IS USDA ACCOUNTING FOR COSTS TO FARMERS CAUSED BY CONTAMINATION FROM GENETICALLY ENGINEERED PLANTS?

HEARING

BEFORE THE

SUBCOMMITTEE ON DOMESTIC POLICY

OF THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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IS USDA ACCOUNTING FOR COSTS TO FARMERS CAUSED BY CONTAMINATION FROM GENETICALLY ENGINEERED PLANTS?

THURSDAY, MARCH 13, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DOMESTIC POLICY,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:13 p.m., in room 2247, Rayburn House Office Building, Hon. Dennis J. Kucinich (chairman of the subcommittee) presiding.

Present: Representatives Kucinich and Issa.

Staff present: Jaron R. Bourke, staff director; Jean Gosa, clerk; Jim Moore, minority counsel; Larry Brady, minority senior investigator and policy advisor; Benjamin Chance, minority clerk; and Chris Espinoza, minority professional staff member.

Mr. KUCINICH. The committee will come to order.

This is a meeting of the Domestic Policy Subcommittee of the Oversight and Government Reform Committee. I am Dennis Kucinich, Chairman of the committee. Congressman Darrell Issa is the ranking minority member.

The hearing title today "Is the USDA Accounting for Costs to Farmers Caused by Contamination from Genetically Engineered Plants?" We have a rather lengthy witness list. What I am going to do is read an opening statement, then defer to my colleague Mr. Issa. It is quite possible votes are going to be called, and in that case we will recess for votes, and then we will come back and continue.

Contamination of conventional crops by genetically engineered [GE] plants can occur in several ways. They can pollinate non-genetically engineered plant species by wind or insects. They can grow as "volunteers" from seed that was unintentionally left in soil from a previous growing season. Or they can be mixed together with nongenetically engineered products in the harvesting, handling, distribution, and/or food processing systems. When genetically engineered plants contaminate the crops of conventional and organic farmers, the farmers pay a heavy price.

Today's hearing will not be about whether GE crops are "good or a bad" thing. Today's hearing is about whether the chief regulator and advocate for the farmers, USDA, and its subagency, the Animal and Plant Health Inspection Service [APHIS], is taking into account the cost to farmers and realities of contamination risk by the GE plants it regulates.

In 2000, America's corn farmers faced a sudden collapse of international and domestic demand for all varieties of U.S. corn. Prices fell considerably when genetically engineered StarLink corn was detected in taco shells by a private laboratory. StarLink had been approved for commercial use by APHIS, though limited to animal feed by the Environmental Protection Agency. Japan temporarily halted imports of U.S. corn. One of our witnesses estimated that the short-term cost to farmers was $500 million. A class action suit was settled for $110 million against the manufacturer of StarLink.

In 2006, America's rice farmers faced a sudden collapse of international demand for U.S. rice. Prices fell considerably when experimental genetically engineered LibertyLink was detected in the commodity rice supply by a foreign customer. APHIS investigated—over 7 months after the contamination was first detected—and concluded that the contamination originated at a field test plot in Louisiana. However, APHIS never determined how the contamination occurred. APHIS took no enforcement action, and, on its own initiative, deregulated LibertyLink rice after the contamination event. One of our witnesses today is an affected grower of conventional rice.

Two-and-a-half weeks ago, APHIS announced another contamination event, this time involving a genetically engineered corn variety called "Event 32." USDA's press release indicates that the cause of the contamination was the sale to farmers of contaminated seed, and that 53,000 acres of contaminated seed were planted in 2007.

According to APHIS, contamination events are rare. But it is unclear if this is accurate. Not a single government agency detected the contamination in any of these events. This is not surprising because the Federal Government doesn't test for crop contamination. We only know about crop contamination when private actors discover it by testing and decide to report it to the public. Sometimes contamination that is discovered by them is not reported.

APHIS is supposed to play a role in preventing contamination. But when the Inspector General, in 2005, published its audit of APHIS's controls over the issuance of permits for field testing of genetically engineered plants, it found, "APHIS had little assurance that field tests are being conducted safely, in a way that minimizes the potential for GE plants to persist in the environment." In all, the Inspector General made 28 recommendations to APHIS. APHIS eventually agreed to corrective action on each of the recommendations.

The National Environmental Policy Act of 1969 [NEPA], requires APHIS to analyze and report in Environmental Impact Statements [EIS] significant environmental impacts and any related economic impacts of decisions to deregulate or field test genetically engineered crops. APHIS has approved 13,500 field tests for GE crop varieties, occurring at more than 79,000 sites around the country, and has also deregulated more than 70 GE plant varieties. Yet APHIS has initiated only four environmental impact studies, all of them in the past year or so. One of them was ordered by a Federal court.

According to APHIS, the reason for the small number of environmental impact studies, in contrast to thousands of notifications,

permits, and deregulations it has issued, is that in nearly all cases APHIS determined that its proposed action did not have a significant impact as defined by the National Environmental Policy Act. However, two recent Federal court judges, reviewing APHIS's determination of, "no significant impact," for proposed agency actions related to two genetically engineered plants, Roundup Ready alfalfa and creeping bentgrass, found that APHIS had acted in an arbitrary and capricious manner, APHIS's determination was inconsistent with the National Environmental Policy Act, and APHIS violated the act.

In a Federal court decision, *Geertson Seed Farms* v. *Johanns,* the judge found that APHIS violated the National Environmental Policy Act by failing to account for the potential economic impact that would result from contamination of non-GE alfalfa by Roundup Ready alfalfa. The court ruled that APHIS had an obligation to evaluate economic costs stemming from a genetic contamination because they were so closely related. The Federal court concluded that the economic effects on the organic and conventional farmers of the government's deregulation decision are a direct result of the transmission of the genetically engineered gene to organic and conventional alfalfa. APHIS was required to consider those effects in assessing whether the impact of its proposed action is significant.

Today's hearing will focus on where APHIS goes from here. How will APHIS incorporate the guidelines provided by these judicial decisions in reforming the way it regulates the GE crop industry? Will APHIS account for the economic impact on farmers caused by GE plant contamination? Will APHIS take seriously the National Environmental Policy Act's recommendations to produce environmental impact statements that analyze environmental impacts and related economic impacts.

Now is the time to pose these questions and conduct oversight. In the wake of these two significant judicial rebukes, the USDA is in the process of overhauling both its GE crop and National Environmental Policy Act regulations.

I thank you very much.

[The prepared statement of Hon. Dennis J. Kucinich follows:]

Opening Statement
Congressman Dennis J. Kucinich, Chairman
Domestic Policy Subcommittee
Oversight and Government Reform Committee

"Is USDA Accounting for Costs to Farmers from Contamination Caused by Genetically Engineered Plants?"

Thursday, March 13, 2008

Contamination of conventional crops by genetically engineered (GE) plants can occur in several ways. They can pollinate non-genetically engineered plant species by wind or insects. They can grow as "volunteers" from seed that was unintentionally left in soil from a previous growing season. Or they can be mixed together with non-genetically engineered products in the harvesting, handling, distribution and/or food processing systems. When genetically engineered plants contaminate the crops of conventional and organic farmers, the farmers pay a heavy price.

Today's hearing will not be about whether GE crops are a "good" or a "bad" thing. Today's hearing is about whether the chief regulator and advocate for farmers, USDA and its subagency, the Animal and Plant Health Inspection Service (APHIS), is taking into account the cost to farmers and realities of contamination risk by the GE plants it regulates.

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any of these events. This is not surprising because the federal government doesn't test for crop contamination. We only know about crop contamination when private actors discover it by testing and decide to report it to the public. Sometimes contamination that is discovered by them is not reported.

APHIS is supposed to play a role in preventing contamination. But when the Inspector General, in 2005, published its audit of APHIS' controls over the issuance of permits for field testing of genetically engineered plants, it found, "APHIS had little assurance that field tests are being conducted safely, in a way that minimizes the potential for GE plants to persist in the environment."[1] In all, the Inspector General made 28 recommendations to APHIS.[2] APHIS eventually agreed to corrective action on each of the recommendations.

The National Environmental Policy Act of 1969 (NEPA) requires APHIS to analyze and report in Environmental Impact Statements (EIS) significant environmental impacts and any related economic impacts of decisions to deregulate or field test genetically engineered crops. APHIS has approved 13,500 field tests for GE crop varieties, occurring at more than 79,000 sites

[1] "Audit Report: Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits," USDA Office of Inspector General, Southwest Region, USDA/OIG-A/50601-8-Te, p. 29 (December 2005).

[2] The IG found many areas of deficiency, including: APHIS failed to conduct inspections at nearly half of all notification field test locations; failed to conduct the number of inspections at pharmaceutical and industrial field sites where it had publicly announced it would; had no knowledge precisely where field tests were occurring and had to call ahead to the sites to be inspected for directions; failed to require plans or proof of destruction of experimental GE crops; failed to record the names of violators it "understated to the public the percentage of inspected sites with compliance infractions" because it included non-inspected sites as well; and took little action against violators when violations were identified.

around the country, and has also deregulated more than 70 GE plant varieties. Yet, APHIS has initiated only 4 EIS's—all of them in the past year or so. One of them was ordered by a federal court.

According to APHIS, the reason for the small number of EIS's—in contrast to the thousands of notifications, permits, and deregulations it has issued—is that in nearly all cases, APHIS determined that its proposed action did not have a "significant impact" as defined by the NEPA. However two recent federal district judges, reviewing APHIS' determination of "no significant impact" for proposed agency actions related to two genetically engineered plants, Roundup Ready alfalfa and creeping bentgrass, found that APHIS had acted in an arbitrary and capricious manner,[3] APHIS' interpretation was inconsistent with NEPA, and APHIS had violated the Act.

In a federal district court decision, *Geertson Seed Farms v. Johanns*, the judge found that APHIS violated NEPA by failing to account for the potential economic impact that would result from contamination of non-GE alfalfa by Roundup Ready alfalfa. The court ruled that APHIS had an obligation to evaluate economic costs stemming from a genetic contamination because they are so closely related. The court concluded that "the economic effects on the organic and conventional farmers of the

[3] In *International Center for Technology Assessment v. Johanns*, a federal district court found that APHIS failed to consider that its proposed notification of a specific confined field test for genetically engineered Roundup Ready creeping bentgrass could have a significant environmental impact. The Court concluded that the absence of appropriate environmental review "manifests arbitrary and capricious agency action which is inconsistent with the terms used in APHIS's own regulations and which violates NEPA." *Int'l Ctr. for Tech. Assessment v. Johanns*, No. Civ. 03-00020, slip op. at 32 (D.D.C. Feb. 5, 2007).

government's deregulation decision are ... a direct result of ... the transmission of the genetically engineered gene to organic and conventional alfalfa. *APHIS was required to consider those effects in assessing whether the impact of its proposed action is 'significant.'*"[4]

Today's hearing will focus on where APHIS goes from here. How will APHIS incorporate the guidance provided by these judicial decisions in reforming the way it regulates the GE crop industry? Will APHIS account for the economic impacts on farmers caused by GE-plant contamination? Will APHIS take seriously NEPA's requirements to produce environmental impact statements that analyze environmental impacts and related economic impacts related?

Now is the time to pose these questions and conduct oversight: In the wake of these two significant judicial rebukes, USDA is in the process of overhauling its both its GE crop and NEPA regulations.

[4] *Geertson Seed Farms v. Johanns*, No. C 06-01075, U.S. Dist. LEXIS 14533, *6 (N.D.Ca. Feb. 13, 2007) (emphasis added).

Mr. KUCINICH. The Chair recognizes Mr. Issa.

Mr. ISSA. Thank you, Mr. Chairman. And thank you for holding this hearing on two important subjects, one clearly within the purview of this committee, one perhaps not within the purview of this committee, but certainly worthwhile discussing here today.

I am always pleased when the Committee on Government Oversight and Reform deals with the question of whether or not the administration is properly adhering to laws passed by the Congress and regulations often created by the administration or passed the administration themselves. Clearly, today that is the focus of this hearing.

I appreciate the fact that genetically modified plants have and continue to be a lively discussion around the world. When I was first elected to Congress in the year 2000, one of the first trips I took was to Europe, and to discover that the Europeans were not just objecting to GMOs in Europe, but actually objecting to the United States giving away free food in Africa if it was the product of GMOs. I found that amazing then; I find it amazing now.

I believe that, in fact, we must try to find better crops for better feeding of the people of the world, and a reduction in erosion and other problems caused by conventional plants.

I might note that contamination is not limited to one crop versus another. In my own home in California, we have been struggling for decades with the glassy-winged sharpshooter, which would not be passing on Pierce's disease for our wine industry and grapes and raisins if it were not for the fact that we are also a citrus producer. The glassy-winged sharpshooter lives in mass quantities without significant damage to oranges, so they make a perfect breeding ground. Unfortunately, oranges and our grape vines often grow close together, and we have been struggling trying to find a way to have those two crops, clearly historic crops, but crops, not be damaged by their collocation. Additionally, California has often been unfairly told by the Japanese that, in fact, our long-grain rice or even California short grain, is somehow indigestible by the Japanese, clearly a protectionist maneuver, and not a legitimate complaint about the quality of what we grow in California.

Having said that, we also know that many naysayers suggest the world is running out of space to produce the world's food supply. I agree that if we cannot get past the 6 billion-plus today, and we get to 12 billion, we will have to produce more food in less space. So, then, why would anyone argue against GM advancements that promise increased yield per acre?

The International Service for the Acquisition of Agri-biotech Applications, the ISAAA, shows that in 2006 the number of hectares globally cultivated with GM crops increased by 12 million hectares. More importantly, that doubled the amount of food produced on those same hectares.

Many argue that pesticides harm our health. I agree. If you believe this, you must ask the question of why would you not want to have improved crops that need less pesticides? The National Center for Food and Agriculture Policy, the NCFAP, concludes in 2004 alone, biotechnology in the United States reduced pesticide use by 34 percent. If soil and water conservation is of concern to

you, then how could you argue against biotech crops which reduce soil erosion and reduce water storage and treatment needs?

The Conservation Technology Information Center reports an increase of no-till acreage farmland due to biotech agriculture reduces soil erosion by 1 billion tons per year. Now, I might note Speaker Pelosi used Federal funds allocated by the House of Representatives to buy carbon credits that were produced by no-till agriculture.

If you believe the growing trade deficit is a problem worth addressing, then how can you argue that curtailing the agriculture community's ability to increase exports somehow serves that purpose? Ag Secretary Ed Schafer announced this week that exports are forecasted to reach a record $104 billion in fiscal year 2008, up $10 billion from November's forecast, and $19 billion from 2007.

Today Don Cameron, a California grower, will tell us exactly how he is able to balance conventional, organic and biotech crops, reaping economic and environmental benefits for all. Mr. Cameron is proof that the use of these new technologies properly can, in fact, allow them to harmoniously work together.

There is a risk. I am here today to say that the government has an obligation to oversee that risk, to constantly monitor it, because, in fact, our food supply is too important not to have the USDA and other Federal agencies adhering to acts of Congress and their own regulations.

So, Mr. Chairman, I look very much forward to this oversight hearing because I do believe that Congress has an absolute oversight responsibility, and I congratulate you for focusing on that today and yield back.

Mr. KUCINICH. I thank the gentleman from California.

Without objection, Members and witnesses will have 5 legislative days to submit a written statement or extraneous materials for the record.

Again, for those who have just joined us, today's hearing will not be about whether GE crops are good or bad. Today's hearing is going to be about whether the chief regulator and advocate for the farmers, USDA, and its subagency, the Animal and Plant Health Inspection Service [APHIS], is taking into account the cost to farmers and realities of contamination risk by the GE plants it regulates.

Now, there are no additional opening statements. The subcommittee will receive testimony from the witnesses before us today. I want to start by introducing our first panel. Mr. Harvey Howington jointly owns a family farm operation with his parents. Until 2006, Mr. Howington farmed 1,200 acres on 3 tracts of land near Lepanto, AR. The farming operation consisted of 500 acres of rice, 700 acres of Roundup Ready soybeans. After the LL601 contamination event in 2006, he decided to quit farming and now rents his farmland to neighboring farmers. He is vice president of the Arkansas Rice Growers Association, and a member of the board of directors of the U.S. Rice Producers Association. From 2002 to 2003, he was president of the Arkansas Seed Growers Association, and remains on its board of directors.

Mr. Todd Leake——

Mr. LEAKE. Leake.

Mr. KUCINICH [continuing]. Leake is a family farmer from Emerado, ND. Mr. Leake annually grows approximately 1,000 acres of wheat, and approximately 500 acres of soybean and 500 acres of navy bean and sunflower. Since 2000, Mr. Leake has been involved in policy issues surrounding the development and potential deregulation of genetically modified wheat.

Mr. David Cameron owns and farms Prado, is it? I am sorry.

Mr. ISSA. Don Cameron.

Mr. KUCINICH. Strike that, I am sorry. Mr. Don Cameron owns and farms is it Prado?

Mr. CAMERON. Prado.

Mr. KUCINICH. Prado. Owns and farms Prado Farms located in Fresno County, CA. Since 1981, he has been the vice president and general manager of the Terranova Ranch, Inc., and farms approximately 5,500 acres of conventional, organic, and biotech crops ranging from organic pima cotton, biotech corn and alfalfa, along with a diversity of other annual crops.

Mr. Fred Kirschenmann farms 3,500 acres of certified organic crops in North Dakota. His family farm was certified in 1980, making it one of the early operations to make the transition. He is also a distinguished fellow for the Leopold Center for Sustainable Agriculture at Iowa State University. Mr. Kirschenmann holds a Ph.D. from the University of Chicago, and has written extensively about ethics in agriculture. He has also held national and international appointments, including the USDA's National Organic Standards Board.

Professor Colin Carter was born and raised on a farm in Alberta, Canada. He obtained a Ph.D. in agricultural economics from the University of California Berkeley in 1980. Professor Carter is currently professor of agriculture and resource economics at the University of California Davis. He has published more than 120 research papers, authored or edited 15 monographs and books, and contributed dozens of chapters to books. He has published in areas of international trade, agricultural policy, futures and commodity markets, and economics of China's agriculture, and the economics of biotechnology adoption in agriculture. Professor Carter was named fellow of the American Agricultural Economics Association in 2000 in recognition of his many contributions to the field of agricultural economics.

Finally, Mr. Ray Clark is a National Environmental Policy Act expert, with more than three decades of environmental management experience. As Associate Director of the Council on Environmental Quality, he implemented the Council's mandate for oversight of the National Environmental Policy Act, reviewed and approved Federal agency regulations with respect to that act, and mediated interagency disputes regarding compliance. As Acting Assistant Secretary of the Army for Installations and Environment, and Principal Deputy Assistant Secretary of the Army, he was responsible for over 14 million acres of land. As an adjunct faculty member at Duke University, Mr. Clark develops NEPA courses and teaches at the Nicholas School of the Environment.

I want to thank all the witnesses for being present, appearing before this subcommittee today. It is the policy of the Committee on

Oversight and Government Reform to swear in all witnesses before they testify. I would ask that you rise and raise your right hands.

[Witnesses sworn.]

Mr. KUCINICH. Let the record reflect that the witnesses answered in the affirmative.

I will now ask that we begin. I want to give the first witness an opportunity to get his testimony in, and then I am going to have to recess to go to vote, and I will be back.

Mr. Howington, I ask that you give a brief summary of your testimony, to keep the summary to 5 minutes in duration. Your entire written statement—this goes to all the witnesses—even though I ask you keep your testimony to 5 minutes, your entire written statement will be included in the record of this hearing. So Mr. Howington, if you would begin.

STATEMENTS OF HARVEY HOWINGTON, CONVENTIONAL AND GE GRAIN GROWER, LEPANTO, AR; TODD LEAKE, CONVENTIONAL AND GE GRAIN GROWER, EMERADO, ND; DON CAMERON, CONVENTIONAL, ORGANIC AND GE CROP GROWER, HELM, CA; FRED KIRSCHENMANN, ORGANIC GRAIN GROWER, MEDINA, ND; COLIN CARTER, PH.D., AGRICULTURAL ECONOMIST, UNIVERSITY OF CALIFORNIA, DAVIS; AND RAY CLARK, THE CLARK GROUP LLC, WASHINGTON, DC

STATEMENT OF HARVEY HOWINGTON

Mr. HOWINGTON. I would like to thank the Chair, Representative Kucinich; the ranking member, Representative Issa; and the members of the subcommittee for the opportunity to speak on this matter of great importance to American farmers. This is my first time to testify before Congress, and it is an honor to be here.

By far and away the most important title I have is father. The greatest gift I have to pass on is the family farm legacy. I am here today to talk to you about a serious threat to that legacy.

I grow GMO crops. Unfortunately, consumer acceptance for all GMO crops is not universal. Rice is the least accepted of all GMO crops. As farmers, we have to grow products consumers want and try to do it at a profit.

In early August 2006, farming was looking pretty good. We had a good crop, and prices were headed up. Then on August 19, 2006, USDA announced Bayer's LibertyLink LL601, a herbicide-tolerant, genetically engineered variety, had been found in non-GMO rice. At the time LL601 had not been approved for human consumption. Reaction was immediate. Japan banned importation of all long-grain U.S. rice. The European Union imposed strict testing requirements on all U.S. rice shipments. That had the effect of stopping all sales to that market. In the 7 days following the announcement, the American rice crop lost $168 million in value, with the futures price dropping from $9.83 a hundredweight to $8.99 a hundredweight.

At the time of the contamination event, global rice prices, supplies were becoming increasingly tight, and the futures price was tracking upward. It is not inconceivable that rice prices approaching $12 a hundredweight could have been realized had it not been for the contamination event. Even if you don't include this loss in

price potential, based on a conservative estimate calculated by the USRPA, the U.S. rice industry loss $1.2 billion due to this contamination event. That figure is consistent with the findings of Dr. Neal Blue, an agricultural economist at Ohio State University.

Farmers were in a quandary. Is my rice contaminated? Can I sell it if it is? What sort of price hit am I going to take? And that was just the rice just harvested. What to plant next year? What varieties are going to be available? Is the seed going to be safe? How much more is the seed going to cost me? What is testing going to cost me? What tests should I have? At what level should it be tested? Are the fields planted in rice last year going to be contaminated this year?

Through all this ordeal the LL601 contamination event caused, three questions remained at the forefront of the minds of rice farmers: How did the contamination occur? Who is responsible? How did it get so widespread before detection occurred?

One thing is perfectly clear. These answers will not be forthcoming from the USDA, whose mandate it is to administer, manage and monitor field trials to ensure that contamination events don't occur. In that regard, the Agency has failed miserably. After spending 8,500 staff hours conducting their investigation, they did not answer a single one of these questions. No enforcement action was taken against Bayer, or anyone else for that matter.

I listened to the USDA's findings on a conference call. It was very difficult listening to the USDA say they didn't know who, they didn't know how, and it happened so long ago we can't do anything about it even if we did. This is not an isolated incident. The LL601 event resulted in a decision to leave farming for many rice producers. Nearly 600 rice farms were lost between 2006 and 2007. While not all quit because of LL601, it had to be a major factor. The impact on local rural economies cannot be calculated.

The USDA needs to conduct more comprehensive environmental analysis before embarking on field trials that pose major economic threats to an agriculture industry or commodity. The decision-making process needs to be more transparent, with an opportunity for farmers to speak and be heard. And most importantly, the burden must be placed on the biotech company to demonstrate how contamination will be prevented in the farming industry.

I appreciate this opportunity. Your efforts to help solve this problem are sincerely appreciated by all the rice farmers I represent here today. I will be happy to answer any questions as best I can.

Mr. KUCINICH. Thank you very much, Mr. Howington.

[The prepared statement of Mr. Howington follows:]

STATEMENT OF HARVEY HOWINGTON
Before the
DOMESTIC POLICY SUBCOMMITTEE
OVERSIGHT AND GOVERNMENT REFORM COMMITTEE

" IS THE U.S. DEPARTMENT OF AGRICULTURE (USDA) ACCOUNTING FOR THE COSTS TO FARMERS FROM CONTAMINATION CAUSED BY GENETICALLY ENGINEERED (GE) PLANTS"

THURSDAY, MARCH 13, 2008
2247 RAYBURN HOB
2:00 P.M.

I would like to thank the Chairman Kucinich, Ranking Member Issa, and the Members of the Subcommittee for the opportunity to speak on this matter of great importance to American farmers.

My name is Harvey Howington. Our farm is a family operation owned jointly with my parents. I farmed 1200 acres on 3 tracts of land near Lepanto, Arkansas, in Poinsett County about 45 northeast of Memphis until 2006. The farming operation consisted of 500 acres of rice and 700 acres of Roundup Ready soybeans. After the LL601 contamination event in 2006, I decided to quit farming and now rent the farmland to neighboring farmers.

I am currently the Vice President of the Arkansas Rice Growers Association (ARGA) and a member of the Board of Directors of the U.S Rice Producers Association (USRPA) serving as an Arkansas Delegate. I am the former President of the Arkansas Seed Growers Association (2003-2004) and am currently a member of its Board of Directors. As President of the Arkansas Seed Growers Association (ASGA), I served on the Arkansas Seek Council which advises the University of Arkansas on public seed policy and foundation seed allocation.

August 19, 2006, is a day that will be indelibly etched in my mind for the rest of my life, and I dare say for the rest of the U.S. rice producers. Most of us were getting our combines ready to head to the fields for harvest. This looked to a profitable year for a change. The rice crop looked good, global supplies of rice were tight and prices on the futures market were on the rise. Then the bomb dropped. That day the USDA announced a "regulated event." Bayer's Liberty Link (LL) 601 - a herbicide tolerant, genetically engineered (GE) seed variety – not approved for commercial use had tested positive in non-GE seed stock. The USDA launched an immediate investigation and U.S. rice producers went into panic mode.

At the time, details of the GE contamination event were sketchy. What we knew was that in January of 2006, GE contamination was discovered by a rice export customer and the seller, Riceland Foods, was contacted. A Riceland investigation confirmed that the contamination was linked to LL601 and Bayer officials were contacted in June of 2006.

In July, Bayer confirmed a positive test for LL601 at .06%, or approximately 6 kernels in 10,000. As required by law, Bayer reported their findings to the USDA.

Why the panic? LL601 is a long grain rice variety that was field tested in Louisiana between 1999 and 2001. Bayer in cooperation with Louisiana State University (LSU) researchers experimented with LL601 to determine its potential for controlling red rice weed problems. Field trials proved ineffective, were terminated and LL601 was abandoned as a "commercial non-starter." The problem is that LL601 found its way into 2003 Cheniere foundation seed stock.

Cheniere is a long grain, conventional seed variety widely used throughout Arkansas and among southern rice producers. The U.S. is a major rice supplier to the global marketplace, providing 12% of the world rice trade. In the 2006 crop year, U.S. rice production was valued at $1.88B according the USDA with approximately 50% of the crop exported to foreign markets. In 2005, 80% of rice exports were long grain varieties.

The problem is that foreign consumers have a wide variety of concerns about the safety of GE crops to the environment and to the public health and have been unequivocal in their demand that food products remain free of GE content. While this belief is not universally held among consumers, it is so widespread that foreign governments and, more importantly, foreign buyers have imposed restrictive tolerances, strict labeling requirements or outright bans on GE crops used in food products.

The rice industry had watched the ferocious debate on commercialization of Roundup Ready (RR) wheat closely and saw the handwriting on the wall. Rice growers and wheat producers in many respects share the same markets. When the Canadian Wheat Board surveyed its buyers and found that 83% were opposed the commercialization of RR wheat, we knew that we could expect a similar reaction from rice buyers. Consequently, even though two commercial varieties of GE rice had been deregulated – LL06 and LL62 – commercial use was withheld for fear of losing significant global markets. That is exactly what happened when the LL601 contamination event was announced.

The reaction to the LL601 was swift and devastating. Japan immediately banned the importation of all long grain U.S. rice and the European Union imposed strict testing requirements on all rice shipments. GE contaminated rice shipments would be destroyed or sent back. Rice prices plunged. 2006 rice crop values plummeted by more than $168 million in the week after the LL601 contamination event was announced as rice futures, based on the market price for September delivery, dropped from $9.83/cwt to $8.99/cwt. During the next 3 days the futures market would drop to $8.93/cwt resulting in a $135 million loss in farmgate prices to rice producers during that 10 day period.

While prices have subsequently rebounded to pre-contamination event levels, the cost to rice producers is probably far greater than these figures suggest. At the time of the contamination event global rice supplies were becoming increasingly tight and the futures market was tracking upward. It is not inconceivable that rice prices approaching $12.00/cwt would have been realized had it not been for the contamination event.

Even without including this loss in price potential, the U.S. rice industry lost **$1.2 billion** as a result of the LL601 contamination event based on a conservative assessment calculated by the USRPA. These figures are consistent with the findings of Dr. Neal Blue, an agricultural economist at Ohio State University.

The negative reaction in the marketplace snowballed during the next few weeks. Thousands of metric tons of long grain rice destined for the U.K. and Germany sat loaded in ships in the port of New Orleans until they could be tested for GE content. Large sectors of the rice industry, including Ebro Peleva – the world's largest rice processor – committed to being GE-Free. Rice traders in Thailand and Vietnam, two of the largest rice trading countries, signed Agreements to be GE-Free in order to capitalize on market opportunities created by the LL601 contamination event. The All India Rice Exporters Association requested a prohibition of GE field trials in basmati rice growing states. Texas millers stopped bidding on rice to adjust handling and processing regimens to cope with the new market realities.

The bad news was not confined to the marketplace nor was the contamination confined to a test plot at an LSU research facility. Independent laboratory tests conducted as part of the on-going USDA investigation indicated that the long grain rice involved in the contamination event came from the 2005 rice crop that had been held in storage facilities in Arkansas and Missouri. Reports from the milling and export industry confirmed widespread positive results for LL601 contamination throughout the Gulf and Delta regions in the 2005 and 2006 crops.

This cataclysmic series of events left rice producers scrambling to find solutions to what seemed to be insurmountable problems. An ongoing debate raged within the rice industry. Do we adopt highly sensitive 35S bar PCR testing measures to satisfy foreign buyers? Do we push foreign countries to adopt higher tolerance levels? Do we ban the sale of Cheniere seed stock in 2007? Do we require random testing at all first points of delivery? Do we advocate for prohibitions and moratoriums on all field testing of GE rice varieties, as did the Rice Producers of California after an independent market study indicated that 40% of the total demand for their rice would have been lost had the contamination event occurred in their state? We were scrambling to fix a mess that we had no part in creating but which threatened the demise of our entire industry.

Throughout all the pain and turmoil that the LL601 contamination event caused, three questions remained at the forefront on the minds of rice producers. How did the contamination occur? Who is responsible? How did it get so widespread before detection occurred?

What we do know is that it is likely that the contamination occurred at the LSU AgCenter Rice Research Station near Crowley, Louisiana. From 1999 to 2001 Bayer and LSU rice breeders conducted field trials on LL601 at the site during which time Cheniere foundation seed stock was grown at the same facility.

Beyond that it is anybody's guess. Speculation abounds, the contamination was caused by LL601 volunteers in any variety of ways, the experimental crop was not devitalized according to stringent USDA regulations – a problem cited in a 2005 Inspector General's Audit critical of USDA administration of GMO field trials, volunteer cross-pollination with GE varieties, birds, human error or flooding – a common practice in rice production. Regardless, the source of the contamination remains unknown. This fact alone is a constant source of irritation among rice producers. At every opportunity that presented itself through public Comment of Environmental Assessments (EAs) going back 3 years to Ventria's Petition to conduct field trials on its pharmaceutical rice variety in California, we have repeatedly argued that contamination could occur by a wide variety of means. Each and every time, USDA dismissed the potential for contamination through a Finding of No Significant Impact.

Maybe we will get answers as the attorneys for the respective parties square off in the 15 class action lawsuits filed on behalf of 300 rice producers to find the guilty party and put a dollar figure on monetary and emotional losses suffered by U.S. rice producers.

One thing is perfectly clear. Those answers will not be forthcoming from the USDA whose legal mandate it is to administer, manage and monitor field trials to ensure that contamination events occur. In that regard, the agency failed miserably. After spending 8,500 staff hours conducting their investigation of the LL601 contamination event, USDA concluded that they could not determine the exact mechanism that GE rice was introduced into the commercial rice supply. Nor could APHIS pursue enforcement actions and/or sanctions against Bayer given the lack of records, available information or other specific evidence to make a definitive determination due to the fact that they had not implemented protocols, policies, record-keeping and other administrative requirements to meet even minimal legal requirements for managing field trials. Due to the lack of records and the failure to save seed samples, the exact mechanism for incursion of the LL601 gene into the Cheniere variety, such as gene flow or human error, could not be determined. Again, these are systemic problems were noted repeatedly in the 2005 Inspector General's Audit.

The USDA did such a poor job of administering these field trials that investigators discovered 7 instances in which field trials were either planted or terminated after the APHIS mandated period for experimentation but no action could be taken since the Statute of Limitations had run. What does this tell you about the quality of care in managing field trials to ensure that contamination does not occur?

The USDA in Lessons Learned concluded that simple bookkeeping changes can cure these problems but the problems are far greater than merely changing accounting practices and protocols. Dr. Steve Linscombe, rice breeder and director of the LSU AgCenter Rice Research Station stated in LSU AgCenter News (8/31.06) that the "standards set by the USDA were followed strictly in the research with LL601, and the field plots of LL rice were isolated from other rice plants. In fact we made sure that the distance between the LL plots and the other conventional rice plots were further than what the research protocols called for. When there was a minimum requirement, we

exceeded it." If that is an accurate statement, an overhaul of the entire field trial plot design is necessary. Had environmental assessments (EAs) or Environmental Impact Statements (EISs) must be conducted prior to the approval of field testing especially when the potential for significant economic loss as a result of contamination exists.

Earlier in my testimony, I alluded to assessments of the economic costs related to the LL601 event. From my perspective many considerations were omitted and for many of those, a price tag does not exist. The LL601 contamination event resulted in a decision to leave farming for many rice producers. Nearly 600 rice farms were lost between 2006 and 2007. While not all were lost due to LL601, the economic loss and the emotional turmoil created by that event was a major factor in many rice producer's decision to call it quits. The assessments alluded to earlier also did not take into account factors such as rural economic impact, impact on southern rice mills and marketers, seed testing and product testing costs, the impact on rice seed dealers, the extensive loss of rice production acreage in 2007 nor the impact on long grain rice futures and cash prices. When added to the equation, the price tag becomes incomprehensible.

The USDA needs to conduct more comprehensive environmental and economic analysis before embarking on field trials that pose major economic treats to an agricultural industry or commodity. The decision-making process needs to be more transparent with an opportunity for farmers to speak and to be heard. And most importantly, the burden must be placed on the biotech company to demonstrate how contamination will be prevented to the satisfaction of the industry and the farmers impacted.

Thank you for the opportunity to express my views through this testimony. Your efforts are sincerely appreciated by all rice producers. I would now be happy to answer any questions you may have.

Mr. KUCINICH. We are going to recess right now. There are two votes on. I think that means that I could be back here in 20 minutes at the earliest. So if we all—I ask all the witnesses don't go too far, but we have about 20 minutes. And so the committee is in recess, and we will resume testimony with Mr. Leake when we return. Thank you.

[Recess.]

Mr. KUCINICH. The committee will come to order. We are going to resume the testimony here with Mr. Leake. Thank you very much for your patience. Let's resume. Thank you.

STATEMENT OF TODD LEAKE

Mr. LEAKE. I would like to thank the Chair, Representative Kucinich; and the ranking member, Representative Issa; and the members of the committee for the opportunity to testify on this matter.

My name is Todd Leake. I own and operate a family farm near Emerado, North Dakota. I farm 2,000 acres, half of that to wheat. North Dakota is the Nation's No. 1 producer of wheat. The crop is critical to our economy and the communities that we support.

Because wheat is so critical to my livelihood, I became concerned when it was revealed in 1999 that North Dakota State University and other ag universities in the region were developing genetically engineered wheat. The basis of my concern was that since the introduction of GE corn, soybeans, and canola in 1996, many of our largest consistent market countries had enacted restrictions or moratorium on the importation of GE crops.

In 2002, U.S. Wheat Associates conducted a survey that concluded that, "buyers in Japan, the EU and Korea have repeatedly and definitively stated that they would not accept genetically modified wheat at any tolerance." These three countries accounted for 44 percent of hard red spring wheat exports. Also in 2002, USDA Foreign Ag Service assessed the information compiled in overseas branch offices regarding buyer attitudes and governmental regulations of GE crops. The findings provided further support to the conclusions contained in the U.S. Wheat Associates surveys. Of the top 10 U.S. wheat-importing countries, all had laws regarding the importation of GE crops.

During that same period, a study of the impact of commercialization of GE wheat was undertaken by Dr. Rob Wisner of Iowa State University, one of the country's most respected agriculture economists. Dr. Wisner's report concluded that if GE wheat were commercialized, U.S. wheat growers would lose between 43 and 52 percent of their total exports, resulting in a net loss of between 32 and 35 percent of the income from that crop. To my farming operation this would clearly result in growing wheat at a loss.

Even with it firmly established the production of GE wheat would be an economic disaster for wheat producers nationwide, research into GE wheat continued unabated. All the major agricultural universities in the region conducted and contracted research and field testing of GE wheat at their extension research centers. Great media attention was paid to the issue of cross-pollination of GE wheat with the breeder stock and the foundation stock also grown at the extension centers. Those breeder and foundation

stocks are the basis from which all future wheat varieties grown in North Dakota are derived.

When Monsanto Corp. petitioned for the deregulation of their Roundup Ready GE wheat, concerns were escalated over the possibility of widespread GE contamination or adventitious presence of GE wheat in the commercial wheat supply as commercialization came one step closer to reality. Farmers and grain buyers alike knew that the segregation would be impossible, that cross-pollinating seed would be spread by machinery. Research from the University of Manitoba predicted that the commercial wheat crop would be contaminated beyond the limits of the importation tolerances of the major importing countries within 5 years.

Between 2001 and 2004, farm group leaders had conversations with USDA/APHIS. When informal discussions failed to produce an agreement on the need for an EIS on GE wheat deregulation, farmers and farmer groups signed a formal petition requesting an EIS be conducted.

In March 2004, accompanied by our legal representatives, Dr. Robert Wisner and other wheat growers and grain merchandisers and farm group leaders, I met with Under Secretary Bill Hawkes and the Acting Director for APHIS on the issue of an EIS on Roundup Ready GE wheat deregulation petition. Ultimately, despite our concerns, our request was denied.

This issue did not end there. Because of the deregulation petition pending before USDA, grain companies from other countries restricting the importation and use of GE wheat began accessing their supplies elsewhere than the United States, in particular from the former Soviet Republics in the Black Sea region. Citing market concerns of nonacceptance, Monsanto shelved its Roundup Ready wheat program in May 2004 and pulled their deregulation at APHIS shortly thereafter.

While I applaud Monsanto's ultimate decision to pull the Roundup Ready wheat deregulation petition based on the sensitivity of the international GE marketing issue, I feel that it should not have been left solely as a corporate decision. The environmental contamination issues and the economic loss issues were clearly within the purview of USDA. These should be addressed under the National Environmental Policy Act. This would allow farmers like myself, who would pay the price for GE contamination, the opportunity to be heard in that process. Thank you.

[The prepared statement of Mr. Leake follows:]

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STATEMENT OF TODD LEAKE
For the Dakota Resource Council
and the
Western Organization of Resource Councils
before the
DOMESTIC POLICY SUBCOMMITTEE
OVERSIGHT AND GOVERNMENT REFORM
COMMITTEE

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I would like to thank the Chairman Kucinich, Ranking Member Issa, and the members of the Subcommittee for the opportunity to testify today on this matter of great importance to all U.S. farmers and American agriculture.

My name is Todd Leake. I own and operate a family farm near Emerado, North Dakota, which is located in Grand Forks County in the northern part of the state. We farm conventionally, growing approximately 1000 acres of wheat, 500 acres of soybeans and 500 acres of navy beans and sunflowers annually. I am a member of the Dakota Resource Council and the North Dakota Farmers Union. The Dakota Resource Council is a non-profit grassroots organization which formed in 1978 to protect North Dakota's land, air, water, rural communities and agricultural economy. The Dakota Resource Council belongs to the Western Organization of Resource Councils, a regional network of seven grassroots community organizations that include 9,500 members and 45 local chapters.

In North Dakota our crop options are limited due to a relatively short growing season and low number of growing degree days. North Dakota is a national leader in cool season crop production. Wheat is a cool season crop and can be grown profitably even in areas where soil quality is poorer. Wheat generates the greatest amount of income for the North Dakota crop producer and is critical to our economic well-being and to the rural communities we support. North Dakota is the nation's leading state in hard red spring wheat production.

Because wheat is so critical to our economic survival, I became concerned when the agricultural press began publishing articles in 1999 regarding ongoing research and field trials of a genetically engineered (GE) hard red spring wheat variety that would be tolerant to Monsanto's Roundup herbicide. As with GE corn, canola, soybeans and cotton varieties that had been deregulated a few years before, the research was a precursor to the commercialization of Monsanto's Roundup Ready (RR) wheat and the agricultural press was touting the new technology as the greatest innovation in the history of wheat production. If the new technology performed as advertised, RR wheat would increase yields, lower production costs and provide a significant environmental benefit through reduced pesticide use.

Despite the accolades, there were significant issues not being addressed by many farmers, agricultural researchers and economists and, most importantly, by policy-makers. The verdict was still out on the safety of these new genetically engineered crops. Major questions regarding environmental impacts, food safety and the adequacy of the regulatory processes were on the minds of consumers worldwide when the StarLink contamination debacle was exposed through independent testing conducted by U.S. consumer groups. And most importantly, the economic consequences of the uncertainty of consumers about the environmental and food safety impacts and the adequacy of U.S. regulatory processes had not been considered.

As testing confirmed StarLink contamination in a wide variety of products ranging from soup to taco shells, the global marketplace was quick to react. Consumer outrage resulted in the enactment of GE market restrictions, prohibitions and labeling requirements in many European and Asian countries. Corn exports dropped to zero in the European Union at a cost of $300 million annually to American corn producers in that market alone.

It was against that backdrop that wheat producers in the Northern Plains and Canada began their assessment of the pros and cons of commercializing Roundup Ready wheat. It did not take a PhD in agricultural economics to realize that we were staring in the face of a potential economic disaster. North Dakota wheat growers export approximately 50% of our crop to foreign markets. By way of comparison, just 20% of the U.S. corn harvest is sold outside the U.S. To make matters worse, the vast majority of wheat importing countries had enacted GE import or labeling restrictions or restrictive tolerances. For the U.S. corn producer options remained. Although not as profitable, GE crops could still be sold as animal feed for livestock since the market restrictions and labeling generally applied only to GE content in food or food products. For the wheat grower those options simply don't exist. The global wheat market is highly competitive and selling wheat for animal feed is simply not an option. Loss of markets in Japan, other Pacific Rim countries and the European Union would have been devastating to North Dakota wheat growers and the economy of the entire state. Wheat growers in other states and Canada would have been devastated, as well.

With our livelihoods at stake, wheat growers in the U.S. and Canada began to organize and educate. We first educated ourselves, then our fellow wheat growers, our farm groups, our friends and allies among consumer and environmental groups, and policy-makers. We believed that if we raised the visibility of this issue and the economic importance of wise and thoughtful decision-making, we would slow the train long enough for clearer minds to prevail.

While there are many facets to the farmer driven campaign that ultimately led to Monsanto's decision to suspend – and later withdraw – its petitions for deregulation in both the U.S. and Canada on May 10, 2004, this testimony will focus on the constant battle with the U.S. Department of Agriculture (USDA) which, from my perspective, sees its job as serving the biotech industry to the detriment of the American wheat grower.

From the beginning of this campaign in 2004 we realized that in the end it would be USDA that would decide whether RR wheat would be commercialized. Early on we determined that a USDA decision to conduct an Environmental Impact Statement (EIS) involving a comprehensive assessment of the environmental and socio-economic impacts of commercializing RR wheat provided the best opportunity to present our case.

I'm not an attorney and don't pretend to be one, but our reading of the National Environmental Policy Act (NEPA) in consultation with well respected environmental litigators indicated that an EIS is required when an agency determined that a major federal action, such as permitting the commercial use of a genetically engineered crop, could have a "significant impact" on the human environment. In determining whether a significant impact exists, the agency weighs a number of factors both environmental and socio-economic. While the threshold question involves the existence of an environmental impact, our conclusion from a farmer's perspective was that the potential for contamination was a virtual certainty. We believed that the potential loss of markets alone should have required a finding of "significant impact," triggering the need for an EIS. As would become apparent to us during the next three to four years, that conclusion was anything but obvious to the USDA.

Between 2001 and 2004, numerous discussions were had with USDA officials regarding the need for an EIS in order to assess the economic impacts on wheat farmers in North Dakota and across the country. Farm group leaders had conversations with the head of the USDA/APHIS Biotechnology Regulatory Services, Cindy Smith. When informal discussions failed to produce an agreement, farm groups in consultation with environmental attorneys from the Center for Food Safety developed and submitted a formal Petition requesting that an EIS be conducted.

The Legal Petition Seeking an Environmental Impact Statement Concerning the Deregulation of Genetically Engineered Wheat sought inclusion of a socio-economic impacts analysis in any environmental impact analysis performed concerning the commercialization of genetically engineered wheat including: the loss of wheat exports resulting from market rejection of GE varieties, the potential loss of U.S. organic wheat

production due to contamination by GE traits and the effects of increased seed prices as a result of royalty and technology use fees.

In March of 2004, accompanied by our legal representatives, an agricultural economist, Dr. Robert Wisner, of Iowa State University, other wheat growers and farm group leaders, I met with Bill Hawkes, then APHIS Undersecretary for Marketing and Regulatory Affairs and Acting Director of APHIS on this issue. In that meeting we detailed the environmental consequences and the economic impacts of the proposed action to commercialize RR wheat, laying out the case for an EIS. Ultimately, despite all of our efforts, our request was denied.

Discussions on environmental impacts always came back to USDA's assumption that, because wheat is a self-pollinating plant and its pollen is viable for only a short period time contamination of non-GM wheat by GM wheat is impossible. However, studies by Drs. A.L Brule-Babel and R.C. Van Acker of the Plant Science Department at the University of Manitoba directly contradicted that assumption. Those findings concluded that while out-crossing events generally occur within 3 meters of the pollen source, out-crossing has been shown to occur up to 27 meters from the source. Those researchers also found that small amounts of gene flow with herbicide tolerant traits can lead to high levels of volunteers when herbicide is applied, since those volunteers will be unaffected. Further they determined that relatively low numbers of volunteers could result in a failure to meet tolerance standards and consequently the marketability of the wheat. They concluded that once GE wheat is released into the environment it is not possible to guarantee the production of 0% GE wheat.

The conclusion of Dr. Brule-Babel's research should in and of itself trigger a broader assessment under NEPA of environmental and socio-economic impacts. If you take those findings and apply them to the 62 million acres of wheat grown in the U.S., the potential for GE contamination is magnified tremendously.

One huge source of aggravation for wheat growers was the "head in the sand" mentality exhibited by USDA when it came to conducting a broader assessment regarding the potential for contamination. Anyone who farms or knows anything about the grain handling and processing system in the U.S. knows the difficulty in keeping Mother Nature contained in nice little boxes.

Even if you assume that pollen drift and out-crossing do not create the potential for contamination, you only have to take a cursory look at how farms operate and grain moves from field to fork. At planting, seed stock contamination would result if RR seed was not completely cleaned from trucks, augers and conveyers, totes, bins and seeding equipment. RR wheat seed would have to be stored in separate bins and harvested grain would have to be delivered to separate grain elevators or mills to prevent commingling.

During harvest combines "throw over" up to 5 bushels per acre and most of that seed is viable and straw choppers can throw seed up to 50 feet, which under the right circumstances can find its way into the neighbor's field. Trucks transporting harvested

grain typically go untarped, blowing viable seed into ditches and nearby fields. Each and every one of these typical farm operations can, and undoubtedly would, be a significant source of RR contamination.

A research study conducted by North Dakota State University (NDSU) in 2000 provides a perfect example of how contamination could occur. Researchers used a combine for a full harvest season cleaning it to the best of their ability at the end of harvest. The thoroughness of the cleaning operation went far beyond what is typical during the rush to get the crops out of the fields. After cleaning was completed, the researchers disassembled the combine and extracted 90 pounds of grain from the "clean" combine.

When you consider the fact that custom harvesters work the fields from Texas into Canada, it is hard to imagine a scenario in which conventional wheat would remain free of contamination, without even considering potential commingling during truck or train transport, at the terminal facilities in the Gulf, Mississippi or the Great Lakes, or on cargo containers and ships that transport the wheat to major foreign buyers.

Even the USDA – though not the Animal and Plant Health Inspection Service (APHIS) saw the handwriting on the wall. In 2002, GIPSA issued a statement published in the Federal Register to the effect that if RR wheat were to be commercialized, the agency could no longer certify that U.S. wheat export would be GE-Free.

While one could argue that all of these potential problems of contamination could be cured with an effective system of segregating GE and non-GE crops through identity preservation processes, you come to the conclusion that totally independent farm, transportation and infrastructure systems would be required. The cost of a separate system for growing, transporting and handling is beyond calculation. However, with competition fierce in the global wheat market, it is clear that those costs could not be passed onto the buyer or the consumer and would fall to the conventional wheat producer to pick up the tab. Our foreign customers made clear that such efforts would be futile, however – rather than mess with the time and cost of testing each bushel of our wheat they buy in order to meet the zero tolerance demands of consumers in Europe, Asia, and elsewhere, foreign pasta, bread and flour companies told us they would buy all of their wheat from Ukraine, Australia and other GM-free countries if any variety of genetically modified wheat was approved for commercial release and planting in the United States.

I am sure that plant biologists, soil scientists, agronomists and a whole host of applied science professionals could fill a library with other analyses on the environmental impacts related to the commercial release of RR wheat onto the farm fields of the northern U.S. and Canada. The fact remains that the USDA looked at the same picture, saw nothing and denied our request for an EIS without ever bothering to take the next step and conduct a realistic assessment of the economic devastation that would inevitably result from the commercialization of RR wheat.

As clear as the certainty of environmental impact, so to was the potential for economic disaster. From the time that wheat growers were told that RR wheat was being developed

for commercialization, we began to assess what would be the consequences to our industry if that became a reality.

Working closely with Canadian wheat producers we initiated a cross-border education program. As the education and media around this effort increased, the visibility of this issue in Canada, the Canadian Wheat Board (CWB) which markets the vast majority of wheat grown in that country, surveyed its clientele on attitudes regarding GE crops and the commercialization of RR wheat in 2002. The survey results confirmed our worst fears. 82% of Canada's international buyers of Hard Red Spring Wheat (by tonnage) and two-thirds of buyers in all classes did not want to buy GE wheat.

That same year the U.S. Wheat Associates (USWA) conducted a similar survey and concluded that "buyers in Japan, the European Union and Korea repeatedly and definitively stated that they would not accept genetically modified (GM) wheat, *at any tolerance"* (emphasis added). Those 3 countries accounted for 44% of total hard red spring wheat exports. My state, North Dakota, would be hit the hardest since we produce 50% of all hard red spring wheat and 50% of our wheat is exported.

In 2002 USDA's Foreign Agriculture Service assessed information being compiled in overseas branch offices regarding buyer attitudes and governmental regulation of GE crops. There findings provided further support to the conclusions in the contained in the CWB in USWA surveys, of the top ten U.S. wheat importing countries all but two countries had laws on biotechnology with laws pending in the remaining two, all had laws regarding the importation of biotech crops, all had laws pertaining to the environmental release of biotech crops and all but two had laws specific for biotech labeling.

While the battle would rage for the next few years – and continues today -- over establishing tolerances for GMO crops in foreign countries, major buyers of U.S. wheat made it clear that their consumers had spoken, and regardless of the outcome of government action, the commercialization of genetically modified wheat would result in the loss of those markets. Statements to that effect were made by the Japanese Flour Millers Association, whose members account for 90% of the total wheat market in that country; the Japanese Food Agency; another major buyer of U.S. wheat, Rank Hovis (Britain's largest flour mill); Grande Molini Italiana SpA (Italy's largest miller, speaking on behalf of the European milling industry; and France's largest wheat miller.

During that period Norway, South Korea, Taiwan, Egypt, the Philippines, Algeria, China, Indonesia, Malaysia and Thailand reiterated their opposition to GE wheat through outright rejection, strict labeling laws, or restrictive tolerances.

Clearly, the global marketplace had spoken. GE wheat had no place in its collective breadbasket. As it became readily apparent that major buyers and markets were not going to change their position, Dr. Robert Wisner, a respected agricultural economist from Iowa State University assessed what the loss of those major markets who mean to the prices that farmers would be paid for their wheat if the RR variety was

commercialized.[1] The results were sobering, if not surprising. Using a variety of scenarios based on the likely loss of markets if RR wheat were commercialized, Dr. Wisner concluded that U.S. wheat growers would lose between 43% and 52% of their total exports resulting in a net loss in the price paid to farmers of between 32% and 35%.

Ultimately, it was U.S and Canadian farmers, working in collaboration with consumers and buyers in major wheat markets, who forced Monsanto's decision to stop its push to commercialize RR wheat. Throughout the four long years, while I tried to manage a farm while educating myself, fellow farmers and anyone who would listen about the perils of RR wheat, the USDA stood quietly by. For an agency chartered to protect the interests of U.S. farmers and American agriculture, their performance was abysmal. The agency ignored the facts and disregarded the law, doing a disservice to the very constituency it was established to protect.

Thank you, Chairman Kucinich and Ranking Member Issa for the opportunity to come before the Subcommittee and offer my testimony. If the Members have any questions, I will attempt to answer them to the best of my ability.

[1] Dr. Wisner's original 2003 report and two subsequent updates can be found at http://www.worc.org/issues/marketrisk-reports.html

Mr. KUCINICH. Mr. Cameron, you may proceed. Thank you.

STATEMENT OF DON CAMERON

Mr. CAMERON. Thank you, and good afternoon, Mr. Chairman. Thank you for providing me the opportunity to share with you and this distinguished subcommittee my experience as a farmer who grows both organic and biotech crops on my farm.

My name is Don Cameron. I am general manager of Terranova, a diversified farming operation located in Fresno County's San Joaquin Valley. At Terranova we farm approximately 26 different crops, including cotton, alfalfa, tomatoes, carrots, garlic, on nearly 5,500 acres.

On our farm we grow organic, conventional, and biotech crops. About 10 percent of our overall production is grown for organic markets, including organic cotton and alfalfa. The remaining 90 percent of the farming at Terranova is a combination of conventional farming practices and crops derived from agricultural biotechnology, which includes biotech cotton, corn, and alfalfa. Our farming operation is living proof that organic and biotech farming practices can coexist in near proximity without one negatively impacting the other.

Over the last decade, millions of acres of biotech crops have been grown in the United States which coexist with organic crop production. In fact, the growth of agricultural biotechnology has been accompanied by a surge in both organic acreage and profits derived from the organic production in this country. Indeed, organic farming has been a profitable component of our farming operation.

What is true for farmers across the United States is also true for me; namely, that farming is a business. Like good businesspeople, we seek to be good stewards of our land while maximizing the opportunities in the marketplace. When we determine each year what crops will be planted, we look at all aspects of each potential crop from expected price, yield, crop rotation, income, expense ratios, and whether we can compete on a global basis with other countries. We have chosen to specialize in organic farming on a portion of our farm to increase diversity and fill a niche in the marketplace. The risk is much higher in organic farming due to the lack of effective treatments for various insects, diseases, and weed problems. We have accepted the risks with the potential for increased profitability. Most insecticides, herbicides, fungicides, and commercial fertilizers are eliminated in organic farming. Hand weeding with contracted labor is our major expense.

Organic farming is a process we have chosen to put in place on a portion of our farm. On the remainder of the farm, we chose to farm with conventional techniques. We use modern technology, with advanced practices, including GPS tractors, plant mapping, integrated pest management, and irrigation management. We also use biotech seed varieties when available for corn, cotton and alfalfa.

The trait we find most useful is the Roundup Ready trait, which allows the plant to resist herbicide Roundup or glyphosate. Why is this so important to us? Because our economic savings that we realize through the use of the Roundup Ready system have been tremendous. Compared to conventional crops, Roundup Ready alfalfa

saves us about $110 per acre, Roundup Ready cotton $165 per acre, and Roundup Ready corn $17 per acre. These savings include the reduction of overall chemical use on our farm, reduced labor costs, and fewer trips across the fields with tractors, which conserves our farm equipment and reduces diesel use, along with emissions and dust particles released into the environment. If we were comparing Roundup Ready weed costs with weed control from our organic production, the savings would be even greater.

To elaborate on that point, here in the United States our labor costs are expensive because we provide a fair wage, safe working conditions, and insurance benefits for our workers. To hand-weed organic crops, I have spent up to $2,000 per acre, as there was no alternative available. This is not an effective use of a dwindling supply of labor. With Roundup Ready crop, my total weeding bill is less than $35 per acre. My crop is clean and free of weeds. For the American farmer and for me to compete in a world marketplace where labor elsewhere may only cost $1 per day, we need technologies like this to remain competitive.

I believe that the flexibility that biotechnology can provide is a major reason that I can successfully grow the variety of crops that we do. The Roundup Ready cropping system leaves no chemical residue that will interfere with the following crops. In the past, we would use herbicides that had long residuals in the soil, which would preclude the planting of sensitive crops following their use. We now have the flexibility to change crops rapidly with major changes in the markets without risk from previous herbicide applications.

I am always asked how we keep pollen flow from one type of farming operation from interfering with the other. We grow many crops for their seeds, both organic and conventionally, and each one is different. We have been dealing with these issues long before the advent of biotechnology crops. If farmers were not successful with this, there would be only one color of corn, one variety of melon, and one type of cotton. We know the biology of each crop we grow, where we need to grow it to maintain and preserve its integrity and its identity. We maintain necessary separation when needed, especially in seed production. In some cases there is no interaction, and in other cases there may be, but we know when to anticipate the interaction and separate the varieties according to their characteristics. We clean our planters, harvesters, bins and trucks to maintain this purity, the same way we separate our organic from our nonorganic or our biotech crops. We talk with our neighbors, we communicate, we work out the issues that may arise. We are also required by our commercial contracts to provide a crop that is virtually free of other varieties, be it biotech to organic or organic to conventional. We maintain separation to ensure this does not happen.

On our farm we consistently maintain a higher level of standards, which exceed the National Organic Standards, to fulfill contract requirements from our buyers. In all my years of farming, I have never lost a market nor income because I grow organic, conventional or biotech varieties on my farm. In short, we were coexisting long before the term was coined.

It is my hope that the United States will remain competitive, and that our Nation's leaders will provide the foresight to keep us in the forefront of modern agriculture production for many years to come. As an American, I do not want to rely on another country for my food and fiber supply. We are the most productive Nation in the world in agriculture, and we need the tools to remain leaders. I know we can grow organic and biotech crops without one jeopardizing the other. I know this because I have been doing it successfully on our farm over the last decade.

Thank you again for the opportunity to share my views. I look forward to answering any questions you may have. Thank you.

Mr. KUCINICH. I thank the gentleman.

[The prepared statement of Mr. Cameron follows:]

OPENING STATEMENT
DON CAMERON
DOMESTIC POLICY SUBCOMMITTEE
OVERSIGHT & GOVERNMENT REFORM COMMITTEE
THURSDAY, MARCH 13, 2008
2247 RAYBURN HOB
2:00 P.M.

INTRODUCTION

Good afternoon, Mr. Chairman. Thank you for providing me this opportunity to share with you and this distinguished Subcommittee my experience as a farmer who grows both organic and biotech crops on my farm.

My name is Don Cameron and I am the General Manager of Terranova Ranch, a diversified farming operation located in Fresno County in California's Central San Joaquin Valley. At Terranova, we farm approximately twenty six different crops -- including cotton, alfalfa, tomatoes, carrots and garlic -- on nearly 5,500 acres. On our farm, we grow organic, conventional and biotech crops.

About 10 percent of our overall production is grown for organic markets, including organic cotton and alfalfa. The remaining 90 percent of farming at Terranova is a combination of conventional farming practices and crops derived from agricultural biotechnology, which also includes biotech cotton, corn and alfalfa.

Our farming operation is living proof that organic and biotech farming practices can coexist in near proximity without one negatively impacting the other. Over the last decade, millions of acres of biotech crops have been grown in the United States, which coexist with organic crop production. In fact, the growth of agricultural biotechnology has been accompanied by a surge in both organic acreage and profits derived from

organic production in this country. Indeed, organic farming has been a profitable component of our farming operation.

WHY MY FARM IS DIVERSIFIED

What is true for farmers across the United States is also true for me, namely that farming is a business. Like any good businesspeople, we seek to be good stewards of the land while maximizing our opportunities in the marketplace.

When we determine each year what crops will be planted, we look at all aspects of each potential crop, from expected price, yield, crop rotation, income to expense ratios and whether we can compete on a global basis with other countries. We have chosen to specialize in organic farming on a portion of the farm to increase diversity and fill a niche in the market place. The risk is much higher in organic farming due to the lack of effective treatments for various insects, diseases and weed problems. We have accepted the risk with the potential for increased profitability. Most insecticides, herbicides, fungicides and commercial fertilizers are eliminated in organic farming. Hand weeding with contracted labor is our major expense. Organic farming is a process we have chosen to put in place on a portion of our farm.

On the remainder of the farm, we chose to farm with conventional techniques. We use modern, technologically advanced practices including GPS equipped tractors, plant mapping, integrated pest management, and irrigation management. We also use biotech seed varieties when available for corn, cotton and alfalfa. The trait we find most useful is the Roundup Ready trait, which allows plants to resist the herbicide Roundup (glyphosate). Why is this so important to us? Because the economic savings we realize through the use of the Roundup Ready system has been tremendous. Compared to

conventional crops, Roundup Ready alfalfa save us about $110 per acre; Roundup Ready cotton about $165 per acre and Roundup Ready corn about $17 per acre. These savings include the reduction of overall chemical use on our farm, reduced labor costs and fewer trips across our fields with tractors, which conserves our farm equipment and reduces diesel use along with emissions and dust particles released into the environment. If we were comparing the Roundup Ready weed control cost with weed control of our organic production, the savings would be greater.

To elaborate on that point, here in the United States, our labor costs are expensive because we provide a fair wage, safe working conditions and insurance benefits to our workers. To hand weed organic crops I have spent up to $2,000 per acre as there was no alternative. This is not an effective use of a dwindling supply of available labor. With a Roundup Ready crop, my total weeding bill is less than $35 per acre and my crop is clean and free of weeds. For the American Farmer and me to compete in a world market place where labor may cost about $1.00 per day, we need technologies like this to remain competitive.

I believe that the flexibility biotechnology can provide is a major reason that I can successfully grow the variety of crops that I grow. The Roundup Ready cropping system leaves no chemical residue that will interfere with the following crops. In the past, we would use herbicides that had long residuals in the soil which would preclude the planting of many sensitive crops following their use. We now have the flexibility to change rapidly with major changes in markets without the risk of harm from previous herbicide applications.

MAINTAINING A DIVERSIFIED FARM

I am always asked how we keep pollen flow from one type of farming operation from interfering with another. We grow many crops for their seeds, both organic and conventionally and each one is different. We have been dealing with these issues long before the advent of biotech crops. If farmers were not successful with this, there would be only one color of corn, one variety of melon, and one type of cotton. We know the biology of each crop we grow and where we need to grow it to maintain and preserve its integrity or identity. We maintain the necessary separation needed, especially in seed production. In some cases there is no interaction and in some cases there is. But, we know when to anticipate interaction and separate the varieties according to their characteristics. We clean our planters, harvesters, bins and trucks to maintain this purity, the same as we separate our organic from non organic or biotech crops. We talk with our neighbors; we communicate and work out any issues that may arise. We are also required by commercial contracts to provide a crop that is virtually free of other varieties, be it biotech to organic or organic to conventional. We maintain separation to ensure this does not happen.

On our farm, we consistently maintain a higher level of standards, which exceed the National Organic Standards to fulfill contract requirements of our buyers. In all my years of farming, I have never lost a market nor income because I grow organic, conventional and biotech varieties on my farm. In short, we were "coexisting" long before the term was coined.

CONCLUSION

It is my hope, that the U.S. will remain competitive and that our nations' leaders provide the foresight to keep us in the forefront of modern agricultural production for many years to come. As an American, I do not want to rely upon another country for my food and fiber supply. We are the most productive nation in the world in agriculture and need the tools to remain leaders. I know we can grow organic and biotech crops without one jeopardizing the other. I know, because I have been doing it successfully on our farm over the last decade.

Thank you again for this opportunity to share my views. I look forward to answering any questions you may have.

Mr. KUCINICH. I just would like to remind the witnesses if they could try to keep their testimony to within 5 minutes to help us facilitate this. Thank you very much.

OK. Mr. Kirschenmann.

STATEMENT OF FRED KIRSCHENMANN

Mr. KIRSCHENMANN. Yes. Thank you. And thank you for inviting us to this hearing.

I would like to add just three observations to those that have been made by my farmer colleagues, and they are all based on our experience on our own farm, farming organically for the last 30 years.

The first observation is that there is perhaps not a misconception, but a misappropriation of information within USDA regarding whether or not organic farmers are harmed in the marketplace by contamination. And USDA quite correctly points out that organic certification is based on a process certification; that is, our product is not routinely tested to find out if there is contamination. We are simply inspected and certified to make sure that we don't use transgenic technologies in our production system, and that is what is meant by process certification.

The problem is that while that is true, there are increasingly people in the organic market who buy our products who are not satisfied with simply the fact that we are certified organic. They, in fact, do their own testing because they know that their consumers are not just concerned about whether we use the technology on our farms, but they simply don't want the GMO in their food. And so increasingly now the customers that we sell to are routinely testing. They have very sophisticated laboratories, and they test to the lowest possible degree that technology allows. And if there is contamination, they simply reject the product.

To give you a case in point, we sell virtually all of our organic Durham wheat to Eden Foods, and Eden Foods is one of those companies that feel that they have a covenant with their customers that they do not want to violate, and so they guarantee to their customers that when they buy their organic pasta, that there are no GMOs in that pasta, and so they routinely test. And I have been to their plant, I have seen their laboratory. It is very sophisticated, uses the most recent technology and science. And I have seen the records of rejecting loads of soybeans when they were delivered when they had small levels of contamination. And, of course, the farmers then had no choice but to take the load back. And, of course, as you can imagine, that is a considerable cost to the grower not only because of the lost market, but also because of the transportation costs, etc., to the plant and back.

So I think it is important for this committee to recognize that in the marketplace increasingly now the buyers are in there because they want to maintain their confidence and their relationship with their customers, are increasingly now testing the product. This is also true, has been routinely true, of organic products exported to Europe, where it routinely gets tested. And all of the companies that we sell our grain to apprise us of the fact that we had better make sure that there are no contaminants in the product before it ever leaves our shores.

Now, all of that, of course, has led us on our farm to simply make a firm decision, and that is that we will not grow any crops on our farm now that have a counterpart that has a GMO crop. So for that reason we had to stop raising canola about 10 years ago, despite the fact that it was a very good crop in our rotation. And the rotation is important, because something that is not often understood by nonorganic farmers is that in order to make an organic system work, you have to have a very complex rotation, which is the way that you prevent infestation from weeds and diseases and other contaminants. And so we have found on our farm that we need to alternate cool-season and warm-season crops, we need to alternate grassy plants with broadleaf plants, we need to alternate leguminous crops with other cash crops. And there are only so many alternatives that we have in making those decisions, because we are limited by climate and other constraints, and also, of course, most importantly, by the market.

So giving up canola was a big loss to our farm. It was a great crop. It worked well in the rotation. It is one of the few broadleaf, cool-season crops that we can grow, and it was a crop that was very lucrative because we were selling it into a high-end organic oil market. And we had to give it up.

The thing that concerns us most at this point is that alfalfa and wheat are now again being threatened to come into the GMO market, and these are two crops which are absolutely essential to our rotation. A third of our production is in wheat, and if we were to lose that, it would be a serious economic blow to our farm.

Mr. KUCINICH. I thank the gentleman.

[The prepared statement of Mr. Kirschenmann follows:]

STATEMENT
OF
FREDERICK KIRSCHENMANN

DOMESTIC POLICY SUBCOMMITTEE
OVERSIGHT AND GOVERNMENT REFORM COMMITTEE
THURSDAY, MARCH 13, 2008
2154 RAYBURN HOB
2:00 P.M.

"IS THE U.S. DEPARTMENT OF AGRICULTURE (USDA) ACCOUNTING FOR THE COSTS TO FARMERS FROM CONTAMINATION CAUSED BY GENETICALLY ENGINEERED (GE) PLANTS"

I would like to thank the Chairman Kucinich and Ranking Member Issa and Members of the Subcommittee for this opportunity to speak on this matter which so greatly impacts the livelihoods of the U.S. organic producer.

My name is Frederick L. Kirschenmann. I am a Professor of Religion and Philosophy currently serving as a Distinguished Fellow at the Leopold Center at Iowa State University after having been the Center's Director since July of 2000. However, I appear before you today as an organic producer and manager of our family's 3,500 acre mixed crop and livestock farm located in south central North Dakota. Of those 3,500 acres, approximately 1,000 acres is still in native prairie which our family uses to graze livestock in the summer months. The remaining 2,500 acres is cultivated. Approximately one-third of that land is in leguminous cover crops – alfalfa and clover. Alfalfa serves as a forage crop for our animals and the clover is a green manure crop which provides essential nutrients for other crop production. The remaining 1,700 to 1,800 acres are planted into small grains that are part of a complex crop rotation plan which I will discuss at great length later in my testimony. We compost all of our livestock manure which is applied to our fields to further improve the health of our soil.

This farming method has proven very successful for our farm family, especially since we made the transition to organic farming in 1976. We have been certified organic since 1980 and due to our record of stable production achieved by virtue of our rotation scheme; we have not had to borrow any operating capital since the certification was received.

I do not come here today pretending to represent organic producers. However, I do have extensive experience in agriculture that compliments my work at the Leopold Center and in the management of my farm, which provides unique insights into how shortcomings at the USDA in the regulation of genetically engineered crops have significantly impacted organic producers economically.

I assisted in the formation of Farm Verified Organic, Inc. – a private organic certification agency – as well as the Northern Plains Sustainable Agriculture Society. I was appointed and have served on USDA's National Organic Standards Board, the USDA's North Central Region Sustainable Agricultural Research and Education (SARE) Administrative Council and on the Board of Directors of the Henry A. Wallace Institute for Alternative Agriculture. I also serve as President of the Stone Barns Center for Food and Agriculture at Pocantico Hills, NY. The Stone Barns Center, initially funded by David Rockefeller and his family serves as a demonstration and education center in sustainable agriculture I am a member of the National Commission on Industrial Farm Animal Production operated by the Johns Hopkins School of Public Health, funded by Pew Charitable Trusts and I am the convening Chair of a multi-state task force, Agriculture of the Middle, which focuses on research and markets for midsize American farms. This group is also responsible for establishing the Association of Family Farms to create standards and markets for the farms which are the focus of Agriculture of the Middle.

In order to understand the monumental challenges posed by genetically engineered crops to the management and profitability of an organic farming system, you need to have a basic understanding of the system itself.

Successful organic farming depends in large part on putting together a mix of crops in a complex crop rotation plan. Since organic producers do not use agricultural chemicals, the mix and sequence of crops in a rotation must help control weeds, suppress pests and diseases, help recycle nutrients as well as being profitable in the up and down world of agricultural commodity markets. Naturally, the crop choices available to accomplish this multi-faceted set of goals is determined by climate, soil type, available markets and practical considerations such as availability of necessary machinery and equipment. We have discovered that coming up with the right mix of crops to achieve these multi-faceted objectives is the most significant challenge in developing a successful organic farming operation.

It has also become equally clear that once a farmer succeeds in finding that delicate balance in his/her crop rotation scheme that any changes to system are very difficult to make without incurring financial costs because each crop performs several functions that enable the entire operation to be economically successfully. It is very important to understand this phenomenon in organic farming, because it is never a simple matter of substituting on crop for another.

On our farm in North Dakota, given its soil and climate constraints, we have found that four crop rotation patterns are critical to achieving the multi-faceted objectives that I discussed earlier. On our farm we alternate cool season crops and warm season crops to help control weeds. If you plant cool season crops several years in a row, cool season weeds establish themselves, producing seeds and making it very difficult to control those weeds after just a few short years. We alternate broad leaf and grassy plants. Planting one or the other in successive years makes it much more difficult to control pests and diseases. We also alternate leguminous and non-leguminous plants so that we can produce a variety of food crops and to "fix" sufficient nitrogen in the soil to sustain crop

production. Finally, we alternate shallow rooted and deep rooted plants to more efficiently use the nutrients throughout the soil profile. The loss of any crop in this complex crop rotation system presents significant management problems as well as the loss of an income producing crop. Given the climate and soil types in North Dakota, as well as available markets, very few options exist to replace crops lost to our crop rotation system.

Canola was a critical crop for us in our complex rotation scheme. Canola is one of the few crops that grow in our climate and soil types that are both a cool season and a broad leaf plant. It is also very attractive in the market since high quality organic canola oil is in big demand in the organic market. We marketed our canola through a farmer-owned cooperative that had long term contracts with several companies on the West Coast. Prior to the forced removal of canola from our crop rotations, 20% of our crop income came from canola.

We were not alone in our use of canola a major income producer. Many crop producers, both conventional and organic in the northern plains in the United States and in the southern provinces of Canada, relied on canola to provide a significant source of income. Prior to the commercialization of genetically engineered (GE) canola, Monsanto's Roundup Ready variety, organic producers where receiving a 100% price premium when compared to conventional varieties and agricultural economists were touting the potential for significant market expansion. As stated in *Nature Biotechnology* (June 2002), *the introduction of transgenic herbicide tolerant canola in western Canada destroyed the growing market for organic canola.* While the commentary in this article was focused on the economic impacts of GE canola in Canada, this scenario was identical to that experienced by U.S. organic canola growers.

In the Environmental Assessment (EA) conducted in accordance with the Petition to Deregulate RR Canola, the USDA noted that Brassica is an open and self pollinating crop in the "mustard" family which includes more than 375 genera and 3200 species. The EA acknowledged that the plants are capable of self-fertilization and intra-specific cross-fertilization; that partial sexual compatibility exists among members of the Brassica family and other closely related species outside the genus; that gene movement is possible to other members of the plant family; and, that honey bees were its primary pollinators. Despite the existence of all these potential avenues of contamination, the USDA concluded that the commercialization of RR canola did not present a plant pest risk nor did the potential exist for the impacts to the human environment through its use in agriculture. Specifically the USDA determined that:

- Neither the introduced genes and their products nor the regulatory sequences controlling their expression presents a plant risk,
- RR canola is neither a weed nor has any significant to become a weed and does not transmit weedy characteristics to sexually compatible plants,
- RR canola will not cause damage to agricultural commodities,
- RR canola will not have a negative impact on agricultural and cultivation practices, and

- RR canola will not be harmful to threatened or endangered species, including bees.

One area of personal aggravation is that the USDA totally failed to consider the impacts of RR canola contamination on organic producers in the EA process. In assessing the potential impacts of RR canola on agricultural or cultivation practices, the agency acknowledged that volunteer seeds and plants could pose a problem but concluded that RR canola would not negatively impact those practices. This determination that volunteers did not represent a significant adverse impact was based on the premise that the problem could be eradicated through the use of 2,4D and/or sulfonylurea type herbicides. Clearly, the impact of volunteers on organic producers was not even considered in reaching that conclusion.

The conclusions reached in the EA defied logic, reason and reality to those of us with experience in growing canola. The fact that canola is open-pollinating with its pollen dispersed and transmitted great distances by bees, animals, wind or other mechanical means over great distances was clearly indicative of a significant probability that contamination could occur. Canola is a very sturdy and prolific plant. That is one of the reasons it is so attractive to farmers in harsh northern climates. From the outset we knew that there was the potential for trouble.

Farmers were not the only ones concerned about the potential for contamination. The scientific and the canola industry had concluded that cross-pollination, volunteer issues and gene movement made contamination a virtual certainty and focused on farm management strategies to minimize contamination.

Within two years after RR canola was commercialized, cross-pollination had resulted in the development of canola hybrid resistant to Roundup, Liberty and Pursuit. In the *Nature Biotechnology* article previously referred to in my testimony, the authors acknowledged that *although the canola industry had predicted that this would occur eventually, this triple resistant hybrid was created by variety cross pollination in just two years.* The fact that the scientific community felt that contamination was a virtual certainty was also apparent in a *Toronto Globe & Mail* article entitled "A New Breed of Superweed." In that article, Phil Thomas, a researcher at Alberta Agriculture's Field Crop Development Centre with 30 years of experience, stated that GE canola can easily outcross between varieties with bees and other insects carrying the sticky pollen from one plant to another while wind also transports the pollen and all the genetic modification that it contains from one field to another. Seeds from the new out-crossed varieties can be carried by wind, animals, birds, humans, and truck and tractor tires to other fields where their pollen can migrate to yet another type of canola. *"This was to be anticipated,"* Thomas concluded. Apparently, the cross pollination and subsequent hybridization was anticipated by everyone but the regulators at the USDA.

When RR canola was introduced into our community, I talked with neighbors who planned to use to it. While the USDA minimized the potential for contamination we knew a huge potential existed for that to occur, and similarly to the approach being

considered by canola crop scientists, our focus was on creating a buffer of sufficient size to minimize the potential for contamination.

We worked cooperatively with our neighbors to try to ensure that our organic canola fields were at least 2 miles from neighboring fields where RR varieties were being grown. Since canola is an insect pollinated crop such distances were critical according to bee apiarians who regularly place bees on our farm. We felt that this approach could work on our farm as long as we could fit our canola fields into rotation patterns that kept the entire system in balance and were are least 2 miles from neighboring RR canola fields.

After two short years, RR canola began to be adopted more heavily in our area and it became impossible to find fields on our farm which could meet the 2 mile buffer requirement and also fit into our rotation patterns, despite the fact that our farm fields extend over a 20 mile range. Additionally, contamination had become an immense problem for canola growers in our area. Organic producers who did not maintain the 2 mile buffer were increasingly becoming contaminated resulting in the loss of lucrative markets and premiums for organic canola. In that short span of time, contamination had become so pervasive that there were no seed dealers in the area that were willing to guarantee that their seed was GE-free. Our only option was to remove canola from our farming system. What USDA had determined was a virtual impossibility became a reality in 2 growing seasons. For anybody that farms for a living, this result was totally predictable.

Removal of canola not only meant the loss of a crop generating one-fifth of total farm income, it also presented a whole new set of challenges in finding a new crop that would fit into our complex rotation system. An alternative broad leaf, cool season crop that was marketable simply did not exist. Consequently, we were left with no other option than to eliminate broad leaf, cool season crop component of our crop rotation and spread the canola acres among our other crops – reducing the effectiveness of our entire rotation scheme. While it is hard to estimate the long term economic loss that resulted from the compromise of our rotation system, the short term economic loss sustained as a direct result of the removal of canola was $50,000 in annual income.

Organic canola producers throughout the northern plains of the United States and the provinces of Canada were similarly impacted. Although I do not have statistics for U.S. producers, an estimated $1 million was lost to Canadian organic canola producers. As has been the experience in virtually every GE crop approved for commercial use, contamination cost us valuable markets. In the spring of 2000, GE canola was found in a breeder's lot of canola seeds imported by Advanta (Winnipeg, MB). Advanta quickly determined that the GE contamination had been caused by gene flow from GM foundation seeds planted in neighboring fields. Despite the fact that Canadian seed growers had followed isolation rules, the genes still moved into conventional foundation seed. This not only created havoc in valuable European markets but resulted in an inability to find non-GE canola seed. This is exactly the same scenario that occurred in

the LL 601 rice contamination incident. While this contamination event occurred in Canada the same scenario occurred throughout the United States.

Canola producers were not the only ones losing valuable markets as a result of GE canola contamination. In 1999 the EU detected unapproved GE proteins in a shipment of honey. As a result honey shipments to the EU dropped $4.8 million between 1998 and 2000 – or by 55%.

While the loss to our farm from the loss of organic canola was sobering, it pales in comparison to the way the introduction of GE wheat or GE alfalfa would effect our operation. Wheat is the lead income producing crop on our farm. Typically, about one-third of our 1700 acres planted to small grains is in wheat. Most of our hard red spring wheat is sold to buyers in Europe. All of our buyers have already warned us that if GE wheat is introduced in the United States they will source their organic wheat from other countries since they have no confidence in our ability to prevent contamination. These buyers have made it clear that their customers/consumers are very adamant about organic products being GE-free. In many cases the fact that products are GE-free is the sole reason that these customers buy organic according to those buyers.

Contrary to representations by the USDA, process-based certifications that products are "organic" and that no GE crops were used in the production of those products are insufficient in this day and age. Organic buyers and processors increasingly utilize strict testing regimens to ensure that the crops they are purchasing are GE-free. We sell the vast majority of our durum wheat to Eden Foods of Michigan. Eden Foods makes a commitment to its customers and guarantees that no genetically modified organisms (GMOs) are contained in their products. In addition to requiring organic certification, Eden Foods, rigorously tests all incoming grains to make sure that they are free of any GE content utilizing tests to detect contamination to the lowest level possible with existing technology. They routinely reject any incoming truckloads of grain that test positive for GMOs. Product testing is rapidly becoming an industry standard in both foreign and domestic markets.

Consequently, the introduction of GE wheat presents an enormous potential loss of income for our farm. This year (2007 crop) we are selling our organic wheat crop for $24-$29 per bushel largely due to global shortages in supply. We normally harvest 19,000 bushels of wheat per year. Losing this year's wheat crop would mean a $494,000 loss to our farm. There is simply no substitute for wheat in our crop rotation. The loss of our organic wheat market would effectively put us out of business.

The introduction of GE alfalfa would have comparable consequences. Alfalfa is one of the few legumes that we can produce on our farm, given soil and climate conditions that can both serve as nitrogen fixing plant and a source of forage for our livestock during the winter months. While we also produce some Yellow Blossom sweet clover to fix nitrogen, it cannot be used as the sole source of forage due to that fact that feeding clover on a constant basis can cause a poisonous disease in the rumen that can cause death in cattle. Accordingly, clover can only be used for about 10% of our forage needs. The loss

of alfalfa due to GE contamination would result in the loss of our primary source of nitrogen for our crops as well as our principle source of winter feed for our livestock. Once again, there is no substitute for alfalfa and its loss would effectively put us out of business.

Organic producers simply cannot afford the business as usual approach that has been used to regulate and approve GE crops. At present, the USDA serves no valuable purpose other than to rubber stamp the crops in the biotech pipeline for commercialization. There is no confidence in the assessment process among farmers, buyers or the marketplace. The lack of an effective regulatory system hurts everyone in food chain from field to fork.

I am hopeful that the result of these hearings will provide an awakening at the USDA to the fact that no one benefits from the status quo. A strong regulatory program for GE crops can benefit all concerned. I am appreciative of the Subcommittee's interest in this topic and their commitment to support the economic livelihoods of the farmers who are dependent on an effective regulatory system for GMOs.

I thank you for the opportunity to express my opinions and experiences on these issues and would be happy to answer any questions that the Chair and Subcommittee Members may have.

Mr. KUCINICH. Professor Carter, please.

STATEMENT OF COLIN CARTER

Mr. CARTER. Thank you, Chairman Kucinich.

Despite the successful commercialization of genetically modified crops in the U.S. agriculture and the successful coexistence of GM and non-GM, farmers in our Nation have suffered huge financial losses due to accidental contamination of their crops with unapproved GM material. The most serious accidents were the contamination of the U.S. corn supply in 2000 and the 2006 contamination of the U.S. long-grained rice supply. In both of these cases, farmers were innocent victims of lax government regulations and poor stewardship by companies developing, testing and selling GM seeds.

StarLink corn was found in hundreds of food products. The problem spread internationally. StarLink contamination was very disruptive, because a large share of the market had zero tolerance for its use, and zero tolerance is virtually impossible to obtain. Less than 1 percent of the U.S. corn acreage was planted to StarLink, yet 70 percent of the in-bound corn samples tested by Japan, our most important foreign market, were positive. I have found that the StarLink contamination resulted in a 6 percent drop in the price of corn that lasted for at least 6 months, costing corn farmers $500 million.

In August 2006, U.S. rice farmers were surprised when the USDA announced that unapproved GM rice had been found in export shipments, and that carrier variety was Cheniere. Apparently, the U.S. Government knew about this accidental contamination for some time before farmers were informed in August. Why the delay in informing farmers?

Just like StarLink, the LibertyLink fiasco has demonstrated that it takes a very long time to clean up contaminated samples. As long as a contamination like LibertyLink drags on, farmers are losing money.

The U.S. exports about 50 percent of its long-grain rice, so foreign market tolerance levels for adventitious presence in GM material is very important. The European Union's imports of U.S. rice came to a virtual halt following the LibertyLink contamination. In a matter of a few business days following the contamination announcement, the Chicago rice futures price dropped sharply, by about 10 percent. Unfortunately for farmers, they were just beginning their harvest, and they suffered a loss to the value of the crop before they had a chance to market it. LibertyLink found its way into the rice foundation seed supply. And unfortunately, the USDA could not explain how this happened.

Then in March 2007, the USDA announced that an additional popular variety of long-grain rice, CL131, was also contaminated with Bayer's LL604 unapproved. The Chicago futures price dropped sharply again.

Cheniere and CL131 were planted on about 30 percent of the southern long-grained rice acreage in 2006. These varieties could not be planted in 2007, causing additional financial losses for rice farmers.

The economic question boils down to the following: What are the benefits and costs of deregulation? In my view, the USDA is not

necessarily taking a hard look at all aspects of this question. Last year Judge Breyer ruled in a case regarding the USDA's deregulation of GM alfalfa, highlighting some important gaps in the current system. The alfalfa case is instructive, but we have to be careful to distinguish between situations of unapproved GM crops used in confined field trials from those approved for commercialization. Both situations can be affected by accidental contamination, but in the first case all farmers stand to lose, and it is often the legal responsibility of the developing company. In the second case it is a coexistence issue between GM and non-GM.

One major problem underscored by the alfalfa case is a lack of Federal rules regarding accidental contamination of organic products. Apparently the USDA does not even know how to handle this issue, as the Agency argued that producers may not necessarily lose their organic certification if they unintentionally sell unorganic crops contaminated with GM. Some organic producers may not agree. As Judge Breyer implies in the ruling, even if the USDA allowed contamination of organic alfalfa through high tolerance levels for adventitious presence, and sellers could still claim organic status when contamination occurs accidentally, this would not guarantee that organic production is sustainable.

The rules should ensure that the production of organic is possible with a reasonably low contamination level. The USDA should provide better evidence on the benefits and costs of deregulation, especially when exports are an important market for the crop in question and there are barriers in those foreign markets. As we learned from StarLink and LibertyLink, this technology is not easily reversible. The USDA might find that new GM crops could be grown, but with certain geographical restrictions, buffer zones, and traceability and segregation rules.

I am not arguing that the Roundup Ready alfalfa case should be generalized to all future releases of GM crops and that a full-blown environmental impact assessment be conducted in all cases. However, in going forward, the USDA should strive to consider which new crops constitute a significant net economic risk and which do not. Even in Europe, or in Canada for that matter, approval of a new GM crop does not entail a formal assessment of commercial market risks of introducing a new crop, but these other countries do consider contamination tolerance thresholds and aim to develop coexistence measures that comply with threshold levels. However, I do caution that stringent market tests could easily transform into a precautionary principle approach, which would be a huge mistake.

To summarize, our mistakes over the StarLink and LibertyLink contamination incidents were major setbacks to the global biotechnology revolution in agriculture. Our trading partners point to these two incidents as evidence that GM crops are not being properly managed in the United States. They are right. We are not doing a great job. The stakes are too high to put our heads in the sand and defend the status quo. Genetically engineered crops hold tremendous promise for the future of United States and world agriculture, but they must be managed and regulated in a way that assures the marketplace that any risks are properly managed.

Mr. KUCINICH. Thank you, Professor Carter.
[The prepared statement of Mr. Carter follows:]

Statement of Professor Colin A. Carter, to Domestic Policy Subcommittee, of the Oversight and Government Reform Committee, March 13th, 2008.

Is USDA Accounting for Costs to Farmers Caused by Contamination from Genetically Engineered Plants?

Good afternoon Chairman Kucinich and committee members. Thank you for inviting me to this hearing. My statement will address two key questions:

1) What are the potential economic impacts on farmers resulting from accidental contamination of their crops by unapproved Genetically Modified material? and

2) What are the elements of a comprehensive analysis of those economic impacts; how do we take a "hard look" at the issue of co-mingling and accidental contamination with regard to approving new GM crops?

Potential and Actual Magnitude of Economic Impacts from Accidental Contamination

Despite the successful commercialization of genetically modified (GM) crops in U.S. agriculture, and the successful coexistence of GM and non-GM crops, farmers in our nation have suffered huge financial losses in recent years due to accidental contamination of their crops with unapproved GM material. The most serious accidents were the accidental contamination of the U.S. corn supply by StarLink Corn in 2000 and then the 2006 accidental contamination of the U.S. long grain rice supply by Liberty Link rice. In both of these cases, the farmers were innocent victims of lax government regulations and poor stewardship by companies developing, testing, and selling GM seeds. In my view, as the Liberty Link case illustrates, the U.S. government may have underestimated the costs to farmers caused by accidental contamination when it established rules for the management of confined field trials of unapproved GM events, and then the government followed through with poor record keeping on field trials.

StarLink Corn

In September 2000, traces of StarLink corn were detected in taco shells in the United States and this led to immediate recalls of hundreds of food products. The problem quickly spread internationally to Japan, Canada, and South Korea where unapproved StarLink corn was discovered in food and animal feed. The StarLink contamination reduced demand from U.S. corn and lowered farm gate prices for corn. For instance, exports of U.S. corn to Japan fell about 8% in calendar year 2001, due to the StarLink contamination.

The U.S. Environmental Protection Agency (EPA) approved StarLink in 1998 for commercial production for animal feed but not for human consumption. This "split license" was flawed regulation from the beginning. Companies selling StarLink claim that they instructed growers to keep it separate from other crops, but a number of growers claimed they never received any such warning

The StarLink contamination was particularly disruptive because a large share of the market had zero tolerance for its use, and zero tolerance is virtually impossible to attain. Less than 1% of the total U.S. corn acreage was planted to StarLink, yet 70% of the inbound corn samples tested by Japan (our most important foreign market) between September and December 2000 tested positive for StarLink. Japan kept testing for StarLink for a long time and they kept finding it for months and months after the incident. So the contaminated corn was not quickly and easily isolated. Instead, it was everywhere in the corn supply. With my colleague Professor Aaron Smith, I have found that the StarLink contamination resulted in a 6% drop in the price of corn that lasted for at least 6 months; translating into a loss of roughly $500 million to the non-StarLink U.S. corn growers.

Liberty Link Rice

In August 2006, U.S. rice farmers were surprised when the U.S. Department of Agriculture Secretary announced that unapproved GM rice (Liberty Link rice) had been found in the 2005 crop of U.S. long-grain rice, and the carrier variety was Cheniere. Apparently the US government knew about the accidental contamination for some time before farmers were informed in August. Why the delay in informing farmers? In terms of farm level impact, there are many similarities between Liberty Link rice and StarLink corn.

Over one year after the 2006 Liberty Link contamination event, there remained concern in key markets over GM content in US long grain rice exports. Just like StarLink, the Liberty Link fiasco has demonstrated that it takes a very long time to clean up contaminated supplies. As long as a contamination like Liberty Link drags on, farmers are losing money.

The U.S. exports about 50 percent of its long-grain rice crop, so foreign market tolerance levels for adventitious presence of GM material is very important for this crop. The European Union (EU) was a significant importer of US rice but this trade came to a virtual halt following the Liberty Link contamination. The EU has zero tolerance for adventitious presence of an unapproved variety like Liberty Link.

In a matter of a few business days following the public disclosure of the Liberty Link rice contamination, the Chicago rice futures price dropped sharply–with the price falling close to 10% in just a few days. Unfortunately for farmers, they were just beginning their rice harvest and they suffered a loss in the value of their crop before they had a chance to market it.

The Liberty Link rice contamination was especially problematic because it found its way into the rice foundation seed supply – which is used to produce rice seed that is

sold to producers for planting. Unfortunately the USDA could not explain how this happened. The contaminated seed ensured that the Liberty Link contamination was widespread throughout the Southern rice crop, and probably extended beyond Cheniere. All southern grain growers were impacted, as samples from the from the five-state growing region – Arkansas, Missouri, Mississippi, Louisiana and Texas – had tested positive for the unapproved genetically engineered trait.

Then, in March 2007, there was a further setback to the U.S. rice industry when the USDA announced that an additional popular variety of long-grain rice, Clearfield CL131, was found to contain Bayer's LL 604 rice. This was yet another of Bayer's unapproved genetically-modified rice seed traits not approved for commercialization, but instead was restricted to only field trial testing. The day after the March 2007 USDA announcement the rice futures market dropped sharply once again.

In total, Cheniere and CL131 were planted about 30% of the southern long-grain rice acreage in 2006. Due to the Bayer contamination events, these varieties could not be planted in the spring of 2007, causing additional financial losses for rice farmers for the next crop year.

The Components of a Comprehensive Analysis of Economic Impacts

The economic effects of deregulation of a GM crop on non-adopters and on domestic and foreign markets are important and essential to any decision whether or not to deregulate, and how to deregulate (e.g., with our without geographical restrictions, etc.). Non-adopters face risk of contamination of their crops through gene flow or accidental mixing, added segregation and testing costs of their non-GM crops, and loss of markets. The economic question boils down to the following: what are the benefits and costs of deregulation? In my view, the USDA is not necessarily taking a hard look at all aspects of this question.

Last year, Judge Breyer ruled in a case regarding the USDA's deregulation of GM alfalfa. This judgment provides suggestions as to how the USDA should better comply with the National Environmental Policy Act (NEPA). Judge Breyer's ruling clearly highlighted some important gaps in the current system, and as an economist, I agree with Judge Breyer's ruling on the key issues dealing with Genetically Modified alfalfa.

The alfalfa case is instructive but we have to be careful to distinguish between situations of unapproved GM crops used in confined field trials from those approved for commercialization but that may create negative externalities for non-adopters. Both situations can be affected by accidental contamination or accidental gene flow. But in the first case, all farmers stand to lose and it is often the legal responsibility of the developing company. In the second case it is a coexistence issue between GM and non-GM farmers. It is therefore a very different issue.

One major problem underscored by the alfalfa case is the lack of federal rules regarding accidental contamination of organic products with GM material: apparently the USDA does not even know how to handle this issue, as the agency argued that producers may not "necessarily" lose their organic certification if they unintentionally sell organic crops contaminated with GM. Some organic producers may not agree as the market test (e.g., for certification) may not be the same as the legal standard.

As Judge Breyer implies in the ruling, even if the USDA allowed contamination of organic alfalfa through high tolerance levels for adventitious presence, and sellers could still claim organic status when contamination occurs accidentally, this would not guarantee that organic production is sustainable because it would not correspond to what organic consumers believe they are buying. The "right to produce organic" is different from the "right to sell a product that is labeled organic", and so the rules should ensure that production of organic is possible with a reasonably low contamination level.

The USDA should provide better evidence on the benefits and costs of deregulation, especially when exports are an important market outlet for the crop in question, and there are regulatory barriers and/or possible buyer resistance in the foreign market. As we learned from StarLink and Liberty Link, this technology is not easily reversible, even if it is only at the field trial stage. How does the U.S. industry best respond to export risk when the GM material in question is not approved in major import markets? Only through comprehensive study can the USDA determine how the U.S. industry can best meet the standards in critical foreign markets.

The USDA might find that new GM crops could be grown but with certain geographical restrictions, buffer zones, and traceability and segregation rules. What are the trade-offs associated with deregulating a new GM crop? The U.S. government should begin by clarifying rules and responsibilities regarding: 1) the management of confined field trials of unapproved GM events; 2) coexistence at the approval stage, at the field level, and in the supply chain; and 3) the thresholds for adventitious presence for organic and non-GM.

I am not arguing that the round-up ready alfalfa case should be generalized to all future releases of GM crops and that a full-blown Environmental Impact Assessment be conducted in all cases. However, in going forward, the USDA should strive to consider which new crops constitute a significant net economic risk and which do not. Even in Europe (or Canada for that matter) approval of new GM crops does not entail a formal assessment of commercial market risks of introducing the new crop. But these other countries do consider contamination tolerance thresholds and aim to develop coexistence measures to ensure domestic and foreign thresholds can be met in practice. I caution that stringent market tests could easily transform into a precautionary principle approach, which would be a huge mistake.

To summarize, current procedures for approving and managing GM crops in the U.S. could be improved. Our mistakes over the StarLink and Liberty Link contamination incidents were major setbacks to the global biotechnology revolution in agriculture. These two big mistakes serve to illustrate the potential costs to farmers of accidental contamination. Our trading partners point to these two incidents as evidence that GM crops are not being properly managed in the United States. They are right; we are not doing a great job. The stakes are too high to put our head in the sand and defend the *status quo*. Genetically Engineered crops hold tremendous promise for the future of U.S. and world agriculture, but they must be managed and regulated in a way that assures the marketplace that any risks are properly managed.

Professor Colin A. Carter
Department of Agricultural and Resource Economics
University of California, Davis

Mr. KUCINICH. We will now hear from Mr. Clark. I would ask Mr. Clark if he could keep his testimony to 5 minutes, and then we will go directly to questions. Thank you.

STATEMENT OF RAY CLARK

Mr. CLARK. Thank you, Mr. Chairman. It is certainly a pleasure to appear here once again before you, before the Domestic Policy Subcommittee, on another issue regarding the National Environmental Policy Act. And you have stated my background, that I am senior partner at The Clark Group after leaving the administration in 2001. My expertise, therefore, lies in the responsibilities and obligations of the executive branch of government as it relates to decisions affecting the human environment, and I am not an expert in genetically modified organisms, but have spent my career studying difficult and complex issues and the resolution of those issues, such as biological defense research and some others that I could name.

APHIS regulates certain genetically engineered organisms that may pose a risk to plant or animal health. And I have said—and I used the word "may." APHIS Biotechnology Regulatory Services regulates introduction of genetically engineered organisms that may pose a risk to plant health. It is a huge responsibility to oversee an industry that is rapidly growing and rapidly becoming more complex. The decisions that APHIS is making now, however, can have long-term beneficial or negative effects on the natural environment, the human community, and the economy.

When Congress passed the National Environmental Policy Act in 1969, the country was feeling the effects of a rapidly growing technology in other areas similar to what we are experiencing today. The rise of the chemical and nuclear industry of the 1950's and 1960's and some of the unintended consequences is in part what led to the passage of the National Environmental Policy Act in 1969.

Congress was prescient enough to know that Federal agencies will respond to requirements rather than oratory aspirations. The statute requires agencies to take a hard look at the impacts of major Federal actions, such as changes to legislation or regulation, approval of projects, and management of the Nation's resources. The Council on Environmental Quality developed the regulations that require agencies to prepare environmental assessments or environmental impact statements on broad actions so they are relevant to policy and are timed to coincide with meaningful decision points in agency planning.

And sometimes it seems like agencies are being asked to peer into a crystal ball, but the courts and the public have understood that the hard-look doctrine does not require agencies to be perfect or to understand absolutely the secondary, tertiary or cumulative effects of programs or policies. But the courts and the public do expect them to at least try. They want to know that the agencies are not captured by a special interest, but are thinking about the balance that must be struck between economic and environmental well-being. And these stakeholders want to know that all of us are being taken into consideration as agencies make decisions.

After agencies consult with the public, they're required to make an informed choice among a reasonable range of alternatives. Again, the agencies are not being asked to make a perfect decision, they are asked to follow a logic trail using a defensible methodology presented in a document that is clear and concise, supported by evidence and understandable to the public.

For complex decisions like disposing of chemical weapons or permitting genetically modified organisms, NEPA provides a structure and a discipline to think rationally and to make a decision that takes multiple objectives into account. NEPA is a tool for agencies that is so intuitive that even if the law did not exist, they would have to create a similar decisionmaking process to help them through these complex decisions.

One of the mistaken practices by the Federal agencies in doing NEPA analysis allows them to believe that NEPA does not apply to economic impacts. The purpose of the impact is—and I quote directly from the statute—"to declare a national policy which will encourage productive and enjoyable harmony between man and his environment; to promote efforts that will prevent or eliminate damage to the environment and the biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural sources important to the Nation."

The Congress recognized the profound impact of human activity on the interrelationships of all of the components of the natural environment, including the indirect effects on human dependence—humans' dependence economically on the environment. And in particular, Congress acknowledged the profound influences that population growth, high-density urbanization, industrial expansion, resource exploitation and technological advances will have on a natural environment should be considered and given a hard look.

In NEPA, there is clearly an intention to understand the relationship between the environment and our economic welfare. In addition, there is a requirement in the CEQ regulations to balance the economic and environmental factors in decisionmaking. For genetically modified organisms, the socioeconomic effects are likely to be interrelated with environmental effects. For example, the genetic drift of genetically engineered traits to nongenetically engineered crops, while an environmental effect, could also have socioeconomic impacts, such as potential effects on the marketability of products in organic markets or with trade partners.

A recent court case affirmed that the modification of a plant's genetic makeup through genetic engineering is an effect on the environment.

The linkage between environment, social and economic effects is precisely the kind of analysis that Congress intended with the statute, and it is precisely the kind of linkage that CEQ saw when the regulations were drafted in 1979. Whether or not those impacts were significant remains a question for the analysts, who must measure significance through an understanding of context and intensity.

Addressing cumulative effects has been a difficult task in the simplest of projects, but the regulation of genetically modified organisms is not the simplest of actions, but is an issue where understanding the potential of cumulative effects is critically important.

One way that I've always thought that we could do something like this is a—taking a hard look—is a programmatic approach to environmental impact analysis, and it will help reduce paperwork and streamline the NEPA process.

Programmatic analyses are appropriate in order to implement broad decisions for Agency programs, policies or plans. It seems particularly useful in broad decisions such as genetically modified organisms. However, I remind you of my earlier statement that significance is measured by both context and intensity. So a programmatic approach would be helpful, but if these decisions are applied in a local environment, an analyst must look at the biological, physical and socioeconomic context where that decision would be applied. In a natural ecosystem, a decision may be beneficial to the environment, but the same decision analyzed in a different socioeconomic context could have a negative effect. That is why programmatic analyses must include tiered analyses to look at the local environment.

Mr. Chairman, I commend APHIS for renewing and revitalizing their NEPA regulations. It is needed, and it is past due. I have reviewed the APHIS NEPA matrix for the regulated release of a genetically modified plant, and I must say this continues to be an old way of looking at NEPA, checking a box to get a document done. There is not any consideration of context or intensity of the potential impact as related to environmental or socioeconomic factors.

You know, APHIS needs to be—needs to move past these old ways. They are at a cutting edge of our new world, our new economy, and they need to embrace new ways of making these crucial decisions that affect all of us.

There has been much work done in this field in the last 5 to 7 years, much of it led by the Council on Environmental Quality and NEPA practitioners throughout the Federal Government, and there are three things that I would think that seem directly applicable to APHIS of which I would recommend a closer look. One is that APHIS should incorporate an ecosystem approach to the decisionmaking beginning at the policy level. This requires a more holistic look at what and who are in the ecosystem and how the biota are responding to natural and man-made changes. Regulations are the real opportunity for agencies to set policies regarding the NEPA process, and they need to be expansive in their thinking about these new regulations.

Two, incorporate a monitoring and adaptive management approach to NEPA. APHIS can therefore spend more time and more money on monitoring impacts and less on predicting with absolute certainty.

And finally, incorporate a collaborative way of decisionmaking. Organic farmers, farmers using genetically modified crops and consumers all have an interest in the ecosystem in which they live and work. CEQ has issued a handbook on developing collaborative processes, and APHIS should examine how better to engage the public.

In conclusion, Mr. Chairman, thank you for the opportunity to provide my thoughts on the matter. APHIS, I believe, has an important and unique role to play in the future of our food supply and the protection of plants. I am sure that their expertise, the willing-

ness of the industry and your oversight will produce valuable results for Americans.

Mr. KUCINICH. Thank you very much.

[The prepared statement of Mr. Clark follows:]

REMARKS BEFORE
THE DOMESTIC POLICY SUBCOMMITTEE
OVERSIGHT AND GOVERNMENT REFORM COMMITTEE
THURSDAY, MARCH 13, 2008
2247 RAYBURN HOB
2:00 P.M.

RAY CLARK
SENIOR PARTNER
THE CLARK GROUP, LLC
WASHINGTON, DC

Introduction

Good afternoon Mr. Chairman and Members of the Subcommittee. It is a pleasure to appear before the Domestic Policy Subcommittee on the important and timely issue of genetically modified organisms and responsibilities of the Animal and Plant Health Inspection Service (APHIS) in the U.S. Department of Agriculture (USDA) under the National Environmental Policy Act (NEPA).

Allow me a brief moment to provide you my background. I am a Senior Partner with the Clark Group, a Washington-based environmental and energy consulting firm. I left public service in 2001 as the Principal Deputy Assistant Secretary of the Army for Installations and Environment. From 1992 until 1999, I served on the Council on Environmental Quality in the Executive Office of the President where we had responsibilities for advising the President on environmental policy as well as oversight of the federal agencies' compliance with NEPA. I have been teaching NEPA implementation at Duke University since 1989 and I am the editor of a book on the history of the passage of NEPA, the current principles and practice, and the future of the statute.

My expertise therefore lies in the responsibilities and obligations of the Executive Branch of government as it relates to decisions affecting the human environment. I am not an expert in genetically modified organisms (GMOs). I have, however, spent most of my career studying difficult and complex issues, ranging from the biological defense research and chemical weapons disposal in the Department of Army, to reviewing and approving NEPA regulations across numerous agencies within the Executive Branch, and to directing projects to better explicate analytical processes such as cumulative effects analysis.

In preparation for this testimony, I have reviewed APHIS and USDA NEPA regulations and procedures, literature on the risks and rewards of genetically modified crops, and court cases relating to GMOs and NEPA.

Issue and Relevance

The Animal and Plant Health Inspection Service (APHIS) is a multi-faceted Agency with a broad mission that includes protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, and administering the Animal Welfare Act and carrying out wildlife damage management activities.[1] These efforts support the overall mission of USDA, which is to protect and promote food, agriculture, natural resources and related issues.[2]

APHIS regulates certain genetically engineered (GE) organisms that may pose a risk to plant or animal health. APHIS' Biotechnology Regulatory Services regulates the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms that may pose a risk to plant health.[3] It is a huge responsibility to oversee an industry that is rapidly growing and becoming more complex. The decisions that APHIS is making now can have long-term beneficial or negative effects on the natural environment, the human community, and the economy.

NEPA Background and Requirements

When Congress passed the National Environmental Policy Act in 1969, the country was feeling the effects of rapidly growing technology, as today. The rise of the chemical and nuclear industry in the 1950s and 1960s, and some of its unintended consequences, in part led Congress to pass the statute that has become our charter for environmental protection. Its magically soaring language asks us to "encourage productive and enjoyable harmony between man and his environment."[4]

Yet, it was prescient enough to know that federal agencies respond to requirements, rather than oratory aspirations. The statute requires agencies to take a "hard look" at the impacts of major federal actions, such as changes to legislation or regulation, approvals of projects, and management of the nation's resources. Such "hard looks" are taken by preparing an environmental assessment or an environmental impact statement which may be prepared, and

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[1] USDA-APHIS. 18 Oct 2007. "About APHIS." Retrieved online from http://www.aphis.usda.gov/about_aphis/.
[2] USDA-APHIS. 18 Oct 2007. "About APHIS." Retrieved online from http://www.aphis.usda.gov/about_aphis/.
[3] USDA-APHIS. 26 Nov 2007. "Biotechnology." Retrieved online from http://www.aphis.usda.gov/biotechnology/index.shtml.
[4] National Environmental Policy Act, 42 U.S.C. § 4321 et seq. (1969).

are sometimes required, for broad Federal actions such as the adoption of new agency programs or regulations.[5] CEQ regulations require agencies to prepare statements on broad actions so that they are relevant to policy and are timed to coincide with meaningful points in agency planning and decision-making.[6]

Sometimes it may seem like they are being asked to peer into a crystal ball, but courts and the public have understood that the hard look doctrine is not a doctrine that requires agencies to be perfect or to understand absolutely the secondary, tertiary or cumulative effects of proposals. But they expect them to try. They want to know that the agencies are not captured by a special interest, but are thinking about the balance that must be struck between economic and environmental well-being. They want to know that all of us are being taken into consideration as agencies make decisions. These decisions include the regulation or deregulation of GMOs.

This thought process can take the form of either a categorical exclusion, an environmental assessment (EA), or an environmental impact statement (EIS). All of these analyses require the agencies to involve and interact with the public on environmental impacts.

> *Federal agencies shall to the fullest extent possible ... encourage and facilitate public involvement in decisions which affect the quality of the human environment.*[7]

After consultations with the public, agencies are required to make a reasoned choice among alternatives. Again, they are not asked to make a perfect decision, but they are asked to follow a logic trail using a defensible methodology to present a document that is clear and concise, supported by evidence, and understandable to the public.

> *Federal agencies shall to the fullest extent possible ... use the NEPA process to identify and assess the reasonable alternatives to proposed actions that will avoid or minimize adverse effects of these actions upon the quality of the human environment.*[8]

For complex decisions like disposing of chemical weapons or permitting a GMO, NEPA provides a structure and a discipline to think rationally and make a decision that takes multiple objectives into account. It is a tool for decision-

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[5] Council on Environmental Quality. Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act of 1969. 40 CFR § 1508.18 (2003).
[6] Council on Environmental Quality. Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act of 1969. 40 CFR § 1502.4 (2003).
[7] Council on Environmental Quality. Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act of 1969. 40 CFR § 1500.2 (2003).
[8] Council on Environmental Quality. Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act of 1969. 40 CFR § 1500.2 (2003).

makers that, if the law did not exist, would create something similar to help them through tough decisions.

> *Ultimately, of course, it is not better documents but better decisions that count. NEPA's purpose is not to generate paperwork--even excellent paperwork--but to foster excellent action. The NEPA process is intended to help public officials make decisions that are based on understanding of environmental consequences, and take actions that protect, restore, and enhance the environment.*[9]

Some would argue that NEPA is a process, the creation of a document, and there are those who are employed in the practice who sometimes carve it into such small pieces that the framers of the statute would hardly recognize it.

One of the mistaken practices by the federal agencies lies in the belief that NEPA does not apply to economic impacts. The purpose of the Act is:

> *To declare a national policy which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation.*[10]

The Congress recognized the profound impact of man's activity on the interrelations of all components of the natural environment. In particular, Congress acknowledged the profound influences of population growth, high-density urbanization, industrial expansion, resource exploitation, new and expanding technological advances, and further, the critical importance of restoring and maintaining environmental quality to the overall welfare and development of man.

In the Act, there clearly is an intention to understand the relationship between the environment and our economic welfare. In addition, there is a requirement in CEQ regulations to balance the economic and environmental factors in decision-making. CEQ regulations mandate that:

> *"Human environment" shall be interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment. This means that economic or social effects are not intended by themselves to require preparation of an environmental impact statement. <u>When an environmental impact statement is prepared and economic or social and natural or physical environmental effects are</u>*

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[9] Council on Environmental Quality. Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act of 1969. 40 CFR § 1500.1 (2003).
[10] National Environmental Policy Act, 42 U.S.C. § 4321 et seq. (1969).

> *interrelated, then the environmental impact statement will discuss all of these effects on the human environment.*[11] [emphasis added]

For GMO crops, socioeconomic effects could be interrelated with environmental effects. For example, the genetic drift of GE traits to non-GE crops, an environmental effect, could also have socioeconomic effects, such as impacts on the marketability of products in organic markets or with trade partners. A recent court case affirmed that, "modification of a plant's genetic make-up through genetic engineering is an effect on the human environment."[12] Another example of relevance is the development of genetic resistance to GE traits from insects or pests or invasive plants (an environmental effect). This could also impact socioeconomics, such as the economic effects of increased or altered insecticide/pesticide application or potential damage to crops from resistant pests.

Nowhere is the linkage between the environment and economic well-being stronger than in the case of GMO, and there is no better example of the need to examine the impacts of decisions than GMO. I believe it is safe to say that APHIS finds it difficult to ensure that plants are free of any kind of contamination, genetic or otherwise. There is a very strong case here for the linkage between the biophysical environment and the social and economic well-being of the farming community at large.

This is precisely the kind of analysis that Congress intended with the statute and it is precisely the kind of linkage that CEQ saw when the regulations were drafted in 1979. Whether or not these impacts are significant remains a question for the analysts who must measure significance through an understanding of context intensity. CEQ regulations define these terms thusly:

> *(a) Context. This means that the significance of an action must be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality. Significance varies with the setting of the proposed action. For instance, in the case of a site-specific action, significance would usually depend upon the effects in the locale rather than in the world as a whole. Both short- and long-term effects are relevant.*
>
> *(b) Intensity. This refers to the severity of impact. Responsible officials must bear in mind that more than one agency may make decisions about partial aspects of a major action. The following should be considered in evaluating intensity:*

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[11] Council on Environmental Quality. Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act of 1969. 40 CFR § 1508.14 (2003).

[12] *Geertson Seed Farms et al. v. Mike Johanns*, Civil Action C 06-01075 (N.D. Cal., February 13, 2007).

> *- The degree to which the effects on the quality of the human environment are likely to be highly controversial.*
>
> *- The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*[13]

Also interrelated is the requirement to address cumulative effects:

> *"Cumulative impact" is the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (federal or non-federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.*[14]

Addressing cumulative effects has been a difficult task in the simplest of projects; the regulation of GMO is not the simplest of actions, but an area where understanding the potential cumulative effects is critically important. In the case of GMO crops, this may include direct impacts, such as the long-term location of GMO crops and the resulting impact on human or ecosystem health. It could also include indirect changes to management practices, such as the combined impacts as a result of combined changes to tillage practices or pesticide application. Additionally, these are interrelated with socioeconomic effects. In the final analysis, these impacts may on the whole be positive and beneficial. But neither NEPA nor CEQ regulations distinguish between beneficial and negative impacts; if they are potentially significant, they have to be analyzed. [15] On the whole, NEPA requires a "hard look" at the impacts.

Programmatic Analyses and Tiering

A programmatic approach to environmental impact analysis is often a good way to reduce paperwork and streamline the NEPA process. Programmatic analyses are appropriate in order to implement broad decisions for agency programs, policies or plans. It seems particularly useful in broad decisions such as genetically modified crops. However, I remind you of my earlier statement that significance is measured by both context and intensity. So a programmatic approach would be helpful, but as these decisions are applied in a local environment, an analyst must look at the biological, physical and socioeconomic context in which that decision would be applied. In one ecosystem, the decision may be beneficial, however in a particular socioeconomic environment it may a

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[13] Council on Environmental Quality. Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act of 1969. 40 CFR § 1508.27 (2003).
[14] Council on Environmental Quality. Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act of 1969. 40 CFR § 1508.7 (2003).
[15] Council on Environmental Quality. Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act of 1969. 40 CFR § 1508.27 (2003).

negative impact to implement exactly the same decision. This is why an important piece of the programmatic approach must include tiered analyses to look at the local environmental context.

Tiered analyses can be very efficient by referencing the broad programmatic statement, thus eliminating any repetitive discussions. In fact, CEQ encourages this kind of efficiency and streamlining in its regulations. Analysts are encouraged to focus on the actual issues ripe for decision at each level of environmental review.[16] Tiering in such cases is appropriate when it helps the agency focus on the issues and exclude any issues already decided or not yet ripe for decision. In the case of GMOs, a programmatic approach seems appropriate; however, there must be a process by which the agency considers the lesser scope projects by tiering from the overall programmatic document. For example, these smaller analyses can be site-specific, crop specific, or ecosystem specific and can incorporate by reference the programmatic analysis, thus making each analysis shorter and more efficient.

I want to reiterate that while taking a programmatic approach is an efficient and effective way to analyze broad decisions, it cannot provide substitute for the lesser scope decisions that must be considered using more specific context and intensity to determine environmental significance.

NEPA is a Requirement and an Opportunity

Mr. Chairman, I commend APHIS for renewing and revitalizing their NEPA regulations. It is needed and past due. I have reviewed the APHIS NEPA matrix for the regulated release of a genetically modified plant and I must say, this continues to be an old way of looking at NEPA: checking a box to get a document done. There is not any consideration of context or intensity of the potential impact as related to environmental and socio-economic factors. How is the timing of the proposed GMO release considered in the matrix? How does the matrix account for any synergistic or indirect impacts? Matrix methodologies are good tools to gather data and inform the decision; however, they must be adaptive and flexible to respond to changing requirements of proposals.

APHIS needs to move past these old ways. They are at the cutting edge of our new world, our new economy and they need to embrace new ways of making these crucial decisions that affect all of us. There has been much work done in this field in the last 5-7 years, much of it led by CEQ and NEPA practitioners throughout the Federal government. There are several things that seem directly applicable to APHIS:

- Incorporate an ecosystem approach to decision-making beginning at the policy level. This requires a more holistic look at what and who are in the

[16] CEQ Regulations §1508.28

ecosystem and how the current biota responding to natural and man-made changes. Regulations are the real opportunity for agencies to set policies regarding NEPA process and they need to be expansive in their thinking about these new regulations. Incorporate a monitoring and adaptive management approach to NEPA. APHIS can therefore spend more time on monitoring, less on predicting, and include more incorporation of collaborative processes in their policies and procedures.

- Incorporate a collaborative way of decision-making. Organic farmers, farmers using genetically modified crops and consumers all have an interest in the ecosystem in which they live and work. CEQ has just issued a new handbook on developing collaborative processes and APHIS should examine how better to engage the entire human community in ecosystems[17].

Conclusion

Mr. Chairman, thank you for the opportunity to provide my thoughts on this important matter. APHIS has an important and unique role to play in the future of our food supply and protection of plants. I am sure that their expertise, the willingness of the industry and your oversight will produce valuable results for Americans.

I will be happy to answer any questions you may have.

[17] Collaboration in NEPA: A Handbook for NEPA Practitioners. October 2007.

Mr. KUCINICH. We're going to go to questions. Professor Carter has asked the indulgence of the committee and the other witnesses since he has a flight to catch. I'm going to go to you directly with questions.

Mr. CARTER. Thank you.

Mr. KUCINICH. I take it that you're not opposed to GE crops in principle; is that correct?

Mr. CARTER. That's correct.

Mr. KUCINICH. OK. And nevertheless you believe that field testing and deregulation of GE crops can have a costly impact on farmers when contamination occurs?

Mr. CARTER. Absolutely.

Mr. KUCINICH. You advised USDA to, "consider which new crops constitute a significant economic risk." Elsewhere in your testimony you state, "especially when exports are an important market outlet," and, "possible buyer resistance in the foreign market." You said those things, right?

Mr. CARTER. I did.

Mr. KUCINICH. OK. As you know, APHIS almost never prepares an environmental impact statement when it permits field testing or deregulation of genetically engineered plants. In your opinion, have you ever reviewed any other forum where APHIS might already do what you advise?

Mr. CARTER. I have not seen any other forum where they've done that, no.

Mr. KUCINICH. That is not the point of the EIS, right? That is the point, rather, of the EIS?

Mr. CARTER. Correct. But I've not seen that elsewhere.

Mr. KUCINICH. As an economist, do you think that preparation of an EIS poses an economic threat to the commercialization of GE crops?

Mr. CARTER. Not necessarily. We heard about GM wheat and GM rice. I mean, the initial release of, for example, GM wheat, in my opinion, should involve an EIS, and ditto for rice. And it would not be a threat to the commercial production of that crop.

Mr. KUCINICH. Could it have a favorable effect on commercialization?

Mr. CARTER. It could.

Mr. KUCINICH. How so?

Mr. CARTER. Well, it could—it could change attitudes and views of firms or individuals that buy the crop. If the EIS is done properly, and it shows that the benefits far exceed the costs, that could change some attitudes and lead to commercialization and greater acceptance.

Mr. KUCINICH. What role, Professor Carter—so overall you're saying that an environmental impact statement might have a favorable—favorable role in influencing consumer acceptance——

Mr. CARTER. That's what I'm saying. Thank you.

Mr. KUCINICH. OK. I want to thank the gentleman.

Mr. Clark, you've had the chance to review APHIS' draft programmatic EIS on new regulations pertaining to genetically engineered crops.

Mr. CLARK. Yes, I have.

Mr. KUCINICH. It was published 5 months after the Roundup Ready alfalfa and creeping bentgrass Federal court decisions, which rebuked APHIS for violating NEPA. I wondered if you noticed, as I did, that the entire discussion of socioeconomic impact is relegated to a 10-page appendix at the end of a 310-page document?

Mr. CLARK. I couldn't help but notice that, because I was looking for—looking for some social economic impact analysis within the body. And I have no objection to putting detail studies in an appendix of an environmental impact statement; however, you're obligated to at least put the meaning of that and to simplify that and to make it understandable to the public in the main document itself.

Mr. KUCINICH. Would you agree that Judge Breyer's decision in Geertson ordered APHIS to make consideration of socioeconomic impact central to determination of whether APHIS's action is significant under NEPA and requires the preparation of an EIS?

Mr. CLARK. I think Judge Breyer's decision was uncommonly clear for a Court decision, and it was absolutely the central point of the entire opinion.

Mr. KUCINICH. So in your opinion, does APHIS's draft programmatic EIS incorporate the directive from Judge Breyer's decision?

Mr. CLARK. If I were the decisionmaker, I wouldn't put it out the way it is now because I don't think it informs the decisionmaker, nor the public.

Mr. KUCINICH. Now, Mr. Clark, Mr. Leake, the grower who is here from North Dakota outlined in his testimony a number of routes of contamination other than pollination. These other routes would include seed left behind in a harvest; the throw-over from straw choppers, from trucks transporting the harvested wheat. And at every link of the chain from field to grain elevator to consumer, these routes of contamination are more mechanical than the biological routes of contamination such as cross-pollination. In your opinion, should these mechanical routes of contamination receive equal consideration as cross-pollination or the biological routes of contamination for the purposes of determining significance under the National Environmental Policy Act?

Mr. CLARK. I think clearly the CEQ regulations anticipate that you'd follow the impacts wherever they came from. But the central point about NEPA and CEQ regulations, that these are about decisions, and if a decision by APHIS results in cross-contamination, it doesn't really matter where it comes from. It is either a direct, an indirect or cumulative impact. It still must be analyzed in the EIS so that the decisionmaker and the public can understand the full import of the decision of APHIS.

Mr. KUCINICH. So you're saying that—you're saying it doesn't matter where it comes from. Your answer to the question would be, yes, that the mechanical routes should receive equal consideration——

Mr. CLARK. It must receive it. It must receive it.

Mr. KUCINICH. So in your testimony you identify a possible shortcoming of the decision matrix APHIS developed in response to two Federal court decisions last year which rebuked APHIS for having

no record of consideration of potential environmental impact from decisions to permit field testing and deregulation of genetically engineered plants. You've said, "there is not any consideration of context or intensity of potential impact as related to environmental and social factors." And you've asked, "how is the timing of the proposed GMO release considered in the matrix; how does the matrix account for any synergistic or indirect impacts."

Do you believe, Mr. Clark, that the decision matrix now used by APHIS ensures that its reviewers will fully comply with the National Environmental Policy Act?

Mr. CLARK. I don't see for the life of me how that matrix will do anything for the decisionmaking because it looks at the action. It is looking at the plant itself down to the ground and not looking at the environment—not looking at either context or intensity.

Mr. KUCINICH. So is that decision matrix sufficient to ensure that APHIS complies with the National Environmental——

Mr. CLARK. No, no.

Mr. KUCINICH. And in your testimony you advise APHIS to incorporate a collaborative way of decisionmaking and refer APHIS to a new handbook on developing collaborative processes issued recently by CEQ. Your testimony to farmers, some of whom met with and petitioned APHIS to prepare environmental impact statements in the past, while APHIS refused their request for petitions, at least APHIS met with the farmers. Is that sufficient?

Mr. CLARK. That is not collaborative decisionmaking, not on anybody's——

Mr. KUCINICH. So describe again a collaborative decision.

Mr. CLARK. Well, collaborative decisionmaking—and let me give you some amount of context here—is that there has been a very strong push by the Council on Environmental Quality to develop collaborative decisionmaking, including cooperating agencies, so that counties—counties in which farmers reside could easily ask to be a cooperating agency of APHIS so that they can use their special expertise with regard to economic impacts on the county, on the farming, on the farming community there. So being a cooperating agency would be a much more collaborative way of doing that. There would be—there is a lot more sophisticated collaborative processes that are described very well in the CEQ handbook.

Mr. KUCINICH. Thank you, Professor Carter. I appreciate you being here. Thank you.

Mr. CLARK. And is available to all of the Federal agencies. I won't take the time here to describe them, but I will say that the Administrative Procedures Act passed in 1947. Even that—even the way that APHIS handled that particular issue wouldn't even comply with the Administrative Decisions Act of 1947.

Mr. KUCINICH. I thank the gentleman.

I want to go to questions now to Mr. Leake. You said that the crop options available to you are limited due to where you are. Climate and latitude are factors in your planning options. Now, if you couldn't grow hard spring wheat profitably, as you fear would occur if a genetically engineered wheat variety is approved by APHIS, what could you and others grow profitably in its place given your climate and latitude?

Mr. LEAKE. I don't think we could continue, because about two-thirds of the acreage of North Dakota has planted a wheat annually, and the rest of North Dakota, at least northern North Dakota, north of Interstate 94, is not suited to corn and soybeans. 1994—or 2004, 2005 or 2006 we had failures or disappointing yields for corn in the northern two-thirds of North Dakota because it requires a lot of moisture and a lot of heat to grow corn and soybeans to get the yields necessary to be profitable.

So we are, as has been mentioned before, very dependent on cool-weather crops, small grains being one of those. However, we do have some other options, which are specialty crops, such as navy beans, pinto beans, black beans, edible bean crops and sunflower. However, there is limited demand for those particular commodities, so we wouldn't be able to substitute those crops into the acreage that wheat now is grown on and still have a price because the supply would exceed the demand.

Mr. KUCINICH. Now, you've written in your testimony that if a contamination event like the StarLink case would happen to wheat crops, the effects would be much worse on farmers. You note that a greater share of the wheat crop is sold on the export market, and the animal feed market isn't a viable backstop for wheat that can't be—that wheat can't be sold for human consumption. Did you make those arguments to APHIS when you were seeking an EIS for Roundup Ready wheat?

Mr. LEAKE. Yes, we did.

Mr. KUCINICH. What did APHIS say?

Mr. LEAKE. Basically when we met with—in March 2004 with Undersecretary Hawkes and the Acting Director of APHIS, we put that argument forth to them. Their final decision on that was not to grant an environmental impact statement. I guess that says it.

Mr. KUCINICH. What did they say to you, though? Was there anything else said?

Mr. LEAKE. Basically the Under Secretary said it was—that they didn't have the authority to pursue an EIS to give us the input into the decision on the petition for deregulation.

Mr. KUCINICH. Did APHIS show you any evidence that they had seriously considered the concerns you were raising?

Mr. LEAKE. No. No, they did not.

Mr. KUCINICH. How did that make you feel? What did you think about that?

Mr. LEAKE. I felt very shut out of the process. I felt like it wasn't a democratic process, that I was a stakeholder—it was my livelihood at stake, and that I wasn't given any consideration, and that the company that was pursuing the deregulation of the Roundup Ready wheat was given consideration, but I as a grower was not.

Mr. KUCINICH. And when that happened—because growers by nature have to look forward—what was going on in your mind when you looked forward from that moment based on the way it was being handled where they didn't really show any real, you know, connection to your concerns?

Mr. LEAKE. Well, in the past, the other Roundup Ready crops, such as soybeans and corn, had been deregulated and introduced into the marketplace. Using that as an example, I fully expected them to deregulate Roundup Ready wheat, and it would be intro-

duced within a year or two. We had been warned directly by our customers in numerous formats, numerous times and places, that they would not access our wheat supplies for importation if we were to be—have GE—or GE crops growing commercially in the United States. And that actually started to happen. So I felt——

Mr. KUCINICH. Would you say—what? Would you repeat that?

Mr. LEAKE. Prior—prior to the introduction of any GE wheat, some of the milling companies in Europe, Ranco was one of them, I believe, was starting to develop commercial ties with wheat suppliers in Kazakhstan and the Ukraine in anticipation of a GE wheat supply from the United States and Canada. This is just business. They anticipated that it would be commercialized; therefore, they could not utilize U.S. wheat supplies. They sought them elsewhere, as they said they would.

Mr. KUCINICH. Now, how—has this affected you financially?

Mr. LEAKE. The—of course, the Roundup Ready wheat deregulation never occurred. So we are still GE-free, and GIPSA, the Grain Inspection, Packers and Stockyards Administration, still issues its letterhead statement that U.S. wheat supplies are GE-free. And that is required by most of the customers that we export our harvest spring wheat to. That has become the—a pivotal document for them to keep accepting U.S. wheat exports.

Mr. KUCINICH. Your testimony states that the EIS, "provided the best opportunity to present," the case of concerned wheat growers about the risk of Roundup Ready wheat. Why, in your opinion, is the public comment period for an environmental assessment or meetings that you have had with APHIS officials not an adequate forum for presenting your case?

Mr. LEAKE. Well, a comment period doesn't have the same ability to garner comments as would be the scoping process of an EIS. During a—scoping meetings, they are held in the areas where people would be affected. They're invited to come and voice their concerns. That is incorporated into the EIS draft. And we also have an opportunity to comment on the draft EIS. This isn't necessarily available in the EA. So I felt that, you know—as a person of North Dakota, I've seen a lot of EIS scoping notices go out on a lot of projects, etc. People have the opportunity to come en masse to voice their concerns. The administrative process of an EA basically shuts out most of the concerned people.

Mr. KUCINICH. Do you think that APHIS based their rejection of your petition on—to prepare an EIS to, you know, hard look at the risk, they base that on science and economics, in your opinion?

Mr. LEAKE. I don't think so, because it is quite apparent to everyone, especially anyone who is involved in farming—Under Secretary Hawkes, when we talked to him, he told me that he was a wheat farmer. I'm quite sure that he was cognizant of the simple process of the economic implications of not being able to export wheat when wheat is—when half the wheat crop in this country is exported. We would find a drop in price.

Mr. KUCINICH. Thank you, Mr. Leake.

Mr. Howington, you raise GE soybeans, but you're here testifying on the effects of unauthorized GE rice release.

Mr. HOWINGTON. Yes, sir.

Mr. KUCINICH. I take it you're not opposed to GE crops in principle?

Mr. HOWINGTON. In principle, no, sir.

Mr. KUCINICH. OK. Do you think your advocacy with APHIS for an environmental impact study that analyzed the effects of contamination is anti-GE crop in principle?

Mr. HOWINGTON. No, sir, not at all.

Mr. KUCINICH. Why would a grower of GE crops have a concern about the development of new GE crops?

Mr. HOWINGTON. My concern is not with—my concern is with contamination. When they call it contamination, and it comes out of my pocketbook, that is my concern.

Mr. KUCINICH. You state that many rice farmers—I think you said about 600 in your testimony—went out of business after the LibertyLink rice contamination event. You yourself now lease out your own land to neighboring farmers, and you don't farm rice anymore.

Mr. HOWINGTON. That's correct.

Mr. KUCINICH. When one farmer quits and another gets bigger, the total number of farmers decreases, and concentration in the industry increases. This has historically been a great deal of—there has historically been a great deal of concentration in the farming business. Is additional concentration in farming attributable to the economic effects of contamination by GE crops as an impact people should be concerned about?

Mr. HOWINGTON. Yes, sir. There are a number of things that contribute to that, but certainly the genetic event we had in 2006, farmers quit simply because of the economic effects of that event.

Mr. KUCINICH. I want to go into this just a little bit. You had the Liberty rice—LibertyLink rice contamination event.

Mr. HOWINGTON. Yes, sir.

Mr. KUCINICH. Once you learned of that, walk me through what happened. You know, how did you find out about it?

Mr. HOWINGTON. We found out about it, and it was—in our part of the world, agriculture is—it is like politics in Washington. It's what goes on. It was on in every paper, it was on every news, it was on all of the reports. It was everywhere.

Mr. KUCINICH. As soon as that happened, what did you do?

Mr. HOWINGTON. I tried to find out what the consequences were going to be for me; wondered what my crop was going to—what was going to happen to my crop, my price, my market.

Mr. KUCINICH. Would you tell this committee for the record what did happen?

Mr. HOWINGTON. The price dropped. It dropped precipitously and very quickly. Unfortunately, I didn't have a lot of my crop priced, which was very common at that time. Rice prices were headed up. We were hoping for a rise in prices. It went the other way.

Mr. KUCINICH. What happened to you?

Mr. HOWINGTON. They went the other way.

Mr. KUCINICH. What happened to you?

Mr. HOWINGTON. That year I didn't get as much for my rice as I was hoping I would.

Mr. KUCINICH. How much of a loss did you take?

Mr. HOWINGTON. I would say in the $50,000, $60,000 range.

Mr. KUCINICH. What does that mean for a small farmer?

Mr. HOWINGTON. A fellow like me whose disposable income is less than that, meant a lot.

Mr. KUCINICH. Did it wipe you out?

Mr. HOWINGTON. I don't want to use the term "wiped me out." I'd say it——

Mr. KUCINICH. Damaged you severely?

Mr. HOWINGTON. It damaged me severely. Farming is a huge risk.

Mr. KUCINICH. It is a family thing, too. What can you tell us about—what kind of effect did this have on your family?

Mr. HOWINGTON. Well, I mean, this is a farm that has been—my grandfather literally cleared this land. My father developed it and leveled it, put wells on it. I came along and farmed it. And I farmed it, started full time in 1980, and it just—the economics of the situation just—and the risk. That is the big thing about farming, it is a huge risk. As I say, my disposable income was less than the $50,000, $60,000 I lost in that event.

Mr. KUCINICH. So tell us about how you felt, though, because, you know, a lot of times this stuff gets academic until it comes down to a personal level. How did it feel?

Mr. HOWINGTON. It was a horrible feeling. It is a—when you realize that where you stand on the totem pole in this deal—obviously throughout this deal, what was going to happen to the farmer was the last consideration. And when you realize where you stand on the totem pole, it is devastating to you. As farmers, we go out every day and we work hard. We work very hard. We risk a lot, you know. And when something like this happens, it is very depressing, very demoralizing.

Mr. KUCINICH. You know, I appreciate you and the witnesses here telling their personal stories because it helps people connect with it. They've got to be in your place. This is your grandfather's farm.

Mr. HOWINGTON. Yes.

Mr. KUCINICH. I mean, this is why I've gone into questioning you in a little bit different way here because I think we need to really understand the impact this had on you. This is—again, there is a lot about this debate that cannot be academic. This affects people's lives in huge ways.

Mr. HOWINGTON. Well, this is a family farm that went by the wayside. It was not the only one by any means that was—that this event contributed to.

Mr. KUCINICH. I want to thank you for your testimony, Mr. Howington, as well as all the other witnesses.

I have some questions for Mr. Kirschenmann. In their EA for Roundup Ready alfalfa, APHIS made the following statements with regard to RR alfalfa's negligible impact on organic alfalfa. They said, "fields"—talking about alfalfa—"are typically harvested before the seed is set and allowed to mature because high-quality forage is the desired product." That is page 14. And they also said, "organic production operations require to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances from enjoining land that is not under organic management." That is on page 13.

Now, do these statements from USDA persuade you that USDA gave serious consideration to the question of impact on organic farming?

Mr. KIRSCHENMANN. I think they gave serious consideration to an abstract farm. They didn't give serious consideration to a real farm because—the reason I say that is——

Mr. KUCINICH. What do you mean by that?

Mr. KIRSCHENMANN. What I mean by that is what they describe is true in theory, but on a real farm you have events like unusual rainfalls, when you can't get in to harvest your alfalfa crop in time before it goes to bloom; or you may have a low area in a corner of a field that you can't get into for several weeks if you have had a lot of rain. Or you may have a drought situation where your alfalfa never gets to a point where it is worth cutting. And so, then, you know, are we really going to expect farmers to cut all that alfalfa just so it doesn't go to bloom? I mean, I think that is pretty unrealistic. So in a real farm, you have those kinds of real situations that don't always work as they seem they should work in theory.

Mr. KUCINICH. So is it possible that they developed this approach with the advice of farmers?

Mr. KIRSCHENMANN. A little doubtful.

Mr. KUCINICH. I'd like to add to the record——

Mr. CAMERON. Mr. Chairman, could I add something to that?

Mr. KUCINICH. Yes. I mean, I'd be happy to have you join into this. Please do.

Mr. CAMERON. I am a real farmer. I grow Roundup Ready alfalfa 200 yards away from my organic alfalfa. I'm not saying that you couldn't come up with a situation to where you could have a problem, but I think good stewards of the land, good farmers, we cut our hay actually prior to bloom.

I agree. We live in California. It doesn't rain much. When it does, it rains in the winter. But I feel confident I could grow Roundup Ready alfalfa side by side to organic alfalfa and not have an issue with contamination or adventitious presence. So what I do understand—there are other situations in the United States, but——

Mr. KUCINICH. Well, I think he has kind of implied that your conclusions would be defined by the climate and latitude a little bit. I mean, they have to have some impact on it, right?

Mr. CAMERON. True. But I agree. If you're going to be an economic farmer, you not going to—you don't want your alfalfa to bloom in the first place. If it does bloom, the time between there and the time that you set the seed is quite some time.

Mr. KUCINICH. I'm not a farmer, but here is the thing I want to ask you, if I may, Mr. Cameron. This same question that we're talking about, the Federal judge, here is what this Federal judge concluded. I want to quote this to see what you think, and then I'd like Mr. Kirschenmann to comment on it, too. Talking about APHIS: "APHIS made no inquiry into whether those farmers who do not want to grow genetically engineered alfalfa can, in fact, protect their crops from contamination, especially given the high geographic concentration of seed farms and the fact that alfalfa is pollinated by bees that can travel more than 2 miles. Neither the EA nor the FONSI identify—FONSI, it is called—identify a simple method that an organic farmer can employ to protect his crop from

being pollinated by a bee that travels from a genetically engineered seed farm, even assuming the farmer maintains a buffer zone."

Now, that is what the Federal judge said in this case. What do you think about that?

Mr. CAMERON. I think your seed requirements are much different than your typical growing of the forage requirements should be. I think separation of a seed grower should be much different than a traditional forage grower.

Mr. KUCINICH. Well, Mr. Kirschenmann, what do you think about that in terms of the impact on organic farming?

Mr. KIRSCHENMANN. Well, the thing that—I mean, I want to commend Mr. Cameron, because he is apparently managing his system very well, but, again, when you look at the situation in terms of rank-and-file farmers, not every farmer, as in any other field, is equally competent, is equally capable of controlling systems.

The thing that is disturbing to me is that we keep having these claims that we have this under control, that there is no problem and no danger of contamination, and yet just here 2 weeks again we had, you know—so, you know, it is—the fact that—Charles Perot at Yale University published a book back in the late 1980's called Normal Accidents, and the case that he made in that was—the reason he called them normal accidents is because they happen. You can't manage any system constantly perfectly. There are going to be mistakes that are going to be made. And the problem in this system, you know, for me and my farm, if somebody makes a mistake, I can't—I can't undo that mistake. It harms me economically. And this is why we made the decision on our farm not to grow any crops that have a GMO counterpart. Now, that works for us now as long as we continue to have a range of crops that we can grow effectively in our rotation and have markets for them. That probably is not going to be the case very far into the future if we continue, you know, bringing new crops into the situation.

And so, you know, I agree that there may be an individual case here and there where you can demonstrate that you can manage it, there isn't a problem. But if you look at the situation and the market as a whole, you can't make that case. The evidence is too clear.

Mr. KUCINICH. Well, I want to thank all of the witnesses for their participation. Each of you came here to communicate experience, which is going to be valuable in the committee being able to make some determination as to where we go. And we have a variety of experience here, and I think that it is very helpful.

Again, this is not the hearing to determine whether the GE technology is good or bad. We're looking at what is APHIS doing or what is USDA doing. That is the committee's charge here. So I want to thank you for shedding some light on this.

I'm going to dismiss the first panel with the gratitude of the committee. Thank you. And we're going to—as they're leaving, we're going to get ready for the presentation from the next panel, which will consist of the Administrator of the Animal and Plant Inspection Service [APHIS], U.S. Department of Agriculture, Cindy Smith.

[Recess.]

Mr. KUCINICH. Before we begin, The administrator has informed the committee that one of her assistants is going to be present. You know, I want to acknowledge that there are areas here that can become very complex, and if I was in the shoes of the Administrator, I would certainly want to have someone nearby who could assist in making sure that the committee gets the, you know, best information that we can. So I want to acknowledge the gentleman. And since you'll be assisting in this, I would ask you to also be sworn so that we can have concurrence in our testimony here. Would both of you please stand and raise your right hands?

[Witnesses sworn.]

Mr. KUCINICH. Thank you. Let the record show that the witnesses answered in the affirmative.

I'd like the gentleman to give his name and his position and his function in the office of the Animal and Plant Inspection Service.

Mr. GREGOIRE. Mr. Chairman, I'm Michael Gregoire.

Mr. KUCINICH. And would you bring your microphone closer? Would you spell Gregoire for the staff here?

Mr. GREGOIRE. Yes. It is spelled G-R-E-G-O-I-R-E. Michael Gregoire. I'm the Deputy Administrator for Biotechnology Regulatory Services in the Animal and Plant Health Inspection Service.

Mr. KUCINICH. OK. OK. And with us is Cindy Smith, who is the Administrator of the Animal and Plant Inspection Service of the U.S. Department of Agriculture. I want to thank both of you for being here, and I would like Ms. Smith to commence with her testimony.

STATEMENT OF CINDY SMITH, ADMINISTRATOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY MICHAEL GREGOIRE, DEPUTY ADMINISTRATOR FOR BIOTECHNOLOGY REGULATORY SERVICES, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Ms. SMITH. Mr. Chairman, thank you for the opportunity be here today.

APHIS is responsible for ensuring that biotechnology-derived crops are as safe for agriculture and the environment as their traditionally bred counterparts. Over the last 20 years, APHIS has effectively overseen the safe adoption of products of biotechnology, with 12,000 field trials grown under our notification procedures and 1,500 field tests grown under the permitting process, encompassing field trials at 79,000 different locations. In addition, we have deregulated more than 70 products in that time.

APHIS is a leader globally in biotechnology regulatory experience. In 2002, we recognized, though, that there were still more—that there was still more that we could do to better position the Agency to respond to the evolving science and growth of biotechnology. That was when BRS was created, and I became the Deputy Administrator of the program.

Since then, we've made a number of significant improvements to APHIS's biotechnology regulation. APHIS has committed increased resources to our regulatory activities. BRS's budget has grown by more than 200 percent in the past 6 years. Staff levels have increased from 25 to 60 employees. We have placed more focus on

key regulatory areas and created dedicated staff for these functions. For example, we established a dedicated compliance and enforcement unit in BRS in 2003. We've automated the regulatory and compliance processes and made a number of significant regulatory changes, as well as numerous revisions, to permit requirements. We now have in place stricter measures for crops producing pharmaceutical and industrial compounds, not only increasing requirements for the regulated community, but also APHIS's role in the oversight of these products. Additionally, we recently launched a new voluntary quality management system for biotechnology developers to foster—to help foster industry commitment to quality controls, quality management and quality compliance.

I share this committee's respect for the National Environmental Policy Act [NEPA]. We have made a number of changes to ensure environmental impacts of our proposed actions are fully considered. We are undertaking comprehensive programmatic as well as product-specific EISs. Our first programmatic draft EIS, which was published in July 2007, will lay the groundwork for a comprehensive updating of our Federal framework.

Our environmental assessments now contain much more detailed scientific analysis and include more scientific references, analysis of effects on organic protection, and a toxicity table for effects of biotechnology-derived crops on nontarget insects. We have also enhanced our documentation for categorical exclusions from NEPA, more closely analyze cumulative impacts, and put in place a formalized process with the U.S. Fish and Wildlife Service to ensure compliance with the Endangered Species Act. We made a number of these changes even before the court rulings directing us to better document our environmental analysis, and other changes came after as our understanding of what the courts expected of our NEPA documentation evolved and we continued our commitment to meeting our environmental obligations.

Mr. Chairman, let me focus the remainder of my remarks on last year's situation regarding Roundup Ready alfalfa, as well at NEPA regulatory changes we're considering, as those were areas you were interested in.

APHIS had prepared an environmental assessment [EA], to determine whether deregulating the alfalfa could have a significant impact on the environment, and issued a finding of no significant impact [FONSI]. In order to comply with the preliminary injunction, APHIS brought Roundup Ready alfalfa back under regulation until the Agency issues a new determination consistent with the court's requirements. The court did not overturn Federal conclusions regarding the safety of the crop for food or feed purposes, but rather concluded that APHIS had not adequately documented potential environmental effects.

Again, we are taking this opportunity to examine and strengthen our NEPA processes. APHIS already considers the social and economic impacts of a proposed action in those cases where there is a clear relationship with environmental impacts. We are strengthening our documentation in this area, both in our recent regulatory decisions and in the alfalfa EIS being drafted. And I look forward to our continued learning in this area as we gain a better under-

standing of how to apply the NEPA process to inform our decision-making.

APHIS is also in the process of promulgating a proposed rule that will make changes to how we implement procedures under NEPA aimed at providing further clarity to this process. These potential changes would more closely tie our decision to prepare an EIS to the language in NEPA. These and other changes we are considering would also clarify that we base our decisions to prepare an EIS or EA on an action's potential effect on the environment.

Mr. Chairman, my statement for the record includes much more detailed information regarding our regulatory system for biotechnology crops, as well as steps we are taking now to enable us to continue regulating the next generation of products. Let me conclude by saying that our actions today to revise and strengthen our regulations, as well as learn from our previous experiences, will hold us in good stead for the future.

I look forward to answering your questions. Thank you again for the opportunity to testify before the subcommittee.

[The prepared statement of Ms. Smith follows:]

Testimony of Ms. Cindy Smith
Administrator
Animal and Plant Health Inspection Service
United States Department of Agriculture

Before the Subcommittee on Domestic Policy
of the
House Committee on Oversight and Government Affairs

March 13, 2008

Thank you for the opportunity to be here today. I am Cindy Smith, Administrator of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS is a multi-faceted Agency with a broad mission area that includes protecting and promoting U.S. agricultural health, regulating organisms derived through biotechnology, administering the Animal Welfare Act, and carrying out wildlife damage management activities.

I began my career with APHIS in 1979, and prior to becoming Administrator was Deputy Administrator of APHIS' Biotechnology Regulatory Services (BRS), shaping the agency's biotechnology regulatory structure, establishing more rigorous requirements for field tests of crops derived through biotechnology, and initiating efforts to review and strengthen the agency's overarching biotechnology regulations. Michael Gregoire, current Deputy Administrator of BRS, is here with me today. We are pleased to provide the Committee with an overview of APHIS' role in regulating agricultural biotechnology.

Biotechnology is a vibrant and promising field that has generated substantial academic and commercial interest, and as Federal regulators it is critical that we keep pace with this new technology. Since USDA first began regulating biotechnology in 1986, we have overseen more than 21,000 permits and notifications for field tests or movements of organisms derived through biotechnology. Here at APHIS, we are committed to meeting not only the challenges that we can see ahead on the horizon but also those that science has yet to discover. It is our responsibility to thoroughly evaluate organisms derived through biotechnology to determine whether they pose a plant pest risk and to ensure they are just as safe for agriculture and the environment as traditionally bred crop varieties, which have been the cornerstone of American agriculture. If they do pose a plant pest risk, it is our responsibility to ensure that such organisms are appropriately regulated and confined.

The regulation of plants derived through biotechnology is where APHIS has the most regulatory focus. The Agency has long recognized that plant-derived biotechnology research was increasing and becoming much more complex. In order to ensure that the Agency remained at the forefront in developing appropriate regulatory policies to address the latest advances in the technology, APHIS created BRS in June of 2002. The program, which started with 25 employees, has grown to a staff of more than 60.

APHIS' regulation of biotechnology has changed a great deal since I first joined BRS, and even more so since 10 or 20 years ago. The creation of BRS was an important step in APHIS' overall

enhancement of the way we regulate biotechnology. While APHIS had adequate controls in place 20 years ago to regulate biotechnology, we recognized that the world we operated in was changing as the field of biotechnology grew. So too did we acknowledge that as we gained increasing experience in regulating biotechnology, we must develop a robust regulatory system using that new knowledge and the latest science available.

With the creation of BRS, we also recognized the need to broaden our outreach to stakeholders beyond the industry that we regulate. As a result, BRS has made a concerted effort to reach out to stakeholders interested in biotechnology including states, tribes, non-governmental organizations, organic growers, food and grain industry, commodity groups, biotechnology providers, and others to make sure that they fully understand the important regulatory changes that have taken place.

APHIS has also strengthened its two-way communication with a varied group of stakeholders through the USDA Advisory Committee on Biotechnology & 21st Century Agriculture. This committee was established in 2003 to examine the long-term impacts of biotechnology on the U.S. food and agriculture system and USDA, and provide guidance to USDA on pressing issues related to the application of biotechnology in agriculture. The committee has 20 members, including academic scientists; representatives from consumer and environmental groups; representatives from biotechnology, food, and shipping industries; farmers, extension specialists, and ex officio members representing other Federal and State agencies. The Committee recently addressed coexistence among diverse agricultural systems in a dynamic, evolving, and complex marketplace through a report released on March 5, 2008, and has addressed other topics including the impacts of mandatory labeling and traceability requirements for biotechnology-derived crops, opportunities and challenges in agricultural biotechnology in the decade ahead, and planning for the future.

In the last 6 years, we have made a number of significant regulatory changes as well as numerous revisions to permit requirements and our decision making process in order to review and further strengthen USDA's existing biotechnology regulatory system. This includes the development of more rigorous measures for crops producing pharmaceutical and industrial compounds, initiation of a process to revise APHIS' current biotechnology regulations, and the launch of a new quality management system for biotechnology developers. I am confident that all of these changes have made a considerable, positive impact on our regulatory system for biotechnology, and that because of this, we are less likely to face the challenges we have in the past.

Regulation of biotechnology is a responsibility that we share with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). Under what is known as the Coordinated Framework, we work in concert to ensure that products derived through biotechnology have been reviewed for safety not only for agriculture and the environment, but also for the food supply. APHIS is responsible for protecting agriculture and the environment. FDA has primary oversight of the safety of food and animal feed. EPA regulates pesticides, including crops with plant-incorporated protectants (pesticides intended to be produced and used in a living plant) to ensure public safety from their use, including pesticide residue on food and animal feed. This coordinated effort is critical for reassuring industry, consumers, and other

groups—both here in the United States and, increasingly, abroad—that biotechnology-derived crops, animal vaccines, and other products are rigorously reviewed for safety.

Biotechnology in the United States

Before I provide you with a more detailed explanation of APHIS' role in regulating organisms derived through biotechnology, I would like to discuss this issue more broadly as it relates to U.S. agriculture and related industries. First, it is imperative that I mention that APHIS regulates agriculture biotechnology products; however we do not promote their use. That being said, it is important that we remain cognizant of trends and information in this country as well as around the world, so that we can respond and adjust our regulatory system appropriately.

Biotechnology is being increasingly adopted around the world for a variety of reasons such as environmental benefits from decreased pesticide use, increased crop yields, and enhanced nutritional value. According to a report released last month by the International Service for the Acquisition of Agri-biotech Applications, in 2007, the United States retained its #1 ranking for adoption of crops derived through biotechnology, with 50% of the world's crop area. We were followed by Argentina, Brazil, Canada, India, and China. And in 2007, USDA National Agricultural Statistics Service NASS reported that 89% of soybean, 92% of cotton, and 86% of corn planted in the United States were biotechnology varieties.

I point these statistics out because it is important to recognize that biotechnology is being adopted in the United States. The U.S. system for regulating biotechnology is based on safety; however the U.S. agricultural industry takes into account many other considerations related to biotechnology such as market effects, international acceptance of the technology, and costs to grow a specific crop. APHIS plays a critical role in biotechnology development in the United States, and that is to determine, based on science, whether a crop derived through biotechnology poses a plant pest risk which may threaten agriculture and the environment, and to take appropriate steps to protect other crops until the plant pest potential can be determined. We achieve this through a specific regulatory structure that guides the safe introduction of organisms derived through biotechnology. Our role as regulators is to maintain a transparent system in which the safety of plant health and the environment is the priority, and once safety is established, to allow the production of all crops deemed to be safe by APHIS, in consultation with our partners in the Coordinated Framework.

As I mentioned, we recognize that there are other factors, beyond safety, for the agricultural industry to consider. That said, it is up to the entire U.S. agricultural industry to determine how to grow individual crops—whether they be traditional, organic, or biotechnology-derived—in a way that will preserve their identity and meet the demands of their markets. For example, the 89% of soybeans grown in the United States have biotechnology-derived traits and have been deemed by APHIS to pose no greater plant pest risk than the 11% of traditional soybeans being grown. Because plant pest risk has been determined not to be a factor in these plants, it is now the responsibility of traditional growers as well as growers of crops derived through biotechnology to take the steps they need to address market issues beyond that risk.

As we monitor the trends in biotechnology in our country and around the world, our regulatory system continues to focus on the safety of the products derived from biotechnology, as the science behind it evolves. We believe it is in the best interest of U.S. agriculture to focus our efforts on these priorities while allowing the industry to determine how varied products can be grown and coexist successfully.

Regulatory Overview

For our part in the coordinated Federal effort, APHIS, under the Plant Protection Act, regulates the interstate movement, importation, and field release of plants, insects, and microorganisms derived from biotechnology through permitting and notification procedures. APHIS works to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of plants derived through biotechnology.

The Permitting and Notification Process

APHIS' field testing requirements for regulated plants are designed to prevent the unintentional environmental introduction, whether by pollen movement, seed or grain commingling, or other means, of a protein or trait produced in these plants that would present a potential plant pest risk to agricultural crops or the environment. Simply put, we don't allow field trials and other introductions of plants derived through biotechnology without adequate safeguards in place to prevent the spread of plant pests.

Companies, universities, and other researchers wishing to introduce a new plant derived through biotechnology must obtain APHIS' authorization before proceeding. This is a step-by-step process in which the applicant must meet multiple requirements. Depending on the nature of the plant, the developer files either a notification or a permit application with APHIS. With either process, the developer must adhere to APHIS regulations and requirements to ensure, through appropriate measures, confinement of the regulated material.

Most plants derived through biotechnology qualify for, and are field tested under, the notification process. The notification process expedites approvals for field testing for certain types of low-risk plants that APHIS has considerable experience in regulating. Examples of plants that may qualify for field testing under the notification process include those altered for pest resistance, herbicide tolerance, male sterility, and delayed fruit ripening. To qualify for the notification process, a plant or trait must meet six safety-related eligibility criteria that center on the plant's potential to pose a risk to plant health or the environment. An applicant must submit required information on the movement, importation, or field release, which APHIS scientists review to determine whether to authorize the applicant's request. To ensure confinement, the developer must perform the field test in a way that meets performance standards that are specified in APHIS' regulations. If a plant does not meet the criteria for notification, the applicant must follow the permitting process.

Permits are more restrictive than notifications and are used for any type of biotechnology-derived plant that may pose an elevated risk to plant health or the environment, or for which APHIS has less regulatory experience and familiarity, such as plants engineered to produce pharmaceutical or industrial compounds. In addition to detailed information on the biological

properties of the biotechnology-derived plant, the permit applicant also must provide thorough descriptions of how field tests will be performed, including specific measures for ensuring confinement and reducing any potential risk that may be associated with the plant. Applicants must also detail how the crops at the site will be destroyed once the field test is complete to prevent persistence in the environment. The planting conditions detailed in the application must meet or exceed the stringent requirements set forth by APHIS. These requirements are specific to each plant variety, and we continually evaluate them to ensure that the latest scientific evidence is taken into account. Using this information, APHIS scientists create a set of permit conditions that applicants must meet when conducting approved field trials or transporting plants derived through biotechnology. Both the permitting and notification process are subject to the requirements of the National Environmental Policy Act (NEPA).

APHIS is committed to ensuring that state interests are fully considered and accommodated in the Agency's permit and notification review processes. Before approving a notification or permit field test in any state, we provide state officials with detailed information about the proposed field test for review and concurrence. If a particular state has science-based concerns, BRS works with that state to address the outstanding concerns, altering test requirements or adding additional safety- or risk-based permit conditions that the state feels is necessary. States are also notified before APHIS issues a permit for the importation or interstate movement of regulated organisms derived through biotechnology.

Pharmaceuticals and Industrials

Science is moving rapidly for crops producing pharmaceuticals and industrials. We recognize that the regulation of these crops must be approached differently than the regulation of other crops derived from biotechnology, and have taken a proactive approach to safely regulating these types of field tests. APHIS' recent efforts to strengthen regulations have provided additional assurances that field trials are safe for agriculture and the environment.

Developers have produced pharmaceutical and industrial compounds using rice, corn, barley, tobacco, and safflower. These crops are grown to produce research chemicals, vaccines, human antibodies, and human blood proteins. Although there has been much attention on these products, relatively few pharmaceutical and industrial field tests have actually taken place. About 60 permits to field test crops that produce pharmaceutical and industrial compounds have been issued since 2003. In comparison, we've approved thousands of field tests for crops derived through biotechnology during that time. APHIS issues permits for crops that produce pharmaceutical and industrial compounds and determines appropriate permit conditions on a case-by-case basis. The Agency conducts NEPA analyses, some of which include public comment periods, to evaluate the environmental effects of such regulatory proposals. I will discuss NEPA compliance in more detail shortly.

We expect research into crops that produce pharmaceutical and industrial compounds to continue growing and that's why we've made changes in our regulatory process to make certain that these crops are evaluated rigorously. In 2003, APHIS imposed new measures for all crops that produce pharmaceuticals and industrials. We increased APHIS' role in the oversight of these products, as well as requirements for the regulated community. We imposed more stringent confinement measures requiring increased isolation distances and fallow zones, the use of

dedicated farm equipment, and restrictions on post-harvest land use on planting food or feed crops on land used to produce pharmaceutical and industrial crops, among other measures.

To ensure that permit conditions for crops producing pharmaceutical or industrial compounds are met, APHIS inspectors conduct at least 5 inspections during the growing season for these crops. These inspections coincide with key times during the growing season: pre-planting, after planting, just prior to harvest, at harvest, and post harvest. After the field test is complete, Agency inspectors follow up with 2 additional inspections to ensure that the plot was completely destroyed and no plants remain.

Compliance

Given the growing scope and complexity of biotechnology, now more than ever, APHIS recognizes the need for scientifically sound, effective safeguards and greater transparency of the regulatory process to ensure that all those involved in the field testing of biotechnology-derived crops understand and adhere to the regulations set forth by the Agency. This need is echoed by the biotechnology industry, stakeholders, and consumers. To that end, in 2003, APHIS established a dedicated Compliance and Enforcement unit in BRS to further ensure adherence to permit conditions.

To ensure compliance with the permit or notification conditions, APHIS inspectors perform targeted inspections and audits of field tests using the relative risk of each type of trial to determine the frequency and number of inspections performed. For example, for sites where developers are cultivating plants to produce pharmaceutical and industrial proteins, APHIS generally inspects seven times throughout field testing, including before, during, and after the field trial. APHIS also maintains oversight of the movement of regulated plants to and from field trial locations. For notifications, which pose less risk and APHIS has more familiarity, criteria are established so that a percentage of these field trials are inspected. This permitting and notification system is designed to restrict introductions of biotechnology-derived plants and plant materials as long as they are regulated by the agency. Under APHIS regulations, companies, universities and other researchers are required to report immediately, orally and in writing, any potential problems, so that the issue can be addressed as quickly as possible.

We at APHIS take compliance and enforcement very seriously. The Agency has authority under the PPA to take or order remedial measures which include the authority to hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of regulated materials if it is determined that such measures are necessary to prevent the dissemination of a plant pest within or throughout the United States. In addition, the PPA allows for civil penalties up to $500,000 for violations of the Agency's biotechnology regulations.

Compliance with APHIS' stringent permit conditions is high, and that is due in large part to the Agency's efforts to work with researchers to ensure that they understand our requirements and can implement them in the field. There have been relatively few compliance incidents, with only 297 in the past five years. Of those, about half were considered minor, such as printing the incorrect name on a permit. We take all violations of our authorities under the PPA seriously and will pursue a variety of enforcement and legal actions, when appropriate.

APHIS' permitting system is designed to prevent any unauthorized spread of materials derived through biotechnology. In August of 2002, the White House's Office of Science and Technology Policy issued a policy statement that acknowledges the potential for low level mixing of genes and gene products from unintended plant sources, and describes the actions the coordinated framework agencies would take in addressing this issue. This mixing can be caused by natural processes such as the movement of seeds or pollen, or human-mediated processes associated with field testing, plant breeding, or seed production.

APHIS recognizes the interest, both domestically and internationally, by stakeholders in understanding how the Agency responds to situations involving an unauthorized low level presence of regulated organisms derived through biotechnology. As many other countries are determining how to approach low level presence situations, APHIS has taken a leadership role in articulating its approach in responding to low level presence. In situations involving the unauthorized release of regulated biotechnology-derived materials, APHIS responds with remedial action that is appropriate to the level of risk and warranted by the facts in each case. We always initiate an inquiry to determine the circumstances surrounding the release, evaluate the risk, and determine, if appropriate, remedial and enforcement actions. If an incident would result in the introduction of material that could pose a risk to agriculture or the environment, the Agency will use its authority under the PPA to mitigate that risk and require remediation measures.

In those cases in which the occurrence of a plant material derived through biotechnology poses no risk to plant health and the environment, APHIS may determine that remedial action is not necessary. This could include occurrences involving a plant that qualifies for APHIS' notification process, which is used for those plants that present minimal risk, as well as if the biotechnology-derived plant is similar to another that has already been deregulated, or shown to not pose a plant pest risk. However, even if APHIS determines that no remedial action is required, this does not preclude the Agency from taking legal action against a company or individual for violation of APHIS regulations.

Deregulation

After a plant derived through biotechnology has been field-tested extensively and the developer can show that it does not pose a plant pest risk, the developer may file a petition for deregulation, which would enable the petitioner to commercialize the product without further APHIS oversight. The developer must submit extensive information about the plant's biology and field test results. In considering the petition, a multidisciplinary team of APHIS scientists carefully reviews the data submitted by the developer, and also weighs other pertinent scientific studies and information.

After conducting an environmental assessment (EA) or an environmental impact statement (EIS) and seeking public comment, APHIS may approve a petition for deregulation if it reaches the conclusion that the biotechnology-derived plant does not pose a plant pest risk. Even if APHIS deregulates a particular biotechnology product, the company must still comply with applicable FDA or EPA requirements. Since we began regulating organisms derived through biotechnology in 1986, we have deregulated more than 70 products.

Alternatively, an extension process can be used in cases where a biotechnology-derived plant is similar to a previously deregulated plant. The extension process, which was established in 1997 and has been used numerous times since, is based on the premise that a plant derived through biotechnology that is similar to a previously deregulated plant with respect to plant genotype and the expressed protein(s) is also similar in terms of any potential risk. Based on a thorough review of information in the extension request, which includes data showing similarity, APHIS may conclude that the new plant, like the previously deregulated plant, does not pose a plant pest risk and therefore will no longer be regulated.

National Environmental Policy Act

While APHIS' determination about the safety of a product derived through biotechnology ultimately is determined on the basis of its plant pest risk to agriculture and the environment, we also must weigh potential impacts on the quality of the human environment as required by NEPA. The Act guides Federal agencies on the integration of environmental and public considerations into decisionmaking processes. NEPA regulations ensure that environmental impacts of proposed actions and reasonable alternatives to those actions are considered but it does not require that the agency plan of action necessarily be the most environmentally benign. That is, under NEPA, environmental impacts inform, not dictate, the decisionmaking process.

Before approving notifications or granting permits for introductions of biotechnology-derived organisms that are considered new or novel (the crop species, the trait, or both), APHIS drafts an EA or EIS, when appropriate, and gives the public the opportunity to comment. We also prepare an EA or an EIS, as appropriate, when determining if a plant or microorganism derived through biotechnology can be deregulated.

The EA preparation process includes consultation and coordination with other Federal, Tribal, State, or local agencies when appropriate; publication and comment on the draft EA; and publication of the final EA. The EA discusses the need for the proposed action, possible alternatives including the "no action" alternative, the potential impacts of the proposed action and alternatives, and information regarding any consultation or agency coordination. If the proposed action does not have a significant impact on the environment, APHIS will issue a Finding of No Significant Impact (FONSI). We have substantially enhanced our development of EAs over the years as we have gained more knowledge and experience with the process. For example, EAs developed by APHIS now contain much more detailed scientific analysis than they did in the past and include more scientific references, analysis of the effects on organic production, and a toxicity table for effects of GE crops on non-target insects.

If we determine that any aspect of the quality of the human environment may be significantly affected by a proposed action, then we will prepare an EIS, which involves a more in-depth inquiry into the proposal and any reasonable alternatives to it. The EIS evaluates the environmental impacts of broad agency actions, such as rulemaking. APHIS may also use the NEPA process to better inform the decisionmaking behind projects of a more narrow scope, such as the deregulation of a specific crop. The evaluation includes a discussion of direct, indirect, and cumulative impacts resulting from the adoption of one of several reasonable alternatives, including the no-action alternative. Additionally, APHIS may also discuss actions that would mitigate any impact of the biotechnology product. An EIS is developed by a multidisciplinary

team and can take several months to several years to complete. The environmental impact statement preparation process includes consultation and coordination with other Federal, Tribal, State, or local agencies when appropriate; publication and comment on the draft EIS; publication of the final EIS; and in some cases, public meetings.

Because APHIS is committed to the NEPA process, the Agency has requested an increase in fiscal year 2009 of $4 million and 21 staff years to further strengthen its regulatory biotechnology oversight through enhanced environmental review and assessments, as well as monitoring and surveillance.

Alfalfa EIS

In order to comply with a March 12, 2007, preliminary injunction order by the United States District Court for the Northern District of California, APHIS brought back under regulation Roundup Ready (RR) alfalfa, until the agency issues a new determination consistent with court requirements. APHIS had previously prepared an EA to determine whether deregulating the alfalfa could have a significant impact on the environment and issued a finding of no significant impact.

The court did not overturn federal conclusions that the alfalfa did not pose a plant pest risk and that it was safe for food and feed purposes, but rather concluded that APHIS had not adequately documented potential environmental impacts. A future decision regarding the deregulation of RR alfalfa will be issued after the completion of an appropriately documented EIS.

To inform the public of our intent to prepare an EIS and invite their participation in the scoping process, a Notice of Intent (NOI) was published in the *Federal Register* on January 7, 2008. The NOI identifies and seeks public comment on potential issues and alternatives to be studied in the EIS. APHIS has identified 18 issues that will be studied in the EIS, including impacts on food and feed, U.S. trade, and threatened and endangered species. The public comment period closed on February 6, 2008, and APHIS is reviewing the responses and is evaluating how these responses may affect the scope of the analysis. Following this analysis, a draft EIS will be prepared and published for public comment.

Regulating for the Future

Programmatic Review and Revision of the Biotechnology Regulations

Efforts to further strengthen our regulations and improve compliance and enforcement have enhanced our ability to protect agriculture and the environment while allowing for the safe field testing, interstate movement, and importation of crops derived through biotechnology. However, as I've mentioned throughout my testimony, we recognize that the science of biotechnology is going to continue to evolve and we must be prepared to keep pace with those changes. That is why APHIS announced plans to review and strengthen our current biotechnology regulations in January 2004, and released a draft EIS related to this proposal in July 2007.

Let me say a few words about our plans for reviewing and strengthening our regulations. Again, we want to make sure we prepare for the future, as the science and technology behind these products continue to evolve. But, just as importantly, we also want to review the entire history

of our regulation of these products and apply the knowledge and experience we've gained to develop a comprehensive revision of the regulations. As I've said, over the last 20 years, we've done an excellent job of making adjustments to our regulations and approach to regulating these products. But these have been incremental changes over time; we are now focused on consolidating and modernizing those previous adjustments, as well as making other broader changes.

The draft EIS is one step in the regulatory revision process and helps inform the development of new regulations. APHIS will use the information and analysis in the draft EIS, public comments that are received, and the latest scientific information to develop new regulations through the rulemaking process. As a part of the rulemaking process, a final EIS will also be prepared to address the public comments received in response to the draft EIS.

The draft EIS evaluates a number of environmental issues associated with potential revisions to existing regulations. Under the PPA, APHIS has broad authority to safeguard American agriculture and protect the environment. The draft EIS considers utilizing authorities in the PPA to expand APHIS' regulatory scope beyond biotechnology-derived organisms that may pose a plant pest risk to include those that may pose a noxious weed risk and those that could be used as biological control agents. In addition, these broader authorities would allow APHIS to evaluate a wider range of impacts to support the Agency's regulatory decisions.

Through the draft EIS, APHIS is also evaluating a tiered permitting system based on potential environmental risk. Under such a system, APHIS would require greater confinement measures and more inspections for field testing biotechnology-derived organisms posing a greater risk or for those with which the Agency has less familiarity. Additionally, we are evaluating a process for continued oversight of crops that do not meet the criteria for deregulation. This permitting system would provide greater transparency to the regulated community and the public on how each organism would be regulated by APHIS.

Revising the current regulatory system will better allow APHIS to meet current and future needs in evaluating and addressing the risks associated with the introduction of organisms derived through biotechnology. It is essential that APHIS have the ability to conduct rigorous assessments and provide sufficient oversight for new and higher risk categories of products. However, when APHIS has enough experience and familiarity with the safety of certain classes of biotechnology-derived organisms, the program also needs the flexibility to allow for streamlined reviews and less oversight. The proposed changes will allow APHIS to focus its oversight and resources on higher risk organisms, while allowing for additional flexibility for those products that have demonstrated safety.

Biotechnology Quality Management System

Last September, APHIS announced a new, voluntary program to enhance the ability of universities, small businesses, and large companies to meet our current regulatory requirements. APHIS is developing the Biotechnology Quality Management System (BQMS) to help the biotechnology industry become better stewards by focusing on the implementation of best management practices so that problems can be prevented. We plan to implement the BQMS system on a limited basis for evaluation purposes this growing season.

In developing the BQMS, APHIS' goal is to assist the regulated community in approaching research in a manner that ensures the greatest level of security and compliance with our regulations. In this way, we're continuing our efforts to reach out to the regulated community and educate them on systematic approaches that can be taken to ensure compliance with our regulations.

The BQMS consists of two program levels that incorporate industry best management practices and principles established by national and international standard setting bodies. The Level-A program will be designed for participants that do not have formal management systems in place, such as small businesses and universities, and will focus on their ability to develop documented procedures, to identify risk control points, and to take preventive action. On the other hand, the Level-B program is intended for participants that have formal management systems in place and grow biotechnology-derived plants at multiple sites, often through the use of cooperators. To meet the additional complexity of this type of operation, Level-B will incorporate ISO 9001 business standards.

The BQMS will include an audit component to verify that participants have procedures in place and that they are performed correctly to meet the regulatory requirements for any given field trial or movement. APHIS will oversee the BQMS program in partnership with USDA's Agricultural Marketing Service (AMS), which will manage the audit component of the program and accredit third party auditors.

Participating organizations will be required to ensure that all personnel are properly trained on the standard operating procedures for working with organisms derived through biotechnology. They must consider the potential impact of early decisions on later steps in the introduction (e.g., plant choice, equipment choice, field test site). They will be required to identify vulnerabilities in their processes and potential risk control points for any introduction, as well as control measures to minimize the risk or occurrence of unauthorized releases.

The BQMS complements a program called, "Excellence Through Stewardship," which is already underway in the biotechnology industry. While industry's program is focused on quality management to ensure product integrity of biotechnology-derived plant products throughout the product life cycle, APHIS' program will emphasize the quality of the process for safely introducing these organisms in compliance with federal regulations.

The BQMS and its associated audits will complement, not replace, APHIS' regulatory compliance and inspection process by focusing on planning and good management practices that can improve a participant's ability to meet regulatory requirements. The current inspection program will continue to cover specific permits and notifications to ensure compliance with regulations.

Lessons Learned

Since 1985, BRS has carried out an effective regulatory program for plants and plant products derived through biotechnology. During this 20 year period, BRS has developed and refined risk-based regulatory requirements, performance standards and permit conditions. These

requirements are based on the best available science.

Over that period, APHIS has effectively overseen approximately 12,000 field trials under the notification procedures and 1,500 field tests under the permitting procedures. These field tests were conducted at over 65,000 sites under notification and 14,000 sites under the permitting procedures. I'm proud to say that there have only been a handful of situations involving serious noncompliance with our regulations.

But as I've mentioned previously, our goal at APHIS is to keep pace with the changing science of biotechnology and enhance our regulatory system as we gain new insight on ways to protect agriculture and the environment from plant pests and diseases. To that end, in October 2007, APHIS released a "Lessons Learned" document outlining additional changes we are considering to strengthen our regulatory system. The document was developed as a result of the lessons learned from the Agency's investigation into the presence of trace amounts of regulated biotechnology-derived rice in two commercial long-grain rice varieties, as well as other biotechnology investigations. We will continue to thoroughly investigate any such incident and are committed to holding parties responsible if they are found to have violated our biotechnology regulations under the PPA, and are also looking at other ways we can prevent such an occurrence in the future and improve the effectiveness of investigations into compliance incidents. Changes we are considering include, among others, increasing isolation distances, requiring developers to create comprehensive contingency plans, and enhancing recordkeeping.

A number of the potential changes are already underway, and a number are being considered in our programmatic EIS. APHIS has taken steps to improve the capabilities of the ePermits, our online permitting system, to more quickly retrieve information that could be pertinent to an investigation. Applicants can now submit permits and notifications online, and we are currently working with stakeholders to design the inspection and enforcement components of ePermits. In addition, we require contingency plans for field trials of plants that produce pharmaceutical compounds, and are considering implementing these requirements across the board.

APHIS is also partnering with several organizations with specialized experience that will complement our current regulatory work. In the fall of 2007, APHIS and the Association of Official Seed Certifying Agencies put in place an agreement to gather and peer review scientific information regarding outcrossing and isolation distances for six key crops, beginning with rice. The results of this analysis will aid APHIS in ensuring that the latest science is incorporated into biotechnology-derived crop isolation distances. APHIS also entered into an agreement with USDA AMS to provide assistance in the event of future potential violations of our biotechnology regulations. This agreement puts in place a specific blueprint detailing how sampling and testing would be conducted by AMS, as they did with the rice investigation. We are also exploring similar agreements with other agencies to utilize their unique expertise.

Finally, I'd like to close by saying that as we continue to make changes to improve the regulatory system for products of biotechnology, we believe it is essential to always keep in mind that this is a constantly evolving system. As always, APHIS is committed to using the latest science to assess how the system is working and to take the steps necessary to ensure that organisms derived through biotechnology are introduced in a way that is safe for U.S. agriculture and the

environment. We're very excited about the regulatory changes that have already occurred as well as those that are on the horizon. In partnership with our sister Agencies FDA and EPA, we're confident that we're ready for the future of agricultural biotechnology.

Thank you again for the opportunity to be here. I'm happy to answer any questions that you may have.

Mr. KUCINICH. Thank you very much.

I have some prepared questions. But before I get to them, you sat back there and you heard the testimony of the farmers. And you know, you heard Mr. Howington talk about how his grandfather had that farm and then what happened with the LibertyLink rice. What about that? When you hear that from a farmer, do you think that maybe somebody failed somewhere?

Ms. SMITH. Well, I guess I have a number of reactions. It certainly emphasizes how seriously we took this situation when it occurred. It emphasized the decisions we made at the time to go contrary to some of our historical procedures in terms of, we historically complete an investigation in terms of a situation such as this before we start talking publicly about it so we don't compromise the nature of the investigation. But what became very clear to us was that we wanted to make sure the farmers knew everything they could to help them prepare for the planting season. And so we made two separate announcements, kind of contrary to what our historic policy had been, letting farmers know about what we had learned. And in addition, another thing that we did was when we learned about the second rice-related event, we took immediate measures, within hours, and we stopped—I may not have the number exactly right—but I think it was in the neighborhood of 98 percent of all the Clearfield rice that was moving to farmers to plant, so that what happened was very—I think there may have been potentially one farmer that planted a very small spot of Clearfield. So we are very empathetic absolutely, and that is partly what drove a lot of the actions that we took during the situation.

Mr. KUCINICH. Well, I mean, after all, two Federal judges concluded that APHIS was in violation of NEPA in two separate genetically engineered plant cases. And in these cases, APHIS review of the deregulation application for Roundup Ready alfalfa and the field testing of Roundup Ready creeping bentgrass were deemed by the courts to be inadequate, "arbitrary and capricious," and in violation of NEPA. Now, you have not appealed these judges' decisions as relate to violations of NEPA; have you?

Ms. SMITH. Actually, we are not. We have an appeal on one of the cases, but we are not disagreeing with the judges' determination that we were in violation of NEPA.

Mr. KUCINICH. Well, APHIS is now preparing an EIS in both cases, though, is that right?

Ms. SMITH. That is correct.

Mr. KUCINICH. And I wanted to ask you a question about APHIS's reaction to those judges' decisions. As you are aware, in the alfalfa case, Judge Breyer concluded, "APHIS made no inquiry into whether those farmers who do not want to grow genetically engineered alfalfa can in fact protect their crops from contamination." He went on to say neither the EA nor the FONSI identify a single method that an organic farmer can employ to protect his crop from being pollinated by a bee that travels from a nearby genetically engineered seed farm even assuming the farmer maintains a buffer zone. And Judge Breyer said, "Neither the EA nor the FONSI contain any reference to any material in support of APHIS's conclusion that gene transmission is highly unlikely to occur with reasonable quality control."

Ms. Smith, do you now feel that APHIS had to make such an inquiry to comply with the National Environmental Policy Act.

Ms. SMITH. The Court directed us to do so, so that's exactly what we are doing, and that's what we have been doing in all of our regulatory decisions since that time.

Mr. KUCINICH. And do you now feel that APHIS has to show the analysis involved in making the inquiry to comply with NEPA?

Ms. SMITH. Absolutely. One of the realities that we faced is that we have a staff of scientists that are top notch experts in terms of science. What we have not historically done as good a job with is to help them understand how to document our requirements under NEPA. And so while our scientists have looked at these issues, have discussed them, we have had much conversation and dialog and research happen, we have not adequately documented in this case what we needed to.

Mr. KUCINICH. Well, let's go back to Judge Breyer for a second. I am going to read some more things, see if we can come to agreement here. Judge Breyer, "an action which potentially eliminates or at least greatly reduces the availability of a particular plant, here nonengineered alfalfa, had a significant effect on the human environment." And he said, "the significant impact that requires the preparation of an EIS is the possibility that the deregulation of Roundup Ready alfalfa will degrade the human environment by eliminating a farmer's choice to grow nongenetically engineered alfalfa." Does APHIS now agree that the possibility of genetic contamination causing a narrowing of farmer choice is a significant impact under the National Environmental Policy Act?

Ms. SMITH. What we are doing is looking at any situation in which an environmental decision will have a significant environmental impact and that will also have a related economic impact, which is what the judge directed us to do.

Mr. KUCINICH. So you are saying you basically agree then? You agree?

Ms. SMITH. You are asking, do we agree that there could be a significant impact of a contamination situation? Is that what you are asking?

Mr. KUCINICH. I will ask it again. I just want to make sure that we have precision here. Does APHIS agree now that the possibility of genetic contamination causing a narrowing of farmer choice is a significant impact under NEPA?

Ms. SMITH. What we have to do is look at the environmental decision, environmental impact, and then look at the economic impacts associated with that. And so that's what we are doing. And so you could envision a situation in which that could be the case.

Mr. KUCINICH. But do you agree with that? Do you agree with Judge Breyer's assessment?

Ms. SMITH. You know, since the judge gave us the order, we are going to do exactly what the judge has told us to do. So we are looking in that avenue, and we are putting the resources into making sure that we have done a very thorough environmental analysis as well as economic analysis for all aspects of that.

Mr. KUCINICH. You haven't appealed that aspect of the judge's decision.

Ms. SMITH. No, we have not.

Mr. KUCINICH. OK. Just again, using Breyer's decision to look at the way you look at these things, he said, "APHIS argues in its brief that the extent of any gene transmission is in any event irrelevant because NEPA requires an agency to consider physical environmental impacts, not economic or financial impacts. APHIS overstates the law." He goes on to say the economic effects on the organic and conventional farmers of the government's deregulation decision are interrelated with, and indeed a direct result of, the effect of the physical environment, namely the alteration of a plant species' DNA through the transmission of a genetically engineered gene to organic and conventional alfalfa. APHIS was required to consider those effects in assessing whether the impact of its proposed action is significant. But its reasons for concluding that the effect on organic and conventional farmers is not significant are not convincing. Now, when Judge Breyer refers to economic effects being interrelated with environmental impacts and significant, he is quoting from the National Environmental Policy Act's implementing regulations. Does APHIS now agree with Judge Breyer that determining the significance of a proposed action under NEPA requires considering economic impacts interrelated with environmental impacts?

Ms. SMITH. We do agree that if there are environmental impacts and economic impacts associated with those, that they need our full analysis, and we will do so in our NEPA analysis, whether it is in an environmental assessment or an environmental impact statement.

Mr. KUCINICH. We have just reviewed a number of areas of Judge Breyer's decision. And it appears that APHIS is ready to incorporate those judicial rulings into your interpretation of your NEPA obligations. Is that correct?

Ms. SMITH. It is correct that we recognize that where there is an environmental impact, a significant environmental impact, that we have to consider the economic impacts related to that, yes, sir.

Mr. KUCINICH. So what are the lessons that you have learned about NEPA obligations from Judges Breyer and Kennedy?

Ms. SMITH. The fundamental thing that we have learned is that we have to do a better job of documenting the work that we are doing. In the previous case, it led us to develop a number of documents to document more precisely whether we need to do a categorical exclusion or an environmental assessment. And just in terms of a point of clarification regarding the previous testimony you heard regarding our documentation we provided you, the documentation we provided you is not intended in any way to be our environmental analysis that we conduct, an environmental assessment or an EIS. That documentation is to very clearly——

Mr. KUCINICH. I am glad you pointed that out.

Ms. SMITH [continuing]. Very clearly to help us determine if that regulatory decision is something that can be categorically excluded from NEPA, from a full NEPA analysis, or if it needs an environmental assessment. And so it is just a start in terms of our just looking at just the categorical exclusion decision.

Mr. KUCINICH. You have a new decision matrix?

Ms. SMITH. We have the matrix we gave you, but that is only in terms of only determining whether a categorical exclusion applies

or if we need to do an environmental assessment, which would be an alternative to that.

Mr. KUCINICH. Since the Breyer and Kennedy decisions, is it fair to say you have a new decisionmaking matrix?

Ms. SMITH. We have strengthened our documentation, that's correct.

Mr. KUCINICH. But it is also—I just, you know, just to make sure we are going in the right direction here, the decision—any decision matrix could be calling for minimal compliance. Are you, in terms of the compliance meter, are you looking for minimal compliance or are you looking to really comply fully?

Ms. SMITH. Right. I don't want to confuse issues here. The purpose of these matrices that we have developed, and I think one has 30-some specific aspects that we are looking at, we have questions in that matrix to help us make sure that we consider every aspect that is relevant in terms of a decision on a categorical exclusion. And in one case, we learned—our lesson learned from one case is that we had to do a better job of documenting that something qualifies for a categorical exclusion. We made changes. We did a good job of that. In the next case, the judge ruled we did document the categorical exclusion appropriately, but we failed to document the exceptions to that categorical exclusion. And so that is the new matrix that you see that we developed as a result of the second case.

Mr. KUCINICH. Will APHIS broaden its interpretation of significant impact so it comes into line with the court's interpretation in Geertson——

Ms. SMITH. I think historically we have, and in the EA that you saw, we took a more closely related to plant pest authority evaluation of the situation, which is what our regulatory authority is. What we heard clearly from the judge is that for any situation in which there is a significant environmental impact, we have to consider the economic impacts. And so we are doing that.

Mr. KUCINICH. So let's talk about Geertson again. Are you looking at the economic impact on farmers resulting from potential contamination?

Ms. SMITH. Yes, we are.

Mr. KUCINICH. OK.

Ms. SMITH. Specifically, I could add, if you are interested, when we announced the EIS, one of the specific areas that we announced that we are scoping for is the economic impacts of Roundup Ready on nonbiotech adopters.

Mr. KUCINICH. A nonbiotech——

Ms. SMITH. Adopters. So in other words, your organic farmer, your traditional farmer that is not growing any biotech.

Mr. KUCINICH. Are deregulation decisions of GE plants inherently likely to have significant environmental impact?

Ms. SMITH. That would be based entirely on the nature of the crop and the trait that has been incorporated into the crop. And that is why we do a very specific deregulation decision for each one of those applications.

Mr. KUCINICH. I mean, you look at the International Center case and what Judge Kennedy said, he said he considers the significance that the size of test plots, the number of test plots with field

tests have in determining environmental impacts. Logically, wouldn't deregulation decisions which allow the unrestricted commercial transport of GE crops, thereby enabling the unlimited planting of GE crops, pose an even greater environmental impact?

Ms. SMITH. That is possible. And we would not make a deregulation decision unless we determine that crop that is being proposed was entirely safe for the environment and agriculture.

Mr. KUCINICH. So should proposed deregulations in this—you know, in these areas require an environmental impact?

Ms. SMITH. In September 2004, as the deputy of BRS, I made a decision that the creeping bentgrass petition application was such that, due to the nature of the crop, it was necessary for us to conduct an environmental impact statement.

Mr. KUCINICH. As you know, APHIS has prepared a draft programmatic EIS in connection with its intention to promulgate new biotech crop regulations. Now, my staff has reviewed the draft EIS carefully, and we are left wondering if it reflects any lessons learned from the rebuke that APHIS received from two Federal courts last year. For instance, take its discussion of socioeconomic impacts. Discussion of those impacts again goes to that 10-page appendix at the end of the 310-page document. And you have already responded to that. Is that——

Ms. SMITH. No, you are asking now, why is that information in an appendix in that document? And I give you two answers for that. First, you referenced the size of that document. And so that should give you a sense of the commitment that we took in terms of the scientific analysis that we conducted to complete that EIS. We had some challenges, though, and we worked with a consultant on how to make that document something that would be very easy for the public to read, because it is very important for us as a regulatory agency in terms of the public confidence in the system and in terms of our making sure that we are complying with NEPA to the spirit of NEPA that document can be as very transparent and can be read well. And I think what we heard from Judge Breyer was the recognition that we need to look at those environmental impacts, but the critical thing for us to consider is the environmental impacts, and then we are considering the economic impacts as they relate to the environment. So that would make sense that the environmental is the main core of your EIS. One thing, though, that we should clarify, too, is that Judge Breyer's decision was on a product-specific EIS as opposed to our programmatic EIS, which is on our full regulatory system. And I would tell you, we place no less importance on the analysis wherever it is in the document. We did all that analysis, conducted that all in a very comprehensive way over a period of years. And the fact that it ended up in an appendix was really more of a decision to help the document be easier to read.

Mr. KUCINICH. OK. We have a 310-page document we are talking about here. There is an assertion, on page 121, "four factors were considered in the evaluation of biological impacts: too negative of an impact; the geographic extent; its duration and frequency; and the likelihood of its taking place." There was no mention of economic impacts, or take the fact that apart from the 10-page appendix, there are only five mentions of the phrase socioeconomic im-

pacts and only 10 mentions of the word contamination. I am just wondering, in light of Judge Breyer's decision, if economic impacts of contamination should have been integrated into the body of the EIS and the analysis of significance and had been discussed more extensively. It still makes me wonder, did you really get the message when I don't see it discussed in any extensive manner?

Ms. SMITH. I would say one point is that it is important to recognize, in order for us to do good analysis, we have to have enough specificity in what we are analyzing——

Mr. KUCINICH. Indeed.

Ms. SMITH [continuing]. To be able to project. So where we are going to have the ability to have much more specificity is going to be on a crop-specific EIS as opposed to a programmatic. In the programmatic EIS, we have to look very broadly at the whole regulatory system and look very broadly at the kinds of issues we are evaluating. And then what we will be doing is using this as the basis to tier to very specific crop-based analysis. In addition, it is important to recognize that when we issue our proposed rule, which we hope to do before too long, there will be a separate very specific economic analysis that will associate, be associated with the issuance of that rule.

Mr. KUCINICH. When you say separate——

Ms. SMITH. We are required to publish at the same time an economic analysis as one of the types of analysis that accompany a proposed regulation.

Mr. KUCINICH. Well, thank you. As you know, the USDA has prepared a draft programmatic environmental impact statement pursuant to its plan to rewrite its regulations for GE organisms. In the future, when USDA is operating under new regulations, you will again face many petitions for permitting field trials and for the deregulation of GE crops. Does anything in your proposed regulations change the kinds of decisions that are subject to preparing an EA or an EIS?

Ms. SMITH. Does the—do our new regulation changes——

Mr. KUCINICH. Anything in your proposed regulations change the kinds of decisions that are subject to either an EA or an EIS?

Ms. SMITH. We have not finalized the regulation yet, so we can't speak to exactly what is in it.

Mr. KUCINICH. OK.

Ms. SMITH. But what we will have is a significant amount of information, a broader regulatory system, one that is based on tiers, a multi-tiered risk-based permitting system. And so the kinds of decisions, depending upon what tier you are in, will be what will determine—they will differ depending upon what the crop is that you are looking at. So if you are looking at a crop that has more risk, potential risk, associated with it or less familiarity, then in those cases, it is more likely that we will be conducting a higher level of analysis.

Mr. KUCINICH. You know, what we are interested in as a subcommittee is under what circumstances you will or would assert that your preparation for a programmatic EIS would relieve APHIS of the requirement to prepare an EA or an EIS.

Ms. SMITH. Oh, no, it would not be our intention to develop—make these regulation changes to do anything that would be con-

trary to CEQ regulations or our own NEPA-implementing regulations, whether it is developing this EIS and regulations or others.

Mr. KUCINICH. Thank you. I would like to talk about isolation distances.

Ms. SMITH. OK.

Mr. KUCINICH. In connection with this, I have a letter that I am going to submit for the record without objection. It is a memorandum to USDA APHIS Regulatory Analysis and Development. Just for the purposes of the staff, it is dated May 31, 2005. Can we make sure they have a copy of that? Mr. Gregoire, would the staff make sure Mr. Gregoire has a copy of this so you know what we are putting in the record in case you have anything that you want to comment on it.

Ms. Smith, as you know, Federal, State and private rice research programs operate a specialized nursery called the Rice Quarantine Nursery near Plymouth, North Carolina, where potentially useful traits are taken from rights germplasm from foreign sources. This activity is obviously sensitive. The germplasm in soil at the nursery could become contaminated, and/or an unauthorized release from the nursery could cause a very serious contamination of the U.S. commercial rice supply. For these reasons, the nursery was located 650 miles east of any commercially produced rice crop. The location was selected, in other words, to isolate the nursery spatially from commercial rice production to prevent contamination.

In 2005, Ventria Bioscience applied to APHIS to field test genetically engineered pharmaceutical rice on a large scale in close proximity to the rice quarantine nursery. APHIS prepared an environmental assessment of the application and concluded there would be no significant impact and approved the application. Now, right here, this document that I will submit for the record is a memorandum protesting the deficiencies of the EA. It comes from a USDA research leader with the Agricultural Research Plant Science Research Unit. So, again, without objection. Specifically, this memorandum alerted APHIS that its EA had failed to consider the potential of, one, Ventria's field tests introducing pathogens that would imperil the Rice Quarantine Nursery; and two, Ventria's field tests posed a small risk that stray rice pollen could be carried by wind currents into the Rice Quarantine Nursery. Could you tell us, if you recall, how did APHIS regard the concerns raised in this memorandum?

[The information referred to follows:]

USDA

United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

1400 Independence
Avenue, SW

Washington, DC
20250

SEP 1 6 2008

The Honorable Dennis J. Kucinich
Chairman
Domestic Policy Subcommittee
Committee on Oversight and Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

Dear Mr. Chairman:

Thank you for your letter of May 30, 2008, requesting documents related to my testimony at the March 13, 2008, hearing of the Oversight and Government Reform Committee, Domestic Policy Subcommittee, titled, "Is the U.S. Department of Agriculture (USDA) Accounting for Costs to Farmers Caused by Contamination from Genetically Engineered Plants?"

I appreciate your continuing interest in the Animal and Plant Health Inspection Service's (APHIS) regulatory oversight of agricultural biotechnology. As I have indicated, it is important to me that you have accurate and relevant information regarding our Agency's role, and I am therefore happy to respond to your request.

On the one enclosed compact disk, you will find electronic versions of all available requested documents. These include, in response to your numbered points:

(1) and **(2)** The two full environmental assessments (EAs) prepared in response to Ventria BioSciences' permit applications for field testing of rice genetically engineered (GE) to express human lactoferrin (applications 04-302-01r and 05-117-01r) and human lysozyme (applications 04-309-01r and 05-117-02r) near Plymouth, North Carolina. On pages 13, 14, and 71 of the pdf of the former EA, and pages 13 and 72 of the latter EA, APHIS responded to issues raised in a May 31, 2005, letter sent by the USDA-Agricultural Research Service's Dr. David Marshall, a researcher based at North Carolina State University (NCSU). Dr. Marshall had expressed concern about the proximity of Ventria's rice to the Tidewater Research Station. Also on this issue, we have included e-mail correspondence between our Agency and NCSU Professor Ronnie Heiniger.

(3) With regard to the incineration of soybeans that included corn engineered to produce pharmaceutical compounds, USDA estimated that at most, there were 4 to 30 grams of corn material to 500,000 bushels of soybean (or, one seventh of one kernel of corn per truckload of soybeans). APHIS' Biotechnology Regulatory Services (BRS) considered conducting an EA related to the incineration. However, we determined that an EA was unnecessary after performing a risk assessment and concluding that any exhaust from the power plant would not be measurably different from the exhaust produced when incinerating soybeans alone. Additionally, we wish to point out that pharmaceutical compounds are proteins and as such, would not have active properties when incinerated.

When determining that an EA was not necessary, APHIS also took into consideration that Big Stone Power Plant—the facility that incinerated the soybeans—is designed to use plant-based fuels such as coal and Renewable Resource Materials (RRM), such as soybeans, as a fuel stock. Item number 11 of the seed disposal agreement states that the "Buyer (Big Stone Power Plant) warrants that it possesses the required Air Quality, Solid Waste, and any other permits required by law to use RRM as an alternative fuel to incinerate the RRM as contemplated by this Agreement. All RRM will be processed and used as a fuel by Buyer in accordance with all applicable federal, state and or local rules and regulations and Buyer agrees that it will not otherwise dispose of or resell any of the RRM." Soybean is frequently used as an alternative fuel in the United States and represents a source of biodiesel and biodiesel fuels that are burned in cars throughout the country. The use of soybeans as an alternative fuel source in a power plant was therefore not considered to raise new environmental issues warranting the preparation of an EA.

The risk assessment and unsigned seed disposal agreement are included in the enclosed documents. Please note that we attempted to obtain a signed copy of the seed disposal agreement from the Farm Service Agency (FSA), which disposed of the soybeans. However, FSA was unable to find a signed copy of the seed disposal agreement and accordingly, our efforts were unsuccessful.

Before listing the pharmaceutical compounds produced by genetically engineered (GE) corn that we had approved for field testing, and that may have contaminated the soybeans planted after the testing was complete, we want to make you aware that this list is confidential business information (CBI) as supplied to us by a private company. We are providing this information to accommodate the Subcommittee's request, but we ask that you recognize that it is CBI and, as such, is protected from disclosure under Freedom of Information Act exemption 4 when release would cause substantial harm to the competitive position of the company that provided the information.

(4) Also included in the documents we are providing is a table of all permit requests submitted since 1997 for GE crops that produce pharmaceutical and industrial substances. The list includes applicants' names, field test locations, and the status of each permit request. We are also providing available farmer/producer/citizen correspondence, as well as our responses, received and sent from 1997 to the present. This correspondence is organized according to fiscal year.

You will also find a wealth of information addressing your request for studies and information relating to isolation distances. We have described these documents and their relevance in the enclosed isolation distance document guide.

I hope this information is helpful and look forward to continued dialogue with your staff on the issues surrounding biotechnology.

Sincerely,

Cindy J. Smith
Administrator

2 Enclosures

Isolation Distance Document Guide

Further explanatory notes for documents relating to request number 4 for "information, including studies, relating to isolation distances."

- *Proceedings from a September 2004 workshop that our Agency conducted to review past results, and obtain an update of the most recent scientific results, relevant to biological dispersal and confinement of GE crops during field testing.* The workshop brought together experts to present and consider past and current information relevant to biological and physical factors that influence the design, implementation, efficacy, and feasibility of measures used to confine transgenic plants and their progeny to the authorized field sites. This included measures that could be taken to limit gene flow beyond the authorized site, commingling with other crops, and persistence of transgenic plants in the environment following termination of the field trial.

  The workshop primarily concentrated on crop plants planted under APHIS permits as plant made pharmaceuticals and plant made industrials. The proceedings considered the body of available scientific data and bibliographies that served as a resource for those (including APHIS officials) involved in the design, evaluation, and research of confinement measures for field trials of GE plants, particularly plants engineered to express pharmaceutical or industrial products. Please note that these proceedings are also publicly available online at http://www.aphis.usda.gov/biotechnology/meetings_confinementworkshop.shtml.

- *APHIS' updated guidance to applicants for permits for field testing or for movement of organisms intended for pharmaceutical or industrial use.* APHIS requirements to conduct field tests or move organisms engineered to produce compounds intended for industrial or pharmaceutical use were strengthened and published for public comment in the March 10, 2003, *Federal Register*. These changes increased the stringency of conditions required to handle these regulated materials. Accordingly, the amount of data required for submission of APHIS' BRS permit applications, and the stringency of procedures used for field testing and movement of these organisms, also increased. The guidance document provides information that an applicant should consider for addressing containment (to a facility such as a laboratory or greenhouse or during movement), confinement (to the field test site), and environmental issues. In particular, pages 18-24 include guidance on appropriate confinement considerations and provide references for some of the documents we base our requirements on, in addition to the information gained from the previously-mentioned confinement workshop. Please note that, like the workshop proceedings, the guidance document is also available online. The address is www.aphis.usda.gov/brs/pdf/Pharma_Guidance.pdf.

We wish to emphasize here that isolation distances used for field tests of plants engineered for pharmaceutical or industrial use are typically several fold greater than those for production of foundation seed. An example is provided in the guidance for corn. For example, with corn—an outcrossing, wind-pollinated species—the tassels can be bagged prior to and through pollen shed, or removed, or planting dates can be staggered so that flowering times do not overlap with non-transgenic corn. With tobacco, a mostly self-pollinating species, flowers are also typically topped (removed) or bagged to prevent cross-pollination. These methods are commonly practiced and can be used to reduce isolation distances.

Other information that APHIS considers on a case-by-case basis when assessing appropriate confinement conditions for these types of trials are the resources available to the applicant such as land, equipment, and personnel, and their qualifications or experience to implement various confinement methods (e.g. bagging or removal of flowers). An employee training program is a requirement. As indicated in the March 10, 2003 *Federal Register* notice, APHIS requires the permittee to implement an approved training program to ensure that personnel are prepared to successfully implement and comply with permit conditions, supplemental permit conditions, and permit standard operation procedures. Further information on this can be found on page 37 of the guidance document.

- *Chapter 7, Code of Federal Regulations (CFR) Sections 201.76-201.78, listing several methods that can be used to achieve appropriate levels of confinement.* Requiring isolation distances, e.g. those set by the Association of Official Seed Certifying Agencies for the production of the purest class (foundation class) of certified seed, is one method that can be used alone or in combination with other methods to ensure adequate reproductive isolation from sexually receptive compatible plants. These methods are adapted depending on the specific plant species, its ability to outcross, the engineered traits, considerations regarding surrounding land use and cropping, and the size of the field trial. (These CFR sections are available online at http://a257.g.akamaitech.net/7/257/2422/14feb 20071500/edocket.access.gpo.gov/cfr_2007/janqtr/pdf/7cfr201.76.pdf.)

- *EAs conducted in response to several field testing permit applications submitted since 1997.* These EAs address isolation distances and thus apply to your request for studies and information related to isolation distances. Please note that these EAs include CBI.

Ms. SMITH. I know we took these concerns seriously. I remember us talking about it within the staff. I remember one of our division directors talking with Mr. Marshall, contacting him about the situation. I can't tell you, I will have to get information back to you on how we resolved this issue.

Mr. KUCINICH. That would be great. I am wondering if you performed additional analysis in the areas identified as deficient. I want to know if you prepared a full blown environmental impact statement. I want to know what the evidence that APHIS took a serious look at the environmental economic impacts identified in the memorandum. And what I am actually asking for is the entire record of that communication to be delivered to the subcommittee so that we can see how that was handled. I would appreciate your cooperation on that.

Ms. SMITH. OK. Sure. I will tell you that this year we are in the process right now of doing an environmental assessment for that same crop in that same area. So we can provide you with that as well.

Mr. KUCINICH. That would be very helpful. And your cooperation is appreciated.

Ms. SMITH. Sure.

Mr. KUCINICH. As you know, APHIS considers applications to release pharmaceutical and industrial crops through its permit process. Pharmaceutical crops are genetically engineered to produce a drug or a component of a drug for the pharmaceutical industry. That review process is more rigorous than the notification process, reflecting the greater risk posed by pharmaceutical crops. What would be the likely consequences to farmers if a contamination event occurred involving a pharmaceutical crop?

Ms. SMITH. Let me tell you a little bit about, there was a situation that occurred previously involving a company, and our inspectors identified for that company that problem that happened. The company had three different problems that came up where they didn't fully comply with our requirements. And in each case, our inspectors were on hand to identify for the company that they were—they had created a problem and that they would have to address it. In this situation, despite the fact that our inspectors found the problems, told them about the problems—we gave them clear information on how to address the problems. It created a situation in which some soybeans were contaminated as a result. We took very quick action. We stopped the movement of those soybeans in place so that they didn't move into the food supply. But as a result, we had been in the process of putting together a variety of—a very good evaluation of how we should be regulating field testing of pharmaceutical and industrial types of crops. And we came out with both a new regulation that required our—new requirements to apply to all crops that contained industrial genes. And we also put new requirements in place that year where we significantly increased both our oversight as well as the requirements on the company. And so an example of the oversight we put in place for us is, while low-risk crops are—a percentage of low-risk crops are personally inspected by APHIS inspectors, these that we have less familiarity with, so they could potentially have more risk associated, we made a decision that for each of these pharmaceutical field

trials that we would inspect seven times or more for each of these inspections. And the way we came up with those inspections was that we thought about what each of the critical control points or the critical decision points were in that research they were conducting.

Mr. KUCINICH. Is this the area—excuse me if you had mentioned this, because I got paged, and we have a vote come up.

Ms. SMITH. OK.

Mr. KUCINICH. Is this the case where APHIS had to buy about half a million bushels of soybeans in order to keep them from going to market?

Ms. SMITH. This is the case where the company didn't have enough assets to immediately cover the cost of the destruction of those soybeans. And so, in order to hold them accountable so that they had to pay close to $4 million in expenses to destroy them, we paid for the cost first, and then, as we do in our types of plant health situations, they entered into a contract with us to repay us back that money.

Mr. KUCINICH. How were they destroyed?

Ms. SMITH. How were they destroyed? Well, we took them to—there was a local facility where they were burned in like an energy facility. And APHIS inspectors oversaw the whole process to make sure that is what happened to them. All of those soybeans were burned.

Mr. KUCINICH. Did anyone do an environmental report on the destruction of half a million bushels of pharmaceutical crops?

Ms. SMITH. I remember that we were in consultation with the Environmental Protection Agency, talking about what was acceptable from their perspective in terms of disposal.

Mr. KUCINICH. Did they give you any documentation? I mean, is there anything documented——

Ms. SMITH. I will have to check and see.

Mr. KUCINICH. Is there any documentation on the exchange between you and the EPA on the destruction of these half a million bushels? I would like to see that.

Ms. SMITH. All right.

Mr. KUCINICH. The committee would like that. Thank you.

And if this is the same case, tell me. Is this the Inspector General found a pharmaceutical crop growing as volunteers in a plot of conventional soybeans, and then there was another State where he found that a soybean field had been harvested before the pharmaceutical crop volunteers had been removed from the field?

Ms. SMITH. This is the same case, but it wasn't the Inspector General that found that. Those were APHIS inspectors who found both of those problems and alerted the company to them.

Mr. KUCINICH. Staff just told me that APHIS inspectors may have had company on their inspection from the Inspector General's Office. It is not something—it is something I have just been told. Take it for what it is worth. It is just that the Inspector General apparently has had some kind of a role here. What would have happened, do you suppose, to the U.S. soybean industry if those pharmaceutical crops had been detected in the marketplace?

Ms. SMITH. Well, I imagine it would have been problematic, which is why we took such immediate action. I personally called

the CEO of that company within minutes of us learning that they had harvested those and sent them on to a grain elevator. And that allowed us to stop them before they had a chance to move.

Mr. KUCINICH. What were those pharmaceutical crops? Do you remember what were they? What were they growing?

Ms. SMITH. I will have to get that back to you. I don't remember now what the were.

Mr. KUCINICH. I would like to see that.

Ms. SMITH. OK.

Mr. KUCINICH. And how many instances do requests to—hold on—how many times do you end up reviewing pharmaceutical crop issues? Does that happen frequently? Is this like more of a concern of APHIS now? Are you getting more and more pharmaceutical crop inquiries and you have to do more testing? What is happening with that?

Ms. SMITH. Actually, we could get you the numbers, but what happened as a result of this particular event, this technology was moving forward at a—it was really getting started in terms of moving forward, this technology of using plants to develop pharmaceutical or industrial proteins. As a result of the problem that was associated with this company, and I think as part of the very serious action that we took, this company actually eventually went out of business. And that gave, I think, a very clear message to the industry that this technology needed to be addressed very carefully. In addition, the requirements that we have put in place have slowed the technology as well, because—and what we have talked about with the technology providers is, this is not just your average biotech; this is very different. We need to have extreme isolations, very stringent, extreme measures in place, and they need to approach this very differently, even to the point of what kinds of farmers they offer to grow these kind of crops.

Mr. KUCINICH. I am glad to hear that you are trying to keep apace of this very specific technology. And what the subcommittee is going to do is to be working with your staff so that we can be able to determine who is applying for the permission to grow what kind of pharmaceutical crops, where they are being grown, what kind of permission, when the permission was granted, and looking at any studies that may exist of any complaints that may have come from farmers, you know, a distance to see if it is possible that—to see if the isolation has kept the crop intact.

Ms. SMITH. Sure.

Mr. KUCINICH. Because, you know, we are talking about pollination by insects, by wind, whatever. I just want you to know we are going to move toward that a little bit more. I want to thank you for your testimony. Mr. Issa has questions that he is submitting for the record. The subcommittee will give to you some follow-up questions. And we will be in touch on this. I want to thank you, Ms. Smith, for the forthcoming nature of your presentation. It is refreshing and much appreciated. So we will continue this dialog with your agency. And I want to thank all the members of your staff, Mr. Gregoire, for their presence here. We will continue our interest in this.

And at this point, this committee stands adjourned.
Ms. SMITH. Thank you, sir.
[The information referred to follows:]

United States Department of Agriculture
Agricultural Research Service

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31 May 2005

MEMORANDUM

TO: USDA/APHIS/Regulatory Analysis and Development

FROM: D. Marshall, Research Leader, USDA/ARS/Plant Science Research Unit

SUBJECT: Docket No. 05-006-2 (Ventria Bioscience – GE Rice)

Each year, the USDA Agricultural Research Service conducts a Rice Quarantine Nursery on the Tidewater Research Station of NCDA & CS, located five miles east of Plymouth, NC. The purpose of this nursery is to introduce new and potentially useful germplasm lines of rice from foreign sources into the USDA/ARS National Plant Germplasm System. The goal is to identify useful traits in the introduced germplasm, then to allow rice breeders and geneticists to access the germplasm for introgression of the useful traits into commercial U.S. rice cultivars, thereby improving the U.S. rice crop and diversifying the genetic base of the crop as to minimize genetic vulnerability.

This nursery is overseen by the Rice Crop Germplasm Committee (CGC), which has members from public (Federal and State) and private rice research programs. Because of the potential for introduced germplasm to contain seedborne pathogens, which could potentially become invasive, all of the introductions are rigorously screened in ARS lab facilities in Raleigh, NC prior to going to the field. Each seed is treated in hot water at 56^0C for 15 minutes, dried, dehulled, treated for 2 hr in 10% bleach, placed in sterile tubes on agar, and grown for approximately 14 days. Any seeds or seedlings showing any disease symptoms are destroyed immediately. Those that are without symptoms are transplanted to the field in Plymouth, NC. (USDA/APHIS/PPQ Departmental Permit No. 63254).

The Rice CGC chose the Plymouth, NC location because it is located approximately 650 miles east of any commercially-produced rice crop. This spatial separation, combined with the prevalent west-to-east movement of weather systems, helps to minimize any potential spread of introduced pathogens into the commercial rice crop.

I have two concerns with the growing of rice on a large scale in the Plymouth, NC vicinity, as stated in the "USDA/APHIS Environmental Assessment: In response to permit applications (04-302-01r and 05-117-01r) received from Ventria Bioscience for field-testing of rice, *Oryza sativa*, genetically engineered to express human lactoferrin". My first concern is with the possible introduction of plant pathogens into the Plymouth, NC vicinity. Should pathogens be introduced on or in the seed brought in by the Ventria Bioscience project, there is the possibility of the

pathogenic microorganisms to survive in or on the soil, on plant debris, or on weeds, and thus possibly becoming established. There is also the possibility of the pathogens to spread to the Quarantine Nursery germplasm. Disease found in the Quarantine Nursery is reason for immediate disposal (via autoclaving) of infected plants. Should this occur, this germplasm would be unavailable to rice breeders and geneticists for improving the U.S. rice crop. As a member of the National Academy of Sciences Committee on Predicting Invasions of Nonindigenous Plants and Plant Pests, I am aware of the potential that small amounts of initial inoculum of pathogenic microorganisms can have on the eventual establishment of new diseases in U.S. crops. I do not believe the Environmental Assessment Report addresses this issue.

My second concern is with the potential movement of pollen out of the Ventria Bioscience rice crop and into the germplasm of the Rice Quarantine Nursery. Although the possibility is quite small, the potential exists for stray rice pollen to be carried via air currents from the Ventria Bioscience fields to the Nursery and pollinating the introduced germplasm. If this were to occur, genes from the rice expressing human lactoferrin could be introduced into the rice germplasm of the National Plant Germplasm System, and thus be disseminated throughout the U.S. This second concern is less likely to occur than my first concern of pathogen introduction and spread. The Environmental Assessment Report addresses the issue of gene flow. Nevertheless, the close proximity of the farm site proposed by Ventria Bioscience to the Tidewater Research Station is cause for concern. The National Plant Germplasm System has been a reliable source for new genes to be introduced into the U.S. rice crop. Rice breeders and geneticists need to be assured that the germplasm they are accessing from the system is true to type and does not contain unwanted genetic material.

[Whereupon, at 5:12 p.m., the subcommittee was adjourned.]
[Additional information submitted for the hearing record follows:]

Submitted for the Record Only
Monday, March 20, 2008
By
Congressman Darrell Issa
On Behalf of
The Biotechnology Industry organization (BIO)

Domestic Policy Subcommittee
Oversight and Government Reform Committee

"Is USDA Accounting for Costs to Farmers Caused by Contamination from Genetically Engineered Plants?"

2247 Rayburn HOB

2:00 P. M.

Thursday, March 13th, 2008

Chairman Kucinich, Ranking Member Issa, and Members of the Committee:

Thank you for allowing us the chance to submit the points below regarding the U.S. Department of Agriculture's role in the regulation of Genetically Engineered (GE) plants.

USDA/APHIS' mandate under the Plant Protection Act is to regulate genetically engineered organisms to protect U.S. agriculture and the environment when these organisms are field tested or grown commercially in the United States. APHIS ' regulatory decisions regarding the field testing and deregulation of biotech-derived crops are subject to the requirements of the National Environmental Policy Act (NEPA).

For each regulatory decision, APHIS must determine if that decision could result in significant environmental impacts and how to analyze the nature of those impacts. The agency will prepare an Environmental Impact Statement (EIS) when the agency determines that significant environmental impacts may occur. If the agency does not know whether significant environmental impacts may occur, the agency prepares an Environmental Assessment (EA). If APHIS, or any agency, determines through an EA that significant environmental impacts may occur, NEPA requires the agency to prepare an EIS before the government action may take place.

Due to the extremely low likelihood of causing significant environmental impacts, some governmental actions may be excluded as a category from the need to prepare an EA or EIS. For APHIS, all confined field trials of GE organisms are "categorically excluded" from the requirement to prepare an EA or EIS. However, APHIS will prepare an EA for those few field trials that raise new issues for the agency or that may have the potential to cause significant environmental impacts. APHIS also prepares an EA for every decision to deregulate a biotech-derived crop and approve its commercial use.

NEPA analyses focus on the natural and physical environment and the relationship of people with the environment. As a consequence, purely economic or social effects are not meant to be discussed in EAs and EISs, nor can purely economic or social impacts, resulting from a government action, trigger NEPA requirements. However, where environmental effects are "interrelated" with economic and social impacts, the agency must include an analysis of those economic and social impacts in the EA or EIS.

The agency determines when such a relationship exists between environmental effects and economic and social effects, and each decision is largely dependant on the facts in each individual case.

In the case of the deregulation of Roundup Ready alfalfa, APHIS determined that certain economic and social effects could occur as a result of deregulation; however the agency decided that these effects were not interrelated with environmental effects and prepared an EA prior to its decision to deregulate. When this decision was challenged in court, the judge felt that an identifiable environmental effect, namely pollen flow from Roundup Ready alfalfa plants to conventional and organic alfalfa plants, could result in economic impacts. The judge then concluded that APHIS must prepare an EIS to describe and analyze these interrelated impacts. APHIS began the preparation of this EIS in 2007.

BIO represents more than 1,180 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.