ADRIFT IN NEW REGULATORY BURDENS AND UNCERTAINTY: A REVIEW OF PROPOSED AND POTENTIAL REGULATIONS ON FAMILY FARMERS

HEARING

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AGRICULTURE, ENERGY AND TRADE

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ADRIFT IN NEW REGULATORY BURDENS AND UNCERTAINTY: A REVIEW OF PROPOSED AND POTENTIAL REGULATIONS ON FAMILY FARMERS

THURSDAY, NOVEMBER 17, 2011

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS, SUBCOMMITTEE ON
AGRICULTURE, ENERGY AND TRADE,
Washington, DC.

The Committee met, pursuant to call, at 10:00 a.m., in Room 2360, Rayburn House Office Building. Hon. Scott Tipton (chairman of the subcommittee) presiding.

Present: Representatives Tipton, Bartlett, Barletta, Schilling, and Critz.

Chairman TIPTON. Good morning, everyone. I would like thank you for joining us. The hearing will now come to order.

I would like to thank all of our witnesses for being here today and we certainly look forward to your testimony. And I would like to thank everyone for taking time out of their busy schedules to join us today. I would like to give a special welcome to Mr. Leonard Felix, a constituent of mine and aerial applicator out of Olathe, Colorado. So Mr. Felix, I certainly welcome you to the Committee and I appreciate you taking the time to be here.

Mr. FELIX. Thank you very much.

Chairman TIPTON. Farmers and ranchers and small business owners today face a sea of onerous new regulations from the federal government. Although our nation's agricultural community is expected to continue increasing food production to feed a growing world population, the current administration continues to contemplate and propose new regulations that would place increased burdens on American agriculture and make production more costly. With our economy struggling to rebound from the downturn, now is not the time to saddle farmers and ranchers with higher costs and more onerous regulations that are driving them out of business.

Today we will examine two EPA regulations threatening family farms and small businesses, a duplicative pesticide permit requirement and potentially tougher air quality standards on farm dust. Both of these issues are of serious concern to farmers across the nation, including my home state of Colorado where agriculture business generates $20 billion in economic activity each year and creates more than 100,000 jobs.

On October 31, 2011, a federal regulation took effect expanding permit requirements for pesticide applications. However, federal law already regulates the registration, labeling, and use of pesticides and provides environmental and public health protection. This expanded requirement is duplicative and another costly form of red tape that brings with it new added environmental protection. The EPA has estimated the expanded permit requirement will affect some 365,000 pesticide users at a total cost of $50 million per year, but the real cost to small business could be much greater.

A second regulatory concern we will examine today that threatens rural economies is the potential for more stringent EPA regulations on farm dust. The EPA is currently in the process of revising the National Ambient Air Quality standards for particulate matter, including dust. While I am pleased that the EPA administrator announced that she does not intend to make current standards for coarse particulate matter more stringent, the revised rule has not yet been finalized. Uncertainty lingers. And there is still no agricultural exemption for farm dust in the EPA's standards. In fact, producers in Arizona already fall within reach of current dust standards and have been forced to change their farming practices as a result. If the agency were to adopt more stringent standards, many more rural areas would be affected.

As some of the witnesses here today will testify, dust is an unavoidable result of agricultural production and a fact of life in rural communities. Planning and harvesting crops and driving down dirt roads naturally stirs up dust. The only way to prevent this dust is to halt or reduce agricultural production and other activities in rural areas. This could be devastating to local economies and potentially cause food prices to rise.

Unfortunately, the two federal regulatory concerns highlighted today are not the only ones that are creating uncertainty and worrying the agricultural community. They are part of a wave of onerous, overreaching proposed and potential regulations that the current administration is considering, leaving family farmers and ranchers adrift in new regulatory burdens. With nearly 1 in 10 Americans unemployed and our country still struggling to crawl out of this economic downturn, it is imperative that we stop the advancement of these and other new job-killing government regulations.

Two of my colleagues on the House Agricultural Committee have introduced legislation to bring regulatory relief and certainty back to the agricultural sector. Congressman Bob Gibbs of Ohio has introduced H.R. 872, the Reducing Regulatory Burdens Act, which would eliminate costly and duplicative permit requirements for pesticide applications near water. Congresswoman Kristy Noem of South Dakota has introduced H.R. 1633, the Farm Dust Regulation Prevention Act, which would give necessary certainty to small business owners in rural America that farm dust will not be included in EPA standards. Providing greater regulatory certainty and regulatory relief to our nation's farmers, ranchers, and rural communities is absolutely critical. Creating an environment conducive for economic growth will enable farmers to grow crops and assist with getting our nation back on the path to future economic prosperity.

Again, I would like to thank our witnesses for participating, and I look forward to their testimonies.

I now yield to my colleague, Ranking Member Critz, for his opening statement.

Mr. CRITZ. Thank you, Mr. Chairman. And thank you, gentlemen, for being here today.

In Western Pennsylvania where my district is located, we take great pride in the outdoors. From the scenic Mon River to the Appalachian Mountains to hunting ruffed grouse in Laurel Ridge State Park, fresh air and clean water are an important part of what makes Pennsylvania a great place to live. Ensuring that all these natural resources remain free of pollutants and contaminants is a top priority. As we pursue these aims we must be mindful that environmental regulation can impose significant costs as well. Too often, however, it has been small firms that have been impacted the most by EPA's rules. In fact, companies with less than 20 employees spend more than $4,000 annually, leaving many hard pressed to make investments in their own business. Balancing these costs with the benefits of such regulation is essential. The reality is that we need to protect the environment without undercutting our nation's main job creators, small businesses.

Today we will examine several regulations that have the potential to impose real costs on family farmers and smaller agricultural businesses. Perhaps most troubling for small businesses are new pesticide requirements under the Clean Water Act. Never before in the nearly 40 year history of this Act has the government required a permit for such use. Making this all the more problematic is that the Federal Insecticide, Fungicide, and Rodenticide Act already regulates pesticide. Such duplication will not safeguard the environment; it will, however, impose new recordkeeping and surveillance responsibilities on the more than 300,000 pesticide users.

We will also look at the potential regulation of farm and agricultural dust. Such dust is a regular byproduct of farming and has been around as long as farmers have been working the land. There are limited signs demonstrating that this dust has any effect on health in rural areas. Even though the EPA administrator has recently stated that it will not regulate farm dust, there is still concern that it may do so in the future. This is not an unfounded concern. The truth is that opinions can change quickly in Washington, D.C. Given that, I believe it is correct to be out front on this issue.

Finally, I am looking forward to examining an EPA issue that could seriously impact farmers in my home state of Pennsylvania. This matter, called the Chesapeake Bay Total Maximum Day Load or TMDL requirement is part of a strategy to protect this watershed. However, it has severe and far-reaching consequences for local farmers, including those in my home state. This so-called pollution diet will put farmers out of business plain and simple. It will effectively remove hundreds of thousands of acres of productive farmland. In fact, the EPA itself projects that roughly 20 percent of cropland in the watershed, or about 600,000 acres, will have to be removed from production. Requiring states to enforce this on behalf of the EPA takes this too far. We are all for protecting this great watershed but not at the cost of putting farms out of business. We have been down this path many times before this year,

whether it is greenhouse gases, coal combustion waste, or the issues before us today. The truth is that EPA is no stranger to overlooking the concerns of small businesses. Instead of neglecting them, the EPA should be conducting meaningful outreach to small firms, especially when their regulation affects family farms and agricultural businesses.

During today's hearing we will be able to listen to the agricultural community and learn about their views on EPA's regulations. Ensuring that the concerns of farmers and their rural businesses are heard is important. I hope that the EPA will take similar actions to increase its outreach in this area. Small farms which constitute more than 90 percent of all farms remain at the center of our country's rural economy. With direct to consumer sales increasing, small farms are poised to grow, providing not just high quality food but also jobs. Given such promise, it is important that the federal government does not extinguish this potential by imposing unnecessary cost and duplicative regulatory burdens on them.

I want to thank all of the witnesses in advance for traveling here today and I look forward to their testimony.

With that I yield back the balance of my time.

Chairman TIPTON. Thank you, ranking member.

If Committee members do have an opening statement prepared I would ask that they submit it for the record. And I would like to take a moment to be able to explain our timing lights for you. You will each have five minutes to deliver your testimony. The light will start out green. When you have one minute remaining it will turn yellow. Finally, it will turn red at the end of your five minutes. If you exceed that you will be ejected. I am kidding. If you would, try to keep it to that time limit and we will try to be lenient so that you can finish up. So.

STATEMENTS OF PHILIP NELSON, PRESIDENT, ILLINOIS FARM BUREAU; LEONARD FELIX, PRESIDENT, OLATHE SPRAY SERVICE, INC., TESTIFYING ON BEHALF OF THE NATIONAL AGRICULTURAL AVIATION ASSOCIATION; RAY VESTER, VESTER FARMS, TESTIFYING ON BEHALF OF THE USA RICE FEDERATION; CARL T. SHAFFER, PRESIDENT, PENNSYLVANIA FARM BUREAU

Chairman TIPTON. I would like to now yield to Congressman Schilling to introduce Mr. Nelson.

Mr. SCHILLING. Thank you, Chairman.

Members of the Committee, it is my pleasure to introduce Mr. Philip Nelson, who is here to testify on behalf of the Illinois Farm Bureau. Mr. Nelson has served as president of the Farm Bureau since December of 2003 and prior to that he served as a vice president from 1999 to 2003. More importantly, Mr. Nelson is a fourth generation grain and livestock farmer from Seneca, Illinois, who basically it is a family-run business which we like to hear in representing basically farmers from all over the United States. I appreciate you traveling all the way here during this very busy time in Illinois, especially with what is going on with harvest time and all that. So we look forward to hearing your testimony and welcome, sir.

STATEMENT OF PHILIP NELSON

Mr. NELSON. Well, Mr. Chairman, members of the Committee, I thank you for the opportunity to share our thoughts and concerns about the matters that have been outlined.

I am Philip Nelson. I am a fourth generation farmer from Seneca, a real community about 75 miles south and west of Chicago. I farm with my wife Carmen, son Kendall, daughter Rachel, and we raise corn, soybeans, alfalfa, cattle, and hogs. I have been asked to testify about the National Pollutant Discharge Elimination System Pesticide General Permit that went into effect the first of November and to say a few words about the potential of proposed dust regulations on ag. But before I do that I would like to point out that we should not even be here today testifying about the NPDES Pesticide General Permit because it should have never went into effect.

As you know, the House of Representatives passed H.R. 872 back in March. I appreciate that several of you voted for that bill. And it is regrettable that this bill needlessly spent this past spring, summer, and all of the fall languishing in the Senate, caught in a stranglehold by a couple of senators upset primarily over the Senate Committee jurisdiction, not over the substance of the bill. I understand that more than 60 senators would vote today in favor of H.R. 872 if only given a chance. They should be given that chance.

The Federal Insecticide, Fungicide, Rodenticide Act [FIFRA] has covered pesticide labeling and application very effectively since 1947. While the new permit process addresses pesticide applications in, over, and near waters of the United States, it duplicates FIFRA. EPA estimates that this new requirement, as was said before, would affect approximately 365,000 pesticide applicators nationwide that performed 5.6 million pesticide applications annually. It will cost $50 million and require over one million hours per year to implement this.

I do not have to tell you that states like Illinois have very limited resources just like the federal government. Spending precious resources for this purpose represents neither good public policy nor a wise use of taxpayer dollars. Furthermore, it does not make our food any safer, our water any cleaner, or provide one iota of environmental benefit above and beyond what we already achieve on our farms. Frustrated? Yes. But what really keeps me lying awake at night is the potential of this for more regulatory creep. It is as if we go to bed one night with one set of regulations and wake up the next morning facing a new set. Every moment that we spend fighting and then working to comply with needless, duplicative regulations takes away from what we do best, producing food.

In the case of the new NPDES Pesticide General Permit, we have good reason to believe that pesticide regulation could be expanded in the future and include other routine applications. If we look at history of similar rules that began innocuously and later expand exponentially, then past actions give us cause for concern about this new permit.

The last issue I raise is one that perhaps is the most troubling and that is that lawsuits that may occur because of the Pesticide General Permit. In Illinois, farmers are already being sued for discharges at livestock facilities that are still being constructed where

on livestock is present. It does not take much imagination to see how this new permit opens the door to new legal challenges that are financially and emotionally draining. This permit does not improve food safety, does not add any additional environmental protection or benefit for society, and does nothing to improve my bottom-line.

We feel the current regulation of pesticides by FIFRA has kept current and is effective to the point we do not need this entirely new permit program. H.R. 872 remains relevant and Congress needs to complete what 292 members of the House supported and likely a strong majority of the Senate would like to see approved.

I would like to further comment on the proposed farm dust regulations. As I cut soybeans this fall, I wondered like most farmers how in the world would EPA even begin to regulate the dust flying off of my combine. How would the agency prevent dust from flying when I dump a load of corn or soybeans at the local grain elevator? Fortunately, administrator Lisa Jackson acknowledged the impracticality of regulating dust and announced there will be no dust regulations on agriculture at this time. But it is truly amazing that a campaign had to be waged to get EPA to finally act. By President Obama's response on his bus tour last August to Illinois, and posed a question by a fellow Illinois farmer, the administrator's words still do not instill tremendous confidence in farmers' minds.

That is why we support H.R. 1633. I look forward to answering your questions. Thank you.

Chairman TIPTON. Thank you, Mr. Nelson.

Our next witness is Leonard Felix, constituent of mine from Olathe, Colorado. Mr. Felix grew up in Olathe on his family's fourth generation farm and currently owns and operates Olathe Spray Company, a small aerial applicator business in Olathe, Colorado. And I would probably be remiss if I did not mention that you help grow some—because of your efforts—some of the best corn in the United States out of the Olathe area.

Mr. Felix, it is great to have you here today and we look forward to your testimony. Please continue.

STATEMENT OF LEONARD FELIX

Mr. FELIX. Chairman Tipton and Committee members, I am president of Olathe Spray Service, Inc., Olathe, Colorado. For 43 seasons I have been providing pest control services to farmers, ranchers, state and federal governments. I am testifying today on the impacts the EPA's NPDES Pesticide General Permit on the early application of pesticides.

I have a firsthand understanding of the burdens this permit will impose on my business, my clients, and other operators. My business is like 1,600 other small businesses in 46 states that make up the aerial application industry of the United States. My business employs 9 full-time persons, including myself and two sons, and 6 to 10 seasonal workers. Like most aerial applicators, we represent a large and diverse group of clients.

Uncompahgre Valley Water Users Association has been serving more than 175,000 acres of Colorado farmland since its construction in 1906. Water collected near the Continental Divide delivered down the Gunnison River and then through a six-mile tunnel into

the South Canal to the Uncompahgre River to the canals and to the rich farmland below. The farmers raise vegetables, forage and grain crops, orchards, grapes, berries, and other specialty crops, all depending totally on this supply of water. The herbicides we apply to the many canals and ditches control reed canary grass, orchard grass, and noxious weeds that would otherwise choke them. We also spray about 60,000 acres of cropland each year. We help control mosquitoes for the Grand Valley pest control district, Orchard City, and Cedaredge townships, and Gunnison County. We also treat private forest for control of insects that are destroying the forests across our west.

We service about 500 customers yearly. Those clients call anytime asking for treatment as soon as possible. With the short season in Colorado we have to put in long days, and once harvest begins, night applications are often required to protect the harvest crews. This pace requires constant attention to the maintenance of our aircraft, frequent calibration of our equipment, and safety checks. We have become experts on pesticide label requirements and state laws. When done with a day's flying it all starts over again after we complete the required recordkeeping.

Now we have a new obligation, satisfying the NPDES permit requirements by the EPA and states. In 2009 when the Sixth Circuit Court of Appeals revoked the EPA's 2006 rule exempting pesticide applications to, over, and near waters of the U.S., it overturned the congressional intent and required EPA to develop NPDES permits requiring hundreds of thousands of pesticide users to be in compliance.

The EPA's general permit was implemented October 31st of this year in six states but it also required similar permits in Colorado and 43 other states. Colorado's Department of Public Health and Environment administers the Colorado permit on private property. However, EPA administers a pesticide general permit on federal and tribal lands. So we will require compliance of both since we do work on all of the above.

These permits will be a huge challenge. Soon there will be enforcement penalties for paperwork and performance violations and activists will be able to challenge operators under the Clean Water Act citizen suit provision. The cost of defending against citizen suit can put us out of business. It is all redundant and unnecessary because FIFRA requires the EPA to ensure pesticide safety before it is allowed to be registered for use.

When working as a for-hire contractor for public and private decision-making clients, EPA has spared applicators part of the planning and reporting burdens required of the government agencies and other large entities. However, EPA considers application participating in the planning of the pest control to be decision makers. These applicators will have additional responsibility of planning and reporting their extensive requirements for documenting maintenance, calibration equipment, assessing weather conditions, minimizing spray drift and offsite movement, and site monitoring.

Completing these activities are part and parcel to the safety and professionalism of our business. Failure to properly update these records could result in penalties up to $37,500 per incident per day and potential citizen suits. Such records do not add anything to en-

vironmental protections provided by the label of the registered products. They just add cost, time-consuming burdens, and open the door for those suits.

So while my sons and I are operating properly applying pesticides products for our clients, we must now also worry about taking notes for permanent records later that evening. Long days and risks are part of being the pilots, but the burdens risk of the NPDES are something we just do not need or want.

Do the general permits improve the environment? Not at all. Agriculture does not need the added burden. States do not need the added expense. And even EPA and the majority of Congress have voiced their opposition to the permits. There is a solution to this nonsense, enact House H.R. 872. I am informed there are 65 or more senators willing to support this legislation if it is brought before the Senate, and we can only hope there is one additional vote, that of the Senate majority leader.

I thank you, and I will entertain any questions you all have.

Chairman TIPTON. Thank you. Next on our panel we have Ray Vester, a third generation rice farmer from Stuttgart, Arkansas. Mr. Vester is testifying on behalf of the USA Rice Federation where he currently serves as chairman of their Environmental Regulatory Subcommittee. Thank you for being here today, Mr. Vester, and we look forward to your testimony.

STATEMENT OF RAY VESTER

Mr. VESTER. Thank you. Mr. Chairman, other members of the Subcommittee, I appreciate the opportunity to be here today to speak to regulatory issues facing the rice industry and other agricultural industry people.

The USA Rice Federation—I am Ray Vester from Stuttgart, Arkansas, the rice—president of the USA Rice Federation Environmental Regulatory Subcommittee. The USA Rice Federation is a national organization representing rice producers, millers, and merchants, and others involved in the rice industry. They are an advocate for the production on milling and sales of rice here in the United States and also the sale of rice around the world.

The rice industry is an industry which is unique to the United States. There are 10 states that produce rice. The six leading states are Arkansas, California, Louisiana, Texas, Mississippi, and Missouri. Four other states produce rice and that is Florida, Tennessee, Kentucky, and Illinois. There are about three million acres of rice raised each year in the United States and an average of about 9,000 farms that produce that rice. It is a $34 billion industry here in the United States, creating 128,000 jobs in that industry, many of which are rural jobs in small communities around the nation. There are 20 billion pounds of rice produced each year, half of which is exported, but the other half is consumed here in the United States. Pests that affect the rice crop are insects, disease, and of course, weeds and grasses, and rice is a crop that is grown in the water. It is an aquatic crop.

I am here today to speak on behalf of the rice industry concerning the NPDES permits which we are looking now at since November 1 has arrived. The first thing that is obvious when you read the permit is that there is education needed in the Office of

Water in the Department—in U.S. EPA. One of the first things you read is that the use of pesticides should be done at the lowest amount of pesticides possible delivered in a precise way to actively control the pest. That is what farmers do each and every day because that is the reason of economy savings. Then the next language that comes up states that the pesticides are only to be applied as a last resort measure when pest conditions can no longer be tolerated. If that approach is followed, then the first approach cannot be reached. If you wait until the last to control the weeds, then you use more pesticides. If you use the pesticides early you use smaller amounts. It would be like taking your child to the emergency room or to the doctor with a sore throat and the doctor tells you, well, he has strep throat and you say, well, you know, he is not sick enough to have antibiotics yet. I will take him home. And you come back at the end of the week and his throat is so sore he cannot speak. He is running a fever. You say, well, I still think he is strong enough to survive. And a week later you find him in the hospital with an IV with antibiotics hoping you save his life. That is the approach the NPDES permit takes when it comes to the application of pesticides on rice or any other crop.

Rice is grown in an aquatic situation. In fields with established borders, levy borders, to keep either water in or out. Water is kept in during the growing season, released during the harvest season, and dried. It is not waters of the U.S. There are waters pumped into the field there. The permits required for any time you apply a pesticide in the waters of the U.S. rice we feel is not planted or grown in waters of the U.S. It is planted and grown in a flooded situation.

The permits are supposedly to permit—to prevent pesticides being released into the waters of the U.S. when, in fact, a permit allows you to release pesticides into the waters of the U.S. We are already covered by FIFRA, which as the speakers have already said that covers all those situations. It is established. Farmers follow those rules and regulations. Aerial applicators follow those rules and regulations. And with the passage of NPDES permits we have double regulation. We are doing the same thing over and over again, costing family farms more and more money to accomplish what is needed. The rice industry is very much against the passage of this.

On the dust issue, it is hard to farm without dust. It is a natural reaction. If you do not have dust, the ground is too wet to work. If you have dust, the ground is ready to be prepared for planting. We are challenged and given the responsibility to raise crops to feed this nation. And with dust regulations that supposedly could be imposed we face a very difficult situation. We stand very much opposed to the dusty regulations that may affect rice farmers and farming in general in the United States.

I would be happy to answer any questions that you might have.

Chairman TIPTON. Thank you, Mr. Vester. Now I would like to yield to Mr. Critz to introduce the final witness.

Mr. CRITZ. Well, Carl, we are going to actually tag team on you today because I did not know until just recently that another member of the Committee, Mr. Barletta, you are actually his con-

stituent. So I am going to give you a very short introduction and then yield to Mr. Barletta to give more of a personal introduction.

But I would like to introduce Carl Shaffer. He is the president of the Pennsylvania Farm Bureau. The Pennsylvania Farm Bureau is the largest farm organization with a volunteer membership of more than 50,000 farm and rural families representing farms of every size and commodity across Pennsylvania. Mr. Shaffer was just recently re-elected to a third term on the American Farm Bureau Federal Board of Directors and appointed to a second term as a member of their executive committee. And something I just learned that I am going to say, Lou, I am not going to let you say it, is that among recognitions for leadership and achievements in agriculture, Mr. Shaffer was named as a master farmer in 1996, which is one of the highest honors awarded to farmers in the Commonwealth. Congratulations.

And I would like to yield to my colleague from Pennsylvania, Mr. Barletta.

Mr. BARLETTA. Thank you, Mr. Critz. And I would like to thank my constituent, Pennsylvania Farm Bureau president, Carl Shaffer, for traveling to Washington for this hearing today.

Mr. Shaffer owns a farm in Mifflinville, which is in Columbia County, a county that was badly flooded just very recently. Mr. Shaffer has worked hard representing all of the farm bureaus across the Commonwealth of Pennsylvania. I look forward to continuing to work with the Farm Bureau on important legislature in the future, and I appreciate Mr. Shaffer taking time out of his busy schedule to share his testimony with us here today.

And I yield back my time and thank you, Mr. Critz.

Chairman TIPTON. Mr. Shaffer, if you would like to continue, please.

STATEMENT OF CARL T. SHAFFER

Mr. SHAFFER. Thank you, Chairman Tipton, and Ranking Member Critz. Thank you very much.

I really appreciate the opportunity to be before you today. As was stated, my name is Carl Shaffer. I am pleased to offer this testimony on behalf of the Pennsylvania Farm Bureau and the American Farm Bureau Federation. I own and operate a farm in Columbia County, Pennsylvania, where I raise green beans for processing, corn, and wheat.

As a small businessman, I struggle to keep up with all the laws and regulations that control how a person operates their business. Of all the federal regulatory agencies, the one that takes the most time and costs me the most in productivity, is the EPA. In just the last three years, the EPA has set in motion a number of new regulations that will change the face of agriculture.

My written testimony highlights five issues. I will discuss two in the short time I have today. One, EPA's burdensome and we believe unlawful, micro management of the Chesapeake Bay Total Maximum Daily Loads and number two, EPA's proposed rulemaking expanding the scope of the waters regulated under the Clean Water Act.

The first issue is occurring right in my backyard. The EPA's TMDL for the Chesapeake Bay. All the land I farm is in the Bay

watershed, and most of the land is within the site of the Susquehanna River. Unfortunately, the EPA does not believe that economic considerations should be taken into account when implicating a TMDL. The overarching problem is that EPA's Bay model is fundamentally wrong. The EPA knows that the model has significant problems and failed to correct it before they finalized the Chesapeake Bay TMDL in December 2010.

A news article recently reported on the lack of scientific credibility and quoted an EPA official dismissing the concerns of local and state government saying "use common sense and let us get on with it." Another EPA official was quoted as saying "none of this stuff should impede the planning for what everyone knows is needed to be done." Well, common sense would tell us that money does not grow on trees. Hard-earned and private capital must be applied in a manner to achieve actual and proven water quality improvements. Common sense would be for EPA to leave the implementation of a TMDL to the states where Congress intended.

A second issue is draft guidance on the Clean Water Act jurisdiction. The draft guidance would greatly expand EPA's regulatory footprint from the value of the land to restrictions on land use. Farms and small business entities will expand negative economic consequences. The EPA is changing the rules of the game and has indicated they do not need to comply with the Regulatory and Flexibility Act and the Small Business Regulatory Enforcement Fairness Act. There is no question that asserting Clean Water Act jurisdiction will limit the activities that farmers, ranchers, and land owners will carry out on their land. The EPA already tries to require permits for changing from one type of farming to another. The guidance will effectively remove the term navigable from the definition of waters of the U.S.

The term and the definition of waters of the United States permeates all sections and programs under the Clean Water Act, including oil spill prevention and control measures, water quality certifications, the just issued pesticide permits, and soon to be issued post-construction storm water regulations.

The economic implications of continued and purposeful federal regulatory overreach will be staggering. These costs will impact the whole economy and this committee should not be surprised when our productivity contracts and jobs are lost to foreign competition. I want to thank you for convening this hearing, and I will be glad to respond to any questions you might have. Thank you.

Chairman TIPTON. Thank you, Mr. Shaffer. I appreciate that. It is always kind of interesting when you get the unintended consequences, which come from regulation. We all want clean air. We all want clean water. And some of the impacts.

We will start out with questioning. I would like to begin actually with Mr. Felix from my home area.

Aerial application and pesticides play a major role in protecting our farmlands, forests, and other invasive species in enhancing the production of food and fiber. Mr. Felix, how will the expanded NPDES permit requirement impact your ability to be able to serve farmers, local governments, and others that rely on timely economic applications of pesticides?

Mr. FELIX. Well, I think currently those kind of applications represent about 40 percent of our business. With the risks that go along with the citizen suit efforts that can be done I am really considering not doing those applications anymore. So as far as the right-of-way worked on the canals, they would not be done timely anymore. I would lose that revenue and also would not need as many employees to get that work done. And the water users would have to be adding to their arsenal of some way of controlling that problem because it is not going to work for us.

As far as the mosquito and the aquatic applications that we have done for adult mosquito control and for junk fish in the DOW waters around there, again, probably would not be able to make those applications anymore. So how they would accomplish, that I do not know, but it is going to put such a strain on my business I do not think I would be able to accomplish those anymore.

Chairman TIPTON. So simply from proposed regulatory requirements you are considering just not doing it anymore? Just simply cannot afford to do it. Is there going to be collateral damage to the community at that point, the farm and ranch community?

Mr. FELIX. Yes, I think so, especially on the irrigation projects and the communities that we would cease to do mosquito applications for.

Chairman TIPTON. How will these new regulations—do you see them impacting or having some good impacts in regard to environmental or public health in terms of expanding protections?

Mr. FELIX. Congressman, we have been doing this work for years and years and the EPA has regulated those products that we use to the point that we are using safer and more appropriate products all the time. And we see no adverse environmental effects from what we are doing so it is not going to change anything. It is just going to make compliance more difficult and more risky for us to be involved in business.

Chairman TIPTON. Thank you. Next question perhaps we can have Mr. Nelson and Mr. Shaffer from our two Farm Bureaus maybe address this issue. EPA administrator Lisa Jackson has proposed retaining the current standard for coarse particulate matter. However, there is no agricultural exemption for farm dust. This uncertainty still lingers throughout the farming community. Mr. Shaffer and Mr. Nelson, in previous years when the EPA has revised air quality standards for the Clean Air Act, has the agency's final rule always reflected what the EPA initially proposed concerning farm dust? Mr. Shaffer.

Mr. SHAFFER. You know, I think it is very easy to look at recent history regarding the EPA. An environmental organization will file a lawsuit against them. And instead of defending themselves in a court they will settle, and thus promulgate a new regulation. We have seen this time and time again. And I think that is the danger of this, that is the way a new regulation is being developed, unfortunately. My feeling is it is the obligation of Congress to develop regulations where it can be brought out in the open, debated, and come with some common sense reasonable regulation, but instead it is almost like the EPA is encouraging somebody to sue them so they can settle and just develop a new regulation upon agriculture.

Chairman TIPTON. Mr. Nelson.

Mr. NELSON. A couple of concerns that I have, and Carl alluded to one of them, I think the intent in Congress when you look at the Clean Air Act is one thing and I think what EPA is proposing is another. And I guess I am very concerned where we have farmers in certain parts of this country right now that cannot even comply with the particulate matter that they are proposing.

As I said in my testimony, when we harvested this fall and you see a natural cause happen when you are harvesting a crop that is ripened, you know, farmers have no control over that. And I think what irritates farmers the most is getting back to a comment that was made earlier, there just needs to be some common sense put into this equation as we talk about this. But in response to your question, I think I am very concerned that, you know, EPA keeps proposing these and keeps handcuffing farmers across this country, not just in Illinois, with their proposed rules.

Chairman TIPTON. I believe that is an important issue, Mr. Nelson. I appreciate you bringing that up because we are seeing some activist groups now encouraging expansion of the particulate matter out into the western states to where when the wind blows—I know in my part of the country and I know Mr. Felix can speak to this as well, we have half of Arizona airborne over us every spring just in terms of the dust coming in. So that certainly does be able to create some challenges for us. I appreciate you bringing that up.

Small business owners raise concerns that the EPA and its rulemaking in terms of clarifying waters in the U.S. is not adhering to mandatory requirements of the Regulatory Flexibility Act and the Small Business Regulatory Enforcement Fairness Act as well. The Farm Bureau Federation and other groups wrote to the EPA to express their concerns on this matter and we would like to be able to submit that in today's hearing record as well.

Given the significant and potentially devastating effect of this rule on small businesses, it is critical that the EPA ensure small businesses have a fair and meaningful opportunity to participate in the federal rulemaking that the agency completes all of the necessary costs benefits analysis. What are some of the costs you see coming out of some of these rulings—potential rulings for EPA dust control?

Mr. NELSON. The first thing that comes to my mind is how are you going to comply? In harvesting, I think you are very limited in what you can do to try to meet that requirement. I look to my colleagues in California that might have a lot of fresh produce, that they drive down a dirt road. They are out of compliance under the proposed rules that they are pushing forward. So I think the compliance issue is one thing that rises to the top of every businessperson involved in agriculture in trying to comply with it.

Chairman TIPTON. Mr. Shaffer, do you have any comments?

Mr. SHAFFER. I would just echo that. But just for instance in Pennsylvania, we have a large amount of dairy farmers for instance and they depend on making hay for cattle feed. Well, you cannot bale hay and put it away wet, or you are going to have spontaneous combustion. So just by the definition of it you have to let hay dry. Thus, when you go to bale it you are creating dust. So honestly, you know, as I said in my testimony, it is laughable when

they say use common sense. Well, this is common sense and to try to regulate particulate matter over dust and things like that, that is not common sense.

Chairman TIPTON. Yeah. The uncertainty is certainly a question.

Mr. Felix, could you maybe address, has it been your experience in terms of applying pesticides that you will wake up one morning and you have new labeling that you may not have been made aware of that can put you out of compliance?

Mr. FELIX. Certainly. This happens quite frequently. As a product comes down the pipeline to us and the label changes come, we are not notified of it. The only responsibility we have is reading that label as we get it. And we have lost uses in the middle of the season. For instance, I was applying a product to spinach and there was a complaint made to the Department of Agriculture and they came in to do the investigation. I went out and got a label off the new products and spinach was not on the label, but the material we carried over for the winter it was. And so these kinds of things are going on all the time on a daily basis and that is why in my testimony I mention we become experts on the label and the proper use of the products in compliance with that label and that was one lesson almost learned the hard way.

Chairman TIPTON. Thank you. Just a couple more questions and then we can get our other members involved here as well.

Mr. Vester, due to the uncertainty of the process to obtain a general permit have you started to consider changes that you will need to make in order to comply with new permitting requirements?

Mr. VESTER. Well, once again we are dealing with U.S. EPA. Most of our farmers have no clue this is there. They receive no notification from anybody. If they read the National Register every morning they might discover that there has been a new rule. We have spent a great deal of time on SPCC [Spill Prevention Controlling Countermeasures], and we were finally able to obtain an extension on implementation of that regulation. EPA has promised. We debated that for five years with EPA. A plan came out with a plan which we had agreed to with a promised five-year implementation and then all of a sudden it changed to one year. It was promised education to know what to do. That was never done. Most farmers even today when they got the extension did not know what they got the extension for. There is very little information that comes from the EPA. It is assumed that we know everything they do. It is difficult to do.

We, in the rice industry, consider and debate the fact that we should be exempt because our water issues on the production of rice is return flow irrigation water and storm water runoff. Those two are exempt by law in the Clean Water Act. Period. But EPA is trying to circumvent that by the fact of writing regulations that bring on environmentalist lawsuits. That is the way they regulate now, judicially, not legislatively. And that is what we face each and every day. And the NPDS permit, as I said earlier, they tell you to use as little chemicals as possible with no set amount which opens that to lawsuit trying to establish what amount. Then they say that you can only use it as a last resort. So who decides what is last resort? And last resort does not work.

You know, we are dealing with an agency that writes rules for what we do and they do not know what we do. They do not know how we do it. They just know that there ought to be rules for it. We have people who have spent their entire life on concrete trying to tell farmers how they should run and operate their business, how they should plant crops, how they should grow crops. The U.S. farmer produces the most abundant, the safest, cheapest supply of food to the American public and we get beat over the head every year because we are not doing it right. You know, I do not know what our answer is. You know, how do you not spray a pesticide on your rice to take care of insects, disease, and grasses and weeds when it is an aquatic crop? Now, the water seldom ever leaves that farm because in our state most of the water is retrieved, placed in reservoirs, and reused.

In the 1980s, EPA did a study in Western Tennessee on rice fields where water was put in and where it came out. And the results of that study were the fact that the rice was cleaner coming out of the rice field than when it was put in, whether it was service water or well water because of the marsh-type atmosphere of a rice field. But that study was never released. It was never made public because it did not give the results they wanted. Water coming out of a rice field is safer and cleaner than the water going in because of its marsh-type atmosphere. It is a daily battle with EPA for us. And we have continuing regulation that, you know, what is our answer? I do not really know.

Chairman TIPTON. Thank you, Mr. Vester. I appreciate that.

I would now like to yield to Ranking Member Critz for his questions.

Mr. CRITZ. Thank you, Mr. Chairman. And because of our testimony and the questions you have answered, I had a whole slew of questions I wanted to ask but you have given me a whole slew of new ones that I want to ask because obviously part of the process here is for us to learn more about what is going on so that we can make educated decisions, but also to make sure that anyone who is listening and that the testimony goes around so that other members of Congress can learn as well.

But because you are my guest, Mr. Shaffer, you get my first question, of course. It is a little off the defined topic of why we are here today but it is such a big issue in Pennsylvania. It is, of course, the Chesapeake Bay discharge concerns. And actually, I was showing Carl when I came in that Farm Bureau News—American Farm Bureau News has Carl on the front testifying before the House Agriculture Subcommittee on Conservation, Energy, and Forestry about Chesapeake Bay issues that we are having in Pennsylvania.

So Mr. Shaffer, your testimony talks about the billions that could be spent on EPA's Chesapeake Bay TMDL. Does anyone know how much this will cost taxpayers and/or businesses?

Mr. SHAFFER. Unfortunately, no. This is the mindboggling part of this. EPA is projecting this regulation and they have never done an economic analysis or cost-benefit analysis on this. Recently, Virginia has come out and they said they are estimating that it is going to cost them $7 billion to comply. New York has come out

with a figure of $6 billion. But the bottom-line is there has not been a cost analysis or a cost-benefit analysis.

And let me make one other point. We look at the Chesapeake Bay and think this is a regional issue but I will tell you exactly what EPA has said. This is a pilot project that they are going to use throughout the United States. So to all your other colleagues across the United States, this is going to be an issue they are going to have to deal with as well.

Mr. CRITZ. Well, and for those in the audience and in the panel, the reason I asked Carl to be here is that he is in Mr. Barletta's district and represents farmers and the Chesapeake Bay watershed really does not impact my district but because of this pilot issue, because of the cost. And when you mention it is going to cost New York $6 billion and Virginia $7 billion, that is not the state, that is the farmers. Is that correct?

Mr. SHAFFER. No, that is the state. Because this is going to go beyond the farms. This is going to go and involve communities. It is going to be involving their regional planning. It is going to involve their municipal water treatment systems. It is going to have very far reaching effects beyond the farm. As you indicated earlier, their own numbers say that they are going to take—we are going to have to take 20 percent of the land out of crop production.

Mr. CRITZ. Six hundred thousand acres. That is right. Yeah.

Mr. SHAFFER. Which is unreal. And looking at their model, as I indicated, it is faulty. They do not indicate in their model that we utilize any best management practices whatsoever where we have been doing it for 40 years utilizing best management conservation practices.

Mr. CRITZ. Thank you. Thank you. And Mr. Felix, you made a comment and I am actually going to say something that is extremely sarcastic and I think you will get it when I am through, is that obviously you have run probably a $20-, $30 billion dollar business and you have a staff of attorneys that go over regulations and things that are coming down. Is that true?

Mr. FELIX. No, sir.

Mr. CRITZ. No, sir. [Laughter.]

So you have 20 employees? One hundred employees?

Mr. FELIX. Actually, nine full-time employees. That includes mechanics, my two sons and myself, and loaders and field scouts. And we provide a turnkey operation. So we go out to the farmer and we check the fields, assist them in decision-making on what kind of applications they need to save them the money they need and still put a crop in their storage so that they can have something to go from one year to the next, whether it is livestock—we do range land, all the farm land around there, forestry. I mean, it is a turnkey thing. We also do surveillance and game surveys for the DOW with the helicopters in the wintertime and provide search and rescue for the communities and the counties in the local area, plus fire suppression for the sheriff departments in the local areas with both aircraft.

Mr. CRITZ. Well, good. And the reason I asked my very sarcastic question at the beginning is that this label change that happens, that comes as a surprise, is that you find you have stock that you cannot use for certain items. And what you are saying is that there

was no notification. It is up to you to somehow—to read the Federal Register every day to find out what is going on because of the impact. So you end up with stock that now has devalued if you have carried something over. Is that——

Mr. FELIX. Well, or you have to use it in a different way or return it. I mean, sometimes we can do that. But if they take a product completely away then you are just stuck with it and you have got to pay to have it disposed of with hazmat people. And that just happened last year with carbofuran.

Mr. CRITZ. I can understand your frustration. That is an interesting item that certainly we need to look at that.

Mr. Vester, you made—you used an example and I want you to further clarify this. And you used the strep throat example for NPDS permitting.

Mr. VESTER. Right.

Mr. CRITZ. Can you go through this again and maybe use a different analogy? Because I am trying to figure out—is that the NPDS is a—you are saying let us wait until the patient is dying before we—well, I will let you explain it because I am trying to get it straight in my head.

Mr. VESTER. I understand. In the NPDS draft permit it makes a statement that you should use the lowest amount of pesticide possible to apply to your crops and apply it specifically so there is no drift. We do that regularly because that is the plan. When you first see one and two leaf grass you spray to kill it. When you first see five to 10 worms every so far in a sweep you spray to get rid of them. When sheath blight and blast, which are funguses that grow in rice, when you find 10 stalks in a certain area, you spray. When the least amount of disease and insects and weeds are there you spray with a small amount of pesticide. But then in the next paragraph or later on they say that pesticide should be the last thing you do to prevent these pests. That you should wait until it is intolerable, I think they say, to apply anything to stop them. So if you do that, if you follow that practice——

Mr. CRITZ. So that is almost contradictory.

Mr. VESTER. It is contradictory because they do not understand. They have written a regulation dealing with something they do not know what they are talking about because if you wait too long then you use a 2X rate in what we call a salvage operation because the weeds are starting to choke the rice out they are so big and strong or the worms have eaten 90 percent of what is there or the fungus has spread so bad it destroys the yield and the quality of the rice. And it would be like taking a child to the doctor or yourself to the doctor with a bad cold and they say you have strep throat and you tell them, well, I am strong. I can survive it. And you keep going back until you are finally in the hospital and the last resort, you take antibiotics. You get an IV because you are dehydrated. It is the same ignorance that you would be if you did not accept what is needed for you physically for health as if you do not do what is needed physically for the health of your crop.

Mr. CRITZ. So it is almost like preventive medicine? Is that——

Mr. VESTER. Well, it——

Mr. CRITZ [continuing.] Spend a little upfront to save the huge amount down the road. And plus, if you are losing crop, you are

losing—you are spending more and losing—you are not making as much.

Mr. VESTER. When you wake up in the morning with a sinus headache and pressure, do you take something to stop it? You do. If you do not, what happens? It keeps getting worse and worse and finally you may have a sinus infection and you go to the doctor. If you walk into your field and you find one and two leaf grass, it takes a small amount of herbicide to kill that. If you wait till it is five- to six-leaf grass it takes an enormous amount of pesticide to kill it. And so on one hand they are telling you, you know, do not use a whole lot but wait to apply pesticides or herbicides until there is no other option. Well, in the first place that is the only option.

Mr. CRITZ. So let us take this a step further. So common sense. We are going to use common sense. We are going to use the reasonable man approach here. Do you spray when you see those two blades of grass? Now, what happens with the permitting? Does it come back that you get pushback from the agency or what—I mean——

Mr. VESTER. We have not, you know, we are starting a new year. Okay? We are regulated at the state level because EPA directly regulates six or seven states and the rest of the states it is delegated to state authority to regulate. In Arkansas it is DEQ. So——

Mr. CRITZ. Pennsylvania—is DEP Pennsylvania or is it EPA?

Mr. SHAFFER. In Pennsylvania the pesticide rules fall under the Department of Agriculture.

Mr. VESTER. And it varies state to state. So we all have different rules and the only stipulation that each state has, they have to have a rule as stringent or more stringent than what the U.S. EPA rule is. You cannot be less stringent. So——

Mr. CRITZ. Right. Okay.

Mr. VESTER. Our rule is just now coming out to be known. So whether we need to—we have to read that rule for the coming year to see if we are going to have to have a permit and what establishes that if it is approved what we write in the EPA. Now, we have only seen and the State of Arkansas has written off the draft regulation because we had to—we had to have the state regulation ready by November 1. Well, EPA did not have the full regulation ready until November 1. So we had, you know, we could not——

Mr. CRITZ. Right. You had to use the draft.

Mr. VESTER. We had to use the draft. Well, the draft does not look anything like the new regulation. So I do not know even if Arkansas or any of the other states have a regulation——

Mr. CRITZ. Or if they will be——

Mr. VESTER [continuing]. That is approved by EPA.

Mr. CRITZ. Yeah.

Mr. VESTER. So, you know, the original draft that EPA—draft that EPA came out with, you know, there was talk that you had to apply for a permit in the winter for the coming year listing all the pesticides you were going to use in that coming year. You do not know. You do not know when you are going to use them. Weather and time of the year dictate what we do as farmers. You know, when the crop is planted. We cannot—we do not have a busi-

ness plan that says today we are doing this and tomorrow we are doing that.

Mr. CRITZ. Right. Right.

Mr. VESTER. You know, like I said, EPA is regulating something they do not know anything about.

Mr. CRITZ. Yeah. Well, I think we had it in Pennsylvania this last year is we had—it was wet early, then it got hot, and then it got wet late again so it changes. So I see what you are saying.

I have one last quick question. Well, I do not know if it is going to be quick. You know me.

But Carl, you had mentioned about EPA, and this is another issue I am trying to get my hands around, EPA issues a rule, gets sued, and then settles and that is now new regulations are created. Can you walk through that a little and maybe give a specific example?

Mr. SHAFFER. Yeah. I can give you a very specific example of it. And that is the Chesapeake Bay TMDL.

Mr. CRITZ. Okay.

Mr. SHAFFER. The Chesapeake Bay Foundation filed a lawsuit against EPA saying they were not acting in a timely—they needed to act in a more timely manner and put more enforcement into cleaning up the Chesapeake Bay. Instead of even leaving that and go to court and have a court decide whether that lawsuit had validity or not, EPA settled and said okay, we will settle. Now it is our responsibility. We have to come out with a whole new set of rules to meet the challenge of the settlement of the lawsuit. So the Chesapeake Bay TMDL came out of just one environmental group suing EPA and EPA not even defending themselves for any practical purpose. They just agreed to settle and put out a whole new set of rules. This is happening time and time again. And unfortunately, as I said in my testimony, you are the entity that should be setting rules and regulations, Congress, and instead EPA is doing this by settlement agreements. And a lot of different issues are being promulgated this way.

Mr. CRITZ. Thanks, Carl. I yield back. Thank you, Mr. Chairman.

Chairman TIPTON. Thank you. I recognize Mr. Barletta for questions.

Mr. BARLETTA. Thank you, Mr. Chairman.

The word I heard most here this morning was the word "common sense." And I could tell you in my short time here in Washington, the 10 months I have been here, I found that common sense is not as common here as it is in Pennsylvania, Illinois, Arkansas, or Colorado.

I think we all agree that farmers have a vested interest in conserving and protecting their land and the agricultural sector is vital to our nation's economy. And also, you know, people may not realize it is vital to our country's national security. It is very, very important that America continues to produce its own food. And I am very concerned about that. Some of the regulations that you have to live under, other countries are not. And we are putting America's farmers at a disadvantage as we have done in manufacturing and then we wonder why we do not have any more manufacturing in America. We are doing the same thing in farming. And I believe it is a national security issue.

But assuming this is true, Mr. Nelson, how can the Environmental Protection Agency justify—how can they justify imposing these burdensome regulations on American farmers?

Mr. NELSON. Well, that is the question we have been asking ourselves as producers because when you start looking at their proposed regulations, whether it is in clean air or clean water. And I think the frustrating part that we see on behalf of the farm community is we are not given any credit for the environmental practices that we have in place. Case in point, over the last two decades we have reduced the use of pesticides almost 30 percent through biotechnology that we use in our crops. Secondly, we probably use 25 percent less fertilizers over the last two decades. We plant filter strips as was alluded to earlier to make the water cleaner. In Illinois, we have private pesticide applicator training. Every three years you go through a training exercise and have to be licensed. So I think the frustration that we have is we have a lot to offer as an ag community to put on the table of practices that we do have in place, which are best management practices but we are not given any credit for that. And I think that is the frustration that we see in the justification of the EPA.

I use a recent court ruling in the Fifth Circuit as it relates to livestock production. It said if you do not discharge, you do not need an NPDES permit. The EPA did not appeal that, but yet at the present time in the state of Illinois and other states, we are facing the fact that the state or the regional EPA offices are saying, well, that was the case in the Fifth Circuit but we are still wanting producers in the case of livestock to obtain permits. And we do not necessarily agree with the definition of a discharge. So I think we are wrestling right now on that segment the same as we are with this general permit of which we tried to have input into the drafting of that, and the final stages of that permit look far different than they did in the drafting phase. So it is a very difficult question to answer but in the eyes of agriculture we have a lot of question marks of how they can justify doing this and taking what we said today and the production side of what we do best and producing a safe, abundant food supply and trying to hinder that.

Mr. BARLETTA. Mr. Shaffer, I agree with you. You are right. The regulations of what we are seeing in Pennsylvania, folks around the country should be paying attention because it will be coming soon to your neighborhood. As you know, much of our congressional district, including your hometown of Mifflinville, is located in the Chesapeake Bay watershed. I know that you, like many other farmers in Pennsylvania, are concerned about EPA's regulatory approach in the Bay watershed. Yet the EPA has been assuring congressional panels that states will have control over implementing water quality programs in the Chesapeake Bay region. Has this been your experience?

Mr. SHAFFER. Absolutely not. The Clean Water Act, in my opinion and our opinion, simply says that the state should have control over their waters. And in implementing the TMDLs the state of Pennsylvania, all the states in the watershed, are required to do water implementation plans. So Pennsylvania started working with the stakeholders, who are farmers and other people, working to develop its first phase of the watershed implementation plan. It had

questions. It reached out to EPA and said, well, is this part of the water plan going to be acceptable or not? And EPA's answer was submit the plan, and we will tell you if it is acceptable. They developed a plan, submitted it. It was immediately rejected and EPA said it did not have enough backstops, enough enforcement. So how do you say the states are controlling their own waters when the EPA is rejecting the plans and dictating what they have to do?

So I am very concerned about that. And, you know, every state is different. Topography is different. Weather conditions might be different. So we go back to common sense. It just makes common sense that each state is in a better situation to develop a plan to protect the waters in its state. A one size fits all plan just will not work.

Mr. BARLETTA. Mr. Shaffer, common sense is a dirty word around here. Thank you, Mr. Chairman.

Chairman TIPTON. Thank you, Mr. Barletta.

You know, listening to you, and Mr. Felix, I hope you do not mind if I share a little bit of a conversation you and I had had before this hearing.

Mr. FELIX. Go ahead.

Chairman TIPTON. I would like to preface this, you know, if you look back at the census in this country—I believe it was 1950–1960—we had 130 million Americans in this country. Our latest census shows we have over 300 million Americans. That population growth is happening worldwide. Mr. Felix, you shared with me in our part of the country, on the west slope of Colorado, that you are seeing fields now that used to grow crops growing subdivisions.

Mr. FELIX. The last crop, asphalt and shingles.

Chairman TIPTON. Asphalt and shingles. And is the experience—we have the rice community represented here, a couple of Farm Bureaus, are you seeing more and more farmers simply throwing up their hands and saying we cannot comply. We do not know what the regulations are going to be. It is not worth the cost. It is not worth $37,500 per day in fines just to try and conduct business and to grow food for the American people? Are you seeing more farmers just reluctantly saying we have had enough?

Mr. FELIX. I will say emphatically on the livestock side they are just frustrated. I just talked about with the definition of a discharge, we think of that as if something were to happen in a lagoon which stores the manure from livestock—would break if something like that would happen. We consider that a discharge. EPA is considering a discharge a rain event that comes off of a roof that hits a ventilation fan that might end up in the grass as a discharge. That is how farfetched this is getting. So the livestock community is very frustrated. And I am seeing people that are middle aged or approaching, you know, the latter part of their life. They are just throwing the towel in and saying forget it.

I think on the crop production side we alluded to this earlier with your sarcasm, Mr. Congressman, but we are getting to a point and it is not a laughable matter that farming operations are going to have to have a regulatory specialist to keep up with regulations to keep their farming operations in compliance. And as I said before, the ironic thing is today an American farmer feeds themselves and about 155 other people. If we continue down this pathway, you

can look out 10 years from now where that number might be half or even a third of that if we keep hamstringing what we do best. And by the same token, I think we consider ourselves to be the true environmentalists who do protect the water that we drink in the farming operations that we are a part of and the air that we breathe.

Chairman TIPTON. Thank you. Anyone else care to comment on that?

Mr. VESTER. Go ahead.

Mr. FELIX. The thought that comes to mind about this whole thing is—and you can take it to the economy even—is that there is no new wealth in this country except for what we grow, what we mine, what we fish out of the oceans or the rivers, and cut from the forests. Everything else is a turnaround, a reuse over and over and over. And without that new wealth from this country, we are going down. You have to have new wealth. It does not come from anywhere else. It is either the sun or the earth. That is it.

Chairman TIPTON. All right. Thank you. Mr. Vester.

Mr. VESTER. You know, to be—I will use a term I do not like—but sustainable rice producer in this day and time—I do not agree with that terminology although I do serve on a committee that we discuss that. But a rice farm in our area, to be sustainable as a family farm, you need to be farming a minimum of 1,500 acres in a crop rotation, which normally there is rice, soybeans, and wheat, or rice, soybeans, and corn. That steadily grows and grows. Farms have to be larger because of the economy of size. No matter how much commodity prices climb, no matter how much you get for a crop each year, the cost of producing that crop comes up right under it. It is a margin about this wide. I tell people that farmers are people who faithfully every year go to the bank and get a crop loan to produce your crop and they mortgage everything they have—their equipment, their crop they are going to grow, the crop they have not sold all of yet, their wife and children, if the bank would accept it as collateral, with the hope and a prayer that by fall when that crop is harvested that the commodity prices will be high enough and the yields will be good enough, which in reality we do not control. A lot of that is controlled by weather conditions. And they have enough return to pay off that crop note and enough money left over till the next crop loan is funded. That is basically what we do because the margins are that thin. Some people are very successful because maybe it has been generations of families buying land but the average farmer, that is what they look at each and every year. With new regulation, new cost, new things they face each and every day, it is very discouraging.

You are not finding—I have to say in our area we have got a lot of young farmers coming in right now who are following dads in and dads are retiring. But people get very frustrated. It gets very difficult. Costs are enormous. Returns are low. And you know, I sit on a bank board and if you look at most crop loans that we look at, the margin in that crop loan, whether they are a corn farmer or a rice farmer, is equivalent to that deficiency payment they received. That is the margin. That is what is left over. Okay? And some years it is not that. This year it will not be that because costs were so high. We were the same way in Arkansas. We had a flood

period. We were dry first. We had floods. We had land that was flooded and could not be planted until late and they lost their crop due to drought. I mean, that is what you face in agriculture. And when the young people can go to town and work 40 hours a week and make more money than mom and dad, why would they stay there? I mean, that is what you look at.

You know, years and years ago it was said if farmers took everything they had invested if they owned land and put it in a savings account at 2 percent interest, they would make more money than they did farming. And that was true. You know, we are kind of—maybe we are not very intelligent. I do not know. But we love what we do. It is a great joy. I have a grandson that is 12 years old and that is all he wants to be. And that is wonderful. But Mr. Felix is correct. We are facing, I think a frightening thing.

I lived through the '70s when they told us to plant fence row to fence row. We were going to run out of food and we did not because some things happened. But are those things going to happen this time? Are we running to the end of the line? You know, I really question that. The economic conditions in the United States right now are going to be devastating to agriculture. We are down—right now we are down to seven major seed companies in the United States. Two of those are considering selling out. Of those seven seed companies, they own the five chemical—major chemical companies in this country. Okay? They have united. All of those seed companies own a chemical company except for one or two. We are down to two major fertilizer providers nationally in the world. When the products you need are that closely held, do you know what happens to the cost of them? They go out the ceiling.

In reality, I think financing is shrinking. Bank of Cooperatives, which loans money to co-ops and big farming operations around the country, in several areas have combined with Farm Credit. Even financing for agriculture is becoming closely held. I really feel personally that we are almost entering a period of feudalism where the margin in agriculture is so small that the farmer is going to have so much wrapped up in fertilizer, seed, and chemicals, and paying for regulatory issues that if he stumbles and has a bad crop he will never be able to climb out of the hole and put those seed companies—and they will finally merge seed, fertilizer, chemical, and finance altogether. They will say that is all right. You can keep farming your farm. You will not own anything but we will pay you a salary. That is where we are headed in agriculture in this country right now. I think we are very close to it. Do you not?

Chairman TIPTON. Thank you.

Mr. FELIX. I think that is where we are headed, a system of feudalism. And, you know, we need to do something for the agricultural community, to slow this down and get it back to where we are a production agriculture feeding the nation and the world.

Chairman TIPTON. Mr. Shaffer, any comment?

Mr. SHAFFER. Just to follow up on your statement of farmers getting disgusted and giving up frustrated. I am as concerned about our young people. Where is the next generation of agriculture going to come from if they are discouraged from even entering into it? And where are the next food providers in this country going to come from if that frustration is carried to the younger generation?

Chairman TIPTON. Thank you. Congressman Critz, do you have another question?

Mr. CRITZ. Well, I had another question but, you know, one quick story is after the tsunami in Japan, you know, a lot of the farmers, because of the nuclear issues, had to move away. And I will never forget they were interviewing one rice farmer in Japan. He said, you know, he did not know what he was going to do because he had been farming—his family had been farming that land for 600 years. And the farmers that I encounter in my district, that is the stock we are talking about. These are people who want to do this and their families want to do this for a long, long time. And it is up to us to try and help. And that is, of course, what this is all about, is trying to be in a position where we can offer some help. You know, obviously, we are never going to solve every problem but we are on your side and we are trying to do our best. And we try to listen and learn to come up with solutions.

But the one question I did have is that when we are talking about this, you know, I am going to go back to our pilot program in Pennsylvania, the Chesapeake Bay issues, if you could look back 20–30 years and compare it to today on the environmental impact that farmers are having at this point, what are the things that farming has done over these last years? And a lot of times I know you can share statistics with us that show that, you know, the work that has been done or the work that is being done on farms now is so much more environmentally friendly than it was in the past because you have implemented a lot of things. And I think, Mr. Shaffer, Carl, you had mentioned in your testimony or in some of the information that part of your heartburn with EPA right now is that they do not give credit to farms that are doing clean up already.

So if anyone or everyone, anyone who wants to comment on the difference now between—between now and if you want to go back 10, if you want to go back 50 years—what the difference is that you are seeing on farms and how you really are the stewards of the land. And the reason I ask this is because I want to make sure it is in the record so everyone gets to hear it.

Mr. SHAFFER. Well, Congressman, and Congressman Barletta, as you know exactly where I live, I was born and raised along the shore of the Susquehanna River. And when I was a child I would go down to the river. The rocks along the bank were fluorescent orange. There was all kinds of things floating in that river and there were no fish. Today it is one of the best smallmouth bass fisheries in the world. The waters have been cleaned up.

My father used to raise beef cattle and I can remember on hot days those cattle standing in the creek to keep cool. Now, my father was not a bad man. He just did not know that was an opportunity for pollution. We have learned that. We now have stream bank fencing. We have adopted so many practices over the last 40–50 years—no-till farming, cover crops—it goes on and on with best management practices. We have done this voluntarily without EPA's foot on our head telling us to do this. And we have been able to do it through the development of technology and new ways of farming that are more environmentally friendly and we have adopted it on our own. And that is why you can go to EPA's num-

bers of how much nitrogen reduction there has been, how much phosphorous reduction there has been, and how much sediment reduction there has been. And it proves it.

And we still, as you mentioned, I was in that Congressional hearing two weeks ago. The administration official from the EPA stood there and said this is like trying to run a 10K race and we are still standing at the starting line. Now, after all we have accomplished, for them to say we are still standing at the starting line, you talk about frustration. There is not any bigger frustration than comments like that.

Mr. VESTER. In the rice industry, compared to 20 years ago, two of the major input costs in rice have always been nitrogen fertilizer and water. We use half the water we used to use because of developments of seed that mature more quickly, because of practices how we do not lose water. It is a precious item to us. Farmers conserve their water faithfully because they have to have it. I would say that nitrogen use has been cut by 40 percent and they are doing experiments now and testing now not run by EPA, run by the Extension Service in our state of how we can use less fertilizer yet.

We have made huge inroads. Nearly all farmers plant grass barriers around their field to keep pollution down, to keep erosion down. Farmers know that their land and what they do is precious to them. It is no different than the man that has a lockbox full of cash money. He is not going to leave the lid open and let the money come out. That is our livelihood. That is what we pass on to our children and to the next generation. That is the way we make our living. We take care of what we have.

As Mr. Shaffer says, you know, it is disheartening to hear people say, well, you are just not doing enough. You know, what you have done, well, anybody would have known to do that. And there is an opinion in U.S. EPA that we are ignorant, straw chewing people who wear overalls and do not have an education. That is what comes across to me.

Mr. CRITZ. And it is interesting because I have yet to meet a farmer that is not highly educated and can talk about agricultural science, pesticide science. I mean, all these things. It is amazing to me. It was actually an education for me because, you know, I guess growing up you read books about farming and it is just you work with your hands, people work with their backs, but the education required is unbelievable.

And to your point, you are doing things so they have to be smarter. The next generation has to be smarter because they are innovating and they are doing good things. I did not mean to interrupt but I am amazed at the level of education farmers have.

Mr. FELIX. I would like to go back to what we were talking about the young farmers and where they are coming from. Our farmers have implemented the very similar things that these other gentlemen have related to, the no-till and the irrigation practices. With the dust controls, we do not plow everything anymore. All those things are being done every day in the interest of not only the environment but also more efficiency and better crops.

But back to the young people. There is a tremendous resource there that if we lose it, I do not know where you are going to get

it back. Because if you think about this green thumb that comes along with a grower or aerial applicator or somebody that understands the cropping system and how to get it done, how to do a minimum amount of applications to get the maximum out of your pesticides, you cannot learn that in school. That is something that is passed on from father to son to son to son. And if you lose that, and I can attest to this because I have got young farmers out there that came from the city and they want to farm. But I can tell you what, they have a heck of a time. And we offer them a lot of help, but even so they make bad decisions and they do stupid things. And it is really difficult to get them up to speed so that they can farm. And most of them do not make it and that is what I see in our area.

Mr. NELSON. And I think a lot has been said but, you know, the one comment that I guess I failed to bring up through this hearing and the frustration the farmers have with these proposed rules is we cannot pass it on. I mean, we are a price taker, not a price maker. And I think that that is a very important point that I think this agency does not understand from time to time.

But getting back to your question, 30-some years ago I graduated from college and, you know, at that time the push was to go towards no-till. And I remember coming home to farm being the only one out of the six in our family that came home to farm with dad. And the first year I said, Dad, we need to rent a drill and we are going to no-till our soybeans. And I thought he was going to kill me because he said, there you are, the college-educated kid that does not get it. And at that time no-till was not very common. But you know something? That year we had above normal rainfall, the soil did not move, the trash was there to protect it, and we looked at the T By 2000 campaign that went on in Illinois in protecting our soils and our fragile lands.

We looked at the conservation programs that we put in place. The water is cleaner. The filter strips have protected our streams and our rivers. And in crop production today I make the comment we use prescription farming. We farm by the square inch, through global positioning. We have auto steer technology. We do not apply pesticides and fertilizers that we do not have to because it impacts our bottom-line, and secondly, we are environmentally friendly in what we do.

And I think shifting gears to the livestock side, being a livestock producer, 30 years ago we raised a lot of our animals in outside facilities. We brought those animals into controlled environments where they live in sheds that are cooled and heated during the winter time. A lot of places better than humans live. And we raise a type of meat today that is rivaled around the world. And yet we also take credit. Thirty years ago we did not think of manure as a bonus to a farming operation. Now we use it in our nutrient management plans that we put in place as practices.

But I guess my closing comment is, you know, a lot has changed in 30 years and it has all been for the good. But yet we do not get credit for that it has been alluded to.

And I will use the analogy. I have a son who would like to push dad out of the farming operation today and take it over but he sees the storm clouds on the horizon of the EPA pushing some of these

rules and he is skeptical about whether or not he wants to be a part of this business. And as Congressmen, as members involved in agriculture, we have to get it right and get this thing under control and get back to the common sense that really, you know, needs to be injected into this debate.

Chairman TIPTON. Well, thank you, gentlemen. I appreciate your comments on that and fellow members of the Committee. Sitting on the Small Business Committee it is an interesting observation. All of our small businesses, be it farming, ranching, small retailers, small production companies across this country. As I have traveled throughout my third congressional district to Colorado, 54,000-plus square miles, at every meeting that we were at, within no more than 10 minutes the EPA comes up. The overreach of this body is enormous and I think, Mr. Nelson, to your point, particularly with our farm and ranch community, something that we cannot ever fail to underscore for the American public is the farmer, the rancher does not set their price; they pay the price, not only in terms of the sweat off of their brow but out of the limited resources that they have. And when we have a moving target, and as Mr. Shaffer was noting, that the EPA views us still at the starting line.

We have seen tremendous improvement because the best custodians of our land is truly our farm and ranch community. And I want you to know on my behalf, and I know on Congressman Critz's behalf and Congressman Barletta as well, this nation owes a deep debt of gratitude to that farm and ranch community and what it is able to provide. And believe me, we will take your admonitions, particularly with the uncertainty that we are seeing out of the EPA greatly frustrating when we ask a state to be able to put forward a plan and then the EPA sits in judgment it is not good enough without guidance. That is unacceptable.

To my ear in particular, I would like to let you know that we have a lot of frustration on both sides of the aisle when it comes to the regulatory bodies right now that are putting out regulations under the legislative mandate of Congress but exceeding that mandate. And there has to be a good solution, a good piece of legislation, and a number of us are working on that simply to be able to address getting it back to that authoritative body. The EPA should not be writing legislation; it should be fulfilling the legislation that Congress had entitled it to be able to do and it is overreached.

So thank you, gentlemen, all for being here. I know that it is no small effort to be able to come here and to be able to participate in these. So as the Subcommittee continues to focus on burdensome regulations that affect our farmers and ranchers and small businesses, I would again like to be able to reiterate how important it is to provide regulatory certainty in relation to our nation's job creators.

[Whereupon, at 11:36 a.m., the Subcommittee was adjourned.]

Congress of the United States

U.S. House of Representatives

Committee on Small Business

2361 Rayburn House Office Building

Washington, DC 20515-0515

House Committee on Small Business
Subcommittee on Agriculture, Energy and Trade
"Adrift in New Regulatory Burdens and Uncertainty: A Review of Proposed and Potential Regulations on Family Farmers"
Thursday, November 17, 2011 10:00 A.M.
2360 Rayburn House Office Building

Witness List

Philip Nelson
President
Illinois Farm Bureau
Bloomington, IL

Leonard Felix
President
Olathe Spray Service, Inc.
Olathe, CO
*Testifying on behalf of the National Agricultural Aviation Association

Ray Vester
Chairman
Vester Farms
Stuttgart, AR

Carl T. Shaffer
President
Pennsylvania Farm Bureau
Mifflinville, PA

November 17, 2011
Testimony of Philip Nelson
House Committee on Small Business –
Subcommittee on Agriculture, Energy and Trade

Good morning, I'm Philip Nelson, a fourth generation grain and livestock farmer from Seneca, Illinois, a small rural community about 75 miles southwest of downtown Chicago. I farm with my wife Carmen, son Kendall, and daughter Rachel and raise corn, soybeans, alfalfa, cattle and hogs.

I'd like to begin by thanking Chairman Tipton and Ranking Member Critz for holding this hearing, and I'd also like to acknowledge the excellent work on behalf of agriculture by the newest member of your panel. Thank you, Congressman Schilling for creating this opportunity for us today.

I've been asked to testify about the National Pollutant Discharge Elimination System (NPDES) Pesticide General Permit that went into effect on the first of November and to say a few words on the potential impacts of proposed dust regulations on agriculture. But before I do, I would like to point out that we shouldn't even be here today discussing a new NPDES pesticide permit because it should have never gone into effect.

Let me be clear: This new permit is a needless duplication of existing law. A bill sitting for the past seven months in the Senate recognizes this fact and would eliminate the need for such a permit.

With strong bipartisan support, the House of Representatives passed H.R. 872 back in March. I appreciate that several of you voted for H.R. 872, and it's regrettable that the bill needlessly spent this past spring, summer, and all of this fall languishing in the Senate, caught in a stranglehold by a couple of Senators upset—primarily over Senate committee jurisdiction--not over the substance of the bill. I understand that more than 60 Senators would vote today in favor of H.R. 872, if only given the chance. They should be given that chance.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) has covered pesticide labeling and application very effectively since 1947. While the new permit process addresses pesticide applications in, over, and near waters of the United States, it duplicates FIFRA. EPA estimates that this new requirement will affect approximately 365,000 pesticide applicators nationwide that perform 5.6 million pesticide applications annually. It will cost $50 million and require over one million hours per year to implement.

We believe these estimates are low, for they do not include the compliance requirements added by the National Marine Fisheries Service (NMFS) for those waterbodies that include endangered or threatened species or federally-listed critical habitat. Nor do they include any potential requirements to be added by the US Fish & Wildlife Service (FWS), for EPA issued its permit before it completed its consultation with FWS. To be sure, the NMFS endangered-species requirements will not apply everywhere EPA's permit will apply, but where they do apply they will make it extremely difficult for anyone to use pesticides for control of pests. That includes not only farmers and ranchers, but irrigation canal operators, forest service agencies, mosquito control districts, utility rights-of-way managers and others responsible for pest control in those areas.

I don't have to tell you that states like Illinois have very limited resources as does the federal government. Spending precious resources for this purpose represents neither good public policy nor a wise use of taxpayer dollars. Furthermore, it doesn't make our food any safer, our water any cleaner, or provide one iota of environmental benefit above and beyond what we already achieve on our farms.

As president of Illinois Farm Bureau, I can speak for Illinois farmers, and I can tell you they're frustrated. Few farmers are aware the permit is even in effect. And even fewer can tell you today whether they will be required to get one, how to comply with it, or even where to go to get it. The time we spend thinking about it, is time away from what we do best. If time is money, then the new NPDES permit represents a waste of time and effort and fails any cost-benefit analysis.

The permitting process itself is complicated. The Illinois permit is 30-pages long and contains many layers of mandates. Most farms are operated by one person and requiring this permit on top of everything else a farmer must do is daunting. Then, if you take the time consuming paper work for little or no environmental benefits and couple it with the fact that farmers cannot pass along the cost involved with implementing the permit's mandates, that only adds to our frustration.

As a farmer, I can assure you I take my stewardship responsibilities seriously. Like all farm families, my wife and I breathe the air, drink the water, and raise our children on the land we farm. We handle and apply crop protection products safely and follow the directions on the label. Farmers are motivated to take care of the land, so the land will continue to take care of us, our children and future generations.

Frustrated? Yes. But what really keeps me lying awake at night is the potential out of this for more regulatory creep. Regulatory creep is a very real concern for farmers. It's as if we go to bed one night with one set of regulations and wake up the next morning facing a new set. Every moment that we spend fighting and and working to comply with needless, duplicative regulations takes us away from what we do best, produce food.

In the case of the new NPDES Pesticide General Permit (PGP), we have good reason to believe pesticide regulation could be expanded in the future to include other routine applications. If we

look at the history of similar rules that begin innocuously and later expand exponentially, then past actions give us great cause for concern with this new permit. At times, regulatory creep can be the result of changing interpretation of law or rules by the U.S. EPA on specific language where there had been years of common agreement on its meaning. For instance, U.S. EPA has chosen not to define what "water's edge" is in the new permit. How this is ultimately interpreted can drastically change how the PGP would impact agriculture. We are also concerned that other proposed laws, regulations, or guidelines on related issues may increase the scope of how the permit is implemented or who is impacted. One example of this is found of the U.S. EPA's Guidance Document that would greatly expand what waters are regulated under the Clean Water Act.

The last issue I want to raise is one that is perhaps the most troubling and that is the lawsuits that may occur because of the Pesticide General Permit. In recent years, we have witnessed an increasing number of lawsuits against farmers. In Illinois, farmers are being sued for discharges at livestock facilities that are still being constructed and where there are no livestock present. It doesn't take much imagination to see how this new permit opens the door to new legal challenges that are financially and emotionally draining Every dollar we spend needlessly defending our livelihoods in court is one we'll never be able to spend on our operations.

This PGP doesn't improve food safety, doesn't add any additional environmental protection or benefit for society, and does nothing to improve my bottom line. We need to focus on improving efficiencies and effectiveness of programs. We feel the current regulation of pesticides by FIFRA has remained current and is effective to the point we do not need this entirely new permit program. H.R. 872 remains relevant and Congress needs to complete what 292 members of the House supported and likely a strong majority in the Senate would like to see approved. The legislation would clarify there is no additional NPDES permit needed for pesticide applications and remove any confusion the Sixth U.S. Circuit Court of Appeals created in its ruling.

I would like to further comment on proposed dust regulations.

"Dust" is a way of life in rural areas of the country. It is raised by activities that are essential for most farm and ranch operations. For example, it is raised by driving on unpaved rural roads, working farm fields with tractors, or moving livestock, it is also generated by naturally occurring conditions, such as blowing winds and dry conditions. Unlike man-made emissions of smaller particulate matter (fine particulate matter), dust is comprised mostly of dirt and organic matter from grass and farm fields.

The Environmental Protection Agency (EPA) has regulated rural dust for many years. Coarse particulate matter (PM10), another name for rural dust, is part of the general category of "particulate matter" that is a criteria pollutant under the Clean Air Act. Under the Clean Air Act, EPA reviews NAAQS for criteria pollutants every five years. The NAAQS for particulate matter was last revisited in 2006, so EPA is undertaking its normal five-year review. We applaud the recent decision of the administrator to propose that the current standard for coarse PM be retained with no change, a decision that will help to prevent many other rural areas around the country from falling into non-attainment status for dust. It will not, however, help those farmers

in Arizona, California, New Mexico and other western and southwestern states whose operations are already being regulated because their areas cannot meet the current standard.

EPA also readily admits that it has little or no data on health impacts in rural areas. It states that "most PM10-2.5 epidemiological studies have been conducted in urban locations in the U.S., Canada, and Europe while a small number of studies have examined the health impacts of dust storm events." (id., 3-14) The applicability of these studies is limited. EPA staff concludes, "Effect estimates for PM10-2.5 were larger in the eastern U.S. than the western U.S., though this difference was not statistically significant (Peng et al., 2008)." (id. P. 3-13).

Given these and other factors, EPA concludes, "Although new studies have become available since the last review and have expanded our understanding of the association between PM10-2.5 and adverse health effects (see above and U.S. EPA, 2009a, Chapter 6), important uncertainties remain." (id, p. 3-15)

As a result, EPA can only "suggest" a causal link between the presence of rural dust and possible short-term health effects. It also admits that the evidence is "inconclusive" with respect to long-term health effects of dust in rural areas.

There are economic consequences associated with not being able to meet ambient air quality standards. An example will illustrate this point. My fellow Farm Bureau President from Arizona, Kevin Rogers, farms near Phoenix, which has not been able to meet current PM10 standards for several years. Part of the reason for being in non-attainment are the huge dust clouds that sweep down from the desert and blow through the Phoenix area. In the past three months, there have been four such naturally occurring storms.

As a result, the state developed the Governor's Agricultural Best Management Practices Committee to develop a general coarse PM permit to include controls on agricultural practices. The committee developed best management practices (BMP) in three different categories, and farmers were required to adopt one BMP in each category. The state law implementing this program was recently amended to require two BMPs from each category. All farmers and ranchers in the non-attainment areas are regulated for farm dust under the Clean Air Act. Farmers and ranchers who choose and accept to perform BMPs are covered under a general air permit. Those farmers and ranchers who do not participate in the BMP program must obtain individual air permits similar to those required of utilities and factories.

BMPs include practices such as: tillage based on soil moisture, not working fields in windy conditions, modifying equipment to prevent PM generation, speed limits on unpaved roads, planting windbreaks and permanent cover crops, to name a few.

Within the past few years, they have seen this program go from requiring one BMP per category to two for participating producers. EPA and the state say that more is needed. EPA is currently pushing for mandatory restrictions against working in fields when the wind reaches a certain speed. All of these activities have economic consequences attached to them and place restrictions on farming operations.

The current regulatory climate provides no certainty to farmers, ranchers and rural America. While we applaud the announcement by the EPA Administrator that EPA will not propose revisions to the current PM10 NAAQS, this does not provide rural America with the certainty that it needs to have normal activities free from regulation for naturally occurring dust. An example will illustrate the point.

A recent petition to EPA filed by WildEarth Guardians illustrates the threats farmers and ranchers in the West and Southwest face from the current regulatory scenario for naturally occurring rural dust. The group claims that data shows that certain areas are currently in violation of the dust standards, and EPA "must designate" these areas as being in non-attainment. States and local authorities are required to develop and implement plans to reduce dust in these areas. Failure to bring such areas back into compliance can result in loss of federal highway funds, among other consequences.

EPA maintains that its efforts on protection resulting from ambient air quality standards are focused on population centers and not rural areas. Yet, of the 15 areas that WildEarth Guardians claims "must be" declared in violation, nine are in areas where the population is less than 20,000 people. The petition wants EPA to clamp down on dust from Pagosa Springs (pop. 1,591), Alamosa (pop. 9000)), Lamar (pop. 8659) and Parachute (pop. 1006) in Colorado. Other areas in violation include: Deming (pop. 14,116), Sunland Park (pop. 14,106), and Chaparral (pop. 14, 631)in New Mexico. Part of Sweetwater County, Wyoming near Rock Springs (pop. 18,000) and part of Jefferson County, Montana (pop. 11, 406 for the entire county, but near a mine) were also cited. These are hardly the population centers on which EPA says these standards are to focus. The regulations to reduce naturally occurring rural dust to acceptable levels will limit driving on unpaved roads, plowing in fields, and hoping the rain falls and the wind doesn't blow.

The lesson is clear: rural areas are one petition or one lawsuit away from EPA regulation of naturally occurring dust. Only legislation such as H.R. 1633, the Dust Regulation Prevention Act, can provide the certainty that farmers, ranchers and residents of rural areas need to ensure that their normal activities that are essential parts of their operations are not unduly regulated by a standard for which there is no proven benefit to human health. By excluding "nuisance dust" from regulation, the bill allows EPA to continue regulating man-made emissions of particulate matter, while at the same time not trying to regulate natural occurrences. The exclusion focuses EPA attention on things that EPA can control, instead of trying to regulate Arizona dust storms or arid conditions in rural areas.

As I cut soybeans this fall, I wondered like most farmers: How in the world would EPA even begin to regulate the dust flying off my combine? How would the agency prevent dust from flying when I dump my load of corn or beans at the local grain elevator? Fortunately, Administrator Lisa Jackson acknowledged the impracticality of regulating dust and announced there will be no dust regulations on agriculture. But it is truly amazing that a campaign had to be waged to get EPA to finally act. Like President Obama's response on his bus tour last August to the question posed by a fellow Illinois farmer, the administrator's words don't instill tremendous confidence in farmers. Again, that's why we support H.R. 1633.

I look forward to answering your questions.

Statement of the American Farm Bureau Federation

TO THE
HOUSE COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON AGRICULTURE, ENERGY AND TRADE

REGARDING: ADRIFT IN NEW REGULATORY BURDENS AND UNCERTAINTY: A REVIEW OF PROPOSED AND POTENTIAL REGULATIONS ON FAMILY FARMERS

November 17, 2011

Presented by Carl Shaffer
President, Pennsylvania Farm Bureau
Testifying on Behalf of the American Farm Bureau Federation

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Thank you, Chairman Tipton and Ranking Member Critz. I appreciate the opportunity to appear before you today and to provide comments on behalf of the small businesses that comprise the farm and rural family members of Farm Bureau. My name is Carl Shaffer, and I have the privilege of serving on the Board of Directors of the American Farm Bureau Federation and as President of the Pennsylvania Farm Bureau. Farm Bureau represents farms of all sizes, but most farmers today are small family businesses which produce virtually all agricultural commodities grown and sold in our great nation and abroad. I am pleased to offer this testimony on behalf of the Pennsylvania Farm Bureau, as well as the American Farm Bureau Federation and its more than 6.2 million member families.

I own and operate a farm in Columbia County, Pennsylvania where I raise green beans for processing, corn and wheat. As a small businessman, I struggle to keep up with all of the laws and regulations that control how a person operates their business. Of all the departments and regulatory agencies in our federal government, the one that takes the most amount of my time and costs me the most amount of money in productivity is the Environmental Protection Agency (EPA). Per Congress' mandate, farms have always been touched by EPA regulation. However, in the last three years, we have seen an increase in regulations both in their scope and cost, as well as in their lack of transparency. For many, there is a strong perception that EPA begins with a presumption that farming activities are harmful for the environment. We have asked for opportunities to provide meaningful input to the policy development process in order to ensure that regulations for farming businesses are workable both for the businesses and the environment. Thus far, there is apparently little success. The only input we are assured of is during the public comment period, which is required for all federal rulemakings, and at that point, EPA has already made its decisions and is simply going through the legal process to finalize an agenda.

Let me began by saying that many farmers are convinced that EPA's goal is to control how farmers farm. In just the last three years, EPA has set in motion a significant number of new regulations that will significantly change the face of agriculture. The changes I see coming are intended to bring far more mandatory pressures on row crop agriculture and to extend and deepen the reach of mandatory regulation to all of livestock agriculture. I will limit my testimony today to five of the EPA regulatory efforts that threaten the continued operations of family farmers and ranchers. Please understand that this list does not cover the tidal wave of regulatory issues about to crash down on agriculture, but the five issues addressed in the balance of my testimony will be acutely felt by small business entities. They are EPA's:

1. Burdensome, and we believe unlawful, micromanagement of watershed total maximum daily load (TMDL) and implementation plan for the entire Chesapeake Bay Watershed;
2. Proposed rulemaking expanding the scope of the waters federally regulated under the Clean Water Act (CWA);
3. Duplicative and costly Clean Water Act permits for normal pesticide applications;
4. National Ambient Air Quality Standards (NAAQS) for coarse particulate matter, or dust; and
5. Unjustified attempt to collect data from both regulated and unregulated livestock operations under Section 308 of the Clean Water Act.

In contrast to EPA's heavy-handed approach of issuing crushing regulatory burdens, agriculture and the U.S. Department of Agriculture (USDA) have worked together over the last few decades to make enormous strides in agriculture's environmental performance by adopting a range of conservation

practices and environmental measures. We are proud of our accomplishments and believe that our overall environmental footprint is smaller today than 50 years ago. Unlike USDA, EPA is literally piling regulation on top of regulation, and guidance on top of guidance to the point of erecting barriers to economic growth. An excellent example of EPAs' over-reach is the Chesapeake Bay TMDL.

Chesapeake Bay TMDL

The land I farm is in the Chesapeake Bay Watershed upstream from the tidal portions of the Bay and within sight of the Susquehanna River. Right now, the Pennsylvania Department of Environmental Protection (DEP) and Department of Agriculture are scrambling to develop and submit for approval the second iteration of EPA's mandated state implementation plan, the Phase II Watershed Implementation Plan (WIP) for the Chesapeake Bay Watershed. Pennsylvania Farm Bureau has been involved in the WIP process since it first began almost two years ago, and sits on the WIP Management Team, a group of industry, governmental and environmental groups working with DEP officials to provide advice and insight on objectives and actions the commonwealth should pursue to reduce pollution in the Chesapeake Bay Watershed in a manner that is environmentally effective and economically feasible. Unfortunately, EPA does not believe that economic considerations of any kind should be taken into account in developing WIPs, and it has refused to conduct a Use Attainability Analysis. EPA's sole perspective is that it will not approve a WIP unless the submitting state provides "reasonable assurance" that EPA's mandated allocations will be met on EPA's own deadline. Any regulation that is intended to control how I farm my land, without consideration of costs make my work that much more difficult. And imposing regulations, regardless of whether the voluntary approaches Pennsylvania farmers have been using for decades actually work, is a blow to agriculture and small business in our region.

Like other states in the Watershed, our state DEP has been working with more than 150 partners and existing state law to reduce pollution in the Bay, and thus far, we are making steady progress. For decades, farmers in cooperation with DEP have been implementing on-the-ground conservation measures to reduce pollution and preserve our waterways. It is not quick enough for EPA, however, because EPA's TMDL has micromanaged and dictated environmental performance to all states in the Chesapeake Bay Watershed. The EPA TMDL has eliminated the congressionally mandated state-driven implementation process by dictating to states how they will meet the TMDL, what load allocations must be met even at the local and individual source level, and threatened and imposed federal backstops if EPA believed the WIPs failed to provide "reasonable assurance" that the EPA caps will be met on its timeline.

Despite EPA's public statements that the WIP development was a state-driven process, EPA's actions demonstrate that it was an EPA-driven process. For example, DEP and other Bay states were required to submit a draft WIP for approval in an extremely tight deadline with constant technical and modeling delays and errors that resulted in an incredible amount of wasted resources. EPA rejected each and every WIP and informed each state what it would need to do to get a "passing" grade and earn EPA's approval, even for non-point sources that should be completely within a state's authority to regulate. Yet, when our DEP asked EPA for more guidance on whether certain practices would meet EPA expectations and load reduction targets, EPA often provided little information. DEP drafted a WIP without having enough information to know whether its policy decisions would ultimately meet EPA's mandate and improve the environment. On Nov. 8, 2010, Pennsylvania's DEP and Department of Agriculture, under the previous administration of then-Governor Ed Rendell, wrote to EPA stating:

> In general, Pennsylvania is concerned that EPA's approach to the Draft Chesapeake Bay TMDL is neither practical, equitable, nor cost-effective and could reverse progress in meeting our water quality goals.

Now, as DEP is trying to develop the Phase II WIP on a similarly hurried timeframe, it looks as if the process is going to repeat itself. Pennsylvania's DEP is reaching out to the 43 state counties in the Bay Watershed seeking information on workable solutions to reduce nutrient and sediment runoff at the local level – an objective that EPA officially required for the Phase II WIPs. The timeline that Pennsylvania is expected to meet, along with the other Bay states, is quite unreasonably ambitious. The Draft Phase II WIP must be submitted to EPA by Dec. 15, 2011 and the final plan is due by March 30, 2012.

One of the fundamental problems Pennsylvania and other Bay states are facing is that the assumptions that went into the Chesapeake Bay Model are fundamentally wrong. Models are tools that, if done properly, can sometimes be used when actual data is not available. But in the Bay, despite years of efforts, the "model world" lacks a connection to reality, particularly in relation to activities and conditions on the farm. In the short time that I have, I want to focus on the lack of scientific realities specific to Pennsylvania agriculture.

- The Chesapeake Bay TMDL: The TMDL limits the amount of nutrients that regulated Pennsylvania agricultural operations in the Susquehanna River Watershed can deliver to the Bay at 761,488.58 pounds of nitrogen, 18,589.44 pounds of phosphorus, and 2,688,715.58 pounds of sediment. These numbers apply to farms in Pennsylvania, even though the Susquehanna River itself is meeting Pennsylvania water quality standards for nutrients. In other words, even though farmers in Pennsylvania meet state water quality standards, because the Bay is still impaired, we must further reduce nutrient loads.

- Nutrient management plans: EPA assumes that only 47.2 percent of Pennsylvania farms have already adopted nutrient management practices. In its TMDL, EPA requires 85 percent of farms to adopt "enhanced nutrient management practices." However, the 47.2 percent baseline is wrong because all Pennsylvania agriculture operations that generate manure are already subject to nutrient management requirements. The problem is that the Bay Model does not recognize non-cost-shared nutrient management practices, so the model grossly misrepresents the on-the-ground reality of nutrient management on Pennsylvania farms. Pennsylvania's draft WIP pointed out this flaw:

  > A significant number of agricultural and other best management practices that have been implemented in Pennsylvania have not been "tracked" and entered into the Chesapeake Bay Model. A significant level of interest in this deficiency was expressed by Pennsylvania's Agricultural Watershed Implementation Plan workgroup. Pennsylvania pilot project efforts in Lancaster and Bradford counties, as well as preliminary evaluation of data from NASS [National Agricultural Statistics Service] indicates that as much as 84 percent of some implemented BMPs [best management practices] have not been entered into the Bay Model, resulting in potentially significant nutrient and sediment reductions not being accounted for in the reductions attributable to Pennsylvania.

- Manure transport out of the Watershed: EPA's Model assumes that only 57,659 tons of manure are transported from Pennsylvania to locations outside of the Chesapeake Bay Watershed. However, Pennsylvania told EPA in Sept. 2010 that all Chesapeake drainage county conservation districts in Pennsylvania report the export of manure from the county, and 227,527 tons left the Chesapeake Bay Watershed.

- Presumption of "lost" manure: EPA's flawed model assumes that at least 15 percent of all manure at an animal feeding operation production area is simply "lost" and ends up in the waterways. Even though EPA was told that this assumption had no factual support, EPA made no changes.

EPA did not correct these gross discrepancies between its Model and reality and finalized the Chesapeake Bay TMDL in Dec. 2010, knowing full well that it had not properly accounted for agricultural BMPs and was misrepresenting manure management in Pennsylvania and other jurisdictions. Instead, EPA promised to make some changes to land use and nutrient management assumptions in the Chesapeake Bay Model in 2011, in time for the revised model to be used for the Phase II WIPs. However, in the new models (Phase 5.3.2), EPA only changed the number of acres of impervious surface and some nutrient management assumptions. It did not address the lack of credit for non-cost-shared BMPs. It did not address the fact that a single piece of land can utilize multiple BMPs. It did not correctly apply the recommendations of the Agricultural Work Group regarding nutrient management. Nor did it address the 15 percent manure loss assumption that is built into the Model. The Model is still grossly flawed and should not be used as a basis for regulation.

As a result, EPA made its Model worse, not better. EPA again rushed to meet the arbitrary deadline it established for state submission of Phase II WIPs and is again requiring states to take actions to meet load allocations based upon a flawed model that does not reflect reality.

In addition to the flawed assumptions used to develop the Model, the Model's general limitations are coming to light as localities attempting to meet "reasonable assurance" at the local level in Phase II WIPs are facing abnormal and absurd results. For example, when Virginia tried to use EPA's Model to determine how much Charles City County needed to reduce sediment, it found that, while the old Model told them that Charles City County needed to *reduce* sediment by 48 percent, the new Model says that Charles City County could *increase* sediment by 406 percent. Obviously, every state and community or small business in the Bay that has been assigned an allocation and a responsibility under EPA's TMDL is concerned. EPA's refusal to take the time to improve its models, or to reduce its reliance on models, is undermining what little confidence agriculture had in the effort. Worse, EPA's federal TMDL could cause people to spend scarce resources on conservation measures that are directed to the wrong sources or the wrong areas.

Finally, in a meeting with EPA on Sept. 16, 2011, the Watershed jurisdictions unequivocally informed EPA that the Model was unacceptable. As noted by the State of Virginia in a Sept. 28, 2011 letter to EPA summarizing that meeting: "the current Watershed Model is undermining the credibility of our collective efforts." In the Sept. 16, 2011 meeting, concerns were raised by Pennsylvania, Maryland and Virginia. For example, Pennsylvania pointed out that EPA's Model continues to assume inaccurate manure application rates. According to Pennsylvania:

> Within EPA's Model about 50 percent of crop land and 90 percent of all row crops receive manure. USDA's National Agricultural Statistics reports that 24 percent of total harvested cropland receives manure.

Faced with backlash, in a letter dated Oct. 5, 2011, EPA finally admitted that its models could not support allocations below the scale of a major river basin. However, EPA is still demanding Phase II WIPs from states that include a narrative of how the states are to meet those river basin-wide allocations. Also, EPA's letter says nothing about the validity of the thousands of binding load allocations that are already in the Final TMDL. EPA is admitting its Model is unsound, but it has not released the sources listed in the TMDL from federally binding mandates. Finally, in a question-and-answer document issued on Oct. 17, 2011, EPA repeated its threats to take retaliatory action against states if they do not meet EPA's ever-changing expectations. Thus, EPA's mandates continue, even as EPA testifies before Congress that the TMDL is not even a "regulation."

In further followup, on Oct. 17, 2011, EPA also released a plan for responding to the modeling concerns raised by the states. Unfortunately, each concern that involved a change to the Model was pushed back to 2017. The only fix EPA is willing to make before 2017 is the recognition of additional BMPs. In response to concerns about wildly varying loadings resulting from the new Model, EPA suggests that states focus their communication on implementation goals rather than pounds per acre reductions. That advice is difficult to follow when the TMDL specifies specific pounds of reductions for over 488 individual sources and communities with large storm sewer systems, as well as aggregate (by river basin) pounds of reduction to be met by all the animal feeding operations, all the row crop agriculture, all septic systems and smaller municipal storm sewer systems in each river basin. If EPA had merely accepted its limited authority under the Clean Water Act and left implementation up to the states, states and localities could have devised their own plans on how to meet the overall reductions.

Despite this valid criticism, EPA continues with its unlawful and unachievable plan. A news article reporting the previously referenced inconsistencies in Virginia quoted an EPA official dismissing the concerns of local and state governments on modeling data saying, "Use common sense. Let's get on with it." Another EPA official is quoted as saying, "None of this stuff should impede the planning for what everyone knows is needed to be done." Unfortunately, common sense tells us as farmers that ever-shrinking public dollars and hard earned private capital must be applied in a manner to achieve actual and proven water quality improvements, not compliance with a model based on assumptions that puts out inconsistent prescriptions for water health. "Common sense" would be to leave the implementation of a TMDL to the states, where Congress intended.

What does all this mean for the small business, especially the farmer? Billions of dollars can be potentially spent to chase paper compliance with a model that uses faulty assumptions rather than valid and readily available data, and a computer model that shows inconsistencies, as displayed in the Charles City County instance. As taxpayers and citizens, we expect a certain level of confidence in federal regulatory directives, especially ones we believe are illegal in the first place. Before EPA can require states to provide "reasonable assurance" that implementation will lead to achieving EPA's flawed targets, the public must have a minimum level of confidence that regulatory mandates and the billions of dollars spent by taxpayers will achieve the promised results. If the billions are spent, the practices are implemented, and reality proves the modeling projections are wrong, then what? Will family farmers,

other small businesses and communities be expected to spend even more monies and resources to pursue other practices and programs directed through a modified model?

As farmers, business-owners and economic engines of the nation's economy, Farm Bureau members are worried that the private investments they are making to improve water quality, based on the flawed Model, will be for naught and will not be credited to them as individuals or to the agricultural industry.

Finally, one of the reasons Congress entrusted TMDL implementation only to the states is that meeting pollutant reduction goals costs money. EPA has established this TMDL and binding regulatory allocations and timelines *regardless of cost*. Clean Water Act and EPA regulations specifically allow states to consider economic consequences and to modify water quality goals when necessary to avoid substantial economic and social disruption. EPA asserts that the TMDL will restore jobs and help the Chesapeake Bay economy, but it has not provided any data to support these claims. The Chesapeake Bay states, however, estimate that implementation will cost billions of dollars (*e.g.*, $7 billion for Virginia, $3 billion to $6 billion for New York). Farm Bureau believes the TMDL threatens the economic health of businesses, individuals and communities throughout the Chesapeake Bay Watershed without improving the Bay any more than the voluntary state-based efforts in place before the federal takeover.

Waters of the U.S.

On May 2, 2011, the EPA and the U.S. Army Corps of Engineers (the Corps) (collectively, the Agencies) published in the *Federal Register* a "Draft Guidance Regarding Identification of Waters Protected by the Clean Water Act" (Draft Guidance) on the issue of Clean Water Act jurisdiction. As you know, in 2001 and 2007, the U.S. Supreme Court issued two opinions that held that EPA does not have unlimited jurisdiction over water in the Clean Water Act. Despite concerted efforts by environmental activists to get Congress to overturn those court decisions, legislation to do so never even came to a vote in a House committee, and similar legislation died in the Senate after passing the committee on a party-line vote. Now, however, EPA apparently wants to proceed on its own, without any change in the law, and undermine two U.S. Supreme Court decisions that affirmed congressional intent in the law.

The Draft Guidance and its supporting economic analysis fail to explain, consider or analyze all of the implications of the Agencies' regulatory over-reach on other important Clean Water Act programs. The Draft Guidance applied broad jurisdiction principles, such as aggregation of all waters in a watershed and the regulation of agricultural, irrigation and roadside ditches to the entire Clean Water Act. We believe that the Draft Guidance also misconstrues the Supreme Court cases, is inconsistent with the Agencies' regulations and, as the Agencies themselves state, significantly expands federal jurisdiction.

First and foremost, because the Draft Guidance (or any ensuing rule) amends the Agencies' existing regulations by describing new conditions under which the Agencies may assert jurisdiction, it must be undertaken in compliance with the Administrative Procedure Act (APA) and all other mandatory statutory and regulatory requirements, including the Small Business Regulatory Enforcement Fairness Act (SBREFA) and the Regulatory Flexibility Act (RFA).

As an initial step down the path of complying with its statutory and regulatory requirements, EPA held an invitation-only "Waters of the U.S. Small Entities Outreach Meeting" on Oct.12, 2011. At the meeting, EPA outlined the contents of the Draft Guidance issued in May 2011. During the meeting, several of the small business entities questioned EPA's plans to use the Draft Guidance as a basis for a proposed rule. The members specifically asked EPA not to finalize the "overly legalistic" Draft Guidance and, instead, to develop regulatory alternatives that would establish clear and understandable limits on jurisdiction.

Farm Bureau expressed its concerns that EPA must comply with the RFA and SBREFA. EPA began the Oct.12 small business meeting by explaining that it was "not legally required" to comply with the RFA and SBREFA, but that it would nonetheless be conducting a process that would be "indistinguishable" from these laws' requirements. We believe that EPA is wrong on both counts. As explained, the Draft Guidance, if implemented either as "guidance" or as a rule, would have significant impacts on small business interests, and EPA should not be allowed to claim otherwise. Moreover, the process that EPA is currently conducting cannot be legitimately described as indistinguishable from the RFA and SBREFA and, as such, will lead to incomplete and flawed data for the basis of a proposed rule.

The small business representatives expressed the belief that a proposed rulemaking expanding the scope of waters regulated under the Clean Water Act would have direct and significant impacts on small business interests. Contrary to what EPA stated in the Oct. 12 meeting, Farm Bureau believes that compliance with the RFA is not optional. An agency promulgating a rule that has "significant" impact on "small entities" must undertake a number of mandatory steps to ensure that the agency adopts the least burdensome alternative for small business. This assessment of alternatives is at the heart of the RFA and SBREFA. If EPA is moving forward with a rule defining and, as stated, "expanding" the scope of Clean Water Act jurisdiction, then EPA must comply with the RFA and SBREFA requirements. EPA tries to wordsmith its way around the RFA by claiming that any proposed rule revising the definition of "the waters of the United States" would merely have "indirect" effects on small entities, and, thus, it need not comply. But there can be no question that EPA's expansion of the scope of "waters of the United States" subject to Clean Water Act regulation has direct effects not only on regulated entities, but also on the entire nation.

As EPA knows, the scope of Clean Water Act jurisdiction has implications that permeate all sections and programs under the Clean Water Act – Section 303 water quality standards, Section 311 oil spill prevention control and countermeasures, Section 401 water quality certifications, the Section 402 point source permit program (including the just issued pesticide permits and soon-to-be-issued post-construction storm water regulations), and the Section 404 dredge and fill permit program. These programs regulate all sorts of diverse activities across the nation. Now, EPA is expanding the CWA program geographically to cover more areas across the landscape, including ditches, dry washes and desert drainages. As a result, EPA's so-called "definitional changes" that broaden the scope of CWA jurisdiction have direct impacts on anyone whose business relies in some part on the use of land. When public or private property is deemed "waters of the United States" by EPA and the Corps, there are numerous and costly impacts that flow from that determination, from the value of land to restrictions on land use. All of these are felt acutely by small business entities.

In Florida, for example, it is estimated that 40 percent of the value of farm land is directly attributable to future development.[1] Thus, when CWA jurisdiction creates permitting requirements associated with the use of the farm land, the value of the farmland decreases significantly. For farmers and ranchers their land is typically their principal asset, and frequently provides collateral for loans and other capital purchases needed to operate their farm or ranch. EPA's determination that CWA jurisdiction exists over ditches and other features may affect farmers' ability to obtain loans. Farmers have direct experience where banks have called loans or demanded more collateral to secure loans when it turned out that the mortgaged property was subject to CWA regulation.

There is also no question that an assertion of CWA jurisdiction significantly limits the activities farmers, ranchers and landowners can undertake on their land. For example, although normal farming activities are supposed to be exempt from CWA permitting requirements, the Agencies often require permits for changing from one type of farming to another or moving dirt into ditches to allow movement of farm equipment from one field to the next. They have also required a permit for cranberry growers to expand their cranberry bogs, ranchers to convert land to orchards, farmers to build a pond on their property, and dairy farmers to expand forage acres to support their dairy herd.

Realistically, a determination that land contains "waters of the United States" subject to CWA jurisdiction often will cause a project to be modified or even abandoned. Obtaining a Section 404 permit typically takes at least a year, costs hundreds of thousands of dollars and requires the support of expert technical consultants (and often lawyers).[2] For those that have the means to apply for a CWA permit, the regulations also impose certain avoidance, minimization and mitigation requirements.[3] Avoidance requirements, which involve leaving some portion of an area proposed for development in an undisturbed condition, result in a net loss of developable land unless other land is made available for development. The cost of avoidance (*i.e.*, development foregone) averages about $400,000 per acre in Southern California and can be well over $1 million per acre in some cities.[4] In extreme cases, the avoidance requirement can render an entire project infeasible or force the applicant to move the project to another site. In the mining context, for example, if the mineral resource is located in a jurisdictional area, the avoidance requirement may mean that the resource can never be extracted.

Mitigation requirements obligate permittees to undertake costly compensatory actions (*e.g.*, restoration of degraded wetlands or creation of man-made wetlands). To meet the compensatory mitigation requirements, permittees can purchase credits from a mitigation bank. Mitigation bank prices for seasonal wetlands are over $200,000 per acre in the Sacramento region.[5] In a number of Corps districts, there are already limited credits available for third party mitigation, and an increase in jurisdiction will

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[1] Plaintiga, A.J., Lubowski, R.N., and R.N, Stavins, *The Effects of Potential Land Development on Agricultural Land Prices*, 52 Journal of Urban Economics 561, 581 (2002).

[2] *See* David Sunding & David Zilberman, *The Economics of Environmental Regulations by Licensing: An Assessment of Recent Changes to the Wetland Permitting Process*, 42 Nat. Resources J. 59, 74 (2002) (study concluding that the average applicant spent $271,596 ($337,577 in 2011 dollar values) to prepare an individual section 404 permit application and $27,915 ($35,954 in 2011 dollar values) to prepare a nationwide permit application).

[3] In addition, applying for a permit under section 404 of the CWA triggers mandatory consultation with multiple state and federal agencies under, for example, the National Environmental Policy Act, the Endangered Species Act, the National Historic Preservation Act and the CWA. These consultations are often lengthy and burdensome and can, for example, take longer than the time it takes to build a house.

[4] David Sunding, *Review of EPA's Preliminary Economic Analysis of Guidance Clarifying the Scope of CWA Jurisdiction* (July 26, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OW-2011-0409-3514.

[5] *Id.*

lead to great uncertainty about, and possible exhaustion of, available mitigation credits. In such situations, this will certainly drive up mitigation costs and cause increased delays.

Furthermore, once a CWA permit is finally obtained, permittees now face the risk that their permit could be retroactively vetoed by EPA despite compliance with the permit's terms and conditions. The threat of an EPA retroactive veto makes it more difficult for individuals to rely on essential CWA permits when making investment, hiring or development decisions, and proponents must now account for the possibility of losing essential discharge authorization after work on the project has been initiated.[6]

If a landowner proceeds with work in an area designated "waters of the United States" subject to CWA jurisdiction, the Agencies can seek, and the court can impose, civil and even criminal penalties for violating the CWA. Michael and Chantell Sackett, for example, faced fines of up to $37,500 per day for unknowingly beginning construction of their family home on land that EPA claims contains jurisdictional wetlands.[7] Similarly, EPA assessed a $120,000 penalty for an Illinois farm that deposited 3,000 cubic yards of material into two acres of forested wetlands without obtaining a required permit. One rancher in California was required to convey a 300-acre parcel for conservation to settle claims that he plowed 33 acres of vernal pools and swales on his land to prepare it for planting.

In addition to CWA penalties, an assertion that land contains "waters of the United States" subject to CWA jurisdiction exposes project proponents to third-party litigation authorized by the citizen-suit provision of the CWA.

Clean Water Act Section 402 and Pesticide Applications

As this Committee is likely already aware, despite agriculture's efforts, the Supreme Court declined to hear a petition to review the Sixth Circuit's decision in *National Cotton Council v. EPA*, the ruling which invalidated EPA's interpretation that pesticide use in accordance with label restrictions is not a discharge of "pollutant" under the CWA. As a result of the *National Cotton Council v. EPA* decision, the discharge of pesticide from a "point source" to "waters of the United States" is requiring permit coverage, as of Oct. 31, 2011. "Point source" and "waters of the United States" are legal terms of art and a frequent topic of litigation, and the full scope of permit requirements for particular pesticide uses remains unclear after the *National Cotton Council v. EPA* decision.

A significant number of farms and small businesses will be impacted by the federal requirement under which the EPA and delegated states must issue CWA National Pollutant Discharge Elimination System (NPDES) general permits for certain pesticide applications.

EPA recently finalized its Pesticide General Permit (PGP), which will establish a model framework for regulating pesticide discharges under the NPDES program. EPA's PGP will apply in six states (Alaska, Idaho, Mass., N.H., N.M. and Okla.). Pennsylvania and 43 other states have been granted primacy to administer NPDES permitting. Pennsylvania's DEP published its draft rule last Dec., which largely mirrored EPA's draft rule, but thus far, DEP has not finalized the rule.

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[6] David Sunding, *Economic Incentive Effects of EPA's After-the-Fact Veto of a Section 404 Discharge Permit Issued to Arch Coal* (May 30, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OW-2011-0409-3514.
[7] *Sackett v. Envtl. Prot. Agency*, 622 F.3d 1139, 1141 (9th Cir. 2010), *cert. granted*, No. 10-1062 (Jun. 28, 2011).

EPA estimates that this new requirement will affect approximately 365,000 pesticide applicators nationwide that perform 5.6 million pesticide applications annually. It will cost $50 million and require over one million hours per year to implement.

The permit's complex compliance requirements will impose tremendous new burdens on thousands of small businesses, communities, counties, and state and federal agencies legally responsible for pest control, and potentially expose them to legal jeopardy through citizen suits over paperwork violations. Ultimately, the permit could jeopardize jobs, the economy and human health protections across America as regulators and permittees grapple to implement and comply with these permits.

The proposed PGP offers permit coverage for only specific types of pesticide use that EPA believes will result in "unavoidable discharges": (1) aquatic weed and algae control; (2) mosquito and other flying insect pest control; (3) aquatic nuisance animal control; and (4) forest canopy pest control.

Any other regulated pesticide discharges would require coverage under an individual permit. The PGP is stringent, imposing numerous recordkeeping, reporting, and use restrictions on covered pesticide use. Permit requirements can be enforced by EPA or interested citizens through lawsuits in federal court with substantial potential penalties.

The proposed PGP does not offer coverage for agricultural applications (other than weed control in ditches). To date, EPA has not explicitly stated that agricultural pesticide application will require NPDES permit coverage if pesticide falls into waters of the U.S. during application. EPA has stated in the PGP proposal, however, that *any* pesticide use will require an NPDES permit "if those activities will result in point source discharges to waters of the U.S." EPA sought public comment on whether additional pesticide uses should be covered under the PGP and whether the proposed permit conditions were appropriate.

Farm Bureau filed comments with EPA explaining that the CWA does not authorize NPDES permit requirements for agricultural pesticide use and most would run off as agricultural storm water. We further explained that agricultural pesticide use is not subject to NPDES permitting because Congress specifically intended that state and local water quality programs – *not* NPDES permitting – would address any incidental water quality effects of agricultural activities such as pesticide use. Agricultural pesticide discharges are therefore beyond the scope of EPA's NPDES permitting authority.

Moreover, the act of applying for, and obtaining, an NPDES permit will cost farmers dearly, in both the literal and figurative sense. Literally, it will cost growers to hire a consultant to complete the necessary mountain of legal paperwork to apply for the permit. Figuratively, as a permit holder, farmers can be sued. Even if a farmer does not get the permit, a private citizen can sue the state (or federal) government for not requiring that farmer to have a permit. Or, they can sue the farmer for an allegedly unlawful discharge. If, through the course of the legal proceedings, it is determined that a farmer was required to have an NPDES permit, the maximum penalty is $37,500 per day.

Therein lays our main concern: EPA ignored the comments it received from the agriculture community and published a rule that offers no guidance on whether EPA believes farmers are required to have this permit for the traditional, land application of pesticides. Farm Bureau does not believe farmers should need a permit, but EPA's regulatory language is purposefully ambiguous. Now farmers face a daunting choice: to apply for a permit or not?

As referenced earlier, EPA's permits will require paper compliance with little actual improvements to our water. In fact, current programs in Pennsylvania, which are replicated across the nation, do improve water quality and do provide enforcement mechanisms for illegal use and application of pesticides. Under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Pennsylvania Pesticide Control Act, our state requires that any farmer or business must have a Pesticide Applicator's license or certification to purchase restricted use pesticides, let alone apply them. In order to obtain this license, an individual must first study for and pass an exam covering application safety, reading of labels and regulatory requirements. In order to keep a license current, holders must complete a specified number of continuing education requirements every three years. Pennsylvania's process that I just described does improve water quality. Conversely, EPA's process of permit requirements and the ambiguity of the published regulation do nothing but increase costs on farms and businesses and create legal uncertainty for the engines of our economy.

Members of the Committee also need to view this issue in the context of how the agency wants to expand its jurisdiction by "clarifying" what are waters of the U.S. According to EPA, waters of the U.S. include land – ditches, erosion features and low-lying land features that may be dry most of the year but are occasionally wet. Even when these features are dry, they would remain waters of the U.S. according to EPA. So now, under certain circumstances, a farmer who is applying pesticides to dry land could need a Clean Water Act permit. This goes well beyond anything Congress intended in the law and is an example of an agency that needs to be reined in.

I would like to thank the House of Representatives for doing its part to prevent this regulatory pickle farmers now face. Unfortunately, the Senate failed to approve language that EPA helped write which would clarify, in statute, that farmers are not subject these rules. We are hopeful that the Senate will take appropriate action, but we will also say its action cannot come quickly enough.

Dust

Coarse particulate matter ($PM_{10-2.5}$) (including dust) consists of particles between 2.5 and 10 micrometers. $PM_{10-2.5}$is primarily found in rural areas, where it is a part of normal rural life. Most of the $PM_{10-2.5}$ in rural areas consists of crustal and organic materials, which are naturally occurring. Dust can be disturbed by such normal activities as driving on unpaved rural roads, working farm fields with tractors, or moving livestock and is also generated by naturally occurring conditions, such as blowing winds and arid conditions.

Unlike the scientific evidence for $PM_{2.5}$, EPA readily admits that there are considerable uncertainties in the scientific knowledge of possible health impacts of these materials. EPA can only "suggest" that coarse PM causes short-term adverse health effects and admits that any link to long term health impacts is "inconclusive."

$PM_{10-2.5}$ has been subject to EPA regulation for several years, through the promulgation of NAAQS. EPA is in the process of its periodic five-year review of the NAAQS for particulate matter and farm dust. Farm Bureau applauds the recent decision of the administrator to propose that the current standard for coarse PM be retained with no change, a decision that will help to prevent many other rural areas around the country from falling into non-attainment status for dust. It will not, however, help those farmers in Arizona, California, New Mexico and other parts of the West and Southwest whose operations are already regulated because they cannot meet current dust standards.

While the administrator's recent announcement that EPA will not propose revisions to the current standard is welcome news, it does not provide the certainty that farmers and ranchers in rural areas need to keep from having their operations regulated due to naturally occurring dust. A recent petition filed by the WildEarth Guardians illustrates the point.

The group claims that data shows that certain areas are currently in violation of the dust standards, and EPA "must designate" these areas as being in non-attainment. States and local authorities are required to develop and implement plans to reduce dust in these areas. Failure to bring such areas back into compliance can result in loss of federal highway funds, among other consequences.

EPA has repeatedly said that the purpose of the ambient air quality standards is to protect public health, primarily in population centers. Yet, of the 15 areas that WildEarth Guardians claims "must be" declared in violation, nine are in areas where the population is less than 20,000 people. The petition demands EPA clamp down on dust from such areas as Pagosa Springs (pop. 1,591), Alamosa (pop. 9,000), Lamar (pop. 8,659) and Parachute (pop. 1,006), all in Colorado. Several other rural areas in New Mexico, Montana and Wyoming are also included in the petition.

Only legislation such as H.R. 1633, the *Farm Dust Regulation Prevention Act of 2011*, can provide the certainty that farmers, ranchers and residents of rural areas need to ensure that their normal activities that are essential parts of their operations are not unduly regulated by a standard for which there are no proven benefits for human health.

Section 308 CAFO Reporting Rule

On Oct. 21, 2011, EPA published an Information Collection Request (ICR) and a proposed NPDES Concentrated Animal Feeding Operation (CAFO) Reporting Rule in the *Federal Register* (76 *Fed. Reg.* 65431). Among the information EPA is proposing to require CAFOs to submit under Section 308 is the location of the production area, either by street address or by latitude and longitude. Section 308(b) requires that information obtained by EPA under that section "shall be made available to the public." This is a huge concern for farmers and ranchers because unlike most factories, most farmers and their families live on their farms and ranches. Therefore, this type of information, if made public by EPA, could have significant security and privacy issues associated with it.

In addition to the facility location information, EPA is proposing to require CAFOs to report contact information, NPDES permit information, information on the type and number of animals at a CAFO, and information on acres available for land application of manure. EPA has not demonstrated that collecting such information from all CAFOs is necessary or of practical utility. In particular, EPA has not demonstrated any necessity for obtaining information from CAFOs that do not discharge.

Under Section 308 of the CWA, EPA has the authority to collect information from point sources whenever required to carry out an objective of the CWA, including the development and enforcement of effluent limitations. However, the CAFO effluent limitations have already been established, and this blanket information request appears to be driven solely by a desire to have a national inventory of production agriculture in order to further EPA's goal of micromanaging and issuing regulations telling farms how to operate.

It is not surprising that EPA has made no effort to support the proposition that collecting information from entities that do not discharge is necessary to carry out the CWA. Courts have repeatedly held that EPA has no CWA permit authority over non-dischargers.[8] Thus, there is no credible argument that obtaining information from non-dischargers is necessary for EPA to carry out its functions under the CWA.

EPA's proposed CAFO Reporting Rule will subject thousands of farmers across the United States to the risk of $37,500 a day penalties for failing to meet an obligation which they know nothing about. When all of the unnecessary costs are added to the security and privacy concerns and the lack of demonstrated necessity, one must conclude that EPA is on a fishing expedition that will be at the expense of farmers and ranchers.

Conclusion

The overwhelming number of proposed regulations on the nation's food system is unprecedented and promises profound effects on both the structure and competitiveness of all agriculture. The trend of the past three years has been toward greater EPA regulatory control over agriculture. It should surprise no one that regulatory compliance drives the need for significant investment. EPA proposals are overwhelming to farmers and ranchers and are creating a cascade of costly requirements that are likely to drive individual farmers to the tipping point. In addition to driving up the cost of producing food, fiber and fuel, these proposals highlight EPA's goal of controlling land use and water supplies. In many cases, the regulations bring with them citizen suit enforcement and judicial review of individual farming practices.

Mr. Chairman and Ranking Member, I commend you for convening this hearing and for all your hard work on behalf of agriculture across the country. I will be pleased to respond to questions.

[8] *National Pork Producers Council v. EPA*, 635 F.3d 738, 751 (5th Cir. 2011) ("[T]here must be an actual discharge into navigable waters to trigger the CWA's requirements and the EPA's authority."); *Service Oil, Inc. v. Environmental Protection Agency*, 590 F.3d 545, 550 (8th Cir. 2009) (holding that EPA had no authority to impose a penalty for a violation of Section 308 before the facility discharges any pollutants).

Testimony of

Ray Vester

On behalf of
The U.S. Rice Industry

Before the
Committee on Small Business
Subcommittee on Agriculture, Energy and Trade
U.S. House of Representatives
Washington, DC
November 17, 2011

Introduction

Mr. Chairman, ranking member, and other members of the subcommittee, I appreciate the opportunity to appear before the House Small Business Subcommittee on Agriculture, Energy and Trade to discuss important regulatory issues facing rice farmers and others in the agricultural industry. My name is Ray Vester and I am a rice producer from Stuttgart, Arkansas and Chairman of the USA Rice Federation's Environmental Regulatory Subcommittee which oversees work on environmental and regulatory issues facing rice farmers.

The USA Rice Federation (USA Rice) is the global advocate for all segments of the U.S. rice industry with a mission to promote and protect the interests of producers, millers, merchants and allied businesses. USA Rice members are active in all major rice-producing states: Arkansas, California, Florida, Louisiana, Mississippi, Missouri and Texas. The USA Rice Producers' Group, USA Rice Council, USA Rice Merchants' Association and the USA Rice Millers' Association are members of the USA Rice Federation.

Rice Industry Overview

Rice is planted on an average of three million acres annually located on approximately 9,000 farms in 10 states: Arkansas, California, Louisiana, Mississippi, Missouri, and Texas as well as Florida, Illinois, Kentucky, and Tennessee. The U.S. rice industry is unique in its ability to produce all types of rice, from long grain, medium grain, and short grain, to aromatic and specialty varieties. Rice production, milling, marketing, and allied segments in the U.S. generate $34 billion in economic activity, and contribute to 128,000 jobs, many of which are critical to the

economic health of rural communities. The U.S. rice industry produces more than 20 billion pounds of rice each year, approximately half of which supplies the domestic market and half is exported. Although the U.S. produces less than two percent of the world's rice, it ranks among the top four rice exporting nations.

Rice is vitally important to food security for the nation and the rest of the world. To meet the increasing demand for rice and compete in the global market, rice growers must implement effective pest management strategies. Insect pests attack all portions of the rice plant and all stages of plant growth. These insect pests include: (1) root feeders, (2) stem borers, (3) leafhoppers and plant hoppers, (4) defoliators, and (5) grain sucking insects. Some insects vector diseases that impact yield or create injury sites that allow colonization of diseases at the feeding site. The most common diseases that impact rice include sheath blight, rice blast, and kernel smut. These diseases occur during the reproductive growth stage and must be controlled with fungicides applied during this time. Weed control is critical to producing rice. While the shallow flood does serve to reduce weed infestations, this is not adequate alone. There are several weed pests that grow and thrive in rice production and while flooded conditions inhibit some weed species, these conditions tend to promote others. In the U.S., approximately 30 percent of the rice crop is lost annually to pests, but this would inflate to 50-100 percent of the crop lost without post-flood pesticide applications. Hence, controlling pests through proper use of pesticides is important to ensuring optimum production and efficiency.

The production cycle of rice is 115-160 days (February to November) depending upon region, variety and planting date. The harvest season also varies by region.

Rice is produced in either a water-seeded culture, in which a shallow flood is maintained from seeding until maturity or in a dry-seeded culture, in which a flood is established at about the 4-5 leaf growth stage and maintained until maturity. Many fields are shaped to a uniform grade to facilitate efficient flood irrigation and field drainage prior to harvest. Either before or after planting, levee (soil berms) locations are laser surveyed and marked at set elevation intervals. The levees are established on the contour, except where precision leveling has been conducted to facilitate straight levees.

National Pollutant Discharge Elimination System Permit

When the U.S. Environmental Protection Agency (USEPA) first announced their plans to create a National Pollutant Discharge Elimination System (NPDES) permit for pesticide use in water, there was confusion within the agency as to how rice is grown. Thus began a long process of trying to educate agency staff within the Office of Water about modern rice farming practices to ensure that rice farming was not included in the permit despite being statutorily exempt under the Irrigation Return Flows[1] section of the Clean Water Act (CWA).

Plant protectants are usually applied in-season based on integrated pest management programs although there are some pre-plant options. These applications are outside the regulatory authority

[1] Clean Water Act exemptions for irrigation return flow and agricultural stormwater runoff, which are excluded from the definition of a point source under Section 502(14) of the CWA and do not require NPDES permit coverage.

of EPA. To be subject to NPDES permitting programs, a site must discharge a pollutant through a point source to a water of the U.S. Rice fields; however, are not waters of the U.S. Therefore, pesticide applications to rice fields do not result in any "discharge into waters of the U.S." Finally, water leaving rice fields is considered either an irrigation return flow or agricultural stormwater runoff, both of which are excluded from the definition of the term "point source." Accordingly, in our opinion rice growers are not required to obtain NPDES permits under the CWA.

Like many producers, rice farmers utilize ditches to drain water from their fields. These ditches are not relatively permanent bodies of water. They hold water when they are being used to drain agricultural stormwater or irrigation return flows. Some of these ditches may be connected to a river or stream or may be connected to irrigation canals that may be connected to a river or stream. Other ditches drain water to an on-site pond or reservoir and the water does not leave the rice farmer's property. These ditches must be maintained to provide adequate drainage capacity and functionality. Frequently, ditch maintenance will involve mechanical removal of weeds or the use of herbicides when the ditches are dry. Occasionally, weeds may be controlled when the ditches contain some water. In the Draft NPDES Permit, EPA appears to recognize that dry ditches are not waters of the U.S.

However, the Draft NPDES Permit was ambiguous about the regulatory status of ditches when they are wet or being used for drainage. Even if water is present in a drainage ditch, it is not a water of the U.S. and the use of herbicides in those ditches is not regulated under the CWA which the Supreme Court noted in their *Rapanos* decision. Even USEPA recognized both in 2002 and 2006 that these ditches are conveyances that have been excluded by Congress from the definition of point source under the CWA. But now with the new permit we are faced with uncertainty about whether or not our ditches are going to be regulated as waters of the U.S. and need a permit for weed control.

Adding to our concerns are the citizen suit provisions of the CWA. These provisions have been misused before by groups threatening legal action against even legally permitted businesses. Most rice producers will have limited resources to respond to, much less fight, an onslaught of litigation brought about by the expansion of the NPDES program to farming. Nothing in the CWA or the permit protects *against* citizen suits aimed at farmers or terrestrial applicators for not obtaining a permit. This establishes an uncertain liability for farmers. In addition, in the Draft NPDES Permit, USEPA attempted to micromanage pesticide applications by using language that will leave producers and applicators open to lawsuits. For example, the agency stated that an entity must use the "lowest effective amount" based on an "optimum frequency" that will "deliver the precise quantity of pesticide needed to achieve the greatest efficacy against the target pest." Without defining these terms they leave it open to interpretations in court.

It's also important to note that registration and labeling of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires that EPA ensure that the use of a pesticide result in 'no unreasonable adverse effect' to humans or the environment, including water quality, and labels are crafted to minimize impacts. For farmers and applicators, the FIFRA label is the law: users who do not follow the label are in violation of federal law. This simple requirement to read and follow the individual labels of each pesticide product makes

compliance for farmers and applicators fall within a reasonable burden and cost. When concerns are noted with a pesticide product, the label can be changed to reflect any new data. When someone violates the label, they can be held accountable under the law. Permits have not been needed for this in the past and are not needed now.

Adding this permit program over top of our existing, protective regulations will not enhance human and environmental protection. It will add paperwork and fees to farming thereby reducing resources that can better be focused on efficiently producing crops. This is a paperwork exercise, pure and simple, but one which will add costs and delays to a program that currently works.

Make no mistake; permits granted under the CWA do not prevent discharges into our waterways. The NPDES is in fact a permit to discharge. In the case of pesticides, it's a permit to discharge an approved product that is already evaluated and regulated by EPA for use in, and impacts to, water. To my knowledge no other permitted discharge is double regulated by EPA.

Furthermore, in the delegated states (those states that have been delegated authority from EPA to run their own water permit programs) confusion has been created over which agency should run this new NPDES program (normally run by an environmental agency) for agriculture (normally overseen by an "ag" department). The permits these states have now are based on the draft Federal permit because EPA delivered their Final Permit on the court-ordered deadline date; too late for states to make significant changes. In addition the endangered species consultation requirements from the Federal wildlife services were not properly vetted in public so there has been confusion in some rice states as to their responsibility to include Federal endangered species permit requirements. Added to these issues of course are the additional costs involved to designing and running a new permit program that will in some respects re-regulate existing Federal and State pesticide programs.

Lastly I would like to point out that when a pest is discovered in a field or irrigation conveyance, the opportunity to successfully control that pest is often very limited by time and weather. But in the Draft NPDES Permit, EPA proposed to allow pesticide applications only when "pest conditions can no longer be tolerated." Micromanagement at this level but without clear policy may delay necessary applications and is inviting outside parties to interpret the meaning and place their own judgment above that of the farmer and applicator in a lawsuit. Adding a cumbersome paperwork procedure such as this permit into the system will cause delays in responding to pests.

Rural Dust Issues
EPA has been considering a change in both the format and stringency of the Coarse Particulate Matter (coarse PM) National Ambient Air Quality Standards (NAAQS).

EPA has discussed a possible change in the format of the coarse PM NAAQS from a PM10, 24-hour average of 150 microgram per cubic meter (µg/m3) format to a PM10 concentration of 85 µg/m3 format.

EPA has evaluated the stringency of the existing and potentially revised NAAQS based only on the limited data provided by the PM10 ambient air monitoring network. Only 12% of the counties in the U.S. have a PM10 monitor and the majority of these monitors are located in urban areas. EPA has not evaluated the stringency of the existing and potentially revised Coarse PM NAAQS in localized areas around fugitive dust sources in rural based operations such as farms and unpaved roads. However, once set, these revised Coarse PM NAAQS-based limits must be met regardless of the cost or availability of technically feasible controls.

If Coarse PM (dust) is regulated at the property line, this can and does impose serious production and economic limits on farms that need to come into compliance with Coarse PM NAAQS, whether those standards are decided by actual air monitors or EPA computer models.

And all this does is regulate rural dust, which are normally heavier particles that settle quickly to the ground after being stirred up. The fact is that in the normal course of producing food for the United States and the world, dust is going to be created no matter how many best management practices are thought up or fines are imposed on producers. Some U.S. farm practices are already regulated by the EPA for such things as wind speeds and direction. Beyond that, farm practices are regulated by the weather. We MUST do certain things at certain times in a certain order to comply with the dictates of Mother Nature. For example, we cannot harvest rice at night to reduce fugitive dust with heavier humidity and moisture precisely because the humidity makes the moisture content of the rice too high to properly harvest the crop and prevent spoilage.

For all intents and purposes, a revised standard as suggested by the agency, which CANNOT be met in rural America, will impose fines, penalties and punishments on producers and others living in rural areas for such things as plowing fields, driving down dirt roads, and livestock moving across dry areas.

Having to comply with an "air permit" will only add to our costs and decrease efficiency or drive more of the producers out of business. It is clear that as more permits, guidance documents, fees, fines and taxes are imposed, small businesses such as family farmers have less capacity to survive and deal with such an expensive and time consuming system. This has been proven time and again in other industries and is being repeated in the agricultural industry.

I thank you for your time, your service, and for inviting me here today to discuss these important issues. I am happy to respond to any questions.

Statement of Leonard Felix

National Agricultural Aviation Association

Before the

House Committee on Small Business
Subcommittee on Agriculture, Energy and Trade

November 17, 2011

Adrift in New Regulatory Burdens and Uncertainty: A Review of Proposed and Potential Regulations on Family Farmers

Chairman Tipton and Subcommittee Members:

My name is Leonard Felix, President of Olathe Spray Service, Inc., headquartered in Olathe, Colorado. For 43 seasons I've been providing pest control services to the citizens, businesses and government of Colorado. I've been asked to testify today on behalf of the National Agricultural Aviation Association on the impacts of EPA's newly-issued pesticide National Pollutant Discharge Elimination System (NPDES) general permit on the aerial application of pesticides. I am glad to provide such comments, and while I'm not a policy expert, I have a first-hand understanding of the burdens this permit will impose on my business, my clients, and others who are similarly situated.

My business is not unlike the 1,600 small-businesses in 46 states that make up the aerial application industry in the United States. Besides me at my business, I have two sons who are also pilots, one mechanic and my daughter-in-law is engaged in bookkeeping. Altogether, there are nine full time employees and six to 10 seasonal workers. The average size of an aerial application business in the U.S. is 2.2 aircraft, and five employees which consist of two pilots—one of which is the owner/operator, a mixer-loader of crop protection products and an office assistant. Despite my business' small size, like most aerial applicators we represent a large and

diverse group of clients. We treat farmland, forest and rangeland pests for private and government clients. We also help treat weeds that threaten water flow in the irrigation canals and diversions of the Uncompahgre Valley Water Users Association in Colorado.

This irrigation association has been serving more than 175,000 acres of Colorado farmland since construction by the Bureau of Reclamation in 1906. Water is collected from the Rocky Mountains near the Continental Divide, down the Gunnison River and then through a 6-mile tunnel into the South Canal, the Uncompahgre River, and through diversions and canals to the rich farmland below. There farmers raise irrigated vegetables, forage, grain crops, orchards, grapes, berries and other specialty crops – and all depend on a steady supply of this essential water. The herbicides we apply keep the water flowing by controlling the reed canarygrass, orchardgrass and other noxious weeds that, left untreated, would choke the many canals and lateral ditches.

Besides these critical irrigation canal treatments, we spray about 60,000 acres of clients' cropland each year for control of weeds, insects and diseases. Plus, we help control mosquitoes for the Grand Valley Pest Control District, Orchard City and Cedaredge Townships, and Gunnison County; we also treat private forests for control of Spruce Budworm and other insects that are destroying forests across the West.

As you can see, we're pretty busy much of the year. It's not uncommon for aerial applicator businesses to have more than 100 clients, we service over 500 yearly. When conditions change quickly or pest emergencies occur, those clients often call at 10 pm or later asking for treatment ASAP. The growing season isn't too long in Colorado, and we have to put in long days. Depending on harvest crews, night applications are often required to protect them and keep up with our customers' and their crops' needs. This pace requires constant attention to the maintenance of our aircraft, frequent calibration of our spray equipment, and safety checks all around. We work to be experts on pesticide FIFRA label requirements and state laws for their use. And when we return from a day's work, it all starts over again after we do the recordkeeping for clients, the state, the FAA, and FIFRA.

Now that I've set the stage, let's add to this scenario an entirely new set of obligations – that of satisfying the new pesticide NPDES permit recently implemented by EPA and states. More than 40 year ago, Congress established FIFRA as the comprehensive pesticide law, and repeatedly passed up opportunities to regulate pesticides under the Clean Water Act. In fact, EPA promulgated a rule in 2006 making it absolutely clear that pesticides applied to waters of the U.S. according to FIFRA are exempt from NPDES permits. Then in 2009, the 6th Circuit Court of Appeals revoked EPA's rule and overturned 40+ years of Congressional intent, requiring hundreds of thousands of pesticide users to also comply with CWA permits.

EPA's pesticide NPDES general permit was implemented October 31 in six states (AK, ID, MA, NH, NM, and OK), but also set the bar for similar permits in Colorado and 43 other states that are authorized to implement their own permits. Colorado's Department of Public Health & Environment (DPHE) administers the Colorado permit on private property; EPA administers their Pesticide General Permit on Federal and Tribal lands. So it will require our compliance with both since we work for all of them. This will be difficult due to the differences in the two permit requirements.

Pesticide NPDES permits are now here – staring us in the face and in the pocketbook. Getting up to speed on them will be a huge challenge. To reduce legal liability, EPA has announced a 120-day phase in period before enforcement begins, and states are generally following suit. But soon, there will be enforcement penalties for a multitude of potential paperwork and performance violations, and activists will be able to challenge operators under the Clean Water Act's citizen suit provisions. The documents permittees file are posted immediately on EPA's website, so activists will be fully armed for legal action whenever they see an opening. Even if you are totally innocent, the costs of defending yourself against a citizen suit can put you out of business, and trigger a cascade of pest control problems down the list of your clients. And it is all unnecessary because FIFRA requires EPA to ensure a pesticide undergo rigorous testing for water safety before it is allowed to be registered for use.

I would also like to describe how the permit's requirements directly affect my work and that of other aerial applicators. Because applicators are generally working as for-hire contractors

for public and private decision-making clients and don't have direct knowledge in advance or authority to control the pest control efforts, EPA has spared applicators a large part of the planning and reporting burdens that government agencies and other large entities must meet. However, there are still unnecessary burdens and problems remaining in the permit to challenge even an experienced crew like mine. And many states are going above and beyond EPA's requirements for water permits.

As part of the permit, there are extensive requirements for documenting maintenance and calibration of our equipment, assessing weather conditions, minimizing spray drift and other off-track movement, site monitoring, and avoiding creeks, ditches and other water bodies that are or could be jurisdictional. Completing these activities is already part and parcel to safety and professionalism in our business, but the permit requires extra documentation of these activities and more with timely records.

For example, failure to properly update these records can be a violation of the permit and result in penalties of up to $37,500 per day and potential citizen suits – *simply over paperwork* that may not have been completed on time because we've been working long hours in the middle of the busy season or a declared pest emergency. Such NPDES records don't add anything to the environmental protections that our professionalism and the FIFRA label builds into every registered pesticide product. They just add costs, time consuming burdens, and open the door for activists to sue using our own information submitted in all the reports and records we're required to keep.

So while my sons and I are working to properly apply the pesticide products for our clients, dodge power lines and other obstacles, and keep track of the wind and weather, we now must also worry about taking notes for completing the NPDES permit records later that evening. Long, hard days and risks are part of being pilots, but the burdens and risks of the NPDES permit are something we don't need or want. Our work requires concentration to ensure safety. We need to be well-rested and focused when we start our day. Unnecessary NPDES PGP paperwork is going to add to an already tedious amount of work to our routines.

At the end of the day, the NPDES permit requires aerial applicators to record:

- Each treatment area spray made during the day, including location and size in acres or linear feet of the treatment area;
- The identification of any treated waters, either by name or by location;
- The pesticide use pattern and target pests treated for;
- Documentation of weather condition assessment completed in the treatment area prior to and during application;
- Name of each pesticide product used including the EPA registration number;
- Quantity of each pesticide product applied to each treatment area;
- Other pesticide application details; and
- Whether or not visual monitoring was conducted during pesticide application and/or post application, and if not, why not, and whether any unusual or unexpected effects identified to non-target organisms.

But it gets worse: Applicators may also be considered by EPA to be Decision-makers if they participate in the planning of the pest control process. If that happens, it opens a whole host of additional requirements and exposes applicators and their clients to Joint and Several Liability for any permit violation that may ultimately occur. Applicators who are also a Decision-maker must also:

- Submit a Notice of Intent (NOI) to be covered and wait for coverage while the NOI is considered. This NOI includes the applicator's legal certification that his/her actions, the pesticides applied, and the timing/methods used will not adversely affect endangered and threatened species, or federally-listed critical habitat.
- Develop and maintain an up-to-date, extremely detailed Pesticide Discharge Management Plan that documents all aspects of the pest control plan and activities conducted under that plan;
- Evaluate various pest management options in a manner similar to Integrated Pest Management (IPM), establish action thresholds, and select pesticide use only when other non-chemical methods are dismissed;
- Monitor activities of applicators and revise pest management measures to implement corrective actions for spills, leaks, or otherwise less than optimal applications;

- Conduct surveillance to observe any possible adverse incidents, especially to any endangered or threatened species present;
- Document all aspects of the above with detailed records;
- Provide timely reports of any changes in methods, corrective actions taken, or adverse incidents observed, and annual reports summarizing all activities.

The bottom line is: do all these requirements improve the environment? No! To repeat, it is all unnecessary because FIFRA requires EPA to ensure a pesticide undergo rigorous testing for water safety before it is allowed to be registered for use. Agriculture doesn't need the added burden, states don't want the added expense, and even EPA and a majority in Congress have voiced their opposition to the permits.

There is a solution to this nonsense: enact H.R. 872. Mr. Chairman, I am aware the House has passed this legislation in a bipartisan fashion, and that there are 65 or more Senators willing to support this legislation if it is brought up for a vote in the Senate. We can only hope there is one more vote soon, that of the Senate Majority Leader.

I appreciate the opportunity to represent my company, the Uncompahgre Valley, and the National Agricultural Aviation Association with this testimony. Thank you.

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Statement of CropLife America

Hearing of the Committee on Small Business Subcommittee on Agriculture, Energy and Trade

Adrift in New Regulatory Burdens and Uncertainty: A Review of Proposed and Potential Regulations on Family Farmers

November 17, 2011

CropLife America is the leading trade association representing the U.S. crop protection industry and our members supply virtually all of the crop protection products used by American farmers. CropLife America's member companies, and members of our counterpart association at RISE[1], proudly discover, manufacture, register and distribute crop protection products for American agriculture, and specialty use products such as those used to protect natural resources, public health and safety.

CropLife America members work with farmers, ranchers and growers everyday to ensure that crop protection tools are registered properly and used correctly. As a matter of fact, America's abundant, affordable food supply depends on the availability of safe, effective crop protection products. As U.S. farm exports average approximately $100 billion, a vast majority of that export value is made possible by the benefits of crop protection products. CropLife America members support modern agriculture by looking forward: each year the crop protection industry spends hundreds of millions of dollars on research and development, with much of that investment going into environmental and safety studies that produce data that meets or exceeds the Environmental Protection Agency's (EPA) information requirements for pesticide registration, reregistration and other needs. As such, the crop protection industry must present significant test data of a product's environmental fate, including its breakdown in water, and movement by runoff, leaching and spray drift. All data must be presented to EPA for risk assessment review before the Agency approves product registration.

CropLife America has a long history of working cooperatively with EPA and the U.S. Congress on issues affecting crop protection, natural resource protection, human health and water quality protection. In that spirit, we share the Committees' concerns about the permitting of pesticide applications under the Clean Water Act (CWA).

Never in the 62 years of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), nor during the 38 years of the CWA, has the federal government required a permit to apply pesticides "to, over or near" waters of the U.S. In fact, Congress specifically omitted pesticides in 1972 when it enacted the CWA, and despite major rewrites since, never looked beyond FIFRA for the regulation of the regular, label-approved uses of pesticides. EPA codified decades of federal policy with its 2006 rule exempting certain pesticide applications from the CWA National Pollutant Discharge Elimination System (NPDES) permitting system when used in accordance with the FIFRA product labels.

Nonetheless, last year, the U.S. 6th Circuit Court of Appeals overturned EPA's 2006 rule, determining that NPDES permits are needed for the legal application of such pesticide products. Agriculture and the rest of the pesticide user community are still baffled by the federal government's choice not to more rigorously defend its 2006 rule. CropLife America believes the 6th Circuit got it wrong. The court agreed that pesticides when applied consistent with FIFRA label directions are not pollutants, and, as such, should not require NPDES permits. But, the court went on to rule that any residues that may remain after the beneficial use has been completed are pollutants, and, in order to control those residues, NPDES permits are necessary when the pesticides are initially *applied.*

At the court's direction, EPA has now finalized the NPDES pesticide general permit (PGP). At a minimum, the permit adds performance, recordkeeping and reporting requirements to millions of pesticide applications per year, and preempts the science-based ecological review of pesticides and label requirements for uses regulated under the FIFRA. And, overnight implementation of the permit nearly doubles the population of entities requiring permits under CWA and the burdens state regulators must bear to implement the permits. In

[1] Responsible Industry for a Sound Environment (RISE) – www.pestfacts.org

addition, the financial burdens will dramatically increase for state agencies, local municipalities, recreation, utility rights-of-way, railroads, roads and highways, mosquito control districts, water districts, canals and other water conveyances, commercial applicators, farm, ranches, forestry, scientists, and many, many others. This is an enormous burden—and, still, no one has suggested any credible related human health or environmental benefits that are not already ensured via FIFRA. EPA developed its PGP to cover the pesticide applications to, over or near waters of the U.S. that had been previously exempted from NPDES permitting under its now-vacated 2006 aquatic pesticides rule. Those uses include: (a) mosquito and other flying insect pest control that develop or are present during a portion of their life cycle in or above standing or flowing water; (b) weed and algae pest control in water **and at the water's edge; (c) animal pest control in water and at the water's edge; and (d) forest canopy pest control** where a portion of the pesticide applied will unavoidably be applied over and be deposited into water. EPA has indicated in its Response to Comments (available here) that other pesticide uses not explicitly described in the PGP under these four categories, such as weed control in utility or transportation rights-of-way (ROW) and forest **floor weed control, will also be covered under the "weed and algae pest control" ca**tegory.

The permit threatens the economic survival of applicators nationwide, either due to the cost of obtaining a permit or due to their vulnerability to citizen law suits under CWA. New requirements for monitoring and surveillance, planning, recordkeeping, reporting and the extraordinary measures expected for compliance with the Endangered Species Act create significant delays, costs, reporting burdens and legal risks from citizen suits for hundreds of thousands of newly-minted permit holders without enhancing the environmental protections already provided by FIFRA compliance.

The final PGP was effective immediately upon publication on October 31, 2011. But, to ease compliance burdens for the many thousands of affected parties who needed time to become acquainted with PGP requirements, the agency announced a phase-in period of 120 days (through February 2012) during which it will focus on compliance assistance related to the PGP, rather than enforcement. However, **EPA's announcement does** *not* mean it will not enforce violations, and CWA citizen suits may be filed at any time. Most of the other 44 states have or are expected to similarly phase-in compliance requirements and enforcement of their PGPs. These **other states' PGPs vary widely, from very restric**tive to minimally restrictive, and are in various stages of implementation. More than half of these state PGPs are designed to protect waters of the state, which are generally more expansive (e.g., include groundwater and most surface waters) than federal waters of the U.S.

CropLife America thanks the Committee for understanding the serious nature of this issue. And, we thank the House for so convincingly passing HR 872 that would settle this issue once and for all by exempting pesticide applications from permitting under the Clean Water Act. Now, we continue to push for the Senate to move the **bill's final passage as soon as possible. Along with so many other stakeholders, we believe that Congress must act** to relieve users and regulators of this tremendous duplicative burden, as well provide instruction to the courts and EPA that Congress did not intend other environmental laws to overtake FIFRA.

October 26, 2011

Jenny Thomas
Wetlands Division
Office of Wetlands, Oceans and Watersheds
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Ms. Thomas:

We are writing on behalf of the small entities that are members of the undersigned organizations to request an additional 60 days to provide responses to the Environmental Protection Agency's (EPA) request for information related to participation in the "'Waters of the U.S.' Small Entities Outreach Meeting" on Oct. 12, 2011. At the meeting, EPA outlined the contents of the "Draft Guidance Regarding Identification of Waters Protected by the Clean Water Act" (Draft Guidance) issued in May 2011 and posed specific questions on the implications of the Draft Guidance on small entities. EPA requested a response to those questions by Oct. 26, 2011. Given the complexity of the analysis required to provide a meaningful response, the two weeks provided is not sufficient time to obtain the information requested. In the interim and for the record, we resubmit our comments filed on the Draft Guidance. *See* Waters Advocacy Coalition, *et al.*, Comments in Response to the Environmental Protection Agency's and U.S. Army Corps of Engineers' Draft Guidance on Identifying Waters Protected by the Clean Water Act, Docket No. EPA-HQ-OW-2011-0409-3514 (July 29, 2011), available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OW-2011-0409-3514. In addition, we also write to explain our concerns regarding EPA's current actions.

We appreciate that EPA and the U.S. Army Corps of Engineers (collectively, the Agencies) appear to be undertaking a long-overdue rulemaking to clarify the definition of "waters of the United States" subject to Clean Water Act (CWA) jurisdiction. But that process must comply with the law. We are concerned that EPA is proceeding on this critical issue with undue haste; is not taking the proper steps to ensure a fair and appropriate opportunity for meaningful participation by small business entities and others; and that outcomes have the appearance, if not the reality, of being preordained.

First and foremost, because the Draft Guidance (or any ensuing rule) amends the Agencies' existing regulations by describing new conditions under which the Agencies may assert jurisdiction, it must be undertaken in compliance with the Administrative Procedure Act (APA) and all other mandatory statutory and regulatory requirements, including the Small Business Regulatory Enforcement Fairness Act (SBREFA) and the Regulatory Flexibility Act (RFA). Yet, rather than first solicit input from the general public, scientific communities, federal and state resource agencies, and small entities to determine the appropriate scope of CWA jurisdiction and the range of issues to be covered by any amendment to their existing regulations, the Agencies appear ready to proceed directly to a rulemaking that mirrors the Draft Guidance. Although

many of the 300,000 comments received on the Draft Guidance urged the Agencies to undertake a rulemaking, they did not suggest that the Agencies simply turn the Draft Guidance into a rule, which is what EPA appears to be doing. Such an approach limits the discussion to EPA's predetermined baseline as established in the Draft Guidance and leads to a complete misunderstanding of the real impacts.

Instead, we believe that EPA should conduct legitimate outreach to small entities and the general public across the nation to determine the appropriate scope and content of any rule defining CWA jurisdiction. As EPA has done in numerous other contexts (*e.g.*, development of Plan EJ 2014, EPA's strategy for advancing environmental justice), the Agencies should conduct a series of public outreach sessions in the Midwest, Southeast, West and East to solicit feedback on the issues to be addressed in and the potential scope of a rulemaking. This kind of outreach would enable the Agencies to obtain real examples from the field (as EPA and the Office of Management and Budget (OMB) have requested that we provide) on the implications of any changes to the existing boundaries of CWA jurisdiction.

Only after such full public outreach should the Agencies issue an advance notice of proposed rulemaking (ANPRM) to obtain written input from the general public, the scientific community, and federal and state resource agencies on issues associated with the definition of "waters of the United States." The Agencies should use responses to an ANPRM to determine the issues to be addressed and the substantive approach for a future proposed rulemaking addressing the scope of CWA jurisdiction. EPA is taking a significant risk, and jeopardizing its own rulemaking, by failing to complete these necessary procedural steps.

Contrary to the statements made in the Oct. 12 meeting, EPA must comply with the RFA. The RFA recognizes the economic importance of small businesses and attempts to ensure that regulations be promulgated with these entities in mind. To that end, agencies promulgating a rule that will have a "significant" impact on "small entities" are required to undertake a number of mandatory steps to ensure that the agency adopts the least burdensome alternative for small business. 5 U.S.C. § 605(b).

At the small entity meeting, EPA characterized its small entity outreach as "indistinguishable" from the outreach required by RFA and SBREFA, but that is flatly wrong. To comply with the RFA, EPA must provide a fair and appropriate opportunity for small business entities to participate in this process. The Small Entity Outreach Meeting did not do that. The invitations were limited to only a very few EPA-selected small business entities. In addition, we are aware that other legitimate small business interests that will clearly be impacted requested to be included in the meeting and were rejected due to space constraints, despite the fact that several participants were allowed to participate by phone. Highlighting the fact that the outreach was inadequate are the attendee lists that clearly show that there were more government personnel in attendance than small business entities (including those who participated by phone).

We appreciate that the Agencies finally appear to be undertaking a long-overdue rulemaking to clarify the definition of "waters of the United States" subject to CWA jurisdiction, but that process must comply with the law, and the conclusions should not be foregone. It is critical that the Agencies take the proper steps to ensure that the regulations provide an appropriate and clear definition of "waters of the United States" consistent with the CWA, and the Agencies must provide a fair and appropriate opportunity for meaningful participation by small business entities, and others, in that process.

Thank you for your attention to this matter.

Sincerely,

American Farm Bureau Federation
Associated General Contractors
International Council of Shopping Centers
National Association of Home Builders

One Page Summary
Testimony of Steve Foglesong
Rancher, Black Gold Ranch, Astoria, Illinois

- Despite EPA's recent claim that it intends to propose retaining the current Coarse Particulate Matter Standard, the Agency could finalize a standard that is very different from the proposed standard. This occurred in both the 1996 and 2006 reviews and therefore, their statement is cold comfort to cattle producers.

- Cattle producers affected by the current PM_{10} standard have incurred individual costs of up to $400,000 in a single year, or more than $1,000 per day. Should EPA lower the standard, much of the Midwest, West and Southwest would move into nonattainment or to the brink of nonattainment, which would put many more cattlemen and women across the country in the position of being forced to bear similar costs or go out of business.

- There is no evidence that rural dust is a health concern at ambient levels, and in fact, renowned scientists have shown great concern over EPA's lack of scientific evidence when reviewing the PM coarse standard.

- EPA is inappropriately regulating dust using scientific studies that show adverse health effects that may all be caused by combustion-type, fine PM, and not actually by dust.

- Cattle producers have been fighting this issue for many years, and hope that this Committee and this Congress can bring permanent relief from this standard by passing H.R. 1633, the Farm Dust Regulation Prevention Act.

Testimony of Steve Foglesong
Rancher, Black Gold Ranch, Astoria, Illinois

Good morning Chairman Whitfield, Ranking Member Rush, and Members of the Subcommittee. Thank you for inviting me to testify this morning. My name is Steve Foglesong, I am a rancher and feedlot operator from Astoria, Illinois and the immediate past President of the National Cattlemen's Beef Association. My family and I run cattle full time on our ranch and cattle feeding operation in Illinois and our grazing operation in Georgia.

Anyone who knows anything about cattle ranching and feeding knows that many operations are located in arid climates where the wind blows and dust gets kicked up and virtually all cattle operations experience dry spells from time to time that make dust a part of every day life. Dust also gets kicked up when ranchers and our neighbors drive their pickups on dirt roads, when we plant and harvest hay and crops, and when we round up cattle for branding or to take them to auction.

The idea that the EPA may decide to require me, and other cattle producers in every part of the country, to somehow control that dust makes me lose sleep at night. It would be ridiculous! The fact is, farmers and ranchers like me want and need certainty about this issue. We need to know that the EPA will not be banging down our door telling us to stop making dust or threatening us with a fine

whenever dust gets kicked up. While I, and ranchers across the U.S., are pleased the EPA has decided not to propose to lower the standard this year, we can't be 100% sure of the outcome of the rulemaking until it is final. In fact, in 1996 EPA proposed to remove the PM10 24-hour standard altogether, only to bring it back in the final rule. And in 2006, the EPA proposed to exempt agriculture dust. That exemption also disappeared in the final rule. In addition, even if the EPA retains the current dust standard, the opportunity remains for the agency to tighten it in the future. That reality will remain a threat unless Congress passes the Farm Dust Regulation Prevention Act which would prevent the EPA from regulating farm dust if it is regulated at the state and local levels of government. Passage of this important legislation would give us the certainty we need to do our jobs of providing delicious, nutritious, safe and affordable beef for families to enjoy around the world without having the threat of unreasonable dust regulations hanging over our heads.

Cattle Operations and Dust

Now, I know that the EPA currently regulates dust. The current regulation doesn't affect my ranch, but it does affect other cattle operations. These operations have found it to be very difficult and expensive to comply.

In fact, in 2009, one cattle operation located in a dust nonattainment area in Arizona spent $400,000 to comply with the current standard. $400,000 in one year! That's over $1,000 per day just to reduce dust. Most of the cost is associated with sprinkling water on cattle pens.

And, that is just the current standard; just think about how much it would cost if the EPA were to lower the standard in the future? If that happens, the simple fact is that many farms and ranches may be forced out of business.

Ranchers have been concerned about that possibility for many years, but most recently the fear surfaced when EPA revealed it was considering making the dust standard essentially TWICE as stringent as the current standard during the current consideration of the PM10 NAAQS (National Ambient Air Quality Standards). NCBA and the Coarse Particulate Matter Coalition commissioned a study on the impact of the possible new dust regulation on rural America. The study determined that vast areas of the Midwest, Southwest, and Western parts of the US would be thrown into nonattainment or to the brink of nonattainment where slight changes in the climate could result in a nonattainment designation.

You can see from the map that this area makes up a large portion of our agricultural land in the US. Those of us in agriculture know that dust is a normal part of our lives. Dust *regulation* by the federal government should not be.

Regulatory uncertainty is unnecessary and unproductive. If EPA follows through with its announcement and does not revise the dust standard such a decision would only provide us with certainty for five years, and provides no relief to those producers who are spending over $1,000 per day on dust control measures right now! We need immediate, permanent relief from dust regulation on farms.

I've heard a lot of cussing from cattle producers about EPA regulations, but with dust regulations this swearing is more colorful than usual. The general feeling is that the EPA has lost its way and is out of control.

The Science

It would be one thing if there were a good reason to regulate farm dust, but there is not!

The regulation of dust under the Clean Air Act is supposed to be based on a finding by scientists of adverse health effects. Historically, there has been no evidence of adverse health effects from dust at ambient levels. But, EPA has decided to regulate it anyway. Why? In 2006, EPA based its decision on the precautionary principle. That's right, EPA's dust regulation is not based on science, but on caution. Incredibly, cattle producers are being forced to spend

$400,000 a year to control dust as a precautionary measure, not because there is any real problem.

Let me explain. Particulate Matter (PM) is separated into two distinct sizes and kinds of matter. Fine PM is combustion-derived material in the size range of 2.5 microns and smaller, known as PM2.5. It's like cigarette smoke, for example. We know that causes a problem. Coarse PM or dust, on the other hand, is bigger particles in the size range of 10 microns and smaller down to 2.5 microns, the size of fine PM. PM10 includes both sizes and kinds of particles.

The reason I mention particle size and composition is because, incredibly, the EPA is regulating dust using scientific studies that show adverse health effects that may all be caused by combustion-type, fine PM - not by dust.

The studies EPA reviewed are studies looking at the health effects of PM10 from URBAN areas that are contaminated with combustion-type, fine PM. Any adverse health effects that the studies reveal may well be caused by the fine PM part, not the coarse PM part. Use of these studies to identify health effects for purposes of establishing a coarse PM "dust" standard is inappropriate, especially for rural areas where urban contaminants are not a concern. The few studies that have attempted to take into account the contamination of dust by co-pollutants have shown that the adverse effects of the isolated dust particle are statistically

non-significant. Nevertheless, the EPA uses a single standard to regulate dust in urban and rural areas. This is particularly inappropriate in rural areas, where urban contaminants are not a concern.

The contaminant issue I mention is just one of many problems with EPA's PM10 studies.

Now, I am not a scientist or a medical doctor, but the reason I know all this is because NCBA asked Dr. Jonathan Borak, Clinical Professor of Epidemiology & Public Health at Yale University's School of Medicine, to review EPA's health studies during the current and last reviews. Dr. Borak is a highly respected scientist and, in fact, was a founding member of one of EPA's scientific advisory committees. He found many problems with the studies on which EPA relies and determined that they do not establish a basis for dust regulation. I have attached his comments to my testimony for the record.

EPA Staff Assessment of Policy Options

During the current consideration of the regulation of dust, EPA's staff has determined that, depending on the weight given the substantial uncertainties regarding adverse health effects, the Administrator could justify either retaining the current PM10 standard or revising it to a level that is essentially twice as stringent.

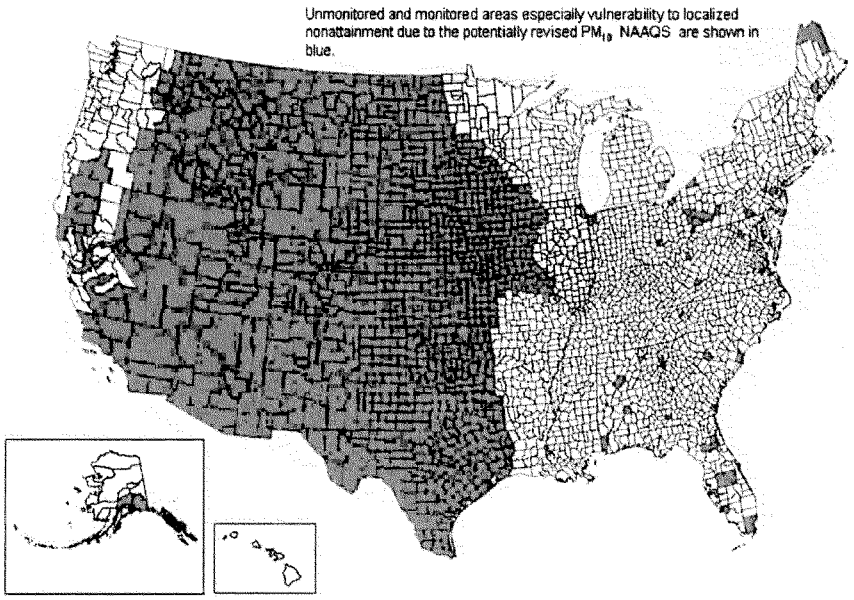
Now, while it would be very good news if the EPA were to finalize a rule that retains the current dust standard, the fact that EPA has considered lowering the standard when the scientific basis is so uncertain is troubling. NCBA is very concerned about the fact that in a few years the EPA may choose to lower the standard and cause great financial harm to our farmers, ranchers and rural communities across America.

The Solution

In an effort to bring a little common sense back into the process, cattlemen believe the best solution is for Congress to pass Representative Kristi Noem's bill, H.R. 1633, the "Farm Dust Regulation Prevention Act of 2011," that would first place a one year moratorium on revising the dust standard, and would prevent the EPA from regulating rural dust where state and local authorities have implemented nuisance dust control measures. If state and local authorities don't control rural dust, the EPA could regulate it only if it made a finding of (1) substantial adverse health effects, and (2) the benefits of regulation outweigh the cost to the regional and local economies.

This is common sense legislation that cattlemen and women strongly support and urge Congress to pass. We thank Representative Noem and the other sponsors of this legislation for their leadership on this important issue. And, we thank you,

Mr. Chairman, and your subcommittee for considering NCBA's testimony on an issue that is critical to cattlemen across the country, and the economic well-being of Rural America.



Areas especially vulnerable to county-wide or localized nonattainment due to the potentially revised NAAQS

JONATHAN BORAK & COMPANY, INC.

Specialists in Occupational & Environmental Health

May 4, 2005

Rogene Henderson, Ph.D.
Chair, Clean Air Scientific Advisory Committee
Lovelace Respiratory Research Institute
2425 Ridgecrest Drive, SE
Albuquerque, NM 87108

Dear Dr. Henderson:

I am writing at the request of the National Cattlemen's Beef Association ("NCBA") in order to share my concerns regarding the scientific basis for the proposed NAAQS for coarse particulate matter ($PM_{10-2.5}$) that is currently under CASAC review. To more properly introduce myself, I have attached a short summary of my experience and qualifications in medicine, epidemiology, toxicology and occupational health science. I currently teach at Yale University.

In reviewing the Criteria Document and the OAQPS Staff Paper (2nd draft), I was struck by the general lack of support for a coarse particulate matter standard. The Staff Paper, for example, acknowledges that there is at best a "limited body of evidence" on the health effects of coarse particulate matter:

> "a growing but still limited body of evidence on health effects associated with thoracic coarse particles from studies that directly use an indicator of $PM_{10-2.5}$." (Staff Paper: 5-58) (emphasis added)

The Staff Paper points to four studies as the principal sources of data linking coarse particulate and morbidity:

> "Three such studies conducted in Toronto (1), Seattle (2,3), and Detroit (4,5) report statistically significant associations between short-term $PM_{10-2.5}$ exposure and respiratory- and cardiac-related hospital admissions, and a fourth study conducted in six U.S. cities (5) reports statistically significant associations with respiratory symptoms in children." (Staff Paper: 5-59)

Exhibit I

234 Church Street, Suite 1100, New Haven, CT 06510 / Telephone (203) 777-6611 / Fax (203) 777-1411

Rogene Henderson, Ph.D.

My concerns about the use of those four studies to justify a $PM_{10-2.5}$ standard are presented below.

My initial concern is that each of these studies was conducted in a location where fine particulate matter ($PM_{2.5}$), rather than coarse particulate matter ($PM_{10-2.5}$) was the predominant form of ambient particulate matter. There should be significant concern about confounding of coarse by fine particulate matter: the well-recognized adverse effects of $PM_{2.5}$ might be wrongly attributed to $PM_{10-2.5}$. Such concern was acknowledged in the Staff Paper:

> "The extent to which the results from these studies are robust to the inclusion of co-pollutants varies depending on the various models used and the number of co-pollutants included in the models. Staff notes that these studies were done in areas in which $PM_{2.5}$, rather than $PM_{10-2.5}$, is the predominant fraction of ambient PM, such that they are not representative of areas with relatively high levels of thoracic coarse particles." (Staff Paper: 5-59) (emphasis added)

Of greater concern is that these four studies contain little if any evidence that $PM_{10-2.5}$ is actually associated with the monitored health effects. The Staff Paper argues that the four studies "in general" do provide such evidence, but particular importance is given to the Detroit study, which Staff judged "strongest of these studies":

> "...staff nonetheless believes that these studies in general, and the Detroit study in particular, do provide evidence of associations between short-term exposures to $PM_{10-2.5}$ and hospital admissions... the Detroit study, which staff judges to be the strongest of these studies, likely reflects exposure levels potentially much higher in the central city area than those reported in that study." Staff Paper: 5-68 (emphasis added)

But review of these reports and their related documentation finds little support for such statements.

The Detroit Study

1) The Detroit study (4,5), which the Staff Paper described as "the strongest", was published by HEI along with a Commentary prepared by the HEI Health Review Committee and an HEI-prepared Synopsis (4). The Commentary and Synopsis disagree with Staff conclusions about the study:

> "...the data do not clearly support a greater effect of one pollutant over another, nor do they establish which pollutants are most likely to cause adverse health effects..." HEI Synopsis

At best, HEI found that the Detroit data provided a rationale to not exclude the possibility that PM_{10} might have an adverse effect ("there may still be a rationale..."), but that finding differs substantially from the Staff Paper conclusion that the Detroit study provided strong "evidence of associations".

> "The finding of elevated and significant effects for $PM_{10-2.5}$ suggests that there may still be a rationale to consider the health effect of the coarse fractions as well as the fine fraction of PM." HEI Synopsis (emphasis added)

Moreover, a 2003 follow-up by Ito, one of the original study authors, re-analyzed the Detroit data by means of different statistical models and affirmed that the study revealed only a lack of specific findings for coarse particulate matter:

> "The conclusions of the original study regarding the lack of relative role of PM by size and chemical characteristics remain the same." (5):152 (emphasis added)

2) In addition to their cautious interpretation of the data, the HEI Health Review Committee raised concerns because the Detroit study analyses were based on comparison of "best lag results", where "best lags" were determined *post hoc* and defined to be those associated with the largest relative risks.

> "The authors' finding of stronger effect for one metric over another was based on a comparison of best lag results. The lag identified as best was chosen after the fact and based on the size of the estimated relative risk." (HEI Commentary: 80).

This statistical approach presents interpretive dilemmas. By selecting lags after the fact and specifically choosing those which yielded largest estimated relative risk, the analyses were inherently biased; i.e., the 'correct' analyses were those that yielded the most significant (positive) effects. Such bias favors the finding of positive associations and disfavors the possibility that significant associations do not exist.

But despite such inherent bias, the observed effects were small. As stressed by the HEI Health Review Committee:

> "Despite using the best lag, most point estimates were similar, and the confidence bands overlapped." (HEI Commentary: 80).

Such findings do not suggest that true effects (if true effects exist) were strong; to the contrary, they raise concerns that the observed effects were due to bias, not to biology and nature. That possibility was specifically addressed by Ito in the 2003 follow-up study, who recognized that the potential magnitude of such biasing:

> "... factors that can change pollution RR estimates ... include the location of monitors, choice of lags, and considerations of distributed lags. These factors can cause differences that vary by up to a factor of two in estimated pollution coefficients." (5): 152

3) The Detroit study was also handicapped because particulate matter data were obtained from ambient monitors in Windsor, Ontario. This poses interpretive difficulties because coarse particulate (e.g., $PM_{10-2.5}$) is expected to deposit more rapidly and more locally than fine particulate. Accordingly, coarse particulate levels in Windsor (several miles from central Detroit) would not necessarily reflect those in Detroit. It is generally accepted that local sources are of particular importance in determining concentrations of coarse particulate (6).

As discussed in the Staff Paper, the study authors indicate that levels measured at the Windsor monitors generally correlated with those from Detroit. However, Staff concluded that $PM_{10-2.5}$ levels were probably much higher in Detroit than in Windsor:

> "In recent years, based on available Windsor and Detroit data from 1999 to 2003, the Windsor monitors used in this study typically have recorded $PM_{10-2.5}$ levels that are generally less than half the levels recorded at urban-center Detroit monitors..." (Staff Paper: 5-68)

Accordingly, the Staff Paper concluded that $PM_{10-2.5}$ exposures in Detroit "may be appreciably higher than what would be estimated using data from the Windsor monitors".

The Criteria Document also addressed concerns about such a lack of spatial uniformity:

> "The degree of spatial uniformity in $PM_{2.5}$ concentrations in urban areas varies across the country. These factors should be considered in using

> data obtained by the $PM_{2.5}$ FRM network to estimate community-scale human exposure, and caution should be exercised in extrapolating conclusions obtained in one urban area to another." (Criteria Document: 3-101) (emphasis added)

The Staff Paper is even more explicit about such concerns:

> "Daily mean $PM_{10-2.5}$ concentrations tend to be more variable and have lower inter-site correlations than $PM_{2.5}$, possibly due to their shorter atmospheric lifetime (travel distances < 1 to 10s of km) and the more sporadic nature of $PM_{10-2.5}$ sources." (Staff Paper: 2-69) (emphasis added)

Thus, assumptions that Windsor PM $_{10-2.5}$ data fairly represent Detroit exposures are at best problematical.

4) The Detroit analytical model incorporated assumptions about correlations between simultaneous measures of coarse particulate and gaseous pollutants. The apparent assumption was that these pollutants had relatively consistent and homogeneous spatial uniformity but, as discussed in the Toronto study (1) (see below), that assumption is not valid. Because there was probably low correlation between $PM_{10-2.5}$ levels measured in Windsor and gaseous pollutant levels measured in Wayne County, the Detroit analyses suffered additional uncertainty.

5) Finally, it is notable that the Detroit analyses considered only one- and two-pollutant models. Notwithstanding the analytical difficulty of more complex analyses, the use of only incomplete models is an important concern. As discussed below, inclusion of multiple gaseous pollutants in the Toronto study (1) analyses eliminated all associations with coarse particulate; it is reasonable to expect that such multi-pollutant analyses would have had similar effects here. Thus, one must be cautious in interpreting the weak associations determined in one- and two-pollutant models as used for Detroit. The HEI Health Research Committee voiced similar concerns:

> "In order to determine the relative effects of several risk factors on a health outcome, ideally all variables under considerations would be included in a single model." (HEI Synopsis: 80)

The Toronto Study

1) The Toronto study (1), published in 1997, did not find statistically significant associations between monitored cardiac and respiratory effects and coarse particulate matter:

> "Particle mass and chemistry could not be identified as an independent risk factor for the exacerbation of cardiorespiratory diseases in this study beyond that attributable to climate and gaseous air pollution." (1)

It is curious that Staff would have cited this study as providing "statistically significant associations between short-term $PM_{10-2.5}$ exposure and respiratory- and cardiac-related hospital admissions" [Staff Paper: 5-59]. To the contrary, this study found no such associations for coarse particulate.

2) In addition, this study provides reasons to doubt the conclusions of the Detroit study. The Toronto study obtained particulate matter data from a monitoring site in downtown Toronto, while gaseous pollutants and COH were measured at several locations including that downtown site. The Toronto researchers noted that spatial correlation was relatively high for fine particulate, but significantly lower for coarse particulate:

> "fine mass and sulfate measurements collected at this site have been shown to be highly correlated ($r > 0.8$) with concentrations over a wide area ... Similar evidence, indicating that a single centrally located site measuring fine particulate matter and sulfates is a reasonable predictor of the average of personal exposures among populations living in urban environments, has been reported for other cities... As expected, the degree of spatial correlation is smallest for coarse particles (r ranges from 0.44 to 0.53)." (1) (emphasis added)

Such relatively poor spatial correlations for coarse particulate underscore the concerns discussed above regarding the use of Windsor $PM_{10-2.5}$ data as a proxy for exposures in Detroit. As spatial correlations for $PM_{10-2.5}$ fall with distance, the uncertainty of analyses based on distant $PM_{10-2.5}$ measures must necessarily increase. Thus the Toronto data make us cautious in interpreting the Detroit findings.

3) The Toronto study differed importantly from the Detroit study in its use of multiple-pollutant models. As increasing numbers of pollutants were included, the effects that might otherwise have been attributed to coarse particulate were eliminated:

> "Even though we could observe statistically significant positive associations for these [fine and coarse] particle measures with health outcomes after controlling for climatic factors, the apparent association disappeared after adjustment for O_3, NO_2, and SO_2." (1) (emphasis added)

Moreover (and not surprisingly), the choice of co-pollutants included in the analysis was important for dealing with the confounding effects of mixed exposures. This pertains to $PM_{10-2.5}$, but was specifically illustrated with respect to PM_{10}:

> "It is recommended that all available air pollution measures be considered in assessing the effects of any single pollutant on health. In our case, for example, TP [PM_{10}] remained a positive and statistically significant predictor for respiratory hospitalizations after adjusting for either O_3, SO_2, or CO separately, an analysis strategy used by many investigators. However, the TP association could be completely explained by NO_2, a risk factor not as widely considered in North American locales as the other criteria pollutants." (1) (emphasis added)

As noted above, similar concerns about one- and two-pollutant models were voiced by the HEI Health Research Committee:

> "In order to determine the relative effects of several risk factors on a health outcome, ideally all variables under considerations would be included in a single model." HEI Synopsis: 80

4) In summary, beyond the important fact that the Toronto study did not find evidence that coarse particulate matter was associated with monitored health effects, the Toronto report presented several methodological bases for questioning the Detroit conclusions. Contrary to descriptions contained in the Staff Paper, this study provided evidence against the adoption of a coarse particulate matter standard.

The Seattle Study

1) The most striking feature of the Seattle study (2,3) is its paucity of empirical data: "Numerous missing PM measurements (see Table 1) potentially limit our analysis" (2). That table, which documents the remarkable extent of missing data, is summarized in a table on the next page.

As can be seen, there were hardly any data for fine particulate matter and there were necessarily still fewer data for coarse particulate, which was calculated as $PM_{10} - PM_{2.5}$.

Rogene Henderson, Ph.D.
May 4, 2005
page 8

Percentage of Missing Particulate Data				
Site	**1st PM Monitoring Year**	**Light Scatter**	**$PM_{2.5}$**	**PM_{10}**
#1	1986	1	72	4
#2	1989	9	81	31
#3	1989	33	100	40

Thus, the Seattle study is largely a theoretical exercise based on imputed data:

> "Our final analyses (and all PM and SO_2 results reported herein) were based on combining the estimates from the six imputed datasets." (2)

2) The Seattle study does not describe specific models used to impute missing data, instead citing only generic discussions. Further, the authors indicate that "six multiple imputation datasets" were created, but the differences among them were not described. In addition, analyses were performed on the "average" values derived from those six datasets, not on each of the individual datasets:

> "For exploratory analyses and model development, we used the average of the six multiple imputation datasets as our exposure data." (2)

No explanation or justification is provided for using an average of the theoretical datasets, rather than considering each dataset separately. The latter approach would have provided insight into the variability among imputation models, while the use of averaging concealed such variability. Averaging also compressed the data, reducing the significance of excursion events while accentuating the significance of mean exposures. Such an approach might be justified if the critical variable was cumulative exposure, but would likely distort results related to peak effects. The significance of such distortions was not considered in the study or in the Staff Paper.

3) Although the report presented only those effects that were statistically most significant, the magnitudes of the reported effects were small. In a follow-up study, Sheppard (3) expressed concern that in light of such small observed effects, bias due to "model selection" and other "computational details" might have resulted in overly "optimistic" study findings:

> "Results of this analysis may be optimistic due to a model selection bias because the most statistically significant effects among three (and up to seven) models were reported for each pollutant." (3)

It is interesting to note the underlying bias revealed by that comment. The Seattle researchers were apparently so inclined to find that coarse particulate matter was significantly harmful that out of 'optimism' they may have wrongly linked coarse particulate matter with disease. At an individual researcher level, such 'optimism bias' might be the equivalent of the more familiar 'publication bias'. (I am not immune to incentives to 'discover and publish', but I would more likely feel 'optimistic' by findings that common, naturally occurring and not readily avoidable exposures were not adverse).

The possibility of such researcher bias causes particular concern given the subjective nature of the Seattle study data (i.e., multiple imputed datasets created by methods not specifically described) and the fact that results were selectively reported for only the most significant effects.

The Six Cities Study

1) This reanalysis of the data from three longitudinal studies found little association between coarse particulate and monitored health effects (7). The Staff Paper describes the report as documenting "statistically significant associations with respiratory symptoms in children" (Staff Paper: 5-59), but that conclusion is misleading. The study actually found that, with one exception, coarse particulates were not associated with respiratory symptoms:

> "For lower respiratory symptoms, the association was stronger for all of the fine-particle measures than for CM [$PM_{10-2.5}$] in single-pollutant regressions. A model including both CM and $PM_{2.5}$ resulted in a substantial reduction in the effect of CM, with little evidence that the remaining effect was different from zero." (7)

2) The only apparent association between coarse particulate and monitored health effects involved cough:

> "Cough in the absence of any other symptoms was the only response in which coarse particles appeared to contribute to an adverse health effect... This coarse particle effect may be due to particle deposition and irritation in the upper airways." (7)

The importance of this finding of probably minimal clinical significance is unclear. It is certainly less important than the effects associated in this study with fine particulate matter exposure:

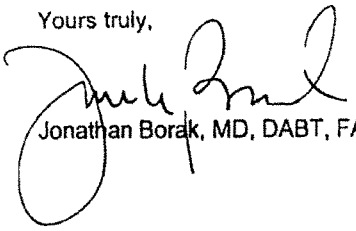
> "In summary, toxicologic and epidemiologic studies indicate that ambient toxic particles are primarily in the fine-particle fraction..." (7)

Summary

My review of these four studies finds a general lack of scientific support for a proposed NAAQS for $PM_{10-2.5}$.

Moreover, I find little justification for the Staff Paper statements that these four studies provide, either in general, or in particular, adequate scientific evidence requisite or necessary to support the adoption of a coarse PM standard.

Yours truly,



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Specialists in Occupational & Environmental Health

August 10, 2005

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Dear Dr. Henderson:

I am writing at the request of the National Cattlemen's Beef Association ("NCBA") in order to express my concerns regarding the scientific basis for the proposed NAAQS for coarse particulate matter ($PM_{10-2.5}$) that is currently under CASAC review. In an earlier letter (dated May 4, 2005), I shared related concerns about the OAQPS Staff Paper (2nd draft) that was then under CASAC review.

Since May, CASAC published its *Review of the National Ambient Air Quality Standards for Particulate Matter (Second Draft PM Staff Paper, January 2005)* and thereafter EPA published a final *PM Staff Paper* ("SP") (EPA-452/R-05-005, June 2005). As a result, the coarse particulate focus has shifted, with attention now directed to the regulation of "urban coarse particles" as distinguished from "non-urban" and "rural coarse particles".

This standard-setting process has continued despite repeated acknowledgement by EPA staff that there is at best a "limited body of evidence" to support a coarse particulate standard. There is inadequate evidence documenting adverse health effects of coarse particulate:

> "a growing, but still limited, body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ as a measure of thoracic coarse particles." (SP: 5-47) (emphasis added)

Likewise, there are significant limitations to the epidemiologic support for such a standard:

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> "staff recognizes that the substantial uncertainties associated with the limited available epidemiologic evidence present inherent difficulties in interpreting the evidence for setting appropriate standards..." (SP: 5-52) (emphasis added)
>
> "The available epidemiologic evidence for effects of $PM_{10-2.5}$ exposure is quite limited and is inherently characterized by large uncertainties, reflective in part of the more heterogeneous nature of the spatial distribution and chemical composition of thoracic coarse particles and the more limited and uncertain measurement methods that have generally been used to characterize their ambient concentrations." (SP: 5-53) (emphasis added)

But even these cautionary notes and caveats are insufficient. As discussed below, the studies cited in the SP contain fewer relevant data and a less compelling "body of evidence" about coarse particulate than is claimed in the SP. In the following discussion, I particularly address statements made in section 5.4 of the SP.

Toxicologic evidence

The evidence presented in the SP begins with consideration of "limited toxicologic studies" that evaluated adverse effects of urban road dust. Two specific studies are cited, Kleinman et al (1) and Steerenberg et al (2). In addition, the SP notes that the CD presented "some very limited *in vitro* toxicologic studies" suggesting that coarse particulate "may elicit pro-inflammatory effects."

Kleinman study (1)

1) In this study, SD rats were exposed to resuspended "road dust" particles of undetermined composition with an MMAD of 4 μm: "only 4 μm MMAD particles were tested" (1). Neither the particle size distribution nor the proportions of particles <2.5 μm and >2.5 μm was reported. Accordingly, it is not possible to know whether observed effects were due to fine particulate, coarse particulate, or both. The probable confounding of the coarse fraction by fine road dust particles was noted by the authors:

> "there are small but significant contributions of crustal elements from road dust to the submicrometer particle faction of PM_{10}" (1).

Because this study could not differentiate the putative effects of $PM_{10-2.5}$ from those of $PM_{2.5}$, it is difficult to see its direct relevance to setting a $PM_{10-2.5}$ standard.

2) Additional animals were exposed to submicrometer particles of ammonium sulfate or ammonium nitrate. Sulfate and nitrate were more consistent and more potent in their effects than was road dust:

> The "most consistent effects were observed in rats exposed to ...sulfate and nitrate"; their relative potency was "SO_4^{-2} > NO_3^- > road dust". (1)

Thus, the authors concluded that the effects observed in the study were mainly due to submicrometer PM_{10} components:

> "This study also supports the hypothesis that the fine fraction of PM10 is more toxic than the coarse fraction." (1).

Because the findings attributed to resuspended road dust were relatively weak and inconsistent, it is difficult to see the direct relevance of this study to setting a $PM_{10-2.5}$ standard.

Steerenberg study (2)

1) These authors evaluated the adjuvant activities of five "ambient" particulates (two samples of diesel exhaust, a residual oil fly ash, and two actual ambient dusts) in two allergenicity models (ovalbumin in BALB/c mice and grass pollen in BN rats. Neither of the actual ambient dusts represented $PM_{10-2.5}$. The first (Ottawa dust, EHC-93) had been previously characterized (3); the count median diameter was 0.5-0.6 μm and the MMAD was 3-4 μm. The second (road tunnel dust) was collected by a device that can classify particulate into three size classes: <0.1 μm, 0.1-2.5 μm and 2.5-10 μm (4), but there is no indication that the administered dust was other than <PM_{10}.

We can reasonably expect that diesel and fly ash samples consisted of mainly submicrometer particles. In addition, a substantial proportion of at least one of the ambient dust particles was <2.5 μm and there is no indication that the second ambient dust did not contain a substantial number of particles <2.5 μm. Thus, it is not possible to attribute observed effects to $PM_{10-2.5}$. Because the study did not differentiate between fine and coarse particulate, it is difficult to see the direct relevance of this study to setting a $PM_{10-2.5}$ standard.

2) All five particle types demonstrated adjuvant activity in the ovalbumin model, but only one (a sample of diesel exhaust) had such activity in the pollen model. The authors raise various concerns about the relevance of the ovalbumin model:

> "ovalbumin might not be the most relevant antigen for respiratory allergy in humans to study the effects of air pollution in an animal model ... more realistic antigens for studying the association between air pollution and allergy are pollen grains or house dust mite antigens." (2)

Because the findings attributed to ambient (i.e., road) dust were seen only in the model deemed less "relevant" and less "realistic", it seems inappropriate that staff so strongly embraced this study as directly relevant to setting a $PM_{10-2.5}$ standard.

Epidemiologic evidence

The SP describes three groups of epidemiologic studies. The first group focused mainly on the associations between PM exposure and morbidity. I expressed my concerns about those studies in my letter of May 4, 2005 and my concerns persist unchanged.

The two other groups included studies that considered "mortality associations ... reported ... in areas with relatively high $PM_{10-2.5}$" and studies that considered various outcomes (e.g., hospitalizations, medical visits, mortality) "in areas where PM_{10} is typically dominated by coarse fraction particles". In the following discussion I present my concerns about those cited studies.

Mortality Studies in Areas with Relatively High $PM_{10-2.5}$

The SP cites three studies (six reports) in support of their statement that statistically significant mortality associations were reported in areas with "relatively high $PM_{10-2.5}$ concentrations". I note that the SP does not define or explain the term "relatively high ... concentrations."

Phoenix study

1) The Phoenix study, published originally in 1997 (5) and after statistical reanalysis in 2000 (6), found "marginally significant ($p<0.10$)" associations between $PM_{10-2.5}$ (referred to as PM_{CF}) and total mortality, but there was no significant association between total mortality and $PM_{2.5}$. PM measures were statistically associated with cardiovascular mortality, but that association was

weakest for $PM_{10-2.5}$. In the statistical reanalysis, the strength of marginally significant associations was reduced.

A great number of statistical analyses were performed on a large number of variables under a variety of lag conditions. The scope of these analyses (but not their actual number) is indicated by the authors in the following statement:

> "Summaries of the RR between the exposure variables and both total and cardiovascular mortality are presented in Table 6 and 7, respectively. Because of space limitations, we only present statistically significant ($p<0.05$) and marginally significant ($p<0.10$) results in the tables, although models were run using all of the pollutants listed in Table 5. We evaluated the associations ... using single-pollutant models." (5)

Because Table 5 lists 17 pollutants and because there were at least 5 lag conditions and two mortality categories, I infer that at least 170 analyses were performed. The authors describe no adjustments and express no concerns about the statistical complexity caused by such multiple comparisons (7).

In such a context, even when authors can justify not adjusting for multiple comparisons, it is difficult to support the assumption that "marginal" and "weak" associations (i.e., $p<0.10$) have much statistical meaning. Such concerns are heightened when "marginal" findings are internally inconsistent (i.e., sporadic findings within a data set) and externally inconsistent (i.e., not supported by most other studies and therefore unexpected). This is the case for the Phoenix coarse particulate data.

2) The lack of significant association between $PM_{2.5}$ and total mortality is surprising and difficult to reconcile with the robust associations documented in most studies (and described in the CD). That finding does not seem adequately explained by merely observing that Phoenix $PM_{2.5}$ represented only a minority of total PM_{10}. In other cities where $PM_{10-2.5} > PM_{2.5}$ (e.g., Topeka in the Harvard Six Cities study (8)), the expected positive association between $PM_{2.5}$ and mortality was observed.

Thus, the lack of an association between $PM_{2.5}$ and total mortality in Phoenix raises concerns about the integrity of the database and whether it is appropriate as the basis for generalization.

3) A negative association was found between soil and total mortality, although soil was well correlated with $PM_{10-2.5}$ ($r=0.66$). Similar findings derive from the Factor Analysis, which reported a significant negative association between "fine

soil" and total mortality; there was no significant association between "fine soil" and cardiovascular mortality.

While it is unlikely that exposure to crustal particulate is protective, these findings support the results of other studies (e.g., (9)) that found few or no adverse health effects attributable to coarse crustal particulate.

4) It is unfortunate that this study used only single-pollutant models:

> "We evaluated the associations between total and cardiovascular mortality and the gaseous pollutants, PM mass metrics, and PM composition metrics using single-pollutant models." (5)

In my earlier letter, I discussed (with respect to the Toronto (10) and Detroit (11) studies) the limitations that stem from use of such models. Based on their study, which found that apparent associations with particulates disappeared after adjustment for co-pollutants, Burnett and colleagues recommended that:

> "all available air pollution measures be considered in assessing the effects of any single pollutant on health". (10)

Likewise, the HEI Health Research Committee echoed that recommendation in its comments on the Detroit study:

> "In order to determine the relative effects of several risk factors on a health outcome, ideally all variables under considerations would be included in a single model." HEI Synopsis: 80 in (11)

The use of single-pollutant models limits the meaningfulness of the conclusions drawn from the Phoenix study.

Coachella

1) The SP cites three reports by Ostro and colleagues that evaluated mortality in the Coachella Valley (12-14). The first report considered only PM_{10}, while the subsequent reports considered PM_{10}, $PM_{2.5}$ and $PM_{10-2.5}$. PM_{10} data were available for a 10-year period, but $PM_{2.5}$ data were available for only 2.5 years. Accordingly, the missing $PM_{2.5}$ and $PM_{10-2.5}$ were "estimated" using a predictive function that estimated $PM_{10-2.5}$ as a cubic function of PM_{10}.

Since $PM_{10-2.5}$ was estimated from PM_{10} by means of a formula fitted to the existing data by ordinary least squares, it is not surprising that a high correlation was found between PM_{10} and $PM_{10-2.5}$. But there was such poor fit for $PM_{2.5}$ data that the authors concluded that "predictive models could not be successfully estimated" (14).

It is disturbing that this study relied on estimated data that could not fit the expected simple relationship: $PM_{10-2.5} = PM_{10} - PM_{2.5}$. I presume that this reflects a decision to derive a best fit equation for only the relationship between $PM_{10-2.5}$ and PM_{10}, rather than finding the best fit to simultaneously predict both $PM_{10-2.5}$ and $PM_{2.5}$. Regardless of the correlation reported, it is difficult to accept that the predictive equation truthfully reflects the nature of PM in the Coachella Valley.

In turn, inferences drawn from these estimated data should be viewed with skepticism.

2) The above concerns about the estimated coarse particulate data also raise concerns about the precision of the Coachella Valley effects data and their appropriateness for quantitative risk assessment. The SP established a criterion ("rough indicator of ... precision") for deciding whether studies effects data were sufficiently precise to be used in quantitative estimates of exposure-response relationships:

> "The natural logarithm of the mortality-days (a product of each city's daily mortality rate and the number of days for which PM data were available) can be used as a rough indicator of the degree of precision of effect estimates ... staff chose to consider only those urban areas in which studies with relatively greater precision were conducted, specifically including studies that have a natural log of mortality-days greater than or equal to 9.0 (i.e., approximately 8,000 deaths) for total non-accidental mortality." (SP, p. 4-6)

Because the Coachella study contained only 2.5 years of $PM_{2.5}$ data and deaths averaged 5.8 per day, the SP excluded this study from quantitative analyses.

Likewise, because there were only 2.5 years of 'real' data for coarse particulate (i.e., measures of $PM_{10-2.5}$ determined literally as the difference between PM_{10} and $PM_{2.5}$), there were too few mortality-days to use the Coachella study for quantitative assessment of exposure-response relationships for coarse particulate.

Rogene Henderson, Ph.D

Six Cities Study

1) The SP cites Steubenville, one of the cities included in the Harvard Six Cities study, as supporting the view that statistically significant mortality associations were reported in areas with "relatively high $PM_{10-2.5}$ concentrations". The study data were originally published in 1996 (8); a statistical reanalysis was published in 2003 (15). The staff view differs from the conclusions of the study authors:

> "The particle associations were specifically with fine particle mass concentrations, with little additional contributions from the coarse particle mass fraction... For the coarse particle mass fraction, the combined effect estimate was weaker, not statistically significant, and inconsistent in the city-specific associations."

2) It is curious that staff put such emphasis on Steubenville, because in the context of estimating exposure-response relationships for $PM_{2.5}$, the SP had earlier discounted the Steubenville data as imprecise:

> "The natural logarithm of the mortality-days (a product of each city's daily mortality rate and the number of days for which PM data were available) can be used as a rough indicator of the degree of precision of effect estimates ... staff chose to consider only those urban areas in which studies with relatively greater precision were conducted, specifically including studies that have a natural log of mortality-days greater than or equal to 9.0 (i.e., approximately 8,000 deaths) for total non-accidental mortality." (SP, p. 4-6)

On the basis of this criterion, Steubenville was excluded from the quantitative analysis.

3) Besides possible imprecision, it is likely that the Steubenville $PM_{10-2.5}$ data were confounded by $PM_{2.5}$.

In five of the six study cities (but not Steubenville), correlations between $PM_{2.5}$ and $PM_{10-2.5}$ were relatively low (0.23-0.45). In Steubenville, however, the correlation was "quite high (0.7)" (8). Furthermore, in ancillary analyses, it was shown that the estimated association with $PM_{10-2.5}$ was explained by $PM_{2.5}$ and that the estimated effect of a given increase in $PM_{10-2.5}$ increased "proportionately with the correlation between $PM_{10-2.5}$ and $PM_{2.5}$" (8).

Thus it seems very likely that the apparent association of mortality and coarse particulate in Steubenville was due to unresolved confounding.

4) It is also noteworthy that in one of the six cities (Topeka) there was a negative association between mortality and $PM_{10-2.5}$ (but not $PM_{2.5}$). Topeka was also the only city for which $PM_{10-2.5}$ levels > $PM_{2.5}$ levels. These findings suggest that in Topeka, a city "subject to windblown dust", coarse particulate was predominantly crustal and therefore associated with a negative exposure-effect relationship. This observation was noted above with reference to the negative mortality association between mortality and soil seen in Phoenix.

Outcomes in Areas where PM_{10} is Dominated by Coarse Particles

The SP cites four studies (five reports) in support of their statement that statistically significant associations were reported for various other health outcomes "in areas where PM_{10} is dominated by coarse particles". I note that the SP does not define or explain the term "dominated by coarse particles."

Tucson study

1) The SP cites a 1997 study of cardiovascular hospitalizations (16) as evidence of adverse health outcomes "in areas where PM_{10} is dominated by coarse particles". However, the study contains no data on ambient levels of $PM_{2.5}$:

> "Unfortunately, no $PM_{2.5}$ data are available in Tucson..." (16).

2) The author notes that in western cities such as Tucson, $PM_{2.5}$ represents a smaller proportion of PM_{10} than in northeast cities:

> "in general, $PM_{2.5}$ is about 50% of PM_{10} in such western locations, vs. about 62% in the northeast." (16)

But in this study the proportion of $PM_{2.5}$ was probably greater than that otherwise expected because the source of PM data was a monitoring station, Garden Grove, that had been selected in part because it was less likely to measure wind blown crustal dust:

> "Several monitoring stations were available in Tucson... most of them were more subject to windblown dust than the Garden Grove station." (17)

3) In addition, the Garden Grove station was "located in a neighborhood site likely to be representative of population exposure" (17). From that, I infer that the station was located in a residential area where PM from domestic and vehicular sources was more likely and crustal coarse PM, as might be associated with arid western dust, less likely. The statement quoted above implies that such exposures are more representative of the sorts of "population exposures" that might be associated with the adverse health outcomes evaluated in the study.

Accordingly, I am cautious to accept the SP conclusion that this study represents an area "where PM_{10} is dominated by coarse particles."

Reno/Sparks study

1) The SP cites a study of hospital admissions for COPD in Reno/Sparks, Nevada (18). But there is no evidence in the study that PM_{10} was "dominated" by $PM_{10-2.5}$. To the contrary, the report contains the following relevant observations:

> a) During the time span of this study, data for $PM_{2.5}$ were not available in this area. Thus, one cannot determine objectively that PM_{10} was "dominated by coarse particles".
>
> b) Higher PM_{10} peaks occurred during the winter season, an observation that the authors propose to be the result of "increased residential combustion due to cold weather in the study area" (18).
>
> c) A negative correlation was found between wind speed and levels of PM_{10}, which suggests that wind blown dust crustal dust was not an important determinant of coarse particulate levels.
>
> d) Levels of PM_{10} were highest on weekdays and lowest on weekends. The authors attribute this difference to reduced weekend vehicular traffic, but they did not differentiate the relative contributions of reentrained road dust vs. vehicular exhaust.

There is apparently no objective evidence in this study that PM_{10} was "dominated" by $PM_{10-2.5}$. Accordingly, it is difficult to see the direct relevance of this study to setting a $PM_{10-2.5}$ standard.

2) It is also notable that this was a relatively small study. The study included 1814 days, but hospital admissions for COPD averaged only 1.72 per day. Applying the "rough indicator of the degree of precision of effect estimates"

described in the SP (p. 4-6) and discussed above, we find that this study does not meet the test. Thus, using staff criteria this study should be regarded as too imprecise to be used for quantitative analyses.

Utah Valley study

1) The SP cites three reports by Pope and colleagues that evaluated respiratory disease and mortality in the Utah Valley (19-21). But there is no evidence in the study that PM_{10} was "dominated" by $PM_{10-2.5}$. To the contrary, the report contains the following relevant observations:

a) Levels of TSP and PM_{10}, but not $PM_{2.5}$ were measured and reported in this study. Thus, one cannot determine objectively that PM_{10} was "dominated by coarse particles".

b) The major sources of PM_{10} in the Utah Valley were combustion-related. Those sources and their proportionate contributions were: steel mill (47-80%); wood burning (~16%); road dust (~11%); diesel fuel and oil combustion (~7%) (19). Accordingly, one would expect that $PM_{2.5}$, not PM_{10} would predominate in the area.

Discussion

The studies cited in the CD and SP raise important concerns about the public health risks of ambient coarse particulates and a number of them lend significant support to a weight-of-evidence assessment of the hazard. Unfortunately, they do not sustain quantitative risk assessment.

For example, even if crustal coarse PM were shown to be inherently harmless, it would be reasonable to suppose that sufficiently high contamination levels could render that particulate toxic. Thus, it is not unreasonable to suggest that urban road dust could be more toxic than wind blown crustal PM. On the other hand, such weight-of-evidence is not sufficient to establish and justify specific exposure standards.

Important data deficiencies currently obstruct the setting of such a standard. It is insufficient to argue on the basis of fine PM studies (e.g., (22)) that significant levels of toxic contaminants can be found in urban coarse PM. It is necessary instead to determine whether and when toxic contaminants achieve levels such that their hazards are more than theoretical. For example, the surface area of a given particulate mass declines exponentially as particle size increases. Thus, for any given mass of PM, one can expect that the dose of adsorbed toxicant

received via inhalation from contaminated particulate will decline rapidly as particulate size increased.

In other words, if crustal coarse particulate is essentially harmless but urban coarse proves harmful at relevant ambient concentrations, then any necessary coarse PM exposure standard developed in response should be focused on those components that make the urban dust harmful (e.g., transition metals; PAHs; latex particles). Whether such standards are set specifically or categorically, they should be derived from toxicologic and epidemiologic studies that consider appropriately sized PM contaminated by well-characterized toxicants. One would also hope that future epidemiologic studies would be of sufficient size and rigor to be acceptable as the basis of quantitative risk assessment. I urge CASAC to lend its full weight to ensure adequate funding is available to support the gathering of further data, and sound research and analysis of the potential health risks from coarse PM that are of concern to it. Such data and research are necessary to determine whether there is a need for a coarse PM to address public health risks at ambient concentrations, and to characterize the indicator and concentration.

Yours truly,

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April 17, 2006

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William Wehrum, Acting Assistant Administrator
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Re: Proposed Coarse PM NAAQS
(Federal Register 71:2620-2708)

Dear Administrator Johnson and Acting Administrator Wehrum:

I have prepared the following comments at the request of the National Cattlemen's Beef Association and the National Mining Association in order to share my concerns about the scientific basis for the proposed NAAQS for coarse particulate matter ($PM_{10-2.5}$) that was recently published in the *Federal Register* (*Fed Reg* 71:2620, 01/17/06).

To introduce myself, I have attached a short summary of my experience and qualifications in medicine, epidemiology, toxicology and occupational health science. I am Associate Clinical Professor of Medicine and Epidemiology & Public Health at Yale University. I teach required graduate courses in both Toxicology and Risk Assessment. I also served for 10 years as a founding member of EPA's National Advisory Committee on Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL).

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Exhibit H

This is the third set of comments that I have submitted on this issue. Twice during the past year, in May and August, I submitted comments to the Clean Air Scientific Advisory Committee. Then as now, my principal concern is the general lack of scientific support for a coarse particulate matter standard and the failure of EPA to appropriately address that deficiency.

Those limitations were acknowledged in various versions of the Staff Paper (e.g., EPA-452/R-05-005, June 2005):

> "a growing, but still limited, body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ as a measure of thoracic coarse particles." (Final Staff Paper: 5-47)

That concern is restated word-for-word in the Proposed Coarse PM NAAQS:

> "In developing this rationale, EPA has taken into account the information available from a growing, but still limited body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ as a measure of thoracic coarse particles." (*Fed Reg* 71:2653)

The Preamble also acknowledges that similar concerns were expressed by the CASAC, which noted:

> "... significant uncertainties resulting from the limited number of studies to date in which $PM_{10-2.5}$ has been measured and the potentially large exposure measurement errors in such studies". (*Fed Reg* 71:2671)

As discussed below, the actual evidence available to support the Proposed Coarse PM NAAQS is substantially more limited than is acknowledged by EPA. The relative insufficiency of evidence linking coarse particulates to human health effects is repeatedly acknowledged in the Proposed Coarse PM NAAQS. For example, consider Section III.A, which describes the Evidence of Health Effects Related to Thoracic Coarse Particle Exposure. In that very important, but relatively short section (it comprises only 10 pages of the Preamble), EPA reiterates 24 times that the evidence linking coarse particulate to health effects is either "limited" or "very limited". By contrast, EPA does not once describe any of the evidence as "sufficient" or "adequate".

Despite that apparent recognition of these limitations, however, EPA presents the actual data from cited studies in a manner that overstates their informational value. More worrisome is the possibility that the Preamble has been constructed in a manner intended to obscure the deficiencies and to minimize objections that might be raised about the lack of scientific justification for the Proposed Coarse PM NAAQS.

1). For example, the Preamble discusses the most important limitations of evidence in a brief section (*Fed Reg* 71:2671-2), distanced from the primary presentation of the cited studies and their data, and relegated mainly to discussion of an "alternative

interpretation" that is strikingly devoid of specific details. Thus, notwithstanding repeated statements about data limitations, many readers will fail to appreciate the actual magnitude of the deficiency of scientific evidence.

a) My concerns are illustrated by the following example. The centerpiece of the presentation of the Evidence of Health Effects is Figure 2 (page 2656), which summarizes the "Effect estimates for associations between short term exposure to $PM_{10-2.5}$ and mortality or morbidity health outcomes ..." The legend to Figure 2 states:

> "for consistency across studies, effect estimates are from single-pollutant, general linear models".

The decision that only data from single-pollutant models would be presented in this centerpiece graphic is at least curious because the compiled literature provides good evidence that single-pollutant models overestimate the effects of coarse particulate. The possibility that such an approach should not be taken, however, is only discussed in the context of the "alternative interpretation":

> "... an alternative interpretation of the available health evidence presented in the Criteria Document and the Staff Paper ... suggests that that the results from one-pollutant $PM_{10-2.5}$ models are confounded by fine particles and gaseous co-pollutants... Taken as a whole, evidence from $PM_{10-2.5}$ epidemiologic studies could be interpreted to suggest that one-pollutant $PM_{10-2.5}$ models suffer from bias due to omitting co-pollutants in the statistical model..." (*Fed Reg* 71: 2671-2)

But even that statement does not reasonably represent the scientific evidence. It implies that this is solely a matter of "interpretation", as though reflective of a philosophical debate. In fact, numerous studies cited in the Proposed Coarse PM NAAQS provide evidence that single-pollutant models overstate the apparent risks of coarse particulate. I am aware of none that proposes the contrary.

For example, consider the Toronto study by Burnett et al. (1), which is cited eight times in the Preamble. That study found that positive associations noted in a single-pollutant model "disappeared after adjustment for O_3, NO_2, and SO_2" (1). But Figure 2 presents only the results of a single-pollutant model from that study, thus wrongly indicating a statistically significant effect of coarse particulate [1]. Or, consider that use of two-

[1] More surprising is footnote #52 (p. 2657), which disclaims the analytical findings of the multiple-pollutant model in Burnett et al. The footnote states that their results "show relatively consistent effects estimates ... except for the models including NO_2 and all four gaseous pollutants". This footnote implies a preference for relying on an incomplete analysis of a complex dataset. Of greater concern is that EPA has apparently discounted the authors' finding that the association "could be completely explained by NO_2, a risk factor not as widely considered in North American locales as the other criteria pollutants" (1). Similar findings and cautionary advice are found in Thurston et al. (12); significant associations with coarse particulates "were merely a statistical by-product of inter-pollutant confounding ... This points out the importance of considering as many pollutants as possible in such analyses, in order to diminish the chances of being misled..."

pollutant models including both $PM_{2.5}$ and $PM_{10-2.5}$ reduced or eliminated the estimated effects of coarse particulate in the Six Cities study (2) and in studies of Detroit (3,4), Los Angeles (5) and eight Canadian cities (6) [2].

I am not alone in pointing to the need to consider multiple-pollutant models in order to correctly understand the effects of coarse particulate. That approach was stressed by the Research Committee of the Health Effects Institute in comments on the Detroit study conducted by Lippmann et al. (3):

> "In order to determine the relative effects of several risk factors on a health outcome, ideally all variables under considerations would be included in a single model."

In the apparent pursuit of "consistency", EPA has selectively presented the least rigorous of the available evidence, thereby minimizing its informational value. Even for those studies which provided results from dual- and/or multiple-pollutant models, EPA has emphasized single-pollutant analyses while discounting the data from more rigorous multi-pollutant analyses. In so doing, EPA has systematically overstated the apparent effects of coarse particulate.

Had EPA correctly acknowledged that the results of single-pollutant models generally overestimate the effects of coarse particulate and that most of the cited studies provided only results of such models, then the even more limited nature of evidence here would have been readily appreciated.

2). Following is another example of the failure to describe and respond to limitations of the evidence presented as justification of the Proposed Coarse PM NAAQS.

In the Final PM Staff Paper (EPA-452/R-05-005, June 2005), EPA Staff described a criterion for deciding whether studies effects data were sufficiently precise to be used in quantitative estimates of exposure-response relationships. In so doing, Staff correctly recognized that some studies are better than others (because of their size or presumably for other reasons) and that studies of lesser quality should not be relied upon as one might rely on studies of higher quality. In particular, the Staff Paper described a "rough indicator of ... precision" that was used for this purpose:

> "The natural logarithm of the mortality-days (a product of each city's daily mortality rate and the number of days for which PM data were available) can be

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The literature cited by EPA is dominated by studies with analytical models that failed to consider other pollutants and risk factors. Thus the conclusions of Burnett et al. and Thurston et al. give added reasons to view the EPA evidence with caution. I do not agree with the Preamble statement that "effect estimates for associations between PM, including $PM_{10-2.5}$, and health endpoints are generally robust to confounding by gaseous co-pollutants" (*Fed Reg* 71:2660).

[2] These studies are all cited in the Preamble. Results of the Los Angeles and the eight Canadian cities studies were excluded from Figure 2 because they used GAM, rather than GLM analytical models.

> used as a rough indicator of the degree of precision of effect estimates ... staff chose to consider only those urban areas in which studies with relatively greater precision were conducted, specifically including studies that have a natural log of mortality-days greater than or equal to 9.0 (i.e., approximately 8,000 deaths) for total non-accidental mortality." (SP, p. 4-6)

That approach (both specifically and generally) has been deleted from the Proposed Coarse PM NAAQS. As a result, EPA has deleted its Staff's criterion for objectively distinguishing between individual studies. It is interesting to note that if EPA had accepted this criterion, then it would have had to acknowledge that results from the Coachella Valley studies (7-9) and the Six Cities study results from Steubenville (10,11) had been judged to be of "lesser quality".

But the Preamble relies on those two studies repeatedly: The Coachella Valley studies are cited 19 times, while the Steubenville data are cited eight times. At no point does the Preamble indicate that EPA Staff had objectively determined that both data were too imprecise to be used for quantitative assessments and thus their conclusion should be viewed with caution. I am concerned that the failure to indicate those Staff determinations serves mainly to conceal the limitations of those studies [3].

3). A third example of the failure to describe and respond to limitations of the evidence relates to the adequacy of the exposure assessments that underlie each of the individual studies. Concerns about the precision and accuracy exposure assessment can not be separated from concerns about the precision and accuracy of the studies themselves.

a) One aspect of my concern involves the spatial location(s) of monitors used to describe the exposures of study populations. It is generally accepted that coarse PM (e.g., $PM_{10-2.5}$) deposits more rapidly and more locally than does fine particulate. Likewise, it is generally accepted that local sources are of greater importance in determining concentrations of coarse particulate (6). Accordingly, it can be expected that measurements from centrally located monitors will less accurately represent regional exposures to coarse particulate than fine particulate (i.e., $PM_{2.5}$). For that reason, measurements of coarse PM obtained at relatively distant monitoring stations should be viewed with caution, and so should studies that rely on coarse PM measurements obtained relatively far from target populations. When such distant measures are used as the basis for epidemiological studies, efforts should be made to demonstrate that the distant measures do accurately reflect the exposures of target populations.

For example, in an analysis and comments submitted separately, Gale Hoffnagle describes marked spatial variation of fugitive coarse PM emitted by ground level sources such as those characteristic of agricultural and mining activities. His analysis indicates that even when levels at such sources reach several hundred mg/m^3, corresponding levels

[3] It is also notable, and perhaps related, that despite a statement in footnote 50 (*Fed Reg* 71:2655) that two subsequent reanalyses of the Steubenville data found essentially no significant associations, the Preamble persists in referring to the original Steubenville data as showing "a statistically significant mortality association".

at a distance of 1000 meters are *de minimis* (i.e., they approach zero mg/m^3). Thus PM monitors located at a distance of 1000 meters or more reflect little or no contribution from such sources.

However, a number of the studies cited in the Preamble depended on coarse PM measurements from distant monitors and were apparently not accurate predictors of target population exposures. In the Detroit study by Lippmann et al. (3,4), particulate matter data were obtained from ambient monitors in Windsor, Ontario, several miles from central Detroit. The Staff Paper and the Proposed Coarse PM NAAQS document that levels measured in Windsor were not representative of those in Detroit:

> "In recent years, based on available Windsor and Detroit data from 1999 to 2003, the Windsor monitors used in this study typically have recorded $PM_{10-2.5}$ levels that are generally less than half the levels recorded at urban-center Detroit monitors..." (Staff Paper: 5-68)

Accordingly, on the basis of that exposure concern, the Detroit study must be regarded as providing only limited informative value.

In the Coachella Valley studies (8,9), particulate measures were obtained in Indio, approximately 25 miles from older population centered in the Palm Springs area at the western end of the Valley [4].

b) A second exposure assessment concern is the manner in which coarse particulate levels are determined. The Preamble notes that $PM_{10-2.5}$ measurements are prone to greater exposure errors than are measurements of $PM_{2.5}$ (*Fed Reg* 71:2660). In addition, $PM_{10-2.5}$ levels calculated by the difference method (i.e., subtracting $PM_{2.5}$ from PM_{10}) can be expected to have larger errors than $PM_{10-2.5}$ levels directly measured using dichotomous samplers; the difference method is impacted by two measurement errors, while the direct measurement method has only one. And when the difference method is performed using data from monitors that are not physically co-located, additional exposure assessment errors result because of non-homogeneous spatial distributions of particulate matter.

Finally, estimation of coarse particulate exposures derived from only PM_{10} measurement in areas where measured PM levels are "dominated" by coarse particulate are by far the most uncertain and least accurate. Because of such uncertainty, the findings of epidemiological studies that rely on those exposure assessments should be viewed as the

[4] The population of the Indio area, which is on the Northern rim of the Valley, differs from that of many of the other Valley communities. For example, according to the 2000 Census, 15.2% of the population was in the 45-64 year age group and 9.1% were over 65 years. By contrast, the corresponding proportions were 26.4% and 26.2% for Palm Springs, 30% and 43% for Ranch Mirage and 26.3% and 27.6% for Palm Desert. Those cities, with significantly older populations more prone to cardiorespiratory diseases, are located approximately 10-25 miles away toward the Western end of the Valley.

least informative, analogous to ecological studies that are suitable for generating, but not testing hypotheses.

Consider the effect of categorizing the studies cited in the Preamble on the basis of their exposure assessments.

a) The highest quality $PM_{10-2.5}$ exposure assessments are those in studies that employed dichotomous samplers.

Dichotomous particulate samplers were used in two Toronto studies (1,12) that considered hospital admissions and two reports from the Harvard Six Cities study, one considering mortality effects (10,11) and other peak flow and asthma in children (2). All four of those studies found no significant effects associated with exposure to $PM_{10-2.5}$.

b) Second tier studies calculated $PM_{10-2.5}$ by the difference method, subtracting $PM_{2.5}$ from levels of PM_{10}. Among the co-location studies cited in the Proposed Coarse PM NAAQS, most suffered important data limitations or deficiencies.

No association of respiratory symptoms and childhood asthma were found for coarse particulate calculated by the difference method in Uniontown and State College (2). There were only marginal associations ($0.05<p<0.10$) between coarse particulate calculated by the difference method and mortality in the Phoenix study (13,14). The Detroit study found small positive associations for coarse particulate but as discussed above, particulate data were obtained miles from the study population and were significantly inaccurate (3,4). The HEI Health Review Committee concluded that data from the Detroit study were inconclusive:

> "...the data do not clearly support a greater effect of one pollutant over another, nor do they establish which pollutants are most likely to cause adverse health effects..." (3) (HEI Synopsis)

The Coachella Valley study (8,9) reported positive associations with mortality and the Seattle study (15,16) reported positive associations with hospital admissions for asthma in non-elderly patients. But both studies suffered from large data gaps that were filled by imputation and arbitrary calculations; in both studies, exposure data were missing for 75% or more of the $PM_{2.5}$ values and, therefore, they were also missing for coarse particulate exposure measures [5].

[5] In the Coachella Valley study, PM_{10} data were available for a 10-year period, but $PM_{2.5}$ data for only 2.5 years. The missing $PM_{2.5}$ and $PM_{10-2.5}$ were imputed using a predictive function that estimated $PM_{10-2.5}$ as a cubic function of PM_{10}. The predictive function was such a poor fit for $PM_{2.5}$ data that the authors concluded that "predictive models could not be successfully estimated" (9). Accordingly, the calculated values, which represented 75% of the $PM_{10-2.5}$ data, can not be viewed as reliable.

The extent of missing data in the Seattle study is no less extreme. The authors observed: "Numerous missing PM measurements potentially limit our analysis" (15). For the three monitoring

c) The lowest tier studies measured only PM_{10} in areas thought to be dominated by coarse particulate and thereby inferred associations with coarse particulate. The lowest tier studies included "positive" studies in Anchorage (17,18,18), Reno (19), Tucson (20), and the Coachella Valley (7). Each also suffered from additional methodological concerns.

In Anchorage (17,18), the health effects were measured in terms of outpatient visits, not episodes of illness, and included events likely to be primarily infectious (e.g., "sore throat, ear aches"). Repeated visits by the same individual (e.g., emergency visits and follow-up office visits) would result in temporal dependence among outcomes that would effectively underestimate variance and overestimate the significance of associations, perhaps leading to inappropriate rejection of the null hypothesis of no effect of particulate exposures. In addition, outcome measures were not associated with the highest levels of exposure, only with lesser exposure levels.

The Reno study (19) provided no evidence that PM_{10} was dominated by coarse particulate. However, two facts suggest that PM_{10} was dominated by fine particulate, not coarse particulate. First, PM_{10} levels were inversely related to wind speeds, suggesting that those levels reflected not wind-blown crustal particulate, but decreased dispersion of suspended fine particulate. Also, the authors noted that:

> "Higher peaks occurred during the winter season. This may be as a result of increased residential combustion due to cold weather in the study area." (19)

If the authors are correct, then those peaks would have represented fine, not coarse particulate. Accordingly, the relevance of the Reno study to coarse particulate exposures is uncertain at best.

The Tucson study, which evaluated cardiovascular hospitalizations, used data from a monitoring station that was "located in a neighborhood site likely to be representative of population exposure", rather than at a site that would have been "subject to windblown dust" (20). Therefore, it is likely that the Tucson PM_{10} exposure data derived from samples that were actually dominated by fine

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stations considered, no $PM_{2.5}$ data were available for 72-100% of days. The authors "imputed" the missing data. The imputation methods were not described, but the authors indicate that six different imputation methods were used and the results of those six methods were averaged. In addition, the "exposure" data were then "weighted" to favor residential areas, but no justification for that arbitrary weighting scheme was provided. Thus, the "exposure data" in this study were mainly synthetic, rather than empirical, and had been transformed in ways that can not be understood and have not been justified. It is difficult to regard this as a valid observational study.

> particulate. Unfortunately, there were no $PM_{2.5}$ data are available to validate the underlying assumptions of this exposure assessment.
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> The Coachella study (7) utilized PM_{10} data from monitors located in Indio, 25 miles from the major population center around Palm Springs, where on average PM_{10} levels were 21% greater than in Indio. Given the higher population and vehicular density in Palm Springs, it seems likely that the higher levels reported during the study period in Palm Springs reflected mainly fine combustion particulate, rather than windblown crust.

By means of such a categorization scheme, it can be seen that most of the evidence in support of the Proposed Coarse PM NAAQS is derived from studies with the lowest quality of exposure assessments, while those with highest quality exposure assessments lend no support.

If EPA had used such a 'quality of exposure assessment' approach to prioritize the evidence available [6], it would have been apparent that support for the Proposed Coarse PM NAAQS is mainly found in the least robust studies. Thus, such an approach would have further emphasized the limitations of supporting evidence.

4). In summary, EPA has systematically presented the results of cited studies in a manner that overstates the evidence linking coarse particulate and health effects.

> Data from inferior single-pollutant models have been presented in the centerpiece graphic of the Preamble, while more rigorous analytical results have been relegated to afterthoughts and footnotes.
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> Studies that EPA Staff deemed to be of inferior quality have been presented as supportive without appropriate qualification.
>
> No apparent effort has been made to distinguish high-quality from lesser-quality studies with respect to the adequacy of their exposure assessments.

One might infer that failure to distinguish between strong and weak studies is motivated by the wish to avoid the exclusion of those positive findings that derive mainly from weaker studies.

5) The Preamble also misleads by its repeated statements that effects associated with coarse PM exposure were not affected by confounding by gaseous co-pollutants:

> "effect estimates ...are generally robust to confounding by gaseous co-pollutants" (*Fed Reg* 71:2660);

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[6] EPA has utilized such an approach for other risk assessments, such as in evaluating evidence of the carcinogenicity of trichloroethylene (e.g., "We divided the cohort studies into three tiers based on the specificity of the exposure information" (25)).

> "associations ... were largely unchanged in most cases when gaseous co-pollutants were included in the models" (*Fed Reg* 71:2657);
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> "effect estimates ... are largely unchanged with the addition of gaseous co-pollutants to the models" (*Fed Reg* 71:2657).

But whether confounding is demonstrated depends on whether the correct co-pollutants have been included in the analytical model. Burnett et al. (1), for example, emphasized this concern: the apparent effects of particulates "could be completely explained by NO_2, a risk factor not as widely considered in North American locales as the other criteria pollutants." Similar conclusions were reached by Thurston et al. (12). Accordingly, the appropriate concern is not whether the effects of particulates are "generally robust", but whether potentially significant confounding has been properly evaluated. Such evaluations should consider "as many pollutants as possible" (12).

EPA has apparently not performed such evaluations. Instead, the Preamble relies on studies that incompletely evaluated possible confounding as evidence that such confounding is insignificant. However, the evidence provided by more rigorous studies indicates that confounding by gaseous co-pollutants can not be disregarded.

6) The limitations of the underlying evidence and the failure of EPA to adequately address and respond to those limitations are illustrated in the manner in which the Preamble argues that $PM_{10-2.5}$ is significantly associated with asthma. As described below, that argument is composed of hypothetical propositions and incorrect descriptions of cited studies.

a) The Preamble first proposes that because $PM_{10-2.5}$ might deposit in the tracheobronchial region, therefore it has the potential to aggravate asthma at the levels of exposure considered in the NAAQS. Following are examples of that proposition:

> "Deposition of particles to the tracheobronchial region is of particular concern with respect to aggravation of asthma" (*Fed* Reg 71:2654);
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> "...has the potential to affect lung function and aggravate symptoms, particularly in asthmatics" (*Fed* Reg 71:2655);
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> "The fractional deposition of elevated coarse particle concentrations is significant in the tracheobronchial region, which is particularly sensitive in asthmatic individuals." (*Fed* Reg 71:2661);
>
> "... the expectation that deposition of thoracic coarse particles in the respiratory system could aggravate effects in individuals with asthma" (*Fed* Reg 71:2668).

The hypothesis (or expectation) that $PM_{10-2.5}$ might aggravate asthma is not necessarily wrongheaded, but its repeated assertion provides neither support nor evidence that such a "potential" effect actually occurs.

b) The Preamble sometimes treats asthma (or "aggravation of asthma") as a distinct disease process, but more generally treats it as merely one of a number of more-or-less generic respiratory diseases.

The following statements, for example, suggest that EPA regards "asthma" as a distinct entity:

> "Evidence available in the last review suggested that aggravation of asthma ..." (*Fed Reg 71*:2656);
>
> "...limited epidemiologic evidence suggesting that aggravation of asthma..." (*Fed Reg 71*:2668);
>
> "The authors conclude that for acute asthma related responses..." (*Fed Reg* 71:2657).

In most places, however, the Preamble does not differentiate between asthma and a variety of acute respiratory diseases (e.g., respiratory infections, pneumonia) and chronic respiratory diseases (e.g., COPD). This is reflected by the following statements:

> "... respiratory morbidity effects, such as aggravation of asthma, increases in respiratory symptoms and respiratory infections..." (*Fed Reg 71*:2655);
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> "...associations between short-term exposure to $PM_{10-2.5}$ with hospital admissions for respiratory diseases, including asthma, pneumonia and COPD..." (*Fed Reg 71*:2657);
>
> "...respiratory morbidity, such as increased respiratory symptoms and hospitalization for respiratory diseases such as asthma or COPD..." (*Fed Reg 71*:2661).

I suspect that the failure to distinguish asthma from those other acute and chronic diseases mainly reflects the paucity of published data specifically linking $PM_{10-2.5}$ and asthma.

c) The striking paucity of evidence linking $PM_{10-2.5}$ and asthma is made clear by the very few studies cited to support that association. Moreover, most of the cited studies provide less support than is implied in the Preamble.

The Preamble cites two studies [7], Hefflin et al. from southeast Washington and Gordian et al. from Anchorage, in which:

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[7] The Preamble actually cites "the last review" - 62 FR 38679 - in which these two studies are specifically identified.

> "...aggravation of asthma and respiratory infections and symptoms were associated with PM_{10} in areas where thoracic coarse particulate were a much greater fraction of PM_{10} than were fine particles" (*Fed Reg* 71:2657).

But, contrary to statements in the Preamble, Hefflin et al. (21) found no association between high-level exposure to PM_{10} and aggravation of asthma, even at 24-hour PM_{10} levels of 1035-1689 $\mu g/m^3$. To the contrary, those authors report:

> "... it is surprising that we not only found no significant association between PM_{10} and asthma, but we found relatively few emergency room admissions for asthma in a community that would be expected to have 4800 persons with asthma." (21)

The Gordian studies (17) suffer from potentially important flaws that limit its informational value. As discussed above, health effects were measured as doctors' visits, not episodes of illness, which may have led to overestimating the significance of associations. In addition, associations were noted for asthma and upper respiratory infections (URI) with a temporal relationship suggesting that onset of URI preceded the onset of asthma attacks [8]. Also, visits were not increased during the peak exposure days, when PM_{10} levels averaged 565 $\mu g/m^3$ and peak levels exceeded 3000 $\mu g/m^3$.

Notably, URI itself has been associated with asthma attacks in asthmatic children (22) and lower airway effects in normal children (23). Because of the apparent cause-and-effect relationship between URI and asthma attacks generally and the apparent correlation between URI and asthma visits in the Gordian study, it is not possible to determine whether those asthma visits reflected PM_{10} exposure vs. URI. In short, it is not possible to determine the extent to which the Gordian data might reflect the adverse effects of PM_{10}.

The Preamble also states that three "new US and Canadian epidemiologic studies" reported associations between short-term exposures to $PM_{10-2.5}$ with hospital admissions for "respiratory diseases, including asthma" (*Fed Reg* 71:2657). The three cited studies are from Toronto, Detroit and Seattle. However, the Preamble statement is incorrect and misleading.

> The Toronto study by Burnett et al. (1) did not find such an association. A multi-pollutant analysis found that any apparent association "was eliminated", with a relative risk of 1.007. It would be improper (and, perhaps, absurd) if EPA regarded relative risks of 1.007 as indicative of meaningful associations.

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[8] Doctors' visits for URI were most closely associated with same-day PM_{10} levels, while asthma visits were most closely associated with prior day PM_{10} levels. That suggests that URI preceded asthmatic symptoms. My personal experience (as an internist, emergency physician, parent and patient) is that visits for acute asthmatic attacks are more likely to occur shortly after the onset of symptoms, whereas URI visits occur after a longer delay, when symptoms and signs seem unusually persistent or severe. Thus, it seems likely that the onset of URI actually preceded asthma by several days.

> The cited Detroit study (16) was not a "new study", but a reanalysis of data from the older Lippmann et al. study (3). As discussed above, the Detroit study relied on particulate levels measured miles away in Windsor, Ontario and the HEI Health Review Committee concluded that data from the Detroit study were inconclusive.
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> Likewise, the Seattle study (16) was not a "new study", but a reanalysis of Sheppard et al (15). As discussed above, exposure data were so lacking that 75% of coarse particulate data were "imputed". Also, the authors noted that wood burning was a "major contributor to PM", that vehicular exhaust was the second largest source of PM, and that the pollutant most closely associated with asthma was carbon monoxide, "an important environmental indicator of incomplete combustion, particularly from mobile sources" (15).
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> Given the lack of measured coarse particulate data and the evidence that combustion-related fine particulate was an important pollutant in Seattle, there is essentially no basis to conclude that coarse PM in Seattle caused asthma-related hospitalizations.

The Preamble also mischaracterizes the findings of Schwartz and Neas (2) with respect to asthma. The Preamble states:

> "The authors conclude that for acute asthma related responses as well as daily mortality, fine particles are a stronger predictor of health response than are thoracic coarse particles." (*Fed Reg* 71:2657)

That statement implies that in addition to the large association seen with fine particles, Schwartz and Neas also found an association between coarse particles and asthma. That is not correct, as reflected by the authors' actual statements:

> "For lower respiratory symptoms, the association was stronger for all of the fine-particle measures than for CM [coarse particle mass] in single pollutant regressions. A model including both CM and $PM_{2.5}$ resulted in a substantial reduction in the effect of CM, with little evidence that the remaining effect was different from zero." (4)

EPA has incorrectly presented these negative findings as though Schwartz and Neas provided support for the Proposed Coarse PM NAAQS.

It is surprising to realize that the above studies reflect the totality of epidemiological data cited in the Preamble as support for the proposition that $PM_{10-2.5}$ aggravates asthma. These studies provide no such support, either individually or as a group.

d) There are other relevant studies that have been ignored in the Preamble discussion of asthma, perhaps because their findings showed no association of coarse particulate and asthma. Consider, for example, the three-year study by Rabinovitch et al. (24) that

specifically considered the effects of wintertime air pollutants on urban minority children at "highest risk for asthma morbidity". The children were students at a special school, operated at the National Jewish Hospital in Denver, which specifically enrolled children with chronic diseases including asthma. The school was located in a community where PM_{10} is dominated by coarse particulate; during the study period, coarse particulate on average comprised 61.2% of PM_{10}.

For two years, exposure data (including PM_{10} and $PM_{2.5}$) were obtained from EPA monitors located 100 meters from the school. During the third year, particulate data were obtained from a community monitoring station located 2.8 miles from the school. Children were monitored for asthma symptoms, asthma exacerbations, twice-daily FEV_1 and peak flows, use of asthma medications, and URI events. School activities were not modified in response to pollution alerts "so as not to bias any potential pollution effects".

Associations between air pollutants and asthma outcomes were found in simple models, but not in complex modeling that included all pollutants and time-dependent covariates such as URI events. Using the more complex model, no significant associations were observed between pulmonary function and PM_{10}. Asthma symptoms were significantly associated with ozone levels, but not PM_{10} and no significant associations were noted between asthma exacerbations and PM_{10}. By contrast, URI symptoms were strongly associated with decreased pulmonary function, increased medication usage, asthma symptoms, and asthma exacerbations.

These findings suggest that exposure to coarse particulate does not provoke asthma symptoms, does not adversely impact pulmonary function and does not induce asthma attacks. The strong associations seen between URI, pulmonary function and asthma lend support to the view that the results of the Gordian studies reflect URI events, rather than coarse particulate exposures.

e) In summary, it should be clear from the very few, very limited, and uncertain studies cited in the Preamble that there is no sound basis for concluding that coarse particulates aggravate asthma or provokes asthma symptoms, even at exposure levels considerably higher than those considered in the Proposed Coarse PM NAAQS. EPA arguments in favor of that association are composed of hypothetical propositions and incorrect or incomplete descriptions of the cited studies.

Conclusion

There is significant paucity of scientific support for the Proposed Coarse PM NAAQS and the scientific studies cited by EPA in support of the NAAQS suffer from significant methodological limitations.

Although EPA repeatedly acknowledges that the database suffers such limitations, it persists in presenting the accumulated data as sufficient to justify the Proposed NAAQS. But in addition to those acknowledged by the Agency, a detailed review of the cited

studies reveals numerous deficiencies that EPA has either not recognized or chosen to ignore.

Unlike many other EPA risk assessments that thoughtfully sorted strong from weak studies, emphasizing evidence from the former and discounting that from the latter, EPA in this case seems unwilling to discard any "finding" that might somehow be construed as supporting its NAAQS. That leads to important inadequacies in the justification and support of its proposed policy.

The majority of findings presented as supporting evidence derive from the methodologically weakest studies, while the methodologically most robust studies yield essentially no support. EPA relies on the least rigorous of analytical approaches (e.g., single pollutant models vs. multi-pollutant models), minimizes or ignores potential confounding (e.g., URI events inducing asthma attacks, gaseous co-pollutants) and, as discussed above, by misrepresenting study findings.

A detailed, balanced reading of the evidence indicates no basis to justify regulating of $PM_{10-2.5}$, only arguments and hypotheses that mainly reflect biological plausibility rather than empirical findings. The general lack of evidence persists even at exposure levels substantially higher than those considered health relevant in the Proposed Coarse PM NAAQS.

I find insufficient scientific justification for the adoption of the Proposed Coarse PM NAAQS.

Yours truly,

Jonathan Borak, MD, DABT, FACP, FACOEM

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JONATHAN BORAK & COMPANY, INC.

Specialists in Occupational & Environmental Health

November 9, 2009

U.S. Environmental Protection Agency
Office of Environmental Information (OEI) Docket
Mail Code: 2822T
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: Integrated Science Assessment for Particulate Matter, Second External Review Draft (July, 2009) Docket ID Number EPA-HQ-ORD-2007-0517

Submitted Electronically

Dear Sir or Madam:

I have prepared the attached comments at the request of the National Cattlemen's Beef Association, the National Mining Association, and the Newmont Mining Corporation in order to share my concerns about the scientific interpretations and judgments that have apparently been adopted by EPA in the Second External Review Draft of the Integrated Science Assessment for Particulate Matter (July, 2009). My comments are filed in support of their comments, which are being submitted separately.

Many thanks in advance for allowing me this opportunity to contribute to the important work of your agency.

Yours truly,

Jonathan Borak, MD, DABT, FACP, FACOEM, FRCP(C)

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EXHIBIT 9

Comments on:
Integrated Science Assessment for Particulate Matter – Second External Review Draft (July 2009)

Jonathan Borak, MD, DABT, FACP, FACOEM, FRCPC

November 9, 2009

I have prepared the following comments at the request of the National Cattlemen's Beef Association, the National Mining Association, and the Newmont Mining Corporation in order to share my concerns about the scientific interpretations and judgments that have apparently been adopted by EPA in the Second External Review Draft of the Integrated Science Assessment for Particulate Matter (July, 2009).

To introduce myself, I am Clinical Professor of Epidemiology & Public Health and Clinical Professor of Medicine at Yale University. I teach required graduate courses in both Toxicology and Risk Assessment. I also served for 10 years as a founding member of EPA's National Advisory Committee on Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL).

This is the fourth set of comments that I have submitted on issues related to the development of an NAAQS for coarse particulate matter ($PM_{10-2.5}$). Two earlier sets of comments were submitted to the Clean Air Scientific Advisory Committee in 2005 and one set to Administrator Johnson in 2006. Then as now, my principal concern is the lack of scientific support for a coarse particulate matter standard.

In these comments, I will focus on the informational limitations and uncertainties of the recent study by Zanobetti and Schwartz (Z&S) [1], a study that seems to play an inordinately important role in the draft ISA. As published and included in the ISA, that study suffers from the following important limitations and uncertainties:

1. The numbers of deaths in the $PM_{10-2.5}$ analyses are not described
2. The $PM_{10-2.5}$ data are subject to unquantified uncertainty
3. The effects of potential confounders and collinearity were not considered
4. The criteria for model selection are not adequately described and only a small minority of results was reported
5. The analytical results are inconsistent
6. The analytical findings cannot be generalized

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[1] Zanobetti A, Schwartz J: The effect of fine and coarse particulate air pollution on mortality: A national analysis. *Environ Health Perspect* 117:898-903, 2009

In the following paragraphs I discuss these concerns in more detail. Ultimately, it is not possible to know whether these limitations reflect inadequacies of the research or its reporting, but in either case the report is not adequate to provide the basis to justify promulgation of a NAAQS for $PM_{10-2.5}$.

1. The numbers of deaths in the $PM_{10-2.5}$ analyses are not described

In their published report, Z&S reported the following information regarding mortality data used in their analysis:

> "In the 112 cities during the study period 1999-2005, there were 5,609,349 total deaths, 1,787,078 for CVD, 397,894 for MI, 330,613 for stroke, and 547,660 for respiratory disease." (p. 900)

This data set seems impressively large and precisely described, but that is not the number of deaths in the analysis. Cities were included in the study if there were exposure data for at least 265 days in a given year and, as documented in the Supplemental Material, many cities were not included for the full study duration. The actual numbers of study days included for each city are not provided. Based on the exclusion of years and days, it is apparent that the actual mortality data were significantly less than reported.

Of greater concern is the fact that only 47 cities were included in the $PM_{10-2.5}$ analyses, of which only 11 (23.4%) were included for the full duration, i.e., 1999-2005. Because the authors provided the average daily numbers of deaths by city, but not the number of days that each city was included in the study, it is not possible to estimate the actual numbers of deaths included in the $PM_{10-2.5}$ analysis. Of the nine cities with the highest daily all cause mortality (i.e., >40/day), $PM_{10-2.5}$ data were available for only four and none was included for the full duration of the study.

In summary, the study report overstates the quantity of mortality data that were included in the analyses. Presumably specific daily mortality data, not average daily data, were included in the time-series analytical model, but those data were not reported and cannot be calculated from the supplemental material. Likewise, the distributions of city-specific mortality were not described.

2. The $PM_{10-2.5}$ data are subject to unquantified uncertainty

2.a Uncertainties due to sampling methods

Environmental data for $PM_{2.5}$ and PM_{10} were obtained from the EPA Air Quality System and $PM_{2.5-10}$ values were calculated using the difference method. It is not clear whether Z&S considered the technical limitations of the data that resulted from differing sampler flow rates and differing collection conditions. The following describes the manner in which EPA addressed those concerns in its assessment of spatial distributions:

> "Since $PM_{10-2.5}$ is not routinely measured and reported to AQS, co-located PM_{10} and $PM_{2.5}$ measurements from the AQS network were used to investigate the spatial distribution in $PM_{10-2.5}$. Only low-volume FRM or FRM-like samplers were considered in calculating $PM_{10-2.5}$ to avoid complications with vastly different sampling protocols (e.g., flow rates) between the independent PM_{10} and $PM_{2.5}$ measurements ... $PM_{2.5}$ concentrations are reported to AQS at local conditions whereas the PM_{10} concentrations are reported at standard conditions. Therefore, prior to calculating $PM_{10-2.5}$ by subtraction, the PM_{10} AQS data were adjusted to local conditions on a daily basis using temperature and pressure measurements from the nearest National Weather Service station." (ISA, p. 3-64)

There is no indication in their report that Z&S adjusted for differing flow rates or otherwise excluded samplers that were not "low-volume FRM or FRM-like" and there is no indication that they adjusted PM_{10} data to local weather conditions.

If Z&S did not exclude high-flow samplers and if they failed to adjust PM_{10} to local weather conditions, then their exposure data fall below the qualitative standards that EPA adopted for its own $PM_{10-2.5}$ studies.

2.b Uncertainties due to data averaging and regional distributions of coarse PM

Environmental data for $PM_{2.5}$ and PM_{10} were obtained at county levels, not for the cities *per se*. Where a city's population extended "beyond the boundaries of one county", the data from those several counties were aggregated. When more than one monitor was available, the results were averaged, but monitors that were not "well correlated" ($r<0.8$) with others in the county (or counties) were excluded. The proximity of monitors to the study's urban populations was apparently not considered, i.e., proximate monitors were not favored over distant ones, and distance was apparently not a criterion for excluding monitors.

This method raises a number of concerns. Z&S acknowledged that some study populations lived far from the monitors:

> "One possible explanation for the lower effect in the Mediterranean region ... is more measurement error due to the extremely large counties in California, where people may live far away from the monitors." (p. 901)

This is of particular relevance because it is generally accepted that coarse PM deposits more rapidly and more locally than does fine particulate. Likewise, it is generally accepted that local sources are of greater importance in determining concentrations of coarse particulate. [2] Thus, one should expect that data from "far away" monitors will less accurately represent regional exposures to coarse particulate than fine particulate (e.g., $PM_{2.5}$). Measurements of coarse PM obtained at relatively distant monitoring stations (or calculated from PM_{10} data obtained at distant monitoring stations) should be

[2] Burnett RT et al: Association between short-term changes in nitrogen dioxide and mortality in Canadian cities. *Arch Environ Health* 59:228-236, 2004.

viewed with caution, and caution is also necessary when evaluating studies that rely on $PM_{10-2.5}$ measurements obtained relatively far from target populations.

When such distant measures are used as the basis for epidemiological studies, efforts should be made to demonstrate that the distant measures accurately reflect the actual exposures of target populations. This specific concern undercut the probative value of the Detroit study by Lippman et al. [3]. The failure of Z&S to demonstrate that calculated $PM_{10-2.5}$ measurements reflected the actual exposures of the study's urban populations raises important concerns about the study's informative value.

The ISA discounts the significance of this concern, asserting that such measurement errors would lead to nondifferential misclassification which, in turn, would bias results toward the null:

> "Because of the greater spatial heterogeneity of $PM_{10-2.5}$, exposure measurement error is more likely to bias health effect estimates towards the null for epidemiologic studies of $PM_{10-2.5}$ versus PM_{10} or $PM_{2.5}$, making it more difficult to detect an effect of the coarse size fraction." (p. 6-131)

However, a recent EPA study in Phoenix contradicted that view. Wilson et al.[4] found that increasing distance from a central monitor was associated with an increasing positive association of $PM_{10-2.5}$ with cardiovascular mortality:

> "The % risk and statistical significance for the association of mortality with $PM_{2.5}$ fell off with distance from the monitor, as would be expected if exposure error increased with distance. However, the % risk for $PM_{10-2.5}$ increased ..." (p. S11)

Thus it should be apparent that the biasing effects of measurement errors, such as those likely to have been present in the Z&S data, cannot be simply discounted on the presumption that such errors will necessarily lead to negative bias. To the contrary, as seen in Wilson et al.[4], they can lead to positive bias and incorrect inferences of causality.

A further concern is the exclusion of monitors that were not "well correlated" with other county monitors, which thereby resulted in exclusion of an unstated amount of data. It would be important to know whether any of the excluded monitors were actually closer to, and therefore more representative of the population in any of the study cities, than the monitors that were included. It would also be useful to know how many monitors and how much data were excluded in this way.

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[3] Lippmann M, et al: Association of Particulate Matter Components with Daily Mortality and Morbidity in Urban Populations. Cambridge: Health Effects Institute, 2000; Ito K. Associations of particulate matter components with daily mortality and morbidity in Detroit, Michigan. In: *Revised Analyses of Time-series Studies of Air Pollution and Health*, Boston: Health Effects Institute, pp. 143-156, 2003.

[4] Wilson WE et al: Influence of exposure error and effect modification by socioeconomic status on the association of acute cardiovascular mortality with particulate matter in Phoenix. *J Expo Sci Environ Epi* 17:S11-S19, 2007.

3. The effects of potential confounders and collinearity were not considered

3a. Bias due to confounding

Z&S performed single pollutant analyses for $PM_{2.5}$ and $PM_{10-2.5}$ and they also performed two-pollutant analyses that included both $PM_{2.5}$ and $PM_{10-2.5}$. They did not consider the confounding effects of gaseous pollutants and they did not consider the probable collinearity between $PM_{2.5}$ and $PM_{10-2.5}$.

Reliance on single pollutant models substantially reduced the probative value of the resulting analysis. The ISA describes the failure to investigate confounding by gaseous copollutants as a "limitation" of the study (p. 6-301). A more general statement of concern is found in a report by the HEI Research Committee, which expressed the view that single-pollutant models provide only limited insights [5]:

> "In order to determine the relative effects of several risk factors on a health outcome, ideally all variables under considerations would be included in a single model."

An even stronger viewed was made by Klemm and colleagues who proposed that single-pollutant models can serve as screening tools, but are not a valid basis for determining the importance of any given pollutant [6]:

> "It is axiomatic ... single-pollutant regressions may be a useful screening tool but cannot provide valid judgments as to the relative importance of a given pollutant." (p. 134)

Beyond such methodological concerns, there are empiric data that document confounding by gaseous copollutants in PM studies. Numerous studies, for example, have reported important confounding of coarse PM by NO_2 for both hospitalizations and mortality. For example:

> A significant effect of $PM_{10-2.5}$ on hospital admissions for respiratory diseases was reported in Toronto when a single-pollutant model was used, but the effect "was eliminated" when NO_2 was included in the analysis model. [7]

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[5] HEI Research Committee Comments in: Lippmann M, et al: *Association of Particulate Matter Components with Daily Mortality and Morbidity in Urban Populations*. Cambridge: Health Effects Institute, 2000; p. 80.

[6] Klemm RJ, et al: Daily mortality and air pollution in Atlanta: Two years of data from ARIES. *Inhal Toxicol* 16(suppl 1):131-141, 2004.

[7] Burnett RT, et al: The role of particulate size and chemistry in the association between summertime ambient air pollution and hospitalization for cardiorespiratory. *Environ Health Perspect* 105:614-620, 1997.

> In a study of 12 Canadian cities, apparent associations of $PM_{10-2.5}$ with mortality were seen in a single pollutant model, but were reduced by more than 50% and became non-significant when NO_2 was included in dual-pollutant model. [2]
>
> In a subsequent pooled analysis of ten Canadian cities, which may have used an overlapping dataset, NO_2 had the strongest association with non-accidental mortality. Apparent effects of PM became non-significant when NO_2 was included in the analytical model. [8]

Because the limitations of single-pollutant regressions are so well recognized, and because confounding of PM studies by NO_2 has been well documented, it is surprising that the ISA has given such prominence to this study, which generally failed to consider gaseous copollutants and specifically failed to consider confounding by NO_2.

Moreover, previous studies (e.g., Burnett et al. [2]; Brook et al. [8]) have reported that NO_2 was associated with seasonality effects similar to those reported by Z&S for $PM_{10-2.5}$. Thus, it seems possible that both the magnitude of the $PM_{10-2.5}$-associated mortality effects reported by Z&S and also the seasonality of these effects are attributable to confounding by NO_2. It is unfortunate that such possibilities were not explored.

3b. Bias due to collinearity

Z&S included $PM_{2.5}$ and $PM_{10-2.5}$ in a two-pollutant model, but they did not evaluate their possible collinearity. This specific concern was raised in the ISA:

> "models that include both PM10-2.5 and PM2.5 may suffer from instability due to collinearity." (p. 6-131)

Such collinearity would raise the possibility that risks were double-counted. It is unfortunate that such possibilities were not explored.

4. The criteria for model selection are not described and only a minority of results was reported

4.a Model selection

Z&S reports results for their time series analyses using PM concentrations averaged over the day of death and prior day (lag01):

> "We investigated the association between $PM_{2.5}$ and PM coarse concentrations averaged over the day of death and day before death and mortality with a time series analysis." (p. 899)

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[8] Brook JR et al: Further interpretation of the acute effect of nitrogen dioxide observed in Canadian time-series studies. *J Expo Sci Environ Epi* 17:S36-S44, 2007.

It is apparent that they also performed numerous other analyses. For example, the refer to a "distributed lag model for 4 days, from the same day and up to 3 days earlier" and Figure 2 graphically presents cause-specific mortality data for each of 4 days (i.e., lag days 0-3). It seems likely that at least five different lag models were explored, but that the only data actually reported were from the lag01 analysis. Z&S also described a number of other variable aspects of their model fitting, including treatments for seasonality, ambient temperature, and day-of-the-week. The authors did not indicate whether they explored the effects of varying the numbers of degrees of freedom in their smoothing procedures; a recent report demonstrated that such decisions can significantly affect analytical results. [9]

It seems probable that numerous models, perhaps many, were fit to the data before a "best fit" model was chosen for the report. It is thus likely that analyses were performed repeatedly, with numerous alternative combinations and choices of parameters and adjustments and smoothing algorithms, but only a very limited set of results was presented. If this is correct, then it raises concerns about overestimation bias due to multiple tests and comparisons.[10]

Because the raw data were not provided, the extent and types of alternative analyses performed were not described, and the results of alternative analyses were not presented, the reported results must be viewed with caution. It seems likely that numerous analyses were performed on this dataset, but only the strongest result reported, thus the findings seem appropriate only for hypothesis generating, not hypothesis testing.

4.b Only a minority of results was reported

The failure to report most of the analytical data can be viewed from another perspective. Z&S analyzed mortality in 47 cities, considering overall mortality plus four mortality sub-categories. They also analyzed those data for each of four seasons plus all seasons combined.

Thus for each lag model, there were 235 individual city results for mortality categories (i.e., 47 (cities) x 5 (mortality categories) = 235) and when seasonality categories were included there were five times as many individual results (i.e., 47 (cities) x 5 (mortality categories) x 5 (season categories) = 1175), where each individual result represented a unique combination of [city-death category-season category]. In addition, for each lag model there were another 26 results representing the averages of those [city-death category-season category] groupings, for a grand total of 1201 analytical results per model.

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[9] Peng RD et al: Seasonal analyses of air pollution and mortality in 100 US cities. *Am J Epidemiol* 161:585-594, 2005.

[10] For example, see Jeffries NO: Multiple comparisons distortion of parameter estimates. *Biostatistics* 8:2500-504, 2007.

If five different lag models were explored, then there would have been more than 6000 results, reflecting individual combinations of [city-death category-season category-lag model]. However, the Z&S report included only 26 results for $PM_{10-2.5}$ (Table 2).

Z&S also stratified cities into six "climate classifications", which further increased the number of analytical results. In their report, they presented only 30 results, reflecting six "climate classifications" and five death categories for one lag model (Table 4).

Because detailed results were not reported, it is not possible to evaluate the consistency of the reported findings across the various cities and seasons, nor is it possible to estimate the uncertainty that characterized those findings. The aggregated results would be substantially less informative if no associations or negative associations with $PM_{10-2.5}$ had been seen in a large proportion of the individual cities. Ultimately, the probative value of these data depends on both the magnitude and consistency of the observed associations.

5. The analytical results are inconsistent

The findings reported by Z&S raise concerns about apparent inconsistencies. Although the report did not include city-specific findings, significant between-city heterogeneity was reported for overall mortality during spring, summer and autumn. Significant heterogeneity was also reported for respiratory mortality during the spring, when the largest positive effect of $PM_{10-2.5}$ was seen. Such heterogeneity suggests that there was a wide range of city-specific findings, with some cities showing no effects and perhaps others with significant negative effects. However, because the actual results were not provided, it is not possible to evaluate these possibilities.

The finding that $PM_{10-2.5}$ has adverse effects mainly during the spring, but not in other seasons is challenging. Z&S speculate that this reflects greater indoor PM penetration during the spring, but they also note that their findings are at variance with a recent NMMAPS report that found a different seasonal distribution of PM_{10}-related mortality in 100 US cities. [9]

The ISA also noted inconsistencies within the Z&S report and between the associations reported by Z&S and the results previously reported by others:

> "An examination of $PM_{10-2.5}$ mortality associations on a national scale found a strong association between $PM_{10-2.5}$ and respiratory mortality, but this association varied when examining city-specific risk estimates (Z&S, 2009). Additionally, copollutant analyses were not conducted in this study, and the associations observed are inconsistent with those reported in single-city studies." (p. 6-246)

In addition, Z&S reported that $PM_{10-2.5}$ was not associated with any effects in the area classified as "dry", a climate area that includes the cities of Phoenix and Albuquerque: "there was no effect in the dry region" (p. 901). But, as noted in the ISA, that finding is inconsistent with the results of at least four other studies:

> "The lack of a $PM_{10-2.5}$-mortality association in the 'dry' region in this study is in contrast to the result from three studies that analyzed Phoenix data and found associations, as reviewed in the 2004 PM AQCD, and Wilson et al." (6-294)

6. The analytical findings cannot be generalized

The plausibility of the Z&S analytical findings rests on a series of hypotheses and speculations:

> The absence of effects in the "Mediterranean region" (i.e., California, Oregon and Washington) might have been due to measurement error because the counties are so large.
>
> The greater effect in spring might have been due to greater penetration of PM into residences.
>
> The regional variation of $PM_{10-2.5}$ effects suggests "regional variations in the toxicity of coarse particles" which requires "further study".

Each of these hypotheses might prove correct, but none has been evaluated and the data needed to independently evaluate them has not been provided.

Thus, these study findings seem inconsistent across seasons, inconsistent between cities, and inconsistent with other published studies. For such reasons, the findings do not provide the basis to generalize, i.e., to describe the risks of $PM_{10-2.5}$ at a national level. The study successfully generates a variety of PM-related hypotheses, but unfortunately it fails to test those hypotheses and it does not serve as a sufficient basis to justify promulgation of an NAAQS.

Summary

The recent Z&S study represents a major effort to evaluate possible associations between $PM_{10-2.5}$ and mortality. It is unfortunate that this report does not allow such associations to be reasonably determined. It should be clear that the findings described in the June, 2009 issue of *Environmental Health Perspectives* leave many unanswered questions and they are not adequate to justify promulgation of a $PM_{10-2.5}$ NAAQS or support any revision to the PM_{10} NAAQS. To the contrary, the plausibility of the findings remains uncertain.

In the interest of understanding the adverse effects of exposure to coarse PM and in order to make full use of the Z&S data, I encourage EPA to ask HEI to review and comment on the data set and the analytical methods, and perform reanalysis if appropriate. It would be a shame to waste the efforts that Z&S have already made, but it would be worse to act on the basis of their published findings.

Jonathan Borak, MD, DABT

Dr. Jonathan Borak is Associate Clinical Professor of Medicine, Epidemiology and Public Health at Yale University, a faculty member of the Yale Occupational and Environmental Medicine Program, and Director of the Yale University Interdisciplinary Risk Assessment Forum. He is also Adjunct Associate Professor of Occupational Medicine at Johns Hopkins University. Dr. Borak received his BA with Honors from Amherst College and earned his MD at New York University. He completed a residency in internal medicine at Montreal's Royal Victoria Hospital, was a Robert Wood Johnson Foundation Clinical Scholar at McGill University, and a Postdoctoral Fellow in Internal Medicine at Yale University. He is Board certified in Internal Medicine, Occupational Medicine, and Toxicology and is a Fellow of the American College of Physicians, the American College of Occupational and Environmental Medicine, and the Royal College of Physicians of Canada.

Dr. Borak's professional activities combine research, teaching, and consulting in the areas of toxicology, risk assessment and clinical medicine. He has published numerous peer-reviewed scientific articles and written or edited textbooks, monographs and book chapters on a variety of medical and scientific issues. He received the 2003 Adolph G. Kammer Merit in Authorship Award and the 2004 Robert A. Kehoe Award of Merit of the American College of Occupational and Environmental Medicine.

Dr. Borak is a founding member of US EPA's National Advisory Committee to Develop Acute Exposure Guideline Levels for Hazardous Substances (recipient of the 2000 Hammer Award of the National Partnership for Reinventing Government) and serves on the National Research Council Committee on Toxicologic Assessment of Low-Level Exposures to Chemical Warfare Agents. He is currently Chair of the Council on Scientific Affairs of the American College of Occupational and Environmental Medicine (ACOEM) and is a former member of the ACOEM Board of Directors. He has served on the National Faculty of the American Heart Association, as Councilor of the American College of Emergency Physicians, on National committees of the American Industrial Hygiene Association, as President of the Occupational and Environmental Medicine Association of Connecticut and as Chairman of the Connecticut State Medical Society Committee on Preventive Medicine and its Committee on Emergency Medical Services.

He is a member of the Editorial Boards of *Journal of Occupational and Environmental Medicine* and *Journal of Occupational and Environmental Hygiene,* was Associate Editor of *Occupational and Environmental Medicine Reports*, and has served as an editorial board reviewer for *Toxicology and Applied Pharmacology, Toxicological Sciences, American Industrial Hygiene Association Journal, Journal of Human and Ecological Risk Assessment, Toxicology and Industrial Health, Annals of Emergency Medicine,* and other peer-reviewed publications. He was editor and course director of the *Core Curriculum in Environmental Medicine* (ACOEM, 1994) was a Guest Editor and Peer Reviewer of ATSDR's *Case Studies in Environmental Medicine* and Peer Reviewer of ATSDR's *Toxicology Profiles.*

Jonathan Borak, MD: Representative Publications

Books and Monographs

Borak J, Callan M, Abbott W: *Hazardous Materials Exposure: Emergency Response and Patient Care.* Englewood Cliffs, NJ: Prentice Hall, 1991.

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Written Testimony Submitted by the Honorable Glenn English
Chief Executive Officer
National Rural Electric Cooperative Association

U.S. House of Representatives
Committee on Small Business
Subcommittee on Agriculture, Energy and Trade

Hearing:
Adrift in New Regulatory Burdens and Uncertainty:
A Review of Proposed and Potential Regulations on Family Farmers

November 29, 2011

Testimony of the Honorable Glenn English, CEO
National Rural Electric Cooperative Association

Submitted for the Record to the
United States House
Committee on Small Business
Subcommittee on Agriculture, Energy and Trade
Hearing on
Adrift in New Regulatory Burdens and Uncertainty:
A Review of Proposed and Potential Regulations on Family Farmers

November 29, 2011

Thank you for the opportunity to offer this written statement for the hearing record on the impacts of new National Pollutant Discharge Elimination System (NPDES) permit requirements under the Clean Water Act (CWA) for the application of pesticides and other chemicals registered under the Federal Insecticide, Rodenticide and Fungicide Act (FIFRA).

NRECA is the not-for-profit national service organization representing over 900 not-for-profit, member-owned electric cooperatives. The great majority of these cooperatives are distribution cooperatives, which provide retail service to over 42 million consumers in 47 states. Kilowatt-hour sales by electric cooperatives account for approximately 12 percent of total electricity sales in the United States. NRECA's members also include 67 generation and transmission (G&T) cooperatives, which supply wholesale power to their distribution cooperative owner-members.

Cooperatives average fewer than seven customers per mile of electric distribution line, the lowest density in the electric utility industry. Electric cooperatives own and maintain 2.5 million miles, or 42 percent, of the nation's electric distribution lines covering three quarters of the nation's land mass, traversing vast, remote stretches of often rugged terrain. Low population densities and expansive distribution networks present unique economic and engineering challenges for electric cooperatives. Despite these challenges, electric cooperatives have a long and successful track record in fulfilling their mission to provide affordable and reliable power to electric cooperative members.

The effort to ensure safe and reliable electric service never ceases and this effort is complicated by service interruptions and outages caused when power lines come into contact with trees or other vegetation. This can occur when vegetation grows or falls on power lines, or when lines sag into nearby vegetation under conditions of high loads or high temperatures. Tree contacts with distribution lines are the top cause of service interruptions and have the greatest impact on service reliability. A loss of electric service is not only costly and inconvenient, but can be life threatening to people on life support systems and can pose safety and health concerns as a result of a loss of heating or air conditioning.

An essential component to keeping electricity safe and reliable is maintaining transmission and distribution line rights-of-way (ROW). The control of vegetation in and along a cooperative's ROW constitutes a major expense. Currently, electric cooperatives implement systematic vegetation management cycles to reduce tree related outages and to expedite service restoration during storms and inclement weather.

In contrast to current practices, early efforts at ROW clearing were reactive and relied heavily on mechanical controls such as mowing and cutting. Such practices had higher costs, were less effective and had a negative impact on wildlife habitat and the environment. Moreover, mechanical controls are a short term fix because after cutting, brush will re-sprout into many more stems than were originally cut, leading to even denser brush that shades and crowds out desirable plants.

Current vegetation management practices at electric cooperatives incorporate the targeted use of specifically selected herbicides, using aerial spraying or ground based applications. Direct exposure to humans and animals is negligible and any herbicide residue not absorbed by the targeted plant is rapidly biodegraded by soil microorganisms or light. Chemical controls result in a dramatic reduction in stem density and reduced maintenance, which leads to significantly lower maintenance costs for the cooperative.

By incorporating the use of chemical controls, some cooperatives have reduced their mowing and ROW clearing budgets by up to 70 percent. The use of herbicides is environmentally favorable due to the resulting growth of low-growing, non-woody plants that do not interfere with power lines and provide natural habitat to the benefit of a variety of wildlife. Employing advanced vegetation management practices is also essential for worker safety, and NRECA evaluates these practices when considering the cooperative's safety accreditation.

The electric utility industry is subject to strict reliability standards under state and federal law. For example, the North American Electric Reliability Corporation (NERC) is a self-regulatory organization that is subject to the oversight of the Federal Energy Regulatory Commission (FERC). NERC is responsible for developing reliability standards applicable to the bulk power system, including a vegetation management standard. FERC has the authority to review and approve the vegetation management standards developed by NERC for large interstate transmission facilities as well as certain other facilities critical to the reliability of the wholesale bulk-power system.

In 2007, NERC issued "FAC-003-1 Vegetation Management," requiring owners of transmission to control vegetation in transmission line ROW. Companies that violate reliability standards such as FAC-003-1 may be fined up to $1 million a day per violation. NERC has authority over higher voltage transmission lines that are integral to the national grid. Lower-voltage distribution lines are regulated by the state regulatory commissions that have the authority to establish and enforce vegetation management standards for distribution systems. The use of herbicides on utility ROW is essential for

maintaining the reliability of electric transmission and distribution systems and for maintaining compliance with strict state and federal reliability requirements.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is the federal regulatory statute that governs the sale and use of pesticides, including herbicides, through registration and labeling requirements. The purpose of FIFRA is to protect human health and the environment from unreasonable adverse effects of pesticides, while taking the cost and benefits of the product into account. The Environmental Protection Agency (EPA) evaluates the risks of exposure associated with the pesticides, and then specifies the approved uses and conditions required to be displayed on the product label.

Federal law prohibits the use of a pesticide in a manner that is inconsistent with the product label guidelines and instructions. Congress clearly established FIFRA as the comprehensive regulatory framework for addressing pesticides, and did not intend for pesticides to be subject to the National Pollutant Discharge Elimination System (NPDES) permitting requirements set forth in the federal Clean Water Act (CWA). In 2006, EPA promulgated a rule to clarify that pesticide applications that comply with FIFRA are not subject to the jurisdiction of the CWA. However, that rule was vacated by the 6th Circuit **Court of Appeal's** 2009 decision in *National Cotton Council v. EPA*. The end result being that effective October 31, 2011, many activities that involve pesticide applications are now subject to the requirements of the NPDES program.

Subsequently, EPA issued a federal pesticide general permit (PGP) that took effect November 1, 2011. The PGP has significantly expanded the NPDES permitting program by virtually doubling the number of entities subject to its requirements. In addition to placing a duplicative regulatory burden on electric cooperatives, the PGP imposes unnecessary cost and complexity for compliance. Whereas before, electric cooperative personnel were compliant so long as they faithfully abided by the instructions on the pesticide label, the PGP now requires the filing of a Notice of Intent to comply with the **PGP along with the familiarity and adherence to the permit's conditions and restrictions.** The most unfortunate aspect to all of this is that while dramatically adding to the regulatory compliance burden and costs of small businesses like electric cooperatives, the PGP will result in little to no environmental benefit.

Fortunately, a broad bipartisan majority of the United States House of Representatives has expressed support for this position by voting to pass H.R. 872, the Reducing Regulatory Burdens Act of 2011. H.R. 872 is common sense legislation that will relieve pesticide applicators from the duplicative regulatory requirement imposed by the *National Cotton Council* decision by removing the redundancy of CWA regulations over pesticides. H.R. 872 is essential to providing regulatory certainty for pesticide applicators like electric cooperatives to focus on providing reliable electric service while maintaining diligent compliance with FIFRA. NRECA applauds the House for quick adoption of H.R. 872 and urges the United States Senate to also pass legislation to address this problem.

NATIONAL STONE, SAND & GRAVEL ASSOCIATION

Natural building blocks for quality of life

NATIONAL STONE, SAND & GRAVEL ASSOCIATION

STATEMENT FOR THE RECORD

OF THE

HOUSE COMMITTEE ON SMALL BUSINESS

HEARING:

ADRIFT IN NEW REGULATORY BURDENS AND UNCERTAINTY: A REVIEW OF PROPOSED AND POTENTIAL REGULATIONS ON FAMILY FARMERS

November 16, 2011

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Thank you, Chairman Graves and Members of the Committee for allowing the National Stone, Sand & Gravel Association (NSSGA) to provide a statement for the record of this hearing on over-regulation. This statement will specifically address the harmful effects of EPA's regulation of nuisance dust on the aggregates industry. Regulating coarse particulate matter is an issue of utmost concern to the aggregates industry; an industry which involves extraction of a foundational material essential to the built environment.

Aggregates Industry

The National Stone, Stand & Gravel Association represents the crushed stone, sand and gravel – or construction aggregates – industries. Its member companies produce more than 90 percent of the crushed stone and 70 percent of the sand and gravel consumed annually in the United States. There are more than 10,000 construction aggregates operations nationwide.

Aggregates are used in nearly all residential, commercial, and industrial building construction and in most public works projects, including roads, highways, bridges, dams, airports, water and sewage treatment plants, and tunnels. While Americans take for granted this essential natural material, aggregates are essential to the built environment. Aggregates make up 94 percent of asphalt and 80 percent of concrete. About 400 tons are used in an average home (not counting the required subdivision work) and 38,000 tons are used to construct one mile of highway. Without aggregates, we would be sitting and driving on dirt.

Aggregates are a high volume, low cost product. Due to high product transportation costs, proximity to market is critical; thus, 70 percent of our nation's counties are home to an aggregates operation. Sales of natural aggregates generate nearly $40 billion annually for the U.S. economy. When combined with related industries, such as cement, concrete and construction equipment and supplies, the transportation construction industry generates more than $200 billion in economic activity every year.

Through its economic, social and environmental contributions, aggregates production helps create sustainable communities and is essential to the quality of life American's enjoy. Yet despite the large amounts of aggregates used in all kinds of construction the aggregates industry has experienced the most severe recession in its history. Production of aggregates in the U.S. has gone from over 3 billion metric tons in 2006 valued at $21 billion to 2 billion metric tons in 2010 at a value of approximately $17 billion, a 4 billion decrease. This production decrease is on top of decreases in 2007, 2008 and 2009. Many aggregates companies have had to lay off employees for the first time in their history. Of particular relevance to this hearing, 70 percent of NSSGA members are considered small businesses. Because so much of the aggregates produced go towards public infrastructure projects like roads, bridges and water treatment plants, increases in the cost of aggregates, such as those from overregulation, are borne by taxpayers.

Industry's Demonstrated Commitment to the Environment and to Sustainability

NSSGA members long ago committed to Guiding Principles for environmental compliance and sustainability, and recognize that the Earth's resources, upon which all of life depends, are finite and that wise environmental stewardship is necessary today to preserve the potential for a quality life for future generations. NSSGA members are committed to full compliance with all pertinent environmental law and regulations, and emphasize sustainable practices.

Since it is the most fundamental component of construction, aggregates are employed in any road or building project, as well as for many environmental purposes. Environmental uses include: erosion control alongside roads, dams, shorelines and bridges, filtration for storm water as well as water and sewage treatment, as 80-some percent of the material used to construct the systems which convey water to be treated as well as clean water, flue gas desulferization in power plant and industrial air emissions, reclamation and habitat creation, and neutralization of acidic discharges.

Regulatory Burden is a Challenge

While there are many environmental benefits to using stone, sand and gravel the number and impact of new regulatory proposals on top of existing heavily regulated operations seem to continue unabated. NSSGA believes that, at this challenging time for our Nation's economy, government should consider the cumulative impact of the costs of

compliance before more rules are imposed on industry. Federal regulatory decision-makers must wield their authority with care, and should base regulatory decisions on published, peer -reviewed assessments of risk. We are wary of rules that create more stringent or even unattainable standards without sufficient statistical, scientific or analytical justification.

Quarry Operations and Dust

NSSGA was relieved at the EPA Administrator's recent decision to not go forward with a proposal to reduce the NAAQS for PM 10. Such a standard would have been devastating to our industry, particularly in Midwestern and Western states. We applaud the responsible behavior on the part of this committee to have this hearing so that the issues that must be considered in law and rulemaking are collected for the record and as a tutorial for the future.

Like agriculture, resource-based industries such as aggregates production have limited opportunities to reduce dust. Most aggregates operations would have to cut production to meet a reduced standard. Dust is generated at an aggregates operation by crushing, screening, conveying, stockpile activity and truck traffic on paved and unpaved roadways. Maximum aggregates production is achieved, and compliance with the current dust standard is maintained, by aggregates producers already using Best Available Control Technologies on their processing plants such as wet suppression, dry collection and enclosures, and properly maintaining roadways. However, these sources are only a

small fraction of dust present at a typical aggregates site; most is from uncontrollable sources such as from roads and windblown dust, particularly in rural areas.

Current Regulatory Requirements

To meet the current National Ambient Air Quality Standard for Coarse Particulate Matter (PM 10), aggregates facilities are required to have permits with state environmental agencies which seek to control dust by limiting production and requiring control technologies such as water sprays, dust collectors or enclosures to limit dust on crushers and other equipment and road maintenance. Quarries demonstrate compliance via air dispersion modeling or monitoring.

Many aggregates facilities struggle to meet the current standard, and changes in operations, even to improve efficiency, are often compromised. For example, one facility wanted to upgrade its operations to increase efficiency and use less fuel. In order to relocate equipment, the changes in the modeled dust emissions would have led to changes in the facility permit. In order to approve the changes in the permit, the state agency required a long road to be paved, which would have cost five hundred thousand dollars. This was even more impractical given that the shape of a quarry changes as the material is mined. Because of this regulatory burden, the changes to plant operations were not made.

Impacts of Dust Over-Regulation

We are pleased with the recent decision by Lisa Jackson to retain the current standard at present. However, a future reduction in the standard would be difficult, if not impossible, to meet for mining, farming, ranching, transportation and other sources of coarse crustal fugitive dust emissions found in parts of the West, Southwest, Midwest and East. The only way to meet a lower fence-line NAAQS, via air dispersion modeling or air monitoring, is to limit annual production in the processing plant and/or the number of trucks traveling on roadways within the property, thus limiting sales to customers (restriction of trade). Limiting aggregates production and sales would create additional job loss and economic strain.

The recent Coarse Particle Coalition study confirms that a reduction in the standard would cause widespread reductions in production and employment at facilities throughout agricultural and resource-based industries. The study showed a lower PM NAAQS would leave more than half of the U.S. vulnerable to violating the standard and put many areas out of conformity with their State Implementation Plans and thus place highway funding in jeopardy.

The dominance of natural dust sources (i.e. windblown dust from arid lands) and municipal unpaved roads is the main reason that some areas in the West and Southwest have been in continual non-attainment with PM10 standards since the late 1980s. There is no practical way to control these sources and reduce the PM10 ambient air

concentrations; nevertheless EPA continues to promulgate unworkable standards that hurt job growth without health benefits.

In Utah, a reduction in the current standard would result in 23 of the 29 counties exceeding the new standard. Although best management practices and strict requirement are already in place, this would result in extreme limits on production and/or facility closures. This would not only impact the jobs at the aggregates operations, but many other infrastructure and construction related jobs as well.

One NSSGA member has calculated that in order to meet a reduced standard, a typical facility would have to reduce production by more than two-thirds. This would substantially change the business model, and lead to plant closure (and the loss of 50 jobs) or a dramatic increase in the price of product. Given that there are over 10,000 operations in the U.S., and virtually every congressional district is home to an aggregates operation, this could result in significant job losses. With the anticipated PM10 NAAQS, NSSGA member companies would have had extreme difficulty in expanding existing facilities or opening new ones to meet construction demands for aggregates.

Taken further, a cut in aggregates production would lead to a shortage of stone, concrete and asphalt for state and federal road building/repair, commercial and residential construction, which in turn would cause an increase in the price of stone for these projects ranging from 80 percent to 180 percent and further suppress employment in the construction industries. Given that infrastructure investment is essential to economic

recovery and growth, this additional burden on the aggregates industry comes at a time when both aggregates supply and jobs are of vital importance.

The Clean Air Act requires EPA to set National Ambient Air Quality Standards to protect public health. However, in evaluating health effects of possible changes in the Standards, EPA has failed to consider the very significant adverse health effects caused by forced unemployment.

Conclusion

NSSGA appreciates this opportunity to explain that the natural dust levels in the ambient air that must be considered in endeavoring to lower the currently strict PM10 NAAQS. Lowering the PM10 NAAQS would have had devastating effects of unjustifiable overregulation of nuisance dust to the aggregates industry, which of course extends to the construction and agricultural sectors among many others. NSSGA is relieved at the recent announcement by EPA that they will not proceed on a reduction of current PM10 levels, and we are grateful for the work of this committee toward that end.

Attachments

NATIONAL STONE, SAND & GRAVEL ASSOCIATION

Natural building blocks for quality of life

NSSGA SUSTAINABLITY GUIDING PRINCIPLES

The members of the National Stone, Sand & Gravel Association (NSSGA) identify sustainability as a business approach that integrates environmental stewardship, social responsibility and economic prosperity to ensure the long-term supply of aggregate materials to society. NSSGA recognizes that sustainable practices are necessary today to preserve the potential for a quality life for future generations. The long-term viability of the aggregates industry is dependent on obtaining and maintaining a social license to operate. NSSGA member companies will enhance their ability to obtain these licenses and to compete effectively when applying sustainability guidelines.

Overarching Practices:

- NSSGA members sustain the communities in which we operate by providing raw materials as natural building blocks for quality of life.
- We are conscious of the need to provide economic, social and environmental value for future generations, and the communities in which we operate.
- We demonstrate a strong and unwavering commitment to safety, health and the environment at our operations.
- We work with appropriate government bodies to establish effective, responsible and balanced laws and other requirements based on sound science.
- We encourage life cycle re-use of products during manufacturing and post-consumer use.
- We maintain adequate aggregate resources in locations that minimize the life cycle impacts of the resource's extraction, delivery and use.
- We encourage proper land use development and planning within communities to ensure long-term aggregate resource availability.
- We adhere to the highest ethical business practices and transparency in all aspects of our operations.
- We recognize that profitability is essential to a sustainable industry and its continued ability to contribute to communities.

Our Members are Encouraged to:

- Develop a site-specific plan for post-mining land use and/or reclamation that engages stakeholders in planning for future needs and interests.
- Plan for the prevention and/or minimization of environmental impacts.
- Adopt and implement an Environmental Management System program to properly manage potential
- Pursue new technologies and practices to improve the operational, safety, health and environmental efficiency of our operations.
- Invest in the personal and professional development of employees to ensure a strong workforce into the future.
- Ensure that employees are treated in a respectful and positive manner, and provide them with competitive compensation programs consistent with performance and industry practice.
- Identify, control and/or eliminate risks associated with occupational injuries and illnesses.
- Encourage employees and contractors to interact responsibly within the community in which we operate and serve.
- Work in partnerships to promote beneficial post-mining land use, including industrial, commercial, and residential and community development, agricultural production, and wildlife conservation, habitat creation and restoration.

NATIONAL STONE, SAND & GRAVEL ASSOCIATION

Natural building blocks for quality of life

NSSGA ENVIRONMENTAL GUIDING PRINCIPLES

The members of the National Stone, Sand and Gravel Association (NSSGA) recognizes that the Earth's resources, upon which all life depends, are finite, and that wise environmental stewardship is necessary today to preserve the potential for a quality life for future generations. To that end, the NSSGA Board of Directors amended these Environmental Guiding Principles on February 11, 2001. The Environmental Guiding Principles were originally adopted January 20, 1991.

The National Stone, Sand and Gravel Association:

- Encourages its members to meet all established environmental regulatory requirements, and where possible to do better than the law and regulations require.
- Believes that environmental laws and regulations should be based on sound scientific, engineering and medical research and on established scientific, engineering and medical principles. To this end, NSSGA will work with lawmakers and regulators and make available the expertise of its member, staff and research facilities to help in shaping the nation's environmental policies.
- Encourages its members to adopt and implement an Environmental Management System (EMS) program to meet its environmental requirements and improve its overall performance. An EMS is a continual cycle of planning, implementing, reviewing and improving the actions that an organization takes to meet its environmental goals.
- Encourages its members to strive for excellence in environmental affairs and to provide leadership by example by demonstrating environmental stewardship in all aspects of their operations.
- Encourages its members to contribute to environmental enhancement by implementing programs such as landscaping and wildlife habitat development.
- Encourages its members to work with community leaders and citizens groups in developing plans for appropriate uses of the land in the community interest, once mining operations have been completed.
- Encourages its members to participate in communicating to the public the importance to society of an environmentally-responsible aggregate industry, and in educating the youth of our country in the wisdom of responsible environmental stewardship in a business setting.
- Believes that wise environmental stewardship is good business, and good for business.

Nov. 21, 2011

The Honorable Scott Tipton
Chairman
Subcommittee on Agriculture, Energy and Trade
218 Cannon House Office Building
Washington, D.C. 20515

The Honorable Mark Critz
Ranking Member
Subcommittee on Agriculture, Energy and Trade
1022 Longworth House Office Building
Washington, D.C. 20515

Dear Mr. Chairman and Mr. Ranking Member,

The undersigned organizations would like to express our strong support for the *Farm Dust Regulation Prevention Act of 2011*, H.R. 1633. H.R. 1633 would bring some much needed certainty to agriculture and other rural businesses by exempting rural "nuisance dust" from EPA regulation if states and localities regulate it on their own. Our organizations strongly support the bill and its effort to keep jobs in rural America.

As you are aware, farming and other resource-based industries are dusty professions. From tilling fields, to driving on dirt roads, to extracting resources, rural Americans deal with dust every day. Working in the soil is where they derive their livelihoods, and where the world derives much of its food and other essential resources. If EPA were to revise the dust standard now or in the future, states would be put in a position of having to impose regulatory restraints on rural operations, increasing the cost of production when that cost is already at historically high levels. And, for what purpose? Scientific studies have never shown rural dust to be a health concern at ambient levels.

While the undersigned organizations welcome EPA's Oct. 14 announcement that the agency plans to propose to retain the current coarse particulate matter (PM_{10}) National Ambient Air Quality Standard (NAAQS), the announcement does not provide the certainty that rural America needs. First, it is common for the agency to finalize a rule that is different from the proposed rule. In fact, in 1996 EPA proposed to remove the PM_{10} 24-hour standard altogether, only to bring it back in the final rule. And in 2006, EPA proposed to exempt agriculture dust, but that exemption also disappeared in the final rule. Second, under the Clean Air Act, EPA must review this standard every five years. That means we could face the same challenges again in just five short years.

Thankfully, this Congress has the opportunity to ease this potential burden on rural America. H.R. 1633 would exempt rural "nuisance dust" from regulation under the Clean Air Act if states and localities regulate it on their own. In the event a state or locality does not regulate rural dust, the administrator could regulate it only if validated scientific analysis show there is a significant health effect from such dust in a particular area and that the costs to the local economy associated with dust regulation would not outweigh any benefits.

H.R. 1633 is common sense legislation that the undersigned strongly support.

Sincerely,

Agribusiness Association of Indiana
Agribusiness Association of Iowa
Agricultural Council of Arkansas
Agricultural Retailers Association
Agri-Mark, Inc.
Alabama Cattlemen's Association
Alabama Pork Producers Association
All-Terrain Vehicle Association

American Farm Bureau Federation and their 51 state affiliates
American Feed Industry Association
American Motorcyclist Association
American Sheep Industry Association
American Veal Association
Americans for Prosperity
Americans for Tax Reform
Arkansas Cattlemen's Association
Arkansas Pork Producers Association
Arkansas Poultry Federation
Arizona Cattle Feeders' Association
Arizona Cattle Growers' Association
Arizona Cotton Growers Association
Arizona Pork Council
California Cattlemen's Association
California Pork Producers Association
CropLife America
Colorado Association of Wheat Growers
Colorado Cattlemen's Association
Colorado Corn Growers Association
Colorado Lamb Council
Colorado Livestock Association
Colorado Pork Producers Council
Colorado Potato Administrative Committee
Colorado Sheep & Wool Authority
Colorado Wool Growers Association
Council for Citizens Against Government Waste
Dairy Farmers of America
Dairy Producers of New Mexico
Dairy Producers of Utah
Dairylea Cooperative
South East Dairy Farmers Association
Stewards of the Sequoia
Florida Cattlemen's Association
Florida Nursery, Growers and Landscape Association
Georgia Agribusiness Council
Georgia Cattlemen's Association
Georgia Fruit and Vegetable Growers Association
Georgia Milk Producers
Georgia Pork Producers Association
Georgia Poultry Federation
Georgia Watermelon Association
Idaho Cattle Association
Idaho Dairymen's Association
Idaho Grain Producers Association
Idaho Pork Producers Association
Idaho Potato Commission
Idaho Wool Growers Association
Illinois Beef Association
Illinois Pork Producers Association
Independent Cattlemen's Association of Texas
Indiana Beef Cattle Association
Indiana Pork
Iowa Cattlemen's Association

Iowa Pork Producers Association
Kansas Livestock Association
Kansas Pork Association
Kentucky Cattlemen's Association
Kentucky Pork Producers Association
Let Freedom Ring
Livestock Marketing Association
Louisiana Cattlemen's Association
Louisiana Pork Producers Association
Maine Hog Growers Association
Michigan Cattlemen's Association
Michigan Pork Producers Association
Milk Producers Council
Minnesota Grain and Feed Association
Minnesota Pork Producers Association
Minnesota State Cattlemen's Association
Mississippi Cattlemen's Association
Mississippi Pork Producers Association
Missouri Cattlemen's Association
Missouri Corn Growers Association
Missouri Pork Producers Association
Missouri Poultry Federation
Montana Pork Producers Council
Montana Stockgrowers Association
Montana Wool Growers Association
National Association of Manufacturers
National Cattlemen's Beef Association
National Chicken Council
National Cotton Council
National Cotton Ginners Association
National Council of Farmer Cooperatives
National Federation of Independent Business
National Grain and Feed Association
National Livestock Producers Association
National Meat Association
National Milk Producers Federation
National Mining Association
National Oilseed Processors Association
National Pork Producers Council
National Potato Council
National Renderers Association
National Stone, Sand, and Gravel Association
National Turkey Federation
Nebraska Cattlemen's Association
Nebraska Grain and Feed Association
Nebraska Pork Producers Council, Inc.
New Hampshire Pork Producers Council
New Mexico Cattle Growers' Association
New Mexico Farm and Livestock Bureau
New Mexico Federal Lands Council
New Mexico Wool Growers, Inc.
New York Producers Cooperative, Inc.
North Carolina Agribusiness Council, Inc.
North Carolina Cattlemen's Association

North Carolina Forestry Association
North Carolina Horse Council
North Carolina Peanut Growers Association
North Carolina Pork Council
North Carolina Poultry Federation
North Carolina Soybean Producers Association, Inc.
North Carolina SweetPotato Commission
North Dakota Corn Growers Association
North Dakota Pork Producers Council
Northeast Ag and Feed Alliance
Northeast Dairy Farmers Cooperatives
North Dakota Stockmen's Association
Ohio AgriBusiness Association
Ohio Cattlemen's Association
Ohio Pork Producers Council
Oklahoma Cattlemen's Association
Oklahoma Poultry Federation
Oklahoma Pork Council
Oregon Pork Producers Association
PennAg Industries Association
Pennsylvania Pork Producers Strategic Investment Program
Public Lands Council
Rocky Mountain Agribusiness Association
Select Milk Producers
Small Business & Entrepreneurship Council
South Carolina Cattlemen's Association
South Carolina Pork Board
South Dakota Agri-Business Association
South Dakota Association of Cooperatives
South Dakota Cattlemen's Association
South Dakota Dairy Producers
South Dakota Grain & Feed Association
South Dakota Pork Producers Council
South Dakota Soybean Association
South Dakota Stockgrowers Association
South Dakota Wheat Inc.
Southern Cotton Growers
Southern Crop Production Association
Southeast Milk Inc.
Southeastern Livestock Network
St. Albans Cooperative Creamery
Tennessee Cattlemen's Association
Tennessee Pork Producers Association
Texas Agricultural Cooperative Council
Texas and Southwestern Cattle Raisers Association
Texas Association of Dairymen
Texas Cattle Feeders Association
Texas Pork Producers Association
The Blue Ribbon Coalition
The Fertilizer Institute
Upstate Niagara Cooperative
USA Rice Federation
U.S. Beet Sugar Association
U.S. Chamber of Commerce

Utah Cattlemen's Association
Utah Pork Producers Association
Utah Wool Growers Association
Virginia Agribusiness Council
Virginia Cattlemen's Association
Virginia Grain Producers Association
Virginia Pork Industry Association
Virginia Poultry Federation
Washington Cattle Feeders Association
Washington Cattlemen's Association
Washington Pork Producers
Western Business Roundtable
West Virginia Cattlemen's Association
Wisconsin Dairy Business Association
Wisconsin Pork Producers
Wyoming Pork Producers
Wyoming Stock Growers Association

United Fresh
PRODUCE ASSOCIATION

November 30, 2011

The Honorable Scott Tipton
Chairman, Subcommittee on Agriculture, Energy & Trade
House Committee on Small Business
2361 Rayburn House Office Building
Washington, DC 20515

The Honorable Mark Critz
Ranking Member, Subcommittee on Agriculture, Energy & Trade
House Committee on Small Business
2361 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Tipton and Ranking Member Critz,

Thank you for holding the November 17, 2011 hearing to examine the impacts of environmental regulations on small businesses. Clearly, government mandates affecting the air, water and soil are particularly relevant to the agriculture industry and this committee's interest in examining all the ramifications of these regulations is very helpful. We appreciate the opportunity to provide comments on how such proposed regulations can affect fresh produce businesses and also the broader business sector of which we are a part, agriculture.

United Fresh Produce Association represents many of the major growers and shippers of a variety of fruits and vegetables. We are the only trade association that exclusively represents the fruit and vegetable industry across the nation. United Fresh has been in existence since 1904 and has over 1200 members in 48 states and those members represent every part of the fruit and vegetable production chain. Our members are engaged in trade that crosses the borders with Mexico and Canada, and members import product from countries across the globe to meet the demands of their customers in terms of selection and year-round availability of fresh fruits and vegetables. With our network of farmers, shippers and retailers spread throughout the U.S., we have a broad perspective on, and interest in, federal agricultural policy.

Agricultural producers face a number of challenges they have little or no control over: weather, international trade factors, and consumer demand, among others. While the government does not owe producers a guarantee of success, the government, in this case, the federal government, can exert a great deal of influence over a producer's chance of success. And given what we do,

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which is feed the U.S. and much of the world, it is critical that the government exert its influence with the utmost care. While producers in the fruit and vegetable industry are impacted by a variety of regulations from different federal agencies, a couple of proposed and potential regulatory actions by the Environmental Protection Agency (EPA) have attracted a great deal of attention: one affecting pesticide applications and the other regarding farm dust.

There has been a great deal of attention and controversy concerning both of these initiatives, but regulations relating to pesticide applications have been the subject of the most judicial, regulatory and legislative activity. In 2009, the U.S. Sixth Circuit Court of Appeals ruled that any pesticide application near, over or in water could constitute a so-called pollutant discharges under the Clean Water Act (CWA) and therefore would require National Pollutant Discharge Elimination System (NPDES) permits. EPA has worked to develop an NPDES permit that would meet the court's ruling. While a six month stay in the deadline for implementing these new permits was granted, EPA's final NPDES permit was issued on October 31 of this year. As you are aware, the Court's ruling vacated EPA's regulations of several years that exempt certain pesticide applications from CWA permitting requirements. While we realize that EPA has taken some steps in an attempt to alleviate the significant burden these permitting requirements will place on pesticide applicators, this new permitting process will still be a hardship on ag producers to comply. Furthermore, the benefit of these permits is questionable, given that aquatic pesticide applications are already regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Producers' hopes that common sense would prevail in addressing this issue were raised this year when the House of Representatives passed legislation clarifying that pesticides regulated under FIFRA should not be subject to CWA permitting requirements. Unfortunately those hopes were dashed when the Senate failed to vote on the legislation prior to October 31 court deadline. With the failure of Congress to pass some kind of moratorium, the final permits went into effect and the uncertainty of how this will be applied by the courts subject to expected lawsuits challenging the implementation of the permit. EPA has stated its intent to not enforce the permitting requirements till January, 2012. Unfortunately, even with this gesture, producers are still vulnerable to citizen action lawsuit liability, which could undermine the protection of our food supply as well as protecting the general population from insect-borne diseases.

Another EPA regulatory issue that generated a great deal of concern in the farm community has been the agency's contradictory statements about their plans for regulating farm dust. Because

of the types of commodities grown and different farming methods used in different kinds of agriculture, this is an issue of particular concern to ag production areas in the Midwest and West. Any kind of agricultural operation has the potential to generate large amounts of dust under unfavorable weather conditions. EPA has responsibility for setting National Ambient Air Quality Standards (NAAQS) for among other things, particulate matter, including coarse particular matter, which is, dust. This responsibility rests with EPA under the Clean Air Act and the purpose is to protect the general public from pollutants that are well-known to have potentially harmful effects, such as industrial soot and car emissions. As part of its prescribed responsibilities, EPA must conduct a review of the standards every five years to determine if they must be revised. A policy assessment done by EPA last spring included a recommendation to strengthen NAAQS standards to a degree that would place rural areas, where dust is widespread and commonly occurring, in "nonattainment" status. Once designated as being in nonattainment, States would have to undertake time-consuming and costly efforts to institute changes to local activities in order to achieve attainment status. In a response to lawmakers concerns about the potential impact of the policy assessment recommendations, EPA did not specifically exclude farm dust from more stringent recommendations. As you can imagine, this raised serious concerns among ag producers as it is hard to overstate how commonly dust occurs in the course of producing a variety of agriculture commodities.

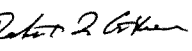
Within the last month, the EPA Administrator has stated that the agency does not intend to regulate farm dust under the more stringent standards recommended by her staff. While this is certainly a welcome development and we certainly hope that EPA will adhere to that statement, it does not remove the ongoing uncertainty to agricultural producers. First, while EPA may have decided to not pursue more stringent enforcement with respect to farm dust currently, EPA does still have the ability to impose more stringent standards regarding farm dust, given its jurisdiction over particulate matter and given EPA's own assertion to lawmakers that the NAAQS are not focused on any particular source or activity which means the agency cannot differentiate between urban and rural sources. Also, EPA has previously sought to exempt agriculture dust from NAAQS, but then reversed its proposal. These factors have caused ag producers to continue to be legitimately concerned about potential EPA actions regarding farm dust in the future.

Legislation has been introduced by Congresswoman Kristi Noem of South Dakota, along with a bipartisan group of cosponsors, seeks to provide some clarity to America's farmers and ranchers about how the government can and cannot regulate farm dust. The bill provides a one-year moratorium on any changes to the dust standard. It provides states and localities flexibility on

how to regulate farm dust and if states and localities do not regulate farm dust, EPA must determine adverse health effects from unregulated dust and determine that the benefits of applying EPA's standards would outweigh the cost to local communities. We urge the members of this subcommittee to give this measure serious consideration as well as continue to closely monitor EPA's activities on this subject to ensure the agency upholds its pledge.

Thank you for this opportunity to add our comments to a valuable examination of the effects of environmental regulations on the agriculture sector. We stand ready to work with you and this committee in the future to ensure that the perspectives of farmers and ranchers is fully considered in developing environmental policies.

Sincerely,



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