shall complete an investigation of a complaint not later than 90 days after the date on which the complaint is filed. A hearing shall be conducted under Section *12.032* (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=AG&Value=12.032*) and an enforcement order issued, if appropriate, not later than 90 days after the date on which the investigation is completed. If it is necessary to commence an action relating to an alleged violation, the action must be commenced not later than 60 days after the date on which the investigation is completed.

(d) After providing at least 14 days' written notice and an opportunity for a public hearing, the department may issue an enforcement order requiring any employer or chemical manufacturer covered by this chapter to comply with this chapter or rules adopted under this chapter. A public hearing held under this subsection is a contested case under Chapter *2001* (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=GV&Value=2001*), Government Code, and may be appealed under that chapter. In the case of a medical emergency, the department may issue an enforcement order immediately and shall provide the opportunity for a hearing on the order within 10 days after the date on which the order is issued.

(e) In the case of a medical emergency, the department may sue in the name of the State of Texas to enjoin any violation of this chapter or a rule adopted or enforcement order issued by the department under this chapter.

(f) If required under this chapter, employers who knowingly disclose false information or negligently fail to disclose a hazard are subject to a civil penalty of not more than $5,000 per violation. This section does not affect any other right of an agricultural laborer or any other person to receive compensation for damages under other law.

(g) If required under this chapter, employers who proximately cause an injury to an individual by knowingly disclosing false hazard information or knowingly failing to disclose hazard information are subject to a criminal fine of not more than $25,000. This section does not affect any other right of an agricultural laborer or any other person to receive compensation for damages under other law.

(h) The department may request the attorney general to represent the department in any legal proceeding authorized under this chapter. An action for civil or criminal penalties or injunctive relief shall be brought in the county in which the alleged violation occurred or is occurring.

(i) Each violation of this chapter or a rule adopted under this chapter constitutes a separate offense.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988. Amended by Acts 1995, 74th Leg., ch. 76, Sec. 5.95(49), eff. Sept. 1, 1995; Acts 1995, 74th Leg., ch. 419, Sec. 3.26, eff. Sept. 1, 1995.

Sec. 125.017. COMPLIANCE WITH HAZARD COMMUNICATION ACT. (a) If an employer is required to comply with Chapter *502* (*http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=HS&Value=502*), Health and Safety Code and with this chapter, the employer is required to comply with only the Hazard Communication Act. However, if an agricultural laborer is not covered under the Hazard Communication Act, the employer shall comply with this chapter for those laborers not covered by the Hazard Communication Act.

(b) If an employer is covered by both the Hazard Communication Act and this chapter, the employer is required to furnish a workplace chemical list under only one of those laws.

Added by Acts 1987, 70th Leg., ch. 903, Sec. 1, eff. Jan. 1, 1988. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 284(92), eff. Sept. 1, 1991.

[Accessed September 8, 2016]

[ATTACHMENT 15]

[*http://www.cdpr.ca.gov/docs/legbills/calcode/030302.htm#a67231*]

California Code of Regulations (Title 3. Food and Agriculture)

Division 6. Pesticides and Pest Control Operations

Chapter 3. Pest Control Operations

Subchapter 3. Pesticide Worker Safety

Article 2. General Safety Requirements

6723.1. Application-Specific Information For Handlers.

(a) The operator of property used for the commercial or research production of an agricultural plant commodity shall display, at a central location, the following application-specific information while employees are employed to handle pesticides:

(1) Identification of the treated area;
(2) Time and date of the application;
(3) Restricted entry interval; and
(4) Product name, EPA registration number, and active ingredients.

(b) The information shall be displayed within 24 hours of the completion of an application and include all applications that have been made to any treated field on the agricultural establishment within ¼ mile of where employees will be working. Once displayed, the information shall remain displayed until the area no longer meets the definition of a treated field or handler employees will no longer be on the establishment, whichever occurs earlier.

(c) The original or copies of documents otherwise required to be maintained by this chapter may be used to meet the requirements of this Section provided they contain the information required by this Section.

Note: Authority cited: Section 12981, Food and Agricultural Code.
Reference: Sections 11501, 12973, 12980, and 12981, Food and Agricultural Code.

6761. Hazard Communication for Field Workers.

(a) Whenever employees are working as field workers in a treated field, the employer shall display at the worksite, a copy of a completed written Hazard Communication Information for Employees Working in Fields (Pesticide Safety Information Series leaflet A–9). In the event that fieldworkers gather at a central location prior to transportation to the worksite, the Pesticide Safety Information Series leaflet A–9 may instead be displayed at that central location. Pesticide Safety Information Series leaflet A–9 shall be written by the department in English and Spanish. Upon request, the employer shall read to the requesting employee, in a language understandable to that employee, Pesticide Safety Information Series leaflet A–9. Pesticide Safety Information Series leaflets are available from the Department.

(b) The operator of the property shall maintain in a central location at the workplace accessible to employees, including the employees of labor contractors, who enter a treated field, the following:

(1) pesticide use records specified in section 6624(b), (c), (d) and (e) for pesticides that have been applied to the field within the last two years;

(2) a Safety Data Sheets (SDS), as specified in Title 8, California Code of Regulations, section 5194, for each pesticide listed in the pesticide use records referred to in subsection (b)(1). If the SDS is not provided by the registrant of a pesticide, the operator of the property shall:

(A) within 7 working days of a request for a SDS from an employee, employee representative or employee's physician, make written inquiry to the registrant of the pesticide, asking that a SDS be sent to the operator of the property. If the operator of the property has made a written inquiry within the last 12 months as to whether the pesticide is subject to the requirement for a SDS or the operator of the property has made a written inquiry within the last 6 months requesting new, revised or later information on the SDS, the operator of the property need not make additional written inquiry. A copy of the written inquiry shall immediately be sent to the person requesting the SDS;

(B) notify the requester of the availability of the SDS or provide a copy of the SDS to the requester within 15 days of receipt of the SDS from the registrant; and

(C) if a response has not been received from the registrant within 25 working days of the date the inquiry was made, send the department a copy of the inquiry with a notation that no response has been received. The operator of the property is not precluded from obtaining and providing the SDS utilizing other more expedient methods in lieu of those provided in this subsection.

(c) The operator of the property shall inform his or her employees, before they are allowed to enter a treated field, of the location and availability of any records and other documents required by subsections (a) and (b). If the employees are employed by a labor contractor, the operator of the property shall inform the labor contractor of the location, or changed location, of the records and other documents. The labor contractor shall provide that information to his or her employees. If the location of the records and other documents changes, the operator of the property and the labor contractor shall promptly inform his or her employees of the new location. The employer, including the labor contractor, shall also inform their employees that they, their physicians and their representatives have a right of access to the information and that the employees are protected against discharge or other discrimination due to the exercise of their rights under this section.

(d) The operator of the property shall provide, upon request of his or her employee, an employee of a labor contractor, employee representative, or an employee's physician, access to any records, documents and information required to be maintained by this chapter. Access shall be granted as soon as possible and not to exceed 48 hours from the date of the request.

Informational Note: Other requirements relating to hazard communication can be found in sections 6602, 6618, 6619, 6724, 6726, 6738, 6744, 6764, 6766, 6770, 6771, and 6776.

Note: Authority cited: Section 12981, Food and Agricultural Code.

Reference: Sections 12980 and 12981, Food and Agricultural Code; and 29 Code of Federal Regulations, Part 1910.1200.

6761.1. Application-Specific Information for Fieldworkers.

(a) The operator of property used for the commercial or research production of an agricultural plant commodity shall display at a central location the following application-specific information, while fieldworkers are employed to work in treated fields on the operator's property:

(1) Identification of the treated field;

(2) Time and date of the application;

(3) Restricted entry interval;

(4) Product name(s), U.S. EPA registration number(s), and active ingredient(s); and

(5) Spray adjuvant product name(s) and California registration number(s) if applicable.

(b) The information must be displayed when the operator of the property receives notice of the completion of an application and before any fieldworkers are allowed to enter the treated field. The information must include all applications that have been made to any field on the operator's property. The information must remain displayed until the area no longer meets the definition of a treated field or fieldworkers will no longer be on the operator's property, whichever occurs earlier.

(d)* The operator of the property and any employer with fieldworkers hired to work on the operator's property, shall display, at the worksite or at a central location where fieldworkers gather, a description of the location of the application-specific information display whenever their fieldworkers are working in a treated field. The description of the location must be specific enough for fieldworkers to find and have unimpeded access to the displayed application-specific information. The location description must be included in the appropriate section of, or as an attachment to, the Hazard Communication Information for Employees Working in Fields (Pesticide Safety Information Series leaflet A–9) pursuant to section 6761(a).

(c)* The original or copies of documents otherwise required to be maintained by this chapter may be used to meet the requirements of this Section, provided they contain the information required by this Section.

Note: Authority cited: Section 12981, Food and Agricultural Code.

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*__Editor's note:__ the entries on the California Government website are reproduced herein as is. Technically, paragraph (d) should follow paragraph (c).

Reference: Sections 11501, 12973, 12980, and 12981, Food and Agricultural Code.

[Accessed September 8, 2016]

[ATTACHMENT 16]

[*http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=d452215d50193ecd758dc85dc47b5e7c&rgn=div8&view=text&node =29:6.1.1.1.1.1.1.20&idno=29*]

e-CFR data is current as of September 8, 2016.

29 CFR Labor

Subtitle B—Regulations Relating to Labor (Continued)

Chapter XVII—Occupational Safety and Health Administration, Department of Labor (Continued)

Part 1910—Occupational Safety and Health Standards (Continued)

Subpart Z—Toxic and Hazardous Substances

§1910.1020 Access to employee exposure and medical records.

(a) *Purpose.* The purpose of this section is to provide employees and their designated representatives a right of access to relevant exposure and medical records; and to provide representatives of the Assistant Secretary a right of access to these records in order to fulfill responsibilities under the Occupational Safety and Health Act. Access by employees, their representatives, and the Assistant Secretary is necessary to yield both direct and indirect improvements in the detection, treatment, and prevention of occupational disease. Each employer is responsible for assuring compliance with this section, but the activities involved in complying with the access to medical records provisions can be carried out, on behalf of the employer, by the physician or other health care personnel in charge of employee medical records. Except as expressly provided, nothing in this section is intended to affect existing legal and ethical obligations concerning the maintenance and confidentiality of employee medical information, the duty to disclose information to a patient/employee or any other aspect of the medical-care relationship, or affect existing legal obligations concerning the protection of trade secret information.

(b) *Scope and application.* (1) This section applies to each general industry, maritime, and construction employer who makes, maintains, contracts for, or has access to employee exposure or medical records, or analyses thereof, pertaining to employees exposed to toxic substances or harmful physical agents.

(2) This section applies to all employee exposure and medical records, and analyses thereof, of such employees, whether or not the records are mandated by specific occupational safety and health standards.

(3) This section applies to all employee exposure and medical records, and analyses thereof, made or maintained in any manner, including on an in-house of contractual (*e.g.,* fee-for-service) basis. Each employer shall assure that the preservation and access requirements of this section are complied with regardless of the manner in which the records are made or maintained.

(c) *Definitions*—(1) *Access* means the right and opportunity to examine and copy.

(2) *Analysis using exposure or medical records* means any compilation of data or any statistical study based at least in part on information collected from individual employee exposure or medical records or information collected from health insurance claims records, provided that either the analysis has been reported to the employer or no further work is currently being done by the person responsible for preparing the analysis.

(3) *Designated representative* means any individual or organization to whom an employee gives written authorization to exercise a right of access. For the purposes of access to employee exposure records and analyses using exposure or medical records, a recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

(4) *Employee* means a current employee, a former employee, or an employee being assigned or transferred to work where there will be exposure to toxic substances or harmful physical agents. In the case of a deceased or legally incapacitated employee, the employee's legal representative may directly exercise all the employee's rights under this section.

(5) *Employee exposure record* means a record containing any of the following kinds of information:

(i) Environmental (workplace) monitoring or measuring of a toxic substance or harmful physical agent, including personal, area, grab, wipe, or other form of sampling, as well as related collection and analytical methodologies, calculations, and other background data relevant to interpretation of the results obtained;

(ii) Biological monitoring results which directly assess the absorption of a toxic substance or harmful physical agent by body systems (*e.g.,* the level of a chemical in the blood, urine, breath, hair, fingernails, *etc*[.]) but not including results which assess the biological effect of a substance or agent or which assess an employee's use of alcohol or drugs;

(iii) Material safety data sheets indicating that the material may pose a hazard to human health; or

(iv) In the absence of the above, a [chemical] inventory or any other record which reveals where and when used and the identity (*e.g.,* chemical, common, or trade name) of a toxic substance or harmful physical agent.

(6)(i) *Employee medical record* means a record concerning the health status of an employee which is made or maintained by a physician, nurse, or other health care personnel or technician, including:

(A) Medical and employment questionnaires or histories (including job description and occupational exposures),

(B) The results of medical examinations (pre-employment, pre-assignment, periodic, or episodic) and laboratory tests (including chest and other X-ray examinations taken for the purposes of establishing a base-line or detecting occupational illness, and all biological monitoring not defined as an "employee exposure record"),

(C) Medical opinions, diagnoses, progress notes, and recommendations,

(D) First aid records,

(E) Descriptions of treatments and prescriptions, and

(F) Employee medical complaints.

(ii) "Employee medical record" does not include medical information in the form of:

(A) Physical specimens (*e.g.,* blood or urine samples) which are routinely discarded as a part of normal medical practice; or

(B) Records concerning health insurance claims if maintained separately from the employer's medical program and its records, and not accessible to the employer by employee name or other direct personal identifier (*e.g.,* [S]ocial [S]ecurity [N]umber, payroll number, *etc.*); or

(C) Records created solely in preparation for litigation which are privileged from discovery under the applicable rules of procedure or evidence; or

(D) Records concerning voluntary employee assistance programs (alcohol, drug abuse, or personal counseling programs) if maintained separately from the employer's medical program and its records.

(7) *Employer* means a current employer, a former employer, or a successor employer.

(8) *Exposure or exposed* means that an employee is subjected to a toxic substance or harmful physical agent in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, *etc.*), and includes past exposure and potential (e.g., accidental or possible) exposure, but does not include situations where the employer can demonstrate that the toxic substance or harmful physical agent is not used, handled, stored, generated, or present in the workplace in any manner different from typical non-occupational situations.

(9) *Health Professional* means a physician, occupational health nurse, industrial hygienist, toxicologist, or epidemiologist, providing medical or other occupational health services to exposed employees.

(10) *Record* means any item, collection, or grouping of information regardless of the form or process by which it is maintained (*e.g.,* paper document, microfiche, microfilm, X-ray film, or automated data processing).

(11) *Specific chemical identity* means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

(12)(i) *Specific written consent* means a written authorization containing the following:

(A) The name and signature of the employee authorizing the release of medical information,

(B) The date of the written authorization,

(C) The name of the individual or organization that is authorized to release the medical information,

(D) The name of the designated representative (individual or organization) that is authorized to receive the released information,

(E) A general description of the medical information that is authorized to be released,

(F) A general description of the purpose for the release of the medical information, and

(G) A date or condition upon which the written authorization will expire (if less than one year).

(ii) A written authorization does not operate to authorize the release of medical information not in existence on the date of written authorization, unless the release of future information is expressly authorized, and does not operate for more than one year from the date of written authorization.

(iii) A written authorization may be revoked in writing prospectively at any time.

(13) *Toxic substance or harmful physical agent* means any chemical substance, biological agent (bacteria, virus, fungus, *etc.*), or physical stress (noise, heat, cold, vibration, repetitive motion, ionizing and non-ionizing radiation, hypo- or hyperbaric pressure, *etc.*) which:

(i) Is listed in the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS), which is incorporated by reference as specified in § 1910.6; or

(ii) Has yielded positive evidence of an acute or chronic health hazard in testing conducted by, or known to, the employer; or

(iii) Is the subject of a material safety data sheet kept by or known to the employer indicating that the material may pose a hazard to human health.

(14) *Trade secret* means any confidential formula, pattern, process, device, or information or compilation of information that is used in an employer's business and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it.

(d) *Preservation of records.* (1) Unless a specific occupational safety and health standard provides a different period of time, each employer shall assure the preservation and retention of records as follows:

(i) *Employee medical records.* The medical record for each employee shall be preserved and maintained for at least the duration of employment plus thirty (30) years, except that the following types of records need not be retained for any specified period:

(A) Health insurance claims records maintained separately from the employer's medical program and its records,

(B) First aid records (not including medical histories) of one-time treatment and subsequent observation of minor scratches, cuts, burns, splinters, and the like which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job, if made on-site by a non-physician and if maintained separately from the employer's medical program and its records, and

(C) The medical records of employees who have worked for less than (1) year for the employer need not be retained beyond the term of employment if they are provided to the employee upon the termination of employment.

(ii) *Employee exposure records.* Each employee exposure record shall be preserved and maintained for at least thirty (30) years, except that:

(A) Background data to environmental (workplace) monitoring or measuring, such as laboratory reports and worksheets, need only be retained for one (1) year as long as the sampling results, the collection methodology (sampling plan), a description of the analytical and mathematical methods used, and a summary of other background data relevant to interpretation of the results obtained, are retained for at least thirty (30) years; and

(B) Material safety data sheets and paragraph (c)(5)(iv) records concerning the identity of a substance or agent need not be retained for any specified period as long as some record of the identity (chemical name if

known) of the substance or agent, where it was used, and when it was used is retained for at least thirty (30) years; [1] and

(C) Biological monitoring results designated as exposure records by specific occupational safety and health standards shall be preserved and maintained as required by the specific standard.

(iii) *Analyses using exposure or medical records.* Each analysis using exposure or medial records shall be preserved and maintained for at least thirty (30) years.

(2) Nothing in this section is intended to mandate the form, manner, or process by which an employer preserves a record as long as the information contained in the record is preserved and retrievable, except that chest X-ray films shall be preserved in their original state.

(e) *Access to records*—(1) *General.* (i) Whenever an employee or designated representative requests access to a record, the employer shall assure that access is provided in a reasonable time, place, and manner. If the employer cannot reasonably provide access to the record within fifteen (15) working days, the employer shall within the fifteen (15) working days apprise the employee or designated representative requesting the record of the reason for the delay and the earliest date when the record can be made available.

(ii) The employer may require of the requester only such information as should be readily known to the requester and which may be necessary to locate or identify the records being requested (*e.g.*[,] dates and locations where the employee worked during the time period in question).

(iii) Whenever an employee or designated representative requests a copy of a record, the employer shall assure that either:

(A) A copy of the record is provided without cost to the employee or representative,

(B) The necessary mechanical copying facilities (e.g., photocopying) are made available without cost to the employee or representative for copying the record, or

(C) The record is loaned to the employee or representative for a reasonable time to enable a copy to be made.

(iv) In the case of an original X-ray, the employer may restrict access to on-site examination or make other suitable arrangements for the temporary loan of the X-ray.

(v) Whenever a record has been previously provided without cost to an employee or designated representative, the employer may charge reasonable, non-discriminatory administrative costs (*i.e.,* search and copying expenses but not including overhead expenses) for a request by the employee or designated representative for additional copies of the record, except that

(A) An employer shall not charge for an initial request for a copy of new information that has been added to a record which was previously provided; and

(B) An employer shall not charge for an initial request by a recognized or certified collective bargaining agent for a copy of an employee exposure record or an analysis using exposure or medical records.

(vi) Nothing in this section is intended to preclude employees and collective bargaining agents from collectively bargaining to obtain access to information in addition to that available under this section.

(2) *Employee and designated representative access*—(i) *Employee exposure records.* (A) Except as limited by paragraph (f) of this section, each employer shall, upon request, assure the access to each employee and designated representative to employee exposure records relevant to the employee. For the purpose of this section, an exposure record relevant to the employee consists of:

(*1*) A record which measures or monitors the amount of a toxic substance or harmful physical agent to which the employee is or has been exposed;

(*2*) In the absence of such directly relevant records, such records of other employees with past or present job duties or working conditions related to or similar to those of the employee to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents to which the employee is or has been subjected, and

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[1] Material safety data sheets must be kept for those chemicals currently in use that are effected by the Hazard Communication Standard in accordance with 29 CFR 1910.1200(g).

(*3*) Exposure records to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents at workplaces or under working conditions to which the employee is being assigned or transferred.

(B) Requests by designated representatives for unconsented access to employee exposure records shall be in writing and shall specify with reasonable particularity:

(*1*) The records requested to be disclosed; and
(*2*) The occupational health need for gaining access to these records.

(ii) *Employee medical records.* (A) Each employer shall, upon request, assure the access of each employee to employee medical records of which the employee is the subject, except as provided in paragraph (e)(2)(ii)(D) of this section.
(B) Each employer shall, upon request, assure the access of each designated representative to the employee medical records of any employee who has given the designated representative specific written consent. [A]ppendix A to this section contains a sample form which may be used to establish specific written consent for access to employee medical records.
(C) Whenever access to employee medical records is requested, a physician representing the employer may recommend that the employee or designated representative:

(*1*) Consult with the physician for the purposes of reviewing and discussing the records requested,
(*2*) Accept a summary of material facts and opinions in lieu of the records requested, or
(*3*) Accept release of the requested records only to a physician or other designated representative.

(D) Whenever an employee requests access to his or her employee medical records, and a physician representing the employer believes that direct employee access to information contained in the records regarding a specific diagnosis of a terminal illness or a psychiatric condition could be detrimental to the employee's health, the employer may inform the employee that access will only be provided to a designated representative of the employee having specific written consent, and deny the employee's request for direct access to this information only. Where a designated representative with specific written consent requests access to information so withheld, the employer shall assure the access of the designated representative to this information, even when it is known that the designated representative will give the information to the employee.
(E) A physician, nurse, or other responsible health care personnel maintaining medical records may delete from requested medical records the identity of a family member, personal friend, or fellow employee who has provided confidential information concerning an employee's health status.
(iii) *Analyses using exposure or medical records.* (A) Each employee shall, upon request, assure the access of each employee and designated representative to each analysis using exposure or medical records concerning the employee's working conditions or workplace.
(B) Whenever access is requested to an analysis which reports the contents of employee medical records by either direct identifier (name, address, [S]ocial [S]ecurity [N]umber, payroll number, *etc.*) or by information which could reasonably be used under the circumstances indirectly to identify specific employees (exact age, height, weight, race, sex, date of initial employment, job title, *etc.*), the employer shall assure that personal identifiers are removed before access is provided. If the employer can demonstrate that removal of personal identifiers from an analysis is not feasible, access to the personally identifiable portions of the analysis need not be provided.
(3) *OSHA access*. (i) Each employer shall, upon request, and without derogation of any rights under the Constitution or the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.,* that the employer chooses to exercise, assure the prompt access of representatives of the Assistant Secretary of Labor for Occupational Safety and Health to employee exposure and medical records and to analyses using exposure or medical records. Rules of agency practice and procedure governing OSHA access to employee medical records are contained in 29 CFR 1913.10.
(ii) Whenever OSHA seeks access to personally identifiable employee medical information by presenting to the employer a written access order pursuant to 29 CFR 1913.10(d), the employer shall prominently post a copy of the written access order and its accompanying cover letter for at least fifteen (15) working days.

(f) *Trade secrets.* (1) Except as provided in paragraph (f)(2) of this section, nothing in this section precludes an employer from deleting from records requested by a health professional, employee, or designated representative any trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in mixture, as long as the health professional, employee, or designated representative is notified that information has been deleted. Whenever deletion of trade secret information substantially impairs evaluation of the place where or the time when exposure to a toxic substance or harmful physical agent occurred, the employer shall provide alternative information which is sufficient to permit the requesting party to identify where and when exposure occurred.

(2) The employer may withhold the specific chemical identity, including the chemical name and other specific identification of a toxic substance from a disclosable record provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) All other available information on the properties and effects of the toxic substance is disclosed;

(iii) The employer informs the requesting party that the specific chemical identity is being withheld as a trade secret; and

(iv) The specific chemical identity is made available to health professionals, employees and designated representatives in accordance with the specific applicable provisions of this paragraph.

(3) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity of a toxic substance is necessary for emergency or first-aid treatment, the employer shall immediately disclose the specific chemical identity of a trade secret chemical to the treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (f)(4) and (f)(5), as soon as circumstances permit.

(4) In non-emergency situations, an employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under paragraph (f)(2) of this section, to a health professional, employee, or designated representative if:

(i) The request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity is essential and that, in lieu thereof, the disclosure of the following information would not enable the health professional, employee or designated representative to provide the occupational health services described in paragraph (f)(4)(ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, employee, or designated representative and the employer or contractor of the services of the health professional or designated representative agree in a written confidentiality agreement that the health professional, employee or designated representative will not use the trade secret

information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (f)(7) of this section, except as authorized by the terms of the agreement or by the employer.

(5) The confidentiality agreement authorized by paragraph (f)(4)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(6) Nothing in this section is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

(7) If the health professional, employee or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the employer who provided the information shall be informed by the health professional prior to, or at the same time as, such disclosure.

(8) If the employer denies a written request for disclosure of a specific chemical identity, the denial must:

(i) Be provided to the health professional, employee or designated representative within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the specific chemical identity.

(9) The health professional, employee, or designated representative whose request for information is denied under paragraph (f)(4) of this section may refer the request and the written denial of the request to OSHA for consideration.

(10) When a heath professional employee, or designated representative refers a denial to OSHA under paragraph (f)(9) of this section, OSHA shall consider the evidence to determine if:

(i) The employer has supported the claim that the specific chemical identity is a trade secret;

(ii) The health professional employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and

(iii) The health professional, employee or designated representative has demonstrated adequate means to protect the confidentiality.

(11)(i) If OSHA determines that the specific chemical identity requested under paragraph (f)(4) of this section is not a *bona fide* trade secret, or that it is a trade secret but the requesting health professional, employee or designated representatives has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means for complying with the terms of such agreement, the employer will be subject to citation by OSHA.

(ii) If an employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health needs are met without an undue risk of harm to the employer.

(12) Notwithstanding the existence of a trade secret claim, an employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process or percentage of mixture information which is trade secret.

(g) *Employee information.* (1) Upon an employee's first entering into employment, and at least annually thereafter, each employer shall inform current employees covered by this section of the following:

(i) The existence, location, and availability of any records covered by this section;

(ii) The person responsible for maintaining and providing access to records; and

(iii) Each employee's rights of access to these records.

(2) Each employer shall keep a copy of this section and its appendices, and make copies readily available, upon request, to employees. The employer shall also distribute to current employees any informational materials concerning this section which are made available to the employer by the Assistant Secretary of Labor for Occupational Safety and Health.

(h) *Transfer of records.* (1) Whenever an employer is ceasing to do business, the employer shall transfer all records subject to this section to the successor employer. The successor employer shall receive and maintain these records.

(2) Whenever an employer is ceasing to do business and there is no successor employer to receive and maintain the records subject to this standard, the employer shall notify affected current employees of their rights of access to records at least three (3) months prior to the cessation of the employer's business.

(i) *Appendices.* The information contained in appendices A and B to this section is not intended, by itself, to create any additional obligations not otherwise imposed by this section nor detract from any existing obligation.

Appendix A to § 1910.1020—Sample Authorization Letter for the Release of Employee Medical Record Information to a Designated Representative (Non-Mandatory)

I, ____ (full name of worker/patient), hereby authorize ____ (individual or organization holding the medical records) to release to ____ (individual or organization authorized to receive the medical information), the following medical information from my personal medical records:

_____

_____

(Describe generally the information desired to be released)

I give my permission for this medical information to be used for the following purpose:

_____

_____

but I do not give permission for any other use or re-disclosure of this information.

Note: Several extra lines are provided below so that you can place additional restrictions on this authorization letter if you want to. You may, however, leave these lines blank. On the other hand, you may want to (1) specify a particular expiration date for this letter (if less than one year); (2) describe medical information to be created in the future that you intend to be covered by this authorization letter; or (3) describe portions of the medical information in your records which you do not intend to be released as a result of this letter.)

_____

_____

_____

_____

Full name of Employee or Legal Representative

_____

_____

Signature of Employee or Legal Representative

_____

_____

Date of Signature

Appendix B to § 1910.1020—Availability of NIOSH Registry of Toxic Effects of Chemical Substances (RTECS) (Non-Mandatory)

The final regulation, 29 CFR 1910.20, applies to all employee exposure and medical records, and analyses thereof, of employees exposed to toxic substances or harmful physical agents (paragraph (b)(2)). The term *toxic substance or harmful physical agent* is defined by paragraph (c)(13) to encompass chemical substances, biological agents, and physical stresses for which there is evidence of harmful health effects. The regulation uses the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS) as one of the chief sources of information as to whether evidence of harmful health effects exists. If a substance is listed in the latest printed RTECS, the regulation applies to exposure and medical records (and analyses of these records) relevant to employees exposed to the substance.

It is appropriate to note that the final regulation does not require that employers purchase a copy of RTECS, and many employers need not consult RTECS to ascertain whether their employee exposure or medical records are subject to the rule. Employers who do not currently have the latest printed edition of the NIOSH RTECS, however, may desire to obtain a copy. The RTECS is issued in an annual printed edition as mandated by section 20(a)(6) of the Occupational Safety and Health Act (29 U.S.C. 669(a)(6)).

The Introduction to the 1980 printed edition describes the RTECS as follows:

> "The 1980 edition of the Registry of Toxic Effects of Chemical Substances, formerly known as the Toxic Substances list, is the ninth revision prepared in compliance with the requirements of Section 20(a)(6) of the Occupational Safety and Health Act of 1970 (Public Law 91–596). The original list was completed on June 28, 1971, and has been updated annually in book format. Beginning in October 1977, quarterly revisions have been provided in microfiche. This edition of the Registry contains 168,096 listings of chemical substances: 45,156 are names of different chemicals with their associated toxicity data and 122,940 are synonyms. This edition includes approximately 5,900 new chemical compounds that did not appear in the 1979 Registry. (p. xi)
>
> "The Registry's purposes are many, and it serves a variety of users. It is a single source document for basic toxicity information and for other data, such as chemical identifiers ad information necessary for the preparation of safety directives and hazard evaluations for chemical substances. The various types of toxic effects linked to literature citations provide researchers and occupational health scientists with an introduction to the toxicological literature, making their own review of the toxic hazards of a given substance easier. By presenting data on the lowest reported doses that produce effects by several routes of entry in various species, the Registry furnishes valuable information to those responsible for preparing safety data sheets for chemical substances in the workplace. Chemical and production engineers can use the Registry to identify the hazards which may be associated with chemical intermediates in the development of final products, and thus can more readily select substitutes or alternative processes which may be less hazardous. Some organizations, including health agencies and chemical companies, have included the NIOSH Registry accession numbers with the listing of chemicals in their files to reference toxicity information associated with those chemicals. By including foreign language chemical names, a start has been made toward providing rapid identification of substances produced in other countries. (p. xi)
>
> "In this edition of the Registry, the editors intend to identify 'all known toxic substances' which may exist in the environment and to provide pertinent data on the toxic effects from known doses entering an organism by any route described. (p xi)
>
> "It must be reemphasized that the entry of a substance in the Registry does not automatically mean that it must be avoided. A listing does mean, however, that the substance has the documented potential of being harmful if misused, and care must be exercised to prevent tragic consequences. Thus, the Registry lists many substances that are common in everyday life and are in nearly every household in the United States. One can name a variety of such dangerous substances: prescription and non-prescription drugs; food additives; pesticide concentrates, sprays, and dusts; fungicides; herbicides; paints; glazes, dyes; bleaches and other household cleaning agents; alkalies; and various solvents and diluents. The list is extensive because chemicals have become an integral part of our existence."

The RTECS printed edition may be purchased from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, D.C. 20402 (202–783–3238).

Some employers may desire to subscribe to the quarterly update to the RTECS which is published in a microfiche edition. An annual subscription to the quarterly microfiche may be purchased from the GPO (Order the "Microfiche Edition, Registry of Toxic Effects of Chemical Substances"). Both the printed edition and the microfiche edition of RTECS are available for review at many university and public libraries throughout the country. The latest RTECS editions may also be examined at the OSHA Technical Data Center, Room N2439—Rear, United States Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (202–523–9700), or at any OSHA Regional or Area Office (See, major city telephone directories under United States Government—Labor Department).

[53 FR 38163, Sept. 29, 1988; 53 FR 49981, Dec. 13, 1988, as amended at 54 FR 24333, June 7, 1989; 55 FR 26431, June 28, 1990; 61 FR 9235, Mar. 7, 1996. Redesignated at 61 FR 31430, June 20, 1996, as amended at 71 FR 16673, Apr. 3, 2006; 76 FR 33608, June 8, 2011]

[Accessed September 8, 2016]

[ATTACHMENT 17]

[*https://www.epa.gov/sap/meeting-materials-december-4-6-2013-scientific-advisory-panel*]

Meeting Materials for the December 4–6, 2013 Scientific Advisory Panel

Topic: Scientific Uncertainties Associated with Corn Rootworm Resistance Monitoring for Bt Corn Plant Incorporated Protectants (PIPs)

Available meeting materials are listed below. *Visit docket EPA–HQ–OPP–2013–0490 for additional background materials* (*http://www.regulations.gov/#%21docketDetail;D=EPA-HQ-OPP-2013-0490*).

You will need Adobe Reader to view some of the files on this page. See *EPA's About PDF page* (*https://www.epa.gov/home/pdf-files*) to learn more.

- *Agenda (December 4–6, 2013) (PDF)* (*https://www.epa.gov/sites/production/files/2015-06/documents/120413agenda.pdf*) (6 pp, 41 K)
- *Panel Members (December 4–6, 2013) (PDF)* (*https://www.epa.gov/sites/production/files/2015-06/documents/120413panel.pdf*) (2 pp, 32 K)
- *Meeting Minutes (December 4–6, 2013) (PDF)* (*https://www.epa.gov/sites/production/files/2015-06/documents/120413minutes.pdf*) (72 pp, 488 K)

Contact Us (*https://www.epa.gov/sap/forms/contact-us-about-fifra-scientific-advisory-panel*) to ask a question, provide feedback, or report a problem.

[Accessed September 8, 2016]

[ATTACHMENT 18]

Records Management Policy

EPA Classification No.: CIO 2155.3	CIO Approval Date: 02/10/2015
CIO Transmittal No.: 15–005	Review Date: 02/10/2018

Issued by the EPA Chief Information Officer, Pursuant to Delegation 1–19, dated 07/07/2005

1. Purpose

- To advance a focus on overall records management responsibilities under the Federal Records Act (FRA), as amended, and other applicable authorities.
- To confirm and align principles, responsibilities and requirements for managing the Environmental Protection Agency's (EPA's) records to ensure that the Agency is in compliance with Federal laws and regulations; EPA policies; and best practices for managing records.
- To provide the framework for specific guidance and detailed operating procedures governing records management.

2. Scope and Applicability

This policy addresses all records made or received by EPA employees under Federal law or in connection with the transaction of public business, and preserved or appropriate for preservation as evidence of EPA functions, organization and activi-

ties or because of the value of the information they contain. This policy applies to all EPA headquarters, regional, laboratory and other organizations.

3. Audience

The audience for this policy includes all EPA organizations, officials, and employees; those who oversee contractors and grantees; and non-EPA employees who manage Agency records, as appropriate.

4. Background

The FRA, as amended, requires all Federal agencies to make and preserve records containing adequate and proper documentation of their organization, function, policies, decisions, procedures and essential transactions. These records are public property and must be managed according to applicable laws and regulations.

The FRA also requires agencies to establish a records management program, defined as a planned, coordinated set of policies, procedures, and activities needed to manage their recorded information. Major elements include periodically issuing up-to-date records management directives, properly training those responsible for implementation and carefully evaluating the results to ensure adequacy, effectiveness and efficiency.

Records serve a number of purposes including: planning for administrative and program needs, providing evidence of EPA activities, protecting legal and financial rights, enabling oversight by Congress and other authorized agencies, documenting the Agency's history, and continuing key functions and activities in the event of an emergency or disaster. Records capture the Agency's institutional memory and preserve the historical record; they are of critical importance in ensuring that the organization continues to function effectively and efficiently. In conformance with the Presidential Memorandum, *Managing Government Records,* November 28, 2011, the Agency must "meet the executive branch-wide effort to reform records management policies and practices. [The results will improve] performance and promote openness and accountability by better documenting agency actions and decisions."

5. Authority

a. 44 U.S.C. Chapter 31—Records Management by Federal Agencies (Federal Records Act) [*http://www.archives.gov/about/laws/fed-agencies.html*]

b. 44 U.S.C. Chapter 33—Disposal of Records [*http://www.archives.gov/about/laws/disposal-of-records.html*]

c. 44 U.S.C. Chapter 35—Coordination of Federal Information Policy (Paperwork Reduction Act of 1980, as amended, Paperwork Reduction Reauthorization Act of 1995, and Government Paperwork Elimination Act) [*http://www.archives.gov/about/laws/fed-information-policy.html*]

d. 36 CFR Chapter XII, Subchapter B—Records Management [*http://www.archives.gov/about/regulations/regulations.html*]

e. OMB Circular A–123—Management's Responsibility for Internal Control [*http://www.whitehouse.gov/omb/circulars/a123/a123_rev.html*]

f. OMB Circular A–130—Management of Federal Information Resources [*http://www.whitehouse.gov/omb/circulars/a130/a130trans4.html*]

g. U.S. EPA, National Security Emergency Preparedness Policy (Order 2040.1A1) [*http://intranet.epa.gov/ohr/rmpolicy/ads/orders/2040-1a1.pdf*]

h. U.S. EPA, Uniform Continuity of Operations (COOP) Plan Policy (Order 2030.1a) [*http://intranet.epa.gov/ohr/rmpolicy/ads/orders/2030-1a.pdf*]

i. Federal Emergency Management Agency (FEMA) Federal Preparedness Circular 65—Federal Executive Branch Continuity of Operations (COOP) [*http://www.fema.gov/pdf/library/fpc65_0604.pdf*]

j. Presidential Memorandum, Managing Government Records, November 28, 2011 [*http://www.whitehouse.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records*]

k. U.S. Environmental Protection Agency, Report on Managing Government Records, March 27, 2012. [*http://intranet.epa.gov/records*—click on "EPA's Response to Presidential Memo" under "Features"]

l. Memorandum for the Heads of Executive Departments and Agencies and Independent Agencies, from The Office of Management and Budget and the National Archives and Records Administration, Managing Government Records Directive, August 24, 2012 [*http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-18.pdf*]

m. The Presidential and Federal Records Act Amendments H.R. 1233, signed by President Obama, November 26, 2014.

6. Policy

a. EPA's Responsibility and Commitment

As a regulatory agency charged with protecting human health and the environment, the EPA is committed to managing the Agency's records properly to comply with legal requirements and to support the Agency's mission. Records identification, management and access are essential in allowing the Agency to meet its mission. The accuracy and consistency of how records are identified, captured, stored and retrieved provide the cornerstone to the effective functioning and transparent operation of the Agency. EPA is required to preserve Agency records in accordance with applicable statutory and regulatory requirements and to facilitate access to information by EPA staff, partners, stakeholders and the public, as appropriate.

The Records Management Policy establishes specific requirements to effectively and efficiently identify, manage, search, retrieve and provide access to records throughout their lifecycle.

b. Creating and Receiving Records

According to the FRA, every Federal agency is required to "make and preserve records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency and designed to furnish the information necessary to protect the legal and financial rights of the Government and of persons directly affected by the agency's activities." Records contain the information that documents how EPA carries out its mission. The Agency's past and current work generates records. Records typically include information which is:

- Created in the course of doing Agency business;
- Received for action;
- Needed to document EPA activities and decisions;
- Required to support EPA's financial and other obligations and legal claims; or
- Communicated to assert EPA requirements or guidance.

All EPA staff generate and receive records and are legally required to maintain them.

Records document the Agency's business and can be found in all media such as paper, e-mail, instant messaging (IM), text messages, telephone messages, voice mail messages, presentations, websites, social media (*e.g.,* Facebook, Twitter, *etc.*), word processing documents, spreadsheets, and information systems. If electronic records are created using any of these media, they need to be transferred to an electronic records management system.

Not all information created or received constitutes a record. Non-records include reference material, supplementary or convenience copies, a draft document or working paper with no substantive comments, and personal information which is unrelated to EPA business.

Some records are transitory in nature, which means they are of short-term (180 days or less) interest, including in electronic form, and have minimal or no documentary or evidential value.

Official Agency business should first and foremost be done on official EPA information systems. The FRA now prohibits the creation or sending of a Federal record using a non-EPA electronic messaging account unless the individual creating or sending the record either: (1) copies their EPA e-mail account at the time of initial creation or transmission of the record, or (2) forwards a complete copy of the record to their EPA e-mail account within 20 days of the original creation or transmission of the record. These FRA requirements are designed to ensure that any use of a non-EPA information system does not affect the preservation of Federal records for FRA purposes, or the ability to identify and process those records if requested under the Freedom of Information Act (FOIA), Privacy Act or for other official business (e.g., litigation, congressional oversight requests, *etc.*). EPA strongly discourages the use of personal e-mail or other personal electronic messaging systems, including text messaging on a personal mobile device, for sending or receiving Agency records, but to the extent such use occurs, the individual creating or sending the record from a non-EPA electronic messaging system must copy their EPA e-mail account at the time of transmission or forward that record to their EPA e-mail account within 20 days of creation or sending.

Additionally, EPA discourages the use of text messaging on a mobile device for sending or receiving substantive (or non-transitory) Agency records. However, EPA recognizes that some Agency staff perform time-sensitive work that may, at times, require the creation of substantive (or non-transitory) records in the form of text

messages for emergency or environmental notification purposes. In those limited instances, staff must continue to save and manage any text message records related to their work, as discussed below.

c. Managing Records

Records are managed for the benefit of EPA and its staff, partners, stakeholders and the public. EPA is committed to maintaining and converting its records to electronic formats, where practical, to facilitate moving away from paper toward more effective and efficient electronic solutions. Non-transitory records should be stored in approved records management systems with records management capabilities or registered information management systems associated with an approved records schedule.

It is important not to use non-EPA systems to conduct Agency business, since such use could potentially lead to the mismanagement of Agency records and/or the unauthorized disclosure of Agency information. In the rare situation when a non-EPA messaging system must be used and a Federal record is created or received on a non-EPA messaging system (such as a personal e-mail account or personal mobile device), pursuant to the FRA, staff must either: (1) copy their EPA e-mail account at the time of initial creation or transmission of the record, or (2) forward a complete copy of the record to their EPA e-mail account within 20 days of the original creation or transmission of the record. Once the message is sent or forwarded to the EPA messaging system, you must save the record in an approved EPA electronic records management system. Once the electronic files have been captured in an approved EPA records management system, they should be removed from non-EPA messaging systems, unless there is a specific obligation (such as a litigation hold) to maintain the files on all systems on which they appear.

Additionally, e-mails forwarding a news article or Web links from a personal e-mail account to EPA's system and e-mails from EPA forwarding a document to a personal e-mail account both create a copy of the e-mail in EPA's e-mail system. Users can then properly preserve the copy of the e-mail record in a record-keeping system to meet their preservation requirements, if needed.

Similarly, users of text messaging, instant messaging or other transient messaging technologies on EPA information systems are responsible for ensuring that messages that result in the creation of a substantive (or non-transitory) Federal records are saved for FRA purposes and placed in a record-keeping system. For example, if a text message on an EPA mobile device is received or sent that qualifies as a substantive (or non-transitory) Federal record, it must be saved into an approved record-keeping system. In order to comply with this requirement, you can forward the text message into the EPA system, so that you may then save it in an approved record-keeping system such as EZ Email Records. When forwarding the text message from the mobile device to the EPA e-mail system, be sure to include the time, date, subject, and sender/recipient of the message whenever possible. Guidance on how to e-mail a text message from a mobile device to yourself is available at *http://intranet.epa.gov/mobiledevices/pdf/Instructions-Saving-Text-Messages.pdf*.

Instant messages (such as Lync chats) that constitute substantive (or non-transitory) records should also be saved into an approved Agency record-keeping system. Guidance on how to save instant messages (Lync chats) is available at *http://intranet.epa.gov/ecms/guides/im.htm*.

d. Access

EPA records must be maintained in an appropriate manner, captured and organized to ensure timely search and retrieval for internal Agency use as well as for responses to outside inquiries. Sensitive records (*e.g.,* sensitive personally identifiable information (SPII), and other Controlled Unclassified Information (CUI)) must be maintained with restricted access in accordance with statutory and regulatory requirements.

e. Implementation

Each office within EPA must establish and maintain a records management program with the following minimum requirements.

1. Create, receive and maintain records providing adequate and proper documentation and evidence of EPA's activities.
2. Manage records in any format (*e.g.,* paper, e-mails, IMs, text messages, electronic documents, spreadsheets, presentations, images, maps, videos, blogs and other social media tools that generate communications) in accordance with applicable statutes, regulations, and EPA policy and guidance, including records schedules.

3. Maintain electronic records (*e.g.,* e-mails, IMs, text messages, electronic documents, spreadsheets, presentations, images, maps, videos, blogs and other social media tools that generate communications) electronically in an approved electronic records system. Non-e-mail electronic records, including electronic records that cannot be forwarded to and managed as an e-mail record, should be saved in their native format in an organized way on an EPA network drive until an approved electronic records management system is available for desktop records.
4. Transfer or migrate records in paper and legacy electronic systems to approved or registered information management systems which are associated with a records schedule for manual management of disposition where practicable and when available. The Registry of Environmental Applications and Databases (READ) often captures information on systems which have a records schedule and require manual disposition.
5. Ensure that non-electronic records are managed appropriately in paper-based official record-keeping systems which facilitate their preservation, retrieval, use and disposition, if they are not appropriate for scanning (or digitization).
6. Maintain records so they can be accessed by staff with a need to know the information for appropriate business reasons and maintained for the required retention period.
7. Secure records to protect the legal and financial rights of the government and persons affected by government activities.
8. Implement a plan to protect essential (vital) records and assess damage to and recover any records affected by an emergency or disaster (*e.g.,* financial, legal and emergency operating records).
9. Ensure that instructions for the management and disposition of records as specified in the approved records schedules are followed.

7. Related Documents

a. *EPA Records Management Manual* [*http://www.epa.gov/records/policy/manual/index.htm*]

b. Additional documents, including forms, guidance and other relevant information are maintained on EPA's records management website. [*http://www.epa.gov/records/*]

c. International Standard ISO 15489–1:2001—*Information and documentation—Records management*—Part 1: General. [*http://www.iso.org/iso/catalogue—detail?csnumber=31908*]

d. International Standard ISO/TR 15489–2:2001—Information and documentation—Records management—Part 2: Guidelines. [*http://www.iso.org/iso/catalogue_detail.htm?csnumber=35845*]

e. NARA Bulletin 2013–03: *Guidance for agency employees on the management of Federal records, including e-mail accounts, and the protection of Federal records from unauthorized removal.* [*http://www.archives.gov/records-mgmt/bulletins/2013/2013-03.html*]

f. NARA Bulletin 2013–02: *Guidance on a new approach to managing e-mail records.* [*http://www.archives.gov/records-mgmt/bulletins/2013/2013-02.html*]

g. NARA Bulletin 2012–02: *Guidance on managing content on shared drives,* December 6, 2011. [*http://www.archives.gov/records-mgmt/bulletins/2012/2012-02.html*]

h. *EPA Privacy Policy,* CIO 2151.0 [*http://www.epa.gov/privacy1/policy/2151/index.htm*]

i. EPA Guidance, *Frequent Questions about E-Mail and Records* [*http://www.epa.gov/records/faqs/email.htm*]

j. EPA Guidance, *Managing Social Media Records*—DRAFT—12/05/12

8. Roles and Responsibilities

a. The EPA's Administrator is responsible for creating and preserving records that adequately and properly document the organization, functions, policies, decisions, procedures and essential transactions of EPA. This responsibility is delegated to the Assistant Administrator (AA) for the Office of Environmental Information (OEI) and Chief Information Officer (CIO). As mandated by the Presidential Memorandum of November 28, 2011, the Administrator is also responsible for designating a Senior Agency Official (SAO) at the Assistant Secretary level or its equivalent who has direct responsibility for ensuring that the Agency efficiently and appropriately complies with all applicable records management statutes, regulations, and NARA policy, and requirements of the OMB/NARA Directive of August 24, 2012—*Managing*

Government Records. The Administrator has designated the OEI AA/CIO as this SAO for records management.

b. OEI is responsible for leadership, planning, overall policy, guidance and general oversight of records management in the Agency, and its incorporation into the broader information resources management framework. OEI is responsible for the following:

1. Incorporating records management requirements and policies into the Agency's overall information resources management (IRM) policy and planning.
2. Designating an Agency Records Officer responsible for:
   - Leading and managing the Agency-wide national records management program.
   - Ensuring Agency senior officials are aware of their programmatic and individual records management responsibilities and requirements.
   - Advising EPA on records management issues and developing Agency-wide records management policies, procedures, guidance, and training materials.
   - Coordinating the approval of the Agency's records schedules and the transfer of records to NARA.
   - Coordinating records management issues with other Federal agencies, including Federal oversight agencies such as the Office of Management and Budget (OMB), NARA, and the General Services Administration (GSA).
   - Providing technical advice and training to all Agency organizations on establishing and maintaining effective records management programs.
   - Evaluating record-keeping practices to determine the effectiveness of the program.
   - Obtaining NARA's Certificate in Federal Records Management.
3. Promulgating and communicating Agency-wide policies and guidance that reflect records management missions and goals and incorporate Federal requirements.
4. Designating other records management staff as required by regulations or as deemed necessary.
5. Assigning overall responsibility for the records management aspects of centrally provided information technology infrastructure, including local area network applications.
6. Ensuring senior Agency officials are aware of their records management responsibilities.
7. Conducting periodic evaluations of records management programs within the Agency as part of the Agency's IRM review and oversight program.

c. Assistant Administrators, Chief Financial Officer, General Counsel and Regional Counsel, Inspector General, Regional Administrators and Laboratory/Center/Office Directors are responsible for the following:

1. Being an advocate for records management in their organization.
2. Personally demonstrating the importance of records management and ensuring their organization is aware of the importance of and processes for managing records.
3. Demonstrating their commitment to the proper management of records in their organization through appropriate means (*e.g.,* sending out messages, being present during days devoted to records management, encouraging managers and staff to take records training).
4. Designating a Records Liaison Officer (RLO) accountable to the Information Management Official (IMO) or other official designated to oversee the program. The IMO or other official designated to oversee the program reports to the Assistant Administrators, Chief Financial Officer, General Counsel, Inspector General, Regional Administrators and Laboratory/Center/Office Directors on a quarterly basis.
5. Ensuring the RLO has adequate skills, resources, time and appropriate authority to perform the job.
6. Overseeing the implementation of a records management program within their area of responsibility to accomplish the objectives identified in Federal regulations and EPA policies and procedures. Minimum program components include responsibilities for:

- Identifying record-keeping requirements for major programmatic and administrative records.
- Ensuring that records are identified, proper records schedules are assigned, and the records are properly stored.
- Developing file plans and indexing approaches where appropriate to simplify the use of, access to, and integration of information within the organization.
- Drafting and updating records schedules for records created and maintained by the organization.
- Implementing approved records schedules to ensure records are not destroyed without proper authorization.
- Reviewing file plans and procedures at least every three years to ensure they are current and updating them as necessary.
- Assisting in planning and implementing information management technology and reviewing the purchase of records management equipment and services to ensure they conform to Federal statutory and regulatory requirements.
- Implementing an essential (vital) records plan to ensure the continuation of key functions and activities in the event of an emergency or disaster.
- Providing records management briefings for all managers and training to staff within their organizations, as needed.
- Actively supporting managers, RLOs, staff and others in carrying out their records management responsibilities.

7. Developing records management oversight roles and communication networks with all program units including field offices and other facilities, as appropriate, to ensure that the records management program is implemented at all sites under their jurisdiction.
8. Developing and disseminating directives and operating procedures, as needed, to supplement Agency-wide policy to meet the unique records management needs of their organizations and to support a records management program within the organization.
9. Ensuring records and other types of required documentary materials are not unlawfully removed from EPA by current or departing officials, employees, or agents.

d. The General Counsel and Regional Counsel provide legal advice and counseling on records management issues as well as assist in determining the retention of Agency records that may be needed for legal purposes.

e. The Inspector General assists in determining the retention of Agency records that may be needed for internal investigation and audit purposes.

f. Managers and supervisors (Office Directors, Division Directors, Branch Chiefs, *etc.*) are responsible for:

1. Ensuring that a records management program is implemented within their organization.
2. Understanding and emphasizing the importance of records management to staff.
3. Designating selected staff as records contacts in order to meet record-keeping requirements and responsibilities as described in this document.
4. Providing support, time, and resources for records contacts to successfully carry out their record-keeping responsibilities.
5. Ensuring that the organization's file plans are current.
6. Obtaining training so that they and their staff can carry out their record-keeping responsibilities.
7. Implementing an essential (vital) records program within the organization.
8. Participating in records program reviews and assessments and developing and implementing corrective action plans to address gaps.
9. Supporting initiatives to move from paper to electronic record-keeping.
10. Ensuring that all records of separating employees have been identified, that temporary records that have met their retention are properly disposed of according to applicable records schedules, and that records that must be preserved have been assigned to other employees.

g. Headquarters, Regional, Laboratory/Center/Office RLOs are responsible for:

1. Creating and updating procedures for their offices in accordance with established EPA and program policies.
2. Performing evaluations of their records management and essential records program.
3. Developing file plans and procedures so records are organized and can be found when needed.
4. Assisting with disposition activities, including retirement of inactive records, transfer of permanent records to NARA, and destruction in accordance with approved records schedules.
5. Reviewing office-specific records schedules annually to ensure they are current, and initiating changes if not.
6. Ensuring sensitive records are protected in accordance with Federal and EPA requirements, and making sure designated individuals maintain access lists to ensure such information is released only to authorized individuals.
7. Coordinating the identification and maintenance of essential (vital) records and submitting an annual inventory and certification of essential (vital) records through senior management to the Agency Records Officer.
8. Reviewing and verifying their organizations' section of the Federal Records Centers invoices on a monthly basis verifying the status of their off-site records and costs.
9. Conducting briefings and training sessions on the records management program.
10. Reviewing and recommending requests for records management equipment, services and supplies.
11. Obtaining NARA's Certificate in Federal Records Management.
12. Completing Records Management Training for RLOs and Records Contacts [*http://intranet.epa.gov/records/training/rlo/index.html*].
13. Organizing, maintaining and training a network of records contacts within the organization.

h. Records contacts are responsible for:

1. Working within their organization as a liaison between the RLO and staff to provide records management training, guidance and support.
2. Being qualified and active in records management issues and participating in records management training when resources are available.
3. Creating file plans specific to their organization.

i. Completing Records Management Training for RLOs and Records Contacts [*http://intranet.epa.gov/records/training/rlo/index.html*]. Information resources and system managers are responsible for:

1. Working with the local RLO, the Agency Records Officer and NARA to establish and update records schedules for electronic systems.
2. Implementing proper record-keeping procedures for existing information systems and ensuring record-keeping requirements are included in proposed systems.
3. Ensuring that information systems intended to carry out electronic records management comply with NARA's and EPA's requirements for electronic record-keeping systems (these requirements available on the NRMP Intranet site [*http://intranet.epa.gov/records/*]
4. Maintaining electronic information systems in accordance with approved records schedules and NARA requirements.
5. Working with their RLO to transfer permanent systems to the National Archives in accordance with approved records schedules and NARA requirements.
6. Ensuring that EPA Internet and Intranet postings containing records are maintained in accordance with Agency record-keeping requirements.
7. Ensuring that prior approval is obtained before the removal of SPII from the Agency network or facility.
8. Coordinating the handling of electronic records and information with the local RLO/records management program and legal office when appropriate.

j. Project Officers (PO)/Contracting Officer Representatives (CORs) and Senior Employee Employment (SEE) program coordinators/monitors are responsible for:

1. Creating and maintaining appropriate records of the management and oversight of their related projects, contracts, staff and SEE employees.

k. Continuity of Operations Program (COOP) planners are responsible for:

1. Working with records management staff to implement the essential (vital) records plan to ensure the continuation of designated COOP essential functions.
2. Ensuring that essential (vital) records are accessible from designated COOP locations.

l. All EPA employees are responsible for:

1. Creating and managing the records necessary to document the Agency's official activities and actions, including those records generated by EPA contractors and grantees, in accordance with EPA record-keeping requirements.
2. Destroying records only in accordance with approved records schedules and never removing records from EPA without authorization.
3. Filing records for safe storage and efficient retrieval and maintaining and disposing of personal papers and non-record materials separately from records.
4. Ensuring that when secondary e-mail accounts for individuals, groups or systems are created for business reasons, the records thus created are appropriately managed.
5. Identifying all records, in any format, in the employee's possession, and transferring them to another EPA custodian before separating or transferring to another organization. Note: Non-records and records which have met their disposition per appropriate records schedule should be destroyed unless subject to FOIA, litigation or audit. Records containing SPII must be shredded.
6. Taking annual records management training and any other related training and participating in records management activities such as records management days, records clean-up days, *etc.*
7. Contractors, grantees and others doing work on behalf of EPA are required to take annual records management training, as appropriate.

9. Definitions

Definitions can also be found on EPA's National Records Management Program Website at *http://intranet.epa.gov/records/*.

Approved Records Management System: (*http://intranet.epa.gov/records/.Approved*) An agency records management application approved for storing electronic Federal records, including applications certified as compliant with the DOD 5015.2–STD standard or meeting the NARA standards for a records management application. Examples include EPA's Correspondence Management System and People Plus. [Need better example].

Authorized Federal Information Management System: A major information system managed by a Federal agency which is used by other Federal agencies. Records in these systems are managed by the agency owning the system. Examples include Concur, Employee Express and eOPF.

Destruction: In records management, the major type of disposal action. Non-records and records which have reached the end of their retention period per the appropriate record schedule can be legally destroyed. Records containing SPII must be shredded, pulped or burned, and never simply placed in the trash.

Disposition: The actions taken regarding records no longer needed for current government business. These actions include transfer to agency storage facilities or Federal records centers, transfer from one Federal agency to another, transfer of permanent records to the National Archives, and disposal of temporary records. Disposition is the third stage of the records lifecycle, and the actions taken regarding non-record materials when no longer needed, including screening and destruction.

Electronic messaging account: The term "electronic messaging account" means any account that sends electronic messages for purposes of communicating between individuals.

Official EPA Information System: Any information system that EPA employees are permitted to access, create, share, store or transmit information on for official government business.

Official record-keeping System: An "information management system which captures, manages and provides access to records through time" and can be electronic or paper-based, until an appropriate electronic record-keeping system becomes available.

Records Schedule: Also called records disposition schedule, records control schedule, records retention schedule, records retention and disposition schedule, or schedule. A document that describes agency records, establishes a period for their retention by the agency, and provides mandatory instructions for what to do with them when they are no longer needed for current government business. The term refers to: (1) an SF 115, Request for Records Disposition Authority, that has been approved by NARA to authorize the disposition of Federal records; (2) a General Records Schedule (GRS) issued by NARA; and (3) a printed agency manual or directive containing the records descriptions and disposition instructions approved by NARA on one or more SF 115s or issued by NARA in the GRS. (Source: 36 CFR 1220.14)

Registered Information Management System: An Agency electronic information system which has an associated records schedule or an information management system which holds records and is manually managed. Such EPA systems should be registered in the Agency's Registry of EPA Applications and Databases (READ) so they can be identified for scheduling, and the retention periods tracked. Examples include the Toxics Release Inventory Processing System (TRIPS), Safe Drinking Water Information System (SDWIS), and the Air Quality System (AQS).

Transitory Record: Records of short-term (180 days or less) interest, including in electronic form (*e.g.,* e-mail messages), which have minimal or no documentary or evidential value. An example of a transitory record is a record documenting routine activities containing no substantive information, such as routine notifications of meetings, scheduling of work-related trips and visits, and other scheduling related activities. See NARA GRS 23/ EPA 167.

10. Waivers

a. **Waiver Process.** The Agency Records Officer may grant waivers to any provisions of this Policy for sufficient cause.

b. **Applications.** Applications for waivers to specific provisions should contain: (1) identification of the Policy provision; (2) a listing of reasons why the Policy cannot be applied or maintained; (3) an assessment of impacts resulting from non-compliance; and (4) the signature of the AA, RA or Laboratory/Center/Office Director, the Chief Financial Officer, the General Counsel, or the Inspector General responsible for the records management program in question.

c. **Notification.** The Agency Records Officer will notify the requesting office in writing of the decision on the waiver request within two weeks of receipt of the request. Circumstances will dictate whether the waiver may be renewed.

11. Related Procedures, Standards and Guidance

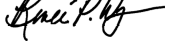
Required procedures and implementation guidelines for this Policy are found on the records management website [*http://www.epa.gov/records/*]. Supporting procedures to implement this Policy at the Program Office or other Administrative level must be approved by the Agency Records Officer in OEI.

12. Material Superseded

CIO 2155.2: Interim Records Management Policy, Dated 06/28/13.
EPA *IRM Policy Manual,* Chapter 10, 1996.
Vital Records Order (Order 2160.1).

13. Additional Information

For further information about this Policy, please contact the EPA Office of Environmental Information, Office of Information Collection.



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