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FORUM TO REVIEW THE BIOTECHNOLOGY PRODUCT REGULATORY APPROVAL PROCESS

A FORUM
before the
COMMITTEE ON AGRICULTURE
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ONE HUNDRED TWELFTH CONGRESS
FIRST SESSION

JANUARY 20, 2011

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CONTENTS

FORUM TO REVIEW THE BIOTECHNOLOGY PRODUCT REGULATORY APPROVAL PROCESS

THURSDAY, JANUARY 20, 2011

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

The Committee met, pursuant to call, at 10:05 a.m., in Room 1300, Longworth House Office Building, Hon. Frank D. Lucas [Chairman of the Committee] presiding.

Members present: Representatives Lucas, Goodlatte, Johnson, King, Neugebauer, Conaway, Fortenberry, Schmidt, Thompson, Rooney, Stutzman, Gibbs, Fincher, Southerland, Crawford, Roby, Huelskamp, Ellmers, Hultgren, Schilling, Peterson, Boswell, Cardoza, David Scott of Georgia, Walz, Schrader, Pingree, and Courtney.

Staff present: Nicole Scott, Patricia Barr, John Goldberg, Debbie Smith, Tamara Hinton, Scott Kuschmider, Clark Ogilvie, Keith Jones, and Jamie Mitchell.

OPENING STATEMENT OF HON. FRANK D. LUCAS, A REPRESENTATIVE IN CONGRESS FROM OKLAHOMA

The CHAIRMAN. This forum of the Committee on Agriculture to review the biotechnology product regulatory approval process will come to order.

First let me welcome all of our returning Members and what is almost an unprecedented number of new Members to the House Agriculture Committee. In the coming days we will have our first business meeting to formally organize the Committee. I expect a very busy schedule over the next year as we work together on behalf of America's farmers, ranchers and agricultural interest.

And I would like to welcome Secretary of Agriculture Tom Vilsack and former Deputy Secretary of Agriculture Chuck Conner. We appreciate your participation in today's public forum and for assisting the Committee in its oversight responsibilities.

Agricultural biotechnology is important to the future of American agriculture. Both of our panelists have a long history of work in support of this issue. In fact, Secretary Vilsack in his previous capacity as Governor of Iowa was recognized by the biotech industry for his efforts. I point to the Secretary's support of biotechnology because while we may disagree on some of the regulatory alternatives under consideration, I am certain the Secretary is committed to the advancement and the availability of biotech products.

We can all agree that the science has consistently demonstrated agricultural biotechnology safety and that those products have enormous benefits. The regulatory approval process for agricultural biotechnology products has run into increasingly troublesome delays.

USDA statutory authority to regulate plant-based products of agricultural biotechnology derives from the Plant Protection Act, the Act is a pure science statute. Under the Act all plant products are subject to regulatory review by USDA' Animal and Plant Health Inspection Service, APHIS. APHIS's authority is to determine if any new product is a plant pest. If the product is found not to be a plant pest, USDA then deregulates it. USDA must base its decisions on quantifiable plant pest risk.

In addition to the APHIS determination, the Food and Drug Administration reviews the safety of food and feed from biotech plants, and the Environmental Protection Agency reviews pesticidal ingredients of biotech plants. This coordinated framework has been required since 1992.

Lately, despite repeated conclusions that individual applications of biotechnology do not pose plant pest risk, activist organizations have successfully sued USDA under the National Environmental Policy Act, NEPA, in a review process that confers no statutory authority to regulate. Regulatory authority as mentioned above derives from the Plant Protection Act, and that Act does not authorize regulation on the basis of rhetorical concerns advanced by activist groups. Unfortunately, we now have a growing list of products that have been held up by the factors the agency has no authority to address.

Herbicide tolerance in alfalfa has been subjected to an extensive multiyear review. It began in the summer of 2005 when USDA found that Roundup Ready® alfalfa had no significant environmental impacts and deregulated it. Following the lawsuit filed in the summer 2006, a judge in the 9th Circuit Court revoked USDA's deregulation decision pending completion of an Environmental Impact Study. The USDA told the court it could accomplish this EIS in 24 months, but 47 months later USDA has now published a final EIS wherein the agency has reached the same conclusion it did 5 years previously.

This should be the end of the debate. A product that has been repeatedly found to be safe should be deregulated. Unfortunately, we now have a new problem. Since USDA has determined that there is no plant pest risk, the only option under the statute is full deregulation, but USDA is considering two additional options. One would have USDA retain full regulatory authority. The Secretary has acknowledged that this is not preferred.

The third option would be to only partially deregulate the product. We are concerned that Option 3 would have a negative impact on all U.S. agriculture. Concerns have been raised that this option was developed to prevent future lawsuits by addressing coexistence between conventional and organic production. That is a political objective and is outside of the scope of the legal authority. I believe USDA has the authority to make its own decisions. I also believe that the recent Supreme Court case on alfalfa came to this very same conclusion. For example, when the courts have arbitrarily in-

tervened and the rulings would have resulted in disastrous economic consequences, USDA has acted. In this regard, because this is still in litigation, we understand that APHIS may be authorized to partially deregulate sugarbeets pending completion of a final EIS.

Beyond that I support farmer's choice. Farmers of most major commodities are choosing to grow biotech crops *versus* non-biotech or organic. More than 90 percent of corn, soybeans, cotton, sugarbeets, alfalfa are biotech crops. All farmers should have the ability to choose their cropping systems.

With regard to organic agriculture, I recognize the tremendous marketing potential and that consumer demand is increasing for those products. However, as we seek to find solutions to the challenges of identity preservation, I cannot support strategies that pit producer against producer. I agree with the Secretary's public statements about grower choice, which is why it is troubling that USDA seems inclined to pursue a path that limits grower choice.

It is important to note that nowhere in the Organic Foods Production Act has Congress limited access to organic producers to the advantages of agricultural biotechnology. It was only after intense lobbying by the organic industry that the proposed organic standards regulations were modified to include restrictions. Organic producers with full knowledge of the compliance cost associated with the standards chose to impose the standards on themselves. The National Organic Standards Marketing Program, approved by USDA, imposes very strict standards on those who choose to grow crops that will be certified organic and carry the USDA organic certified label. We all agree that the label carries with it marketing benefits, costs, and responsibilities. I am sensitive to the difficulties organic producers face, but I cannot support proposals that shift the financial burden from those who chose to produce organic to those producers who chose a different cropping system.

Mr. Secretary, once again I thank you for your time today. I expect you will be spending a bit of time with us in this Committee in the coming months, and it is my hope that we can all work together to find solutions to the challenges rural America faces.

[The prepared statement of Mr. Lucas follows:]

PREPARED STATEMENT OF HON. FRANK D. LUCAS, A REPRESENTATIVE IN CONGRESS FROM OKLAHOMA

Let me first welcome all of our returning Members and what is an almost unprecedented number of new Members to the House Agriculture Committee. In the coming days, we will have our first business meeting to formally organize the Committee. I expect a very busy schedule over the next year as we work together on behalf of America's farmers, ranchers, and agricultural interests.

I would like to welcome Secretary of Agriculture Tom Vilsack and former Deputy Secretary of Agriculture Chuck Connor. We appreciate your participation in today's public forum and for assisting the Committee in its oversight responsibilities.

Agricultural biotechnology is important to the future of American agriculture. Both of our panelists have a long history of work in support of this issue. In fact, Secretary Vilsack, in his previous capacity as Governor of Iowa, was recognized by the biotech industry for his efforts.

I point to the Secretary's support of biotechnology because while we may disagree on some of the regulatory alternatives under consideration, I am certain the Secretary is committed to the advancement and availability of biotech products. We can all agree that the science has consistently demonstrated agricultural biotechnology's safety and that those products have enormous benefits.

The regulatory approval process for agricultural biotechnology products has run into increasingly troublesome delays. USDA's statutory authority to regulate plant based products of agricultural biotechnology derives from the Plant Protection Act. The Act is a pure science statute.

Under the Act, all plant products are subject to regulatory review by USDA's Animal and Plant Health Inspection Service (APHIS). APHIS's authority is to determine if any new product is a plant pest. If the product is found to not be a plant pest, USDA then deregulates it. USDA must base its decisions on quantifiable plant pest risk.

In addition to the APHIS determination, the Food and Drug Administration reviews the safety of food and feed from biotech plants and the Environmental Protection Agency reviews pesticidal ingredients of biotech plants. This coordinated framework has been required since 1992. Lately, despite repeated conclusions that individual applications of biotechnology do not pose plant pest risks, activist organizations have successfully sued USDA under the National Environmental Policy Act (NEPA). NEPA is a review process that confers no statutory authority to regulate. Regulatory authority, as mentioned above, derives from the Plant Protection Act and that Act does not authorize regulation on the basis of rhetorical concerns advanced by activist groups. Unfortunately, we now have a growing list of products being held up by factors the agency has no authority to address.

Herbicide tolerance to alfalfa has been subjected to an extensive multi-year review. It began in the summer of 2005 when USDA found that Roundup Ready® alfalfa had no significant environmental impacts and deregulated it. Following a lawsuit filed in the summer of 2006, a Judge in the 9th Circuit Court revoked USDA's deregulation decision pending completion of an Environmental Impact Statement (EIS). USDA told the court it would complete the EIS in 24 months. But, 47 months later, USDA has now published a final EIS wherein the agency has reached the same conclusion it did 5 years previously.

This should be the end of the debate. A product that has been repeatedly found to be safe should be deregulated.

Unfortunately, we now have a new problem.

Since USDA has determined that there is no plant pest risk, the only option under the statute is full deregulation. But, USDA is considering two additional options. One would have USDA retain full regulatory control. The Secretary has acknowledged this is not preferred. The third option would only partially deregulate the product.

We are concerned Option 3 would have negative impacts on all U.S. agriculture. Concerns have been raised that this option was developed to prevent future lawsuits by addressing coexistence between conventional and organic production. That is a political objective and is outside the scope of legal authority.

I believe USDA has authority to make interim decisions. I also believe the recent Supreme Court case on alfalfa came to this same conclusion. For example, when courts have arbitrarily intervened and their rulings would have resulted in disastrous economic consequences, USDA has acted. In this regard, because this is still in litigation, we understand that APHIS may be authorized to partially deregulate sugarbeets pending completion of a final EIS.

Beyond that, I support farmer's choice. Farmers of most major commodities are choosing to grow biotech crops *versus* non-biotech or organic. More than 90 percent of corn, soybeans, cotton, sugarbeet, and alfalfa are biotech crops. All farmers should have the ability to choose their cropping system.

With regard to organic agriculture, I recognize the tremendous marketing potential and that consumer demand is increasing for these products. However, as we seek to find solutions to the challenges of identity preservation, I cannot support strategies that pit producer against producer. I agree with the Secretary's public statements about grower choice, which is why it's troubling that USDA seems inclined to pursue a path that limits grower choice.

It is important to note that nowhere in the Organic Foods Production Act has Congress limited access for organic producers to the advantages of agricultural biotechnology. It was only after intense lobbying by the organic industry that the proposed organic standards regulations were modified to include restrictions.

Organic producers, with full knowledge of the compliance costs associated with the standard, chose to impose these standards on themselves. The National Organic Standards (NOS) marketing program, approved by USDA, imposes very strict standards on those who choose to grow crops that will be certified "organic" and carry the USDA organic-certified label. We all agree the label carries with it market benefits, costs, and responsibilities.

I am sensitive to the difficulties organic producers face, but I cannot support proposals that shift the financial burden from those who choose to produce organic to other producers who choose a different cropping system.

Mr. Secretary, once again I thank you for your time today. I expect you will be spending a bit of time with this Committee in the coming months. It is my hope that we can all work together to find solutions to the challenges rural America faces. I now yield to our Ranking Member, Representative Peterson for any comments he would like to make.

The CHAIRMAN. I now yield to Ranking Member Peterson for any comments that he would like to make. Mr. Ranking Member.

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

Mr. PETERSON. Thank you, Mr. Chairman. And first of all, I want to congratulate you on taking over the chairmanship of the Committee and we wish you well, and we are going to do our part to help you be successful and make this Committee work.

We also want to welcome the returning Members and the new Members of the Committee. You will find that this is one of the few bipartisan committees in the Congress and it does not happen by accident. It takes a lot of work and we work at it very hard to make sure that we listen to each other and understand each other, and I think we come up with better solutions because of it.

So I look forward to working with all of you, and I want to welcome the Secretary to the Committee and Mr. Conner. I recognize the Committee is not formally organized and we are jumping into a complex topic, but this Department has some decisions to make so I think today's discussion is appropriate.

As many people know, USDA's release of the final EIS on Roundup Ready® alfalfa on December 16th lays out two options, including a partial deregulation, so-called Option 3. It is worth noting that the recently completed EIS on alfalfa is one step in a drawn out process that has taken decisions about alfalfa production largely out of the hands of the agriculture community and moved them into the courtroom, litigated by lawyers and decided by judges who have no connection to agriculture and in a lot of cases no understanding of agriculture, which concerns me.

I understand the concerns of those who think that restrictions listed under Option 3 could have a negative long-term consequences for biotech product development and approval. It is a highly unusual step that arguably creates more questions than answers with respect to the science-based regulatory process, trade policy with respect to biotechnology, and perhaps even the reexamination of previously approved biotech traits.

So I look forward to discussing those issues with the Secretary today. But I don't think we are completely looking at the big picture unless we recognize that endless litigation is a fact of life it appears under the current biotech approval process. And if the only answer to the alfalfa question is one that leads us right back into the courtroom, where USDA's track record in recent years is very poor, then I am not sure how that benefits biotechnology in the long run.

On the sugarbeet issue, in particular the folks that I have talked to have just about had it with these lawsuits that is causing big problems, big concerns for us in my part of the world and other

places where they produce sugarbeets. I have talked to the Secretary about this enough times to know that he has about had it with, too, with these lawsuits.

Along those lines, there has been a lot of discussion about the Secretary's efforts to bring stakeholders together to discuss agriculture's coexistence amongst those who understand agriculture rather than the courts. Now whether or not these folks can reach an agreement remains to be seen, and I do recognize that having these discussions while the Department is trying to reach a conclusion on the alfalfa issue is causing problems for a lot of people.

I also don't know if I share the Secretary's optimism because some folks apparently will use every tool possible to try to shut down biotech crops. But I really think he is genuinely looking for an answer that doesn't involve endless litigation.

You know, one of the issues that I would like to find out about today is the process whereby we got into this. How did the decision get made that we were going to just do an Environmental Assessment instead of an Environmental Impact Statement in the first place? You know, it appears that you gave our opponents ammunition by taking a shortcut. I don't know. And so I would be interested in finding out how that decision was made. What was the thought going into it, both on alfalfa and sugarbeets. You know, who was involved? Who weighed in? Just how was that whole process developed, because I think it is unfortunately unrealistic to think that we are going to be able to avoid this and it just appears that you are going to go have to do an EIS on these deals, and you might as well do it sooner rather than later, or we are going to just get back into this loop.

Some have expressed concerns about this partial deregulation, that it is beyond the scope of the Plant Protection Act. I think I share some concerns in that regard. It may be that we decide out of this process that there needs to be changes in that Act so that we can deal with this. I think that would be an appropriate discussion for this Committee to have.

So I look forward to hearing from the Secretary, hearing from former Deputy Secretary Conner, and I thank the Chairman for the time.

[The prepared statement of Mr. Peterson follows:]

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

Good morning. Thank you Chairman Lucas for holding today's forum and welcome, Secretary Vilsack and Mr. Conner, to the Committee. I recognize that the Committee has not formally organized and we are jumping into a complex topic, but the Department has some decisions to make very soon and I welcome today's discussion.

As many people know, USDA's release of the final Environmental Impact Statement on Roundup Ready® alfalfa on December 16 lays out two options, including a partial deregulation option, the so-called Option 3.

It is worth noting that the recently completed EIS on alfalfa is one step in a drawn out process that has taken decisions about alfalfa production largely out of the hands of the agriculture community and moved them into the courtroom, litigated by lawyers and decided by judges who have no connection to agriculture.

I understand the concerns of those who think the restrictions listed under Option 3 could have negative long-term consequences for biotech product development and approval. It is a highly unusual step that arguably creates more questions than answers with respect to the science-based regulatory process, our trade policy with re-

spect to biotechnology, and perhaps even the re-examination of previously approved biotech traits. I look forward to discussing those issues with the Secretary today.

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On the sugarbeet issue in particular, the folks I have talked to have just about had it with these lawsuits. And I have talked to the Secretary enough times to know that he has about had it, too.

Along those lines, there has been a lot of discussion about the Secretary's efforts to bring stakeholders together to discuss agricultural coexistence among those that understand agriculture rather than the courts.

Now whether or not these folks can reach an agreement remains to be seen, and I do recognize that having these discussions while the Department is trying to reach a conclusion on the alfalfa issue is causing problems for a lot of people. I also don't know if I share the Secretary's optimism because some folks will use every tool possible to try and shut down biotech crops. But I think that he is genuinely looking for an answer that doesn't involve endless litigation.

Some have expressed concerns that a partial deregulation is beyond the scope of the Plant Protection Act. I look forward to hearing from the Secretary on this particular question today.

Again, I thank the Chairman for calling today's forum and look forward to hearing from our panelists.

The CHAIRMAN. And the chair thanks the Ranking Member and would note that the chair would request other Members to submit their opening statements for the record so that the forum participants may begin their statements to ensure that there is ample time for questions. And with that we would like to welcome our first panelist to the table, the Honorable Tom Vilsack, the Secretary of the United States Department of Agriculture here in Washington, D.C. Mr. Secretary, thank you for coming.

STATEMENT OF HON. THOMAS J. VILSACK, SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Secretary VILSACK. Thank you, Mr. Chairman, and thank you, Representative Peterson and Members of this Committee, for the opportunity to appear before you today to discuss a very important topic to American agriculture, the complex issues surrounding biotechnology and USDA's role in regulating it.

Today's meeting considers a topic that is critically important to U.S. agriculture. Over the last 2 decades we have experienced rapid development and widespread adoption by producers of new technologies like biotechnology. Biotechnology has already delivered significant benefits to farmers and consumers, and it holds tremendous promise for agriculture here in the United States, and I might say around the world.

Over the past 20 years, due to improved plant breeding practices in biotechnology, yields have increased and new varieties have been developed that will resist pests and drought, and reduce the amount of water and fertilizer needed to raise a crop. Recognizing the benefits of these products today, more farmers are planting biotech varieties of crops.

We believe at USDA that biotechnology stands to play a significant role in our effort to support our drive towards energy independence, conserve our natural resources and meet the world's growing demand for food, feed, fiber and fuel.

At the same time there has also been strong growth in the organic sector and in non-genetically engineered production, all to meet the requirements of specific and expanding markets.

The growth of these markets is great for U.S. agriculture. It means farmers, ranchers, and growers have a range of ways to meet consumer needs and preferences both here and around the world. It means they can grow their operations in the best way for their operation while contributing to the success and vitality of rural America.

The growth and promise of biotechnology, the fact that it can provide critical assistance in meeting domestic and global challenges, including food security and climate change, is due in large part to the innovative culture of American agriculture.

I need to state clearly and emphatically, I have no doubt about the safety of the products our regulatory system at USDA has approved over the last 2+ decades and that we will continue to approve in the weeks, months, and years ahead.

The rapid adoption of GE crops has coincided with the rapid expansion of demand for organic and non-GE products, resulting in real practical difficulties for some non-GE producers to meet the needs of their markets. These conflicts have produced ongoing litigation and resulted in uncertainty for producers and technology innovators.

We are at a critical juncture and a crucial juncture in American agriculture where the issues causing the litigation and uncertainty must be addressed so that the potential contributions of all sectors of agriculture can be fully realized.

As part of USDA's efforts to expand U.S. agriculture, we must ensure that our regulatory oversight is timely, consistent, effective, and grounded in sound science. We must ensure that we keep pace with the latest scientific developments and do so transparently. The Plant Protection Act gives the Secretary of Agriculture, through the Animal and Plant Health Inspection Service, the authority to prohibit or restrict the importation, exportation, and the interstate movement of plants, plant products, certain biological control items, noxious weeds, and plant pests. It is under these authorities that APHIS regulates the importation, interstate movement, and safe field testing of GE products.

In regulating biotechnology products, APHIS works closely with the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency as part of the Coordinated Framework for Regulation of Biotechnology. The three agencies work together to ensure that development, testing and use of biotechnology products occurs in a manner that is safe for plants and animal health, human health and the environment.

USDA's biotechnology program has been in place since 1986, and APHIS has developed a framework for regulating biotechnology that is rigorous and based on sound science. Since the program began APHIS has overseen the adoption of numerous biotechnology products, with 26,000 field trials grown under our notification procedures and 3,000 field trials conducted under our permitting process, which encompasses field trials at 86,000 different locations. In addition, we have deregulated over 75 products.

It is not a static program. To farmers, ranchers, and growers it is one that has grown and evolved as technology, often driven by the needs and demands of producers, has changed. As we move forward we must be cognizant of the needs of all producers in all types of production.

We are at a crossroads with the Department's ability to handle the demands of the industry and producers. The length of time it takes APHIS to complete the petition process has increased dramatically, and we are engaged in a process improvement program to reduce the amount of time. However, the combination of increased number and the complexity of the petitions combined with time consuming litigation has really slowed us down. I fear that if we don't address these issues comprehensively, innovation will be discouraged, not encouraged.

The procedural and legal challenges related to GE sugarbeets and GE alfalfa have taken years. APHIS made its initial decision, as the Chairman indicated, to deregulate GE alfalfa in June of 2005. Yet here we are nearly 6 years later with the process not yet concluded. GE sugarbeets were granted non-regulated status in March of 2005, and the case is still in litigation in Federal court. As these cases continue the market uncertainty increases and those involved in agriculture lack sufficient guidance for planning and determining how to react or which products to use.

The situation needs to be resolved. The legal challenges and the resulting effects have created uncertainty for all growers. Growers need to be able to order seed, to make planting decisions, but have difficulty when the legal challenges cause so much uncertainty. There are companies and researchers who have devoted significant resources to developing safe products that can help us meet our food security needs that find themselves fighting in court awaiting to see how a judge's decision in a separate case will affect theirs.

I strongly believe that these decisions regarding these critical issues should not be decided solely by the courts. Litigation creates uncertainty and often results in winners and losers. To help minimize that uncertainty, as well as other impacts in the cost of litigation, we are committed at USDA to seeking solutions that will end or limit litigation and thereby benefit agriculture as a whole.

On December 16, 2010, the USDA released its final Environmental Impact Statement, EIS, on the potential environmental effects of granting genetically engineered alfalfa non-regulated status. This is the line of alfalfa that has been genetically engineered to be resistant to the herbicide commonly known as Roundup.

The EIS provides an exceptionally comprehensive evaluation and analysis of the potential environmental impact of granting or denying the petition for non-regulated status. In addition to the draft EIS's two alternatives of either granting or denying non-regulated status, the final EIS examined a third alternative that was included in response to ideas presented during the comment period. This third alternative looks at the impacts of establishing geographic restrictions and isolation distances for GE alfalfa's production, and it mirrors a healthy and productive conversation between GE, non-GE and organic interest that is already underway in the industry and continues to evolve. Every interest engaged in the conversation shares the goal of protecting the right of every pro-

ducer to grow on their land what they believe and decide is best. Every interest engaged in this conversation, to my knowledge, recognizes the fundamental property right interest inherent in this discussion, and I believe that many participants have found the discussion important and beneficial.

Now some have questioned the need for this discussion, and have suggested that USDA is moving away from a science-based, rules-based decision making process. I want to reassure everyone on the Committee that USDA will continue to adhere to a scientific risk-based decision-making process and that our decisions will continue to be driven by science.

I look forward to our discussion here and I hope you share my belief that farmers, ranchers, and growers are in the best position to decide what is best for their operation.

Again, I would like to thank the Chairman and the Committee for the opportunity to appear before you this morning. I look forward to trying to answer as many questions as I can.

[The prepared statement of Mr. Vilsack follows:]

PREPARED STATEMENT OF HON. THOMAS J. VILSACK, SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Chairman Lucas, thank you and thank you to Representative Peterson and Members of the Committee for the opportunity to appear before you today to discuss an important topic to American agriculture—the complex issues surrounding biotechnology and USDA's role in regulating it.

Today's meeting considers a topic that is critically important to U.S. agriculture. Over the last 2 decades, we have experienced the rapid development, and the widespread adoption by producers, of new technologies like biotechnology. Biotechnology has already delivered significant benefits to farmers and consumers and it holds tremendous promise for agriculture here in the United States, and around the world. Over the past twenty years, due to improved plant breeding practices and biotechnology, yields have increased and new varieties are being developed that will resist pests and drought, and reduce the amount of water and fertilizer needed to raise a crop. Recognizing the benefits of these products, today, more farmers are planting biotech varieties of crops. We believe that biotechnology stands to play a significant role in our effort to support our drive toward energy independence, conserve our natural resources, and meet the world's growing demand for food, feed, fiber, and fuel.

At the same time, there has also been strong growth in the organic sector, and in non-genetically engineered production, all to meet the requirements of specific and expanding markets.

The growth of all these sectors is great for U.S. agriculture. It means farmers, ranchers, and growers have a range of ways to meet consumer needs and preferences both here and around the world. It means they can grow their operations in the way best for their operation while contributing to the success and vitality of rural America.

The growth and promise of biotechnology—the fact that it can provide a critical assist in meeting domestic and global challenges, including food security and climate change—is due in large part to the innovative culture of American agriculture. I need to state clearly and emphatically—I have no doubt about the safety of the products our regulatory system at USDA has approved over the last 2+ decades and that it will continue to approve in the months and years ahead.

The rapid adoption of GE crops has coincided with the rapid expansion of demand for organic and other non-GE products, resulting in real, practical difficulties for some non-GE producers to meet the need of their markets. These conflicts have produced ongoing litigation and resulted in uncertainty for producers and technology innovators. We are at a crucial juncture in American agriculture where the issues causing the litigation and uncertainty must be addressed, so that the potential contributions of all sectors of agriculture can be fully realized.

USDA's Biotechnology Regulatory Program

As part of USDA's efforts to expand U.S. agriculture, we must ensure that our regulatory oversight is timely, consistent, effective, and grounded in sound science. We must ensure that we keep pace with the latest scientific developments, and that we do so transparently. The Plant Protection Act gives the Secretary of Agriculture, and through delegated authority the Animal and Plant Health Inspection Service (APHIS), the ability to prohibit or restrict the importation, exportation, and the interstate movement of plants, plant products, certain biological control organisms, noxious weeds, and plant pests. It is under these authorities that APHIS regulate the importation, interstate movement, and safe field testing of GE organisms. In regulating biotechnology products, APHIS works closely with the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency, as part of the Coordinated Framework for Regulation of Biotechnology. The three agencies work together to ensure the development, testing, and use of biotechnology products occurs in a manner that is safe for plant and animal health, human health, and the environment.

USDA's biotechnology program has been in place since 1986, and APHIS has developed a framework for regulating biotechnology that is rigorous and based on sound science. Since the program began, APHIS has overseen the safe adoption of numerous biotechnology products, with 26,000 field trials grown under our notification procedures and 3,000 field tests conducted under our permitting process, which encompasses field trials at 86,000 different locations. In addition, we have deregulated over 75 products.

It is not a static program. To farmers, ranchers, and growers, it is one that has grown and evolved as technology—often driven by the needs and demands of producers—has changed. As we move forward, we must be cognizant of the needs of all producers and all types of production.

Challenges Facing the Biotechnology Review Process

We are also at a crossroads with the Department's ability to handle the demands of industry and producers. The length of time it takes APHIS to complete the petition process has increased dramatically, and we are engaged in a process improvement process to reduce the amount of time. However, the combination of an increased number and complexity of the petitions combined with the time consuming litigation has really slowed us down. I fear that if we don't address these issues comprehensively, innovation will be discouraged not encouraged.

The procedural legal challenges related to GE sugarbeets and GE alfalfa have taken years. APHIS made its initial decision to deregulate GE alfalfa in June 2005. Yet here we are nearly 6 years later with the process not yet concluded. GE sugarbeets were granted non-regulated status in March 2005, and the case is still in litigation in Federal court. As these cases continue, the market uncertainty increases, and those involved in agriculture lack sufficient guidance for planning and determining how to react or which products to use.

The situation needs to be resolved. The legal challenges, and the resulting effects, have created uncertainty for all growers. Growers need to order seed and make planting decisions, but have difficulty when the legal challenges cause so much uncertainty. There are companies and researchers who have devoted significant resources to developing safe products that can help us meet our food security needs, but find themselves fighting in the courts, or waiting to see how a judge's decision in a separate case will affect them.

I strongly believe that the decisions regarding these critical issues should not be decided solely by the courts. Litigation creates uncertainty and often results in winners and losers. To help minimize that uncertainty, as well as the other impacts and costs of litigation, USDA is committed to seeking solutions that will end or limit litigation and thereby benefit agriculture as a whole.

Roundup Ready Alfalfa

On December 16, 2010, the USDA released its final Environmental Impact Statement (EIS) on the potential environmental effects of granting genetically engineered alfalfa non-regulated status. This is the line of alfalfa that has been genetically engineered to be resistant to the herbicide commonly known as Roundup.

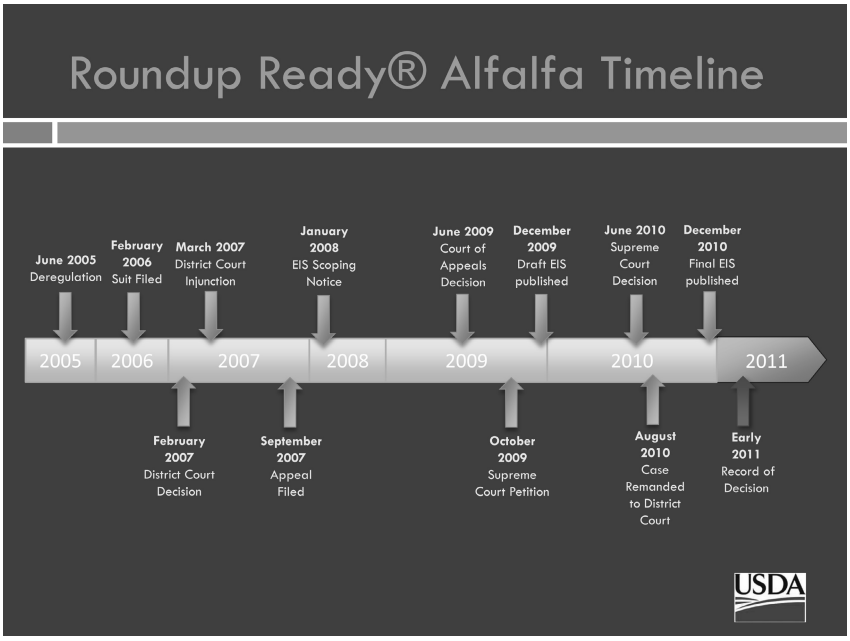
The EIS provides an exceptionally comprehensive evaluation and analysis of the potential environmental impacts of granting or denying the petition for non-regulated status. In addition to the draft EIS's two alternatives of either granting or denying non-regulated status, the final EIS examined a third alternative that was included in the response to ideas presented during the comment period. This third alternative analyzes the impacts of establishing geographic restrictions and isolation distances for GE alfalfa's production, and it mirrors a healthy and productive con-

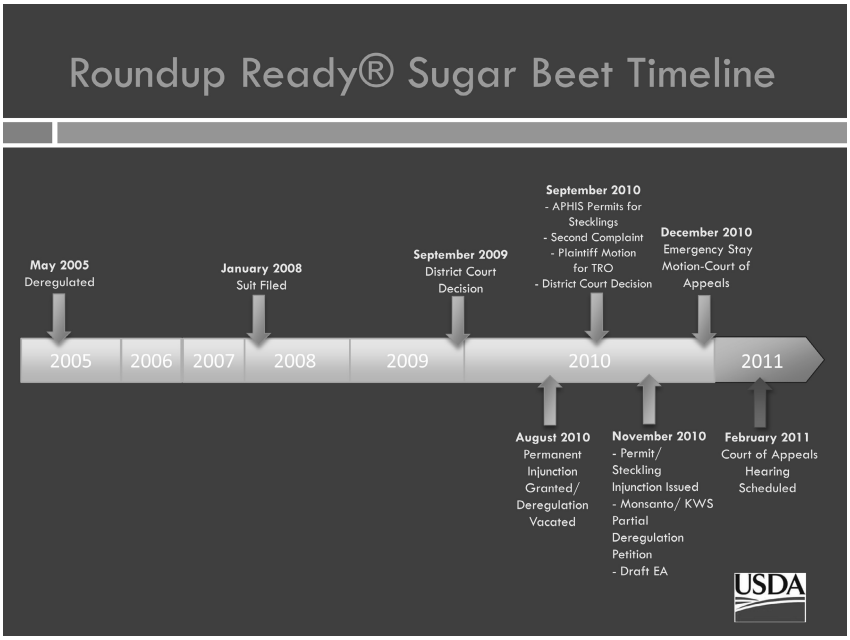
versation between GE, non-GE, and organic interests that is already underway in the industry and that continues to evolve. Every interest engaged in the conversation shares the goal of protecting the right of every producer to grow on their land what they believe and decide is best. And, I believe that many participants have found the discussion important and beneficial.

Some have questioned the need for this discussion and have suggested USDA is moving away from a science based, rules based decision making process. I want to reassure everyone that USDA will continue to adhere to a scientific, risk based decision making process and that our decisions will continue to be driven by science. I look forward to our discussion here and I hope you share my belief that farmers, ranchers, and growers are in the best position to decide what is best for their operations.

Again, I would like to thank the Committee for the opportunity to appear before you this morning and I look forward to answering any questions that you may have.

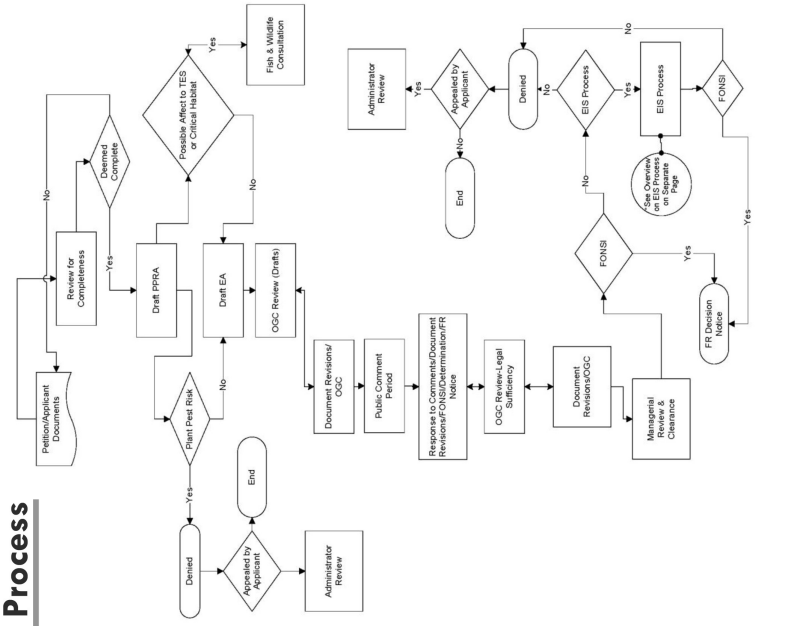
CHARTS


Roundup Ready® Alfalfa Timeline
June 2005 Deregulation
February 2006 Suit Filed
March 2007 District Court Injunction
January 2008 EIS Scoping Notice
June 2009 Court of Appeals Decision
December 2009 Draft EIS published
June 2010 Supreme Court Decision
December 2010 Final EIS published
2005
2006
2007
2008
2009
2010
2011
February 2007 District Court Decision
September 2007 Appeal Filed
October 2009 Supreme Court Petition
August 2010 Case Remanded to District Court
Early 2011 Record of Decision
USDA

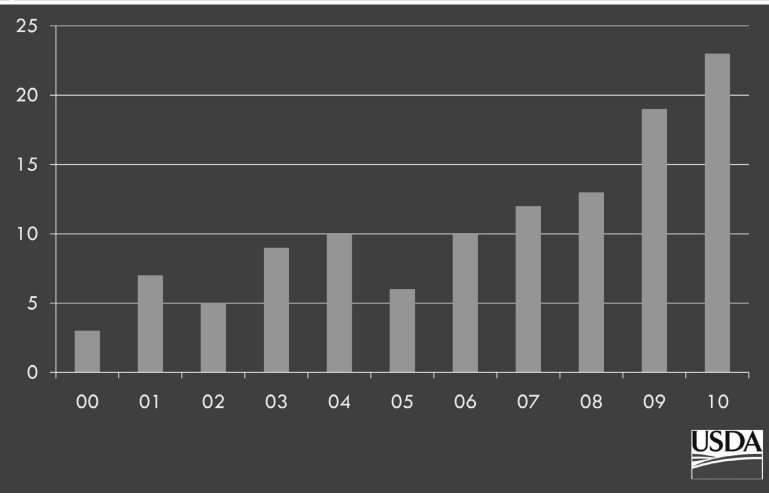

Roundup Ready® Sugar Beet Timeline
May 2005 Deregulated
January 2008 Suit Filed
September 2009 District Court Decision
September 2010 - APHIS Permits for Stecklings - Second Complaint - Plaintiff Motion for TRO - District Court Decision
December 2010 Emergency Stay Motion-Court of Appeals
2005
2006
2007
2008
2009
2010
2011
August 2010 Permanent Injunction Granted/ Deregulation Vacated
November 2010 - Permit/ Steckling Injunction Issued - Monsanto/ KWS Partial Deregulation Petition - Draft EA
February 2011 Court of Appeals Hearing Scheduled
USDA

USDA

BRS Petition Process



Number of pending petitions at end of each calendar year



Pending Petitions for Nonregulated Status

1. Syngenta rootworm resistant corn
2. Monsanto glyphosate hybridization system corn
3. Monsanto Dicamba Tolerant Soybean
4. Okanagan Specialty Fruits, non-browning apple
5. Virginia Tech disease resistant peanuts
6. Dow herbicide tolerant soybean
7. Bayer "Double HT" soybean
8. Dow AAD-1 herbicide tolerant corn
9. Monsanto modified-oil soybeans
10. Monsanto modified-oil soybeans
11. Monsanto insect resistant soybeans
12. Stine Seed Farm herbicide tolerant corn
13. Monsanto drought tolerant corn
14. BASF herbicide tolerant soybean
15. ArborGen cold-tolerant eucalyptus
16. Bayer "Liberty TwinLink" cotton
17. DuPont/Pioneer SPT corn
18. Florigene altered-color roses
19. Syngenta Cot67B Cotton
20. Syngenta alpha-amylase corn
21. Monsanto glyphosate tolerant alfalfa
22. Monsanto glyphosate tolerant sugar beet
23. Scotts/Monsanto glyphosate-tolerant creeping bentgrass

The CHAIRMAN. Thank you, Mr. Secretary. The chair would like to remind Members they will be recognized for questioning in the order of seniority for Members who were here at the start of the forum. After that Members will be recognized in the order of arrival. I will repeat that one more time. We will recognize you in the order of seniority if you were here at the beginning of this process and after that in your order of arrival. I appreciate the Members' understanding.

Mr. Secretary, before I get to the questions I would like to comment on the suggestion in your statement that there are some questioning the value of having a conversation of coexistence, and I want to clarify that concern that we are hearing that this is not a conversation that is taking place, but the concern is with the forum and the timing of those conversations. The USDA currently is engaged in a decision making process on a petition to deregulate a specific crop. What is of concern here is the report that this conversation started with a comment something to the effect of from USDA, and I think it is a pretty accurate quote, our preference is to have you all help us do it as best we can. But if that is not possible then we will do the best we can.

I would hope that you would recognize that at a time when you have a company waiting for a decision that could cost the industry millions of dollars, thousands of jobs, comments like that create more of an atmosphere of, well, less than cooperation, a sense of cooperation. I would hope that you and your entire staff would bear in mind that you have instructed your staff that this is not acceptable.

Equally important, and the focus of today's forum, is the question of whether the issues and options raised in the discussion of coexistence are political issues that fall outside your legal mandate to determine the safety of those products under and Plant Protection Act. On this issue I promise you a series of, I hope, relatively painless questions.

With that said, Mr. Secretary, how many biotech varieties have been fully deregulated by USDA; in other words, approved without any of the coexistence restrictions that are envisioned within the so-called Option 3 for partial regulation of alfalfa?

Secretary VILSACK. Mr. Chairman, I believe we have approved 75 products. I am not familiar with the conditions or circumstances of all of the approvals, but I think we have approved 75. There have been some that were withdrawn before we got to the approval process, but I think it is 75.

The CHAIRMAN. That is an impressive number, Mr. Secretary. How many of those varieties contain a similar glyphosate tolerance gene as that which has been incorporated into the Roundup Ready® alfalfa product under consideration?

Secretary VILSACK. I would have to ask, if I could, Mr. Chairman, Cindy Smith.

The CHAIRMAN. Of course.

Secretary VILSACK. We are going to guess, if that is all right, Mr. Chairman, roughly ten percent.

The CHAIRMAN. And is it correct that each review of the currently available Roundup Ready varieties of crop seed that USDA

has deregulated were determined by USDA to be substantially equivalent to their conventional counterparts?

Secretary VILSACK. I think that is a correct statement.

The CHAIRMAN. Is it correct that each review of the biotech alfalfa product conducted by USDA has concluded that the product is substantially equivalent to conventional alfalfa?

Secretary VILSACK. That is safe to say, Mr. Chairman.

The CHAIRMAN. I promise you I am not Perry Mason, but I do appreciate your answers. It appears to many observers—and I guess that dates me, doesn't it, referring to Perry Mason—it appears to many observers that—and that was a weak attempt at humor—that the partial deregulation option presented by USDA will have a much broader impact on all of U.S. agriculture, our international negotiations and further development of these important products. Please explain if you could, Mr. Secretary, your thinking on how a partial deregulation alternative would promote these mutually stated goals.

Secretary VILSACK. Mr. Chairman, this has been a long and torturous process that alfalfa has gone through. As you indicated, this started in 2005. Since then, courts have come in and have essentially directed us to perform a more extensive evaluation under an Environmental Impact Statement. And if I might take your question and just try to briefly address the Ranking Member's question. We are instructed under the NEPA process to consider two approaches. One is the Environmental Assessment, the other is the Environmental Impact Statement. We had prior to the last several years used the EA fairly successfully in moving this process forward to get to the 75 products that have been deregulated.

Recently there have been questions about the comprehensive nature of those assessments which have led courts to direct us to do more extensive reviews in the form of an Environmental Impact Statement. We have done that, and our belief is that the reason for the courts directing us to do that is that they believe that those Environmental Impact Statements ought to, "inform the process," going forward.

We produced an extensive EIS in connection with alfalfa, it is roughly 2,300 pages, and in it we identified a number of issues. When we put the draft EIS out for comment, we received a number of comments back, and in an effort to try to be responsive to those comments we took a look at various alternatives. We now have an opportunity for review of the final EIS and that in turn creates another opportunity for us to be informed as we end up making a decision. The review period has to occur for at least 30 days, and it is our intention to make a decision as close to the end of that 30 day period as possible, because we understand and appreciate that folks need to know what they can plant, what they can't plant, and we are on track to do that.

When we proposed the various alternatives, what happened is it created and generated a dialogue between differing interests, and I think that it has been a positive experience for those who have participated in that dialogue. Now why do I say that? Because I think it has allowed us to better understand the unique nature of alfalfa. It has better allowed us to understand the greater awareness of stewardship contracting that is taking place in the market.

It has allowed us to have questions raised about the process of verifying those stewardship contracts, and it has underscored the importance of trying to build more of a trusting relationship between various interests of agriculture, all of which are positive, and perhaps most positive of all is it has helped us at USDA begin to look at ways in which we can use tools outside of this process to help further create this sense of cooperation. So, for example, issues have been raised during this discussion about the purity of seed and whether or not there will be in fact an assurance that we will continue to have purity of seed so that anybody who wants to do organic, anyone who wants to do identity preserved non-GE will always have that option. We can play a role in that. So it has been an informative process.

The CHAIRMAN. Mr. Secretary, I ask one last question with the indulgence of my colleagues here. You have obviously been a biotech supporter for decades. Looking once again at this international negotiations issue, looking at the kind of efforts that this country and your Department have been a part of for decades, does it concern you that if ultimately the segregated concept is what the Department decides to do, does it worry you what that does to our decades of persuading our trading partners and our friends around the world that if you use sound science, if you follow established rules that these products are absolutely safe and this segregation business is not necessary, does that cause you personal angst?

Secretary VILSACK. It would cause me angst, Mr. Chairman, if the decision we made was not science-based and not rules-based, because that has been the consistent approach of this government for a considerable period of time and it is something that we have been critical of in other international forums.

Let me say in terms of my experience with biotechnology in other countries, we developed when I first came into office an overall strategy for how we might be better positioning biotechnology in the international community. That involves better public diplomacy, it involves better articulation of the benefits of biotechnology. It involves identifying countries in areas of the world that are more receptive of biotechnology and encouraging them to speak to their counterparts, whether it is in Africa or Asia, about the important role that biotechnology can play in food security. And so we are looking at this strategically and comprehensively. And I think that is one of the reasons why I think this forum is important because it gives us yet another opportunity, a public opportunity to talk about the benefits of biotechnology, and also talk about the need for American agriculture to have choices and diversity.

The CHAIRMAN. Thank you, Mr. Secretary. And before I turn to my colleague, the Ranking Member, for his questions I would note to the underclassmen the first bell has rung. There will be a second bell. At the second bell I advise you to work your way to the floor since the new management seems to be very focused on time limitations on those votes.

Mr. Ranking Member.

Mr. PETERSON. Thank you, Mr. Chairman. So the reason the decisions were made apparently is because the Environmental Assessment was working, and so they decided that with the case of sugarbeets and alfalfa that was probably going to be okay, and so

that is why they did the Environmental Assessment instead of the EIS.

Secretary VILSACK. Obviously I was not the Secretary at the time those decisions were made, Representative, but I believe that it is reasonable to assume that if the process had worked and had not been subject to question and had not been overturned in the past it was reasonable for people to say that is the approach we should take. What your question, and what this discussion underscores, is the more petitions we get, and we now have 23 pending, the more complex the issues become, the more awareness folks have about the various alternatives, the more diversification that is taking place in agriculture, the more markets that are being created, the greater the need is for us to have a comprehensive conversation about this and to figure out if there are ways in which we can streamline the process. I don't think there is anybody in this room that believes 6 years is appropriate. I know I don't, and I know that I indicated to Administrator Smith that I want to shorten that time if at all possible.

We are going to continue to follow the rules. If we think an EA is appropriate, then I think we are required to follow the rules. If we think an EIS is more appropriate under the framework, we will use an EIS.

Mr. PETERSON. Do you think that these folks that oppose biotech, do you think they picked on sugarbeets and alfalfa because they are small crops and they are easy to pick on? Do you think that was——

Secretary VILSACK. I wouldn't know the motivation and wouldn't want to question the motivation of anyone involved in this, Representative, but I would simply say this, EISs are very expensive and very time consuming. And we have to figure out a way either beefing up the capacity of APHIS in terms of more people and more resources to handle these petitions on a more timely basis, or develop a better way of dealing with the industry so the industry can provide assistance and help in putting EISs together and having us critically review them. There has got to be a way to reduce this time.

Mr. PETERSON. Do you think you have the authority to implement Option 3?

Secretary VILSACK. I think that the statute indicates that we have three decisions that can be made with reference to any petition. One is to say we are going to continue to regulate it, another is to say we are not going to regulate it at all, and the third is we are going to deregulate it in part. So I think we have those three authorities. I think that is fairly clear under the statute. We have to make sure that whatever option we choose we do it in a way that is consistent with the science. We understand that, we appreciate that, and we know that that is our responsibility.

Mr. PETERSON. So at this point, the Department, you don't think you need any additional authority or this Committee needs to be involved in looking at the Act to make changes to try to accommodate what you are trying to do?

Secretary VILSACK. I wouldn't say that you don't need to look at the Act. I mean, the reality is this Act was enacted I believe in the early 1980s, and we have seen a tremendous expansion of this

technology and we have seen these conflicting interests being raised. I think that certainly merits a review. I am not in a position today to suggest specific changes, but I think the clearer the direction is to us in terms of the Environmental Assessment, the EIS, do you want to continue to give us options? If so, we are going to continue to make decisions pursuant to that framework. Are there ways in which we have a set of regulations that are pending right now relative to noxious weed? That might be something that you would want to take a look at as well.

Mr. PETERSON. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Ranking Member. And we are now at the second bell on the floor votes. Mr. Secretary, if you would indulge us, we are going to recess for a few minutes, go vote, and come right back, sir.

Secretary VILSACK. I will be here.

The CHAIRMAN. Thank you very much.

[Recess.]

The CHAIRMAN. The forum will reconvene. I will now recognize the gentleman from Virginia, Mr. Goodlatte, for 5 minutes.

Mr. GOODLATTE. Thank you, Mr. Chairman.

Mr. Secretary, welcome. We are delighted to have you back. I want to follow up on the line of questioning from the Ranking Member, Mr. Peterson. To review the timeline, USDA did an Environmental Assessment resulting in the determination of substantial equivalence. USDA then got sued. After the suit, the agency took 4 years to complete an Environmental Impact Statement that, while though admittedly a more comprehensive document, came to the exact same conclusion. This seems to me to be an expensive and time-consuming process to come to the same conclusion. To the extent that we are scrutinizing the current statutory framework, shouldn't we be looking at ways to eliminate unnecessary procedural steps?

Secretary VILSACK. Representative, I share with you the concern about the time, and I share with you the concern about the length of time it has taken, which is why, if I could—if you could put the chart up that shows the process that we have; no, not that one, the process. It is hard to see, but I think you have copies of this. This is the process that we have to go through with reference to an EIS, which is one of the reasons why it takes time. And the concern I have is that we are now faced with 23 applications, and the number of applications is increasing at a rate of five to ten a year. So we have to figure something out to continue to do what we need to do and what we are directed to do under NEPA, and what we are directed to do under the Plant Protection Act. We have to figure out a way to do it more quickly.

Mr. GOODLATTE. Would you be willing to work with this Committee to look at legislative solutions to that?

Secretary VILSACK. We are willing to work with committees, we are willing to work with the industries. We are willing to work within USDA, as we are in process improvement. The statute directs us to make decisions within 6 months and it would be great if we did that, but we haven't. And I am deeply concerned that the length of time, part of which is resulting in litigation, the length of time is just, it makes it more difficult to innovate.

Mr. GOODLATTE. Thank you. Let me ask another timing issue. I have been a supporter of biotech for a long time. I have been out to the gentleman from Illinois' district and looked at some of the amazing things that a company in his district is doing. I am not opposed to the conversations that have occurred at your request with the biotech and organic industry. I think that is good. I am concerned about the timing of those conversations, however, roughly a month before Roundup Ready® alfalfa needs to be approved to meet their spring 2011 planting deadline.

We are mixing a marketing issue of the standards different industries have regarding the level of adventitious presence, AP, that is acceptable in their alfalfa crops, basically concerns of the organic industry, with the plant pest safety review that is the focus of APHIS' approval of biotech products.

Can you explain why those conversations were not held earlier, and how we separate those two issues to preserve our science-based regulatory system? When we start confusing issues related to marketing, people want to distinguish their organic crops from regular crops and the products that come from those. I certainly understand that, but that is a separate issue from the safety issue that is APHIS' responsibility, and we need to move ahead.

Secretary VILSACK. Let me, first of all, reassure the Committee that we understand the time constraints that we are under, the importance of making a decision in a timely fashion, and we intend to make that decision in a timely way. We have a review period that expires, I believe, on January 24, and I have directed staff to make all efforts to get a final record of decision prepared as quickly after the 24th as possible, and we will do that.

There are so many complexities to this issue, Representative, that there needs to be an extended conversation about a variety of issues. Part of what has occurred as a result of this dialogue is that in a number of areas, the parties have come together. They had not, many of them had not talked to each other before. They have come together. They have identified areas where they agree. They have identified areas where they clearly disagree, and they have also identified areas where there needs to be further dialogue. And what we have to do at USDA is figure out a process consistent with the Administrative Procedure Act, or outside of government, to have some kind of formal process by which this conversation will continue, because there are a multitude of issues that need to be looked at so that we streamline the process, we encourage innovation and, at the same time, we respect the property rights of every farmer who wants to farm how they see fit.

Mr. GOODLATTE. I understand. But you need to keep the marketing issues separate from the safety issues. And we should not be—when the safety issues have been addressed, we should not hold up farmers who are depending upon being able to plant during the spring planting period from being able to move forward and do that, and I think that is the problem.

Secretary VILSACK. Just to be clear about this, the time period, we had to wait—by our rules and regulations we had to wait at least 30 days after the final EIS was submitted to allow folks to review and provide whatever additional input that they wanted to

provide. So this 30 day period is still running and will expire on the 24th of January.

Mr. GOODLATTE. But we could act then and still be in time to plant crops.

Secretary VILSACK. And it is the intent that we will act very, very shortly after that.

Mr. GOODLATTE. Thank you Mr. Secretary. I have one last question, with the forbearance of the Chairman. I am the new Chairman of the Subcommittee on Intellectual Property, Competition, and the Internet on the Judiciary Committee, and I have been watching the anti-trust hearings that your agency has conducted with the Department of Justice. You focused one of those hearings on the seed industry and need for more competition.

I would recommend that this agency commit more resources to ensuring that when we have new entrants to the seed industry, instead of having them navigate a system that has resulted in significant losses and an agency that took 46 months to complete a court-ordered Environmental Impact Statement, we must do more to encourage this type of investment, and I fear we are sending the wrong signals.

Secretary VILSACK. Well, that is one of the reasons why we instructed the APHIS staff to take a look at process improvement, to streamline the process. That is one of the reasons why we are taking a look at how we might be able to work with the various industries to facilitate the Environmental Impact Statement. It is one of the reasons why we are proposing a change in regulations that would, for some, limit the amount of work that we had to do in this area. So, I mean there are a number of things that we are doing right now, Representative, to try to shorten the process. We don't disagree with you that it has taken too long and we are trying to figure out ways to shorten it.

Mr. GOODLATTE. Thank you very much, Mr. Secretary.

The CHAIRMAN. The chair now turns to the gentleman from Oregon, Mr. Schrader.

Mr. SCHRADER. Thank you, Mr. Chairman. Thanks for being here, Mr. Secretary, good to see you.

If you could just comment briefly, I am a big supporter of genetically engineered products here in our country. To me it seems pretty obvious it is the only way we are going to be able to feed the world. To me it seems like an avenue for energy independence, particularly for our ag community to be able to compete in that arena.

Could you comment very briefly on those two issues as far as the role that GE crops play?

Secretary VILSACK. Well, Representative, one of the things that I have been trying to encourage folks outside of the United States to recognize is that we have a growing world population that continues to expand. The amount of land capable of producing crops is not necessarily going to grow. The chances are that it could very well shrink with urbanization and the spreading of cities. And that is why we are looking at a multitude of ways to try to deal with this issue of do we have food security, will we have food security, how will we accomplish it. One way to do that is by figuring out how to increase productivity of crops. And there is no question that biotechnology has increased productivity.

In my lifetime, for a variety of reasons, including biotechnology, corn production has increased 300 percent, wheat production nearly 200 percent, and soybean production over 200 percent. So it is a productivity issue.

It is also an issue relative to the environment. I think there is genuine concern about water quality, genuine concern about issues concerning soil, and biotechnology is one strategy that we are looking at to reduce the amount of pesticides and chemicals that are required in order to continue to have the productivity. So there are environmental issues.

And clearly, our capacity to be more productive has resulted in our ability to export. And I think this year is a good example of the dramatic impact that exports can have on farm income and on job growth. One billion dollars of ag exports equals 8,000 to 9,000 jobs, and this year we are looking at a record amount of ag exports. So there is an economic concern, there is a food security concern, and there are environmental concerns.

Mr. SCHRADER. Thank you very much.

If I listen to your testimony and read some of the concerns from the different trade groups, and listen to some of my farmers back in the Willamette Valley in Oregon, I see this as actually a little bigger issue. It would appear that the courts, either willingly or unwillingly, are being thrust into the role of agriculture decision maker when they, frankly, don't have a lot of expertise in that area. But I see beyond genetically engineered crops that allow us to feed the world and provide a better environment. It would appear that this issue of coexistence goes beyond that.

And I will give you an example. In my valley there is a big concern about the growth in the canola industry for ethanol and other great products. But at the same time, there is actually a pest that is common in canola, that if it was to take root would also affect a lot of the brassicas that are grown in the valley in my area. So beyond just the GE issues, to me this coexistence thing is sort of real, and I don't know how we get at that; perhaps giving you more authority, as has been alluded here. But it seems to me we have a choice. Either the courts will dictate how this is done, or USDA will hopefully come up with some better solutions that are more ag-friendly as to how this should be done. Could you comment on that?

Secretary VILSACK. Well, I think this is a conversation that is really important to American agriculture. I think it is also important to rural development. If you give farmers and growers and ranchers a multitude of choices, then they are in a position to figure out what is the very best choice for their operation, the very best choice for their family and their community.

I think we at USDA need to be in the business of trying to figure out how we can facilitate and make those choices easier, and how we recognize and respect the property rights of individual farmers. That requires us to help create a level of trust between the various aspects of agriculture so that they feel, as is the case with some of these products, where they feel it is appropriate and necessary to talk about the various—to communicate. I mean, one of the keys here to different production systems being able to work side by side or in the same community is the capacity to communicate. I think

that happens at the local level. I think farmers go across the road and talk to their neighbor. I think we have to figure out how to replicate that in a more global sense, and that means creating some kind of forum, some kind of process where we can deal with these complex issues. Whether it is legislation or regulation, or the market or a combination, I think we have to have this conversation, and that is my goal here is to let's have the conversation, because I don't know that anybody disagrees that we have to have that. And we have to figure out a way to do it and build those lines of trust. And you know, maybe we were unartful in this process, but at least we are all talking about it.

Mr. SCHRADER. Thank you. I yield back.

Secretary VILSACK. Thank you. The chair now turns to the gentleman from Illinois, Mr. Johnson.

Mr. JOHNSON. Thank you, Mr. Chairman. Let me, by way of a parenthetical, just add one option to my distinguished colleague and good friend from Oregon's options as to how best to control this arena. He has alluded to the Department and the courts. I would add to the mix our market system, our free enterprise system, our system that has served this country for about 250 years and made the agricultural sector the envy of the world. And I would suggest, as a philosophical matter, that the more we go down the path of unnecessary regulation and the more we exceed what I think is either statutory and/or commonsense authority, the more we are going to diminish our agricultural sector and its spot in the sun.

And I think you would agree, Mr. Secretary, in a time of a failing world economy and a difficult economy here at home, we can look to our agricultural sector as one that has not only been a bright spot but whose progeny throughout the economy has been very, very good for us. Just a parenthetical comment.

Let me just ask a couple of questions and then just follow a stream of consciousness, if you will, that will carry me through my 5 minutes. You had indicated in response to a question before that you believe that the Department has statutory authority to regulate plant-based biotech crops. Can you specifically point to the portion of the United States Code that gives you that authority?

Secretary VILSACK. CFR Part 340, section 340.6.

Mr. JOHNSON. Which provides?

Secretary VILSACK. Essentially indicates——

Mr. JOHNSON. Not essentially. It provides what?

Secretary VILSACK. The regulations direct the Department to have one of three options that it considers.

Mr. JOHNSON. Do you want to provide that for us for the Committee, because there are certainly a good many people, including myself, a good many others in this sector, who do question the statutory authority of the Department. Not directing this to you, Mr. Secretary, but I think it is endemic of a problem throughout our system today where, when we go home, as we are in about 25 minutes, for the weekend, then the government is controlled by people who are unelected and whose statutory authority is somewhat questionable. So I do question that authority. And I would like to see your, at least your indication of what you believe that authority is.

Let me ask if the Department has calculated in any way, the economic impact that these new regulations on alfalfa, on farmers, specifically, what the impact is now and what it will be down the line.

Secretary VILSACK. There has not been a specific economic analysis, Representative, if you are talking about a thorough and a complete analysis that would normally require our Chief Economist to get engaged. There has been a recognition that what is being discussed in the various alternatives is, in some parts of the country, in a sense, already being done by the industry.

When you talk about stewardship contracting, for example, and you distinguish between the various pollinators that are involved with alfalfa and you distinguish various zones and ranges of protection, that is already in a number of stewardship contracts that are being considered. So what we are talking about is an extension of that.

Now, there has been some indication during the course of the review process, feedback to us, that a significant percentage, as much as 20 percent of the country, could potentially be impacted by this. I have not had a chance to verify whether that is accurate or not.

Mr. JOHNSON. So the answer is there may have been some vague assessment, but you certainly can't provide that for us today.

Let me go back to your answer to a previous question when I asked you the question as to the basis for the Department's statutory authority. When I went to law school, I believed, and I still believe, although I haven't practiced for a while, that the CFR to which you made reference is not the statute. Those are regulations. I am talking about the specific statutory language passed by the Congress that enables you to extend your authority. CFR is not statutory language, Mr. Secretary.

Secretary VILSACK. Well, it is the Plant Protection Act.

Mr. JOHNSON. Well, what you quoted for us was not statutory authority. It was regulatory action, and that is my very point. Regulatory actions are not statutory authority. And my concern is that we are now extending into significant new areas the path that can lead from alfalfa to wheat to corn to soybeans, which would have dramatic impacts, dramatic, staggering impacts on American agriculture. And I would suggest that this is being done with at least questionable statutory authority, and I would like you to provide for us what that authority is. And if, in fact, you think this Congress needs to buttress up or limit or expand that area, then we certainly would have an opportunity to look at it. But I think this body, and not unelected bureaucrats, ought to be the people who are making those regulations and laws for American agriculture.

Secretary VILSACK. Congressman, I would be happy to provide you portions of the Plant Protection Act under subtitle A, section 411 and others. I would be happy to provide that to you.

USDA's authority to regulate genetically modified crops is derived from the Plant Protection Act (PPA), and the Animal and Plant Health Inspection Service (APHIS) currently carries out its biotechnology regulatory program under 7 USC 7701–7786 of the PPA. Additionally, APHIS prepared and published a proposed rule (the comment period is now closed), which solicited comments on

the question of whether its biotechnology regulations should include use of the PPA's noxious weed authority.

Mr. JOHNSON. My last question is, do you believe—and I do appreciate your being here with us. I appreciate your previous calls, your courtesy to me. I think your Department is doing its very best. We may have a little philosophical difference about what "very best" means, but I do appreciate your good faith.

And my last question is, do you believe that these new regulations that we are looking at could well become a precedent for a whole wide variety of new biotech crops, or are you going to limit this to alfalfa?

The CHAIRMAN. The gentleman's time has expired. If the Secretary would like to answer, of course.

Secretary VILSACK. Honestly, one of the things that I have learned in this process is how unique and significant the various crops are that are being subject to this review and regulatory process. I would not want to hazard an opinion today that anything we do on any of these decisions, whether it is sugarbeets or whether it is alfalfa or whether it is corn, or whatever it might be, is necessarily precedent setting. I think what we have to follow is the precedent that is fairly clear, and that is that we have to do this in a timely way. We have to do it in a science-based way, and we have to do it within the framework of the rules as they exist and as you all have legislated, and that is what we intend to do.

The CHAIRMAN. The chair now recognizes the gentleman from Iowa, Mr. Boswell, for 5 minutes.

Mr. BOSWELL. Thank you, Mr. Chairman. I too would like to join with Mr. Peterson in congratulating you on your chairmanship, and knowing something of your background, I think that we will communicate, and I realize that, not too much different than I, back home is a lady named Linda that is kind of looking after the herd. But anyway, so much for that. I appreciate it.

Mr. Secretary, we went through, in our state, a process of farmers market, and we have seen it balloon and go on and on and on, and I am leading up to a point I want to make here. Unbeknownst to me, unexpected, one of my granddaughters, in a very urban setting, has started a market, door-to-door organic food, and it looks like she is going to make it. Recently, another grandchild came out of an urban setting in a different place and said they would like to try some farming, but he wants to garden; truck batch is what we call it. So I took an old feed lot and I plowed him up an acre. I don't know how that is going to work out just yet.

I have been kind of maintaining for a while that there is the market out there for those that want the organic-type foods, and more power to them. We don't object to that. But I feel like that we must keep our course on genetically approved science. I have been saying this for years with Iowa State University there, that we have to use the science to feed this population, like Mr. Schrader said. It is growing at a speed that we can't really get a grip on, it seems to me. And we are going to see some demands that we don't even think about, so we have to use the science. I feel that reasonable people can sit down and work this out. There is a place for each. And I am going to stay with that hope. I am

kind of an eternal optimist since I am a farmer, so I am going to keep that going.

But I think that we have to keep the science in this. And we have to work this out because the demands of this hungry world are growing at a pace that is almost unbelievable. And so we have quite a challenge.

And with that, I just wonder what your reaction is. One of our questions about, if you choose Option 3, what do the other agencies feel about this; the coexistence of this in general? In particular, how does the proposed partial deregulation fit with the trade policies taken on biotech by our negotiators in the WTO? Do you have any comment on that?

Secretary VILSACK. Representative, we are very sensitive to the issues that you have raised about trade and about a rules-based and science-based system. As long as the review process has not expired, I don't think it would be appropriate for me to suggest what we are going to decide or what the nature of our decision is going to be. But I do want to reassure this Committee that we understand and appreciate all of the issues that you are raising with your question, and we will take those, and should take those into consideration in the decisions that we make.

The trade question is complicated because there are a number of trade issues here in addition to the WTO. There are markets that we—with non-GE products and organic products that are also subject to trade discussions and subject to trade agreements, market agreements, and so forth, that are pretty profitable for folks, and we want to make sure we preserve those export opportunities.

The one message I have gotten from this Committee that has been very consistent, whether it is a Republican or Democratic speaking to me, is that you want us to focus on exports because you see this as a way of increasing farmer income. And I agree, and we have done that and will continue to do that. That is the reason this conversation is so important because it creates options. It allows farmers to do with their land what they wish to do. And we have to figure out how we build the level of trust and the communication process, whether it is inside or outside of government, how we do that in a way that allows the genetically engineered crop to be grown in one area, the organic crop to be grown in another area, the non-GE crop to be grown, and how they can all sort of live in the same world, because these are great market opportunities, all of them. They are all great market opportunities.

Mr. BOSWELL. I appreciate that. I think they are beholden to all of us to try to say to the folks engaged, talk to each other. And there seems to me like good sense tells me there is room for each. But I am signed on to the letter we sent you, a bunch of us sent you a while back. And we have to use the science, or I don't see how we feed this world we live in.

Secretary VILSACK. There is no disagreement on that.

Mr. BOSWELL. Okay. Thank you very much. I yield back.

The CHAIRMAN. I now recognize the gentleman from Texas, Mr. Conaway, for 5 minutes.

Mr. CONAWAY. Thank you, Mr. Chairman.

Mr. Secretary, before I get to the question I thought I was going to ask you, your response to Mr. Johnson's question about the eco-

nomic impact on alfalfa, that you had no idea what this might or might not do, is startling. Did I misunderstand that?

Secretary VILSACK. With respect, that is not quite what I said.

Mr. CONAWAY. Okay. Help me understand.

Secretary VILSACK. He asked if there was an economic analysis, and I wasn't certain whether he was talking about an extensive economic analysis that would be the Chief Economist's office. We obviously understand and appreciate because, in the marketplace today, there are stewardship contracts already in place. And part of the stewardship contracts, I mean, there is a double-edged sword here. The economic analysis can go two ways. If you don't have protections, how does that impact and affect the capacity of non-GE crops and organic crops to the market?

Mr. CONAWAY. You have made those assessments; you have that information available to you, that you have some sense of what the economic impact is of the various routes you go?

Secretary VILSACK. We have an understanding and appreciation of the impact. But it can't be just one aspect of this. You have to look at the economic impact on all production.

Mr. CONAWAY. Yes. Well, I was thinking that 8 years of testing on alfalfa already and 6 years of this process, surely during that Environmental Assessment, Environmental Impact Statement, somehow you figured out there were some economic issues involved in the deal.

Secretary VILSACK. Well, part of the Environmental Impact Statement is to take a look at a variety of issues. That is why it is 2,300 pages in length.

Mr. CONAWAY. I am not sure length represents good.

Secretary VILSACK. I am not suggesting it was good or bad. I am just suggesting it was lengthy.

Mr. CONAWAY. Okay. A couple of days ago our President, in an op-ed, and I think an Executive Order, began to talk about the impact that regulations have on jobs, on everything. Where does all of this—where does that Executive Order have an impact on what you are doing with this and the broader issues, if you are trying to deal with regulations?

Secretary VILSACK. I think it supports the directive I gave to APHIS some time ago to take a look at ways in which we could streamline the process in terms of getting approvals. I think it falls four square with the proposals we are making in terms of revising our rules to create more flexibility, to short-circuit some of the process in areas where there is probably little or no disagreement, to focus our attention and resources on where the risk may be greatest. I think it is very consistent with the President's directive, very consistent.

Mr. CONAWAY. Okay. What I heard you say is that we are going to work on our processes. What I was hoping the President intended was to look at the impact that your regulations have on whatever it is you are trying to regulate, and that impact would be the minimum amount needed to do whatever it is you need to do. I understand streamlining your own stuff and trying to shorten that. Great. But the impact on the industries ought to have somewhere in that, I think that is what he was alluding to.

Secretary VILSACK. You are right. Time is money, so the process does matter. And we are dealing with a variety of sectors of agriculture here that are impacted by this decision. So it is not just one aspect of agriculture that is impacted. It is not just GE, it is not just non-GE, it is not just organic. It is actually all three.

Mr. CONAWAY. Okay. There have been reports that, as a part of one of the solutions, I guess the partial regulatory solution would involve a compensation fund. Can you give us any sense of who runs that fund, who funds that fund, and who gets money out of that fund?

Secretary VILSACK. Just to be clear about this, I don't know that that has been discussed as part of the discussion relative to alfalfa specifically. It is part of the discussion, as is indemnification agreements which are already being discussed in other crop areas in this discussion about how we coexist, as well as insurance products. I mean, there are a variety of options that are being looked at in ways to try to address any economic issues that might be forthcoming.

Mr. CONAWAY. Who would house the fund? Hypothetically, who would house it and who would fund it and who would get money out of it?

Secretary VILSACK. None of those questions have been asked or answered. The point of this is that these are preliminary conversations.

Mr. CONAWAY. Well, actually they have been asked at least once. I just asked it. Go ahead. I am sorry.

Secretary VILSACK. This is a serious conversation, and I appreciate the opportunity to talk about this, and if I can just take 30 seconds of the Committee's time. When I was up in North Dakota, I had an opportunity to visit with sugarbeet growers, and these poor guys are just sort of scratching their head. All they want to do is farm. And they are confused and concerned about the complexity of the process that they find themselves in. And we talked about ways in which a system of trust could be created so that everybody could do, on their land, what they wanted to do without interference and without being damaged.

I mean, the reality is if you have an organic crop, whatever it might be, and something happens to that organic crop that makes it no longer organic, there is an economic consequence of that. And the same is true with identity-preserved non-GE.

And so we started just talking about ways in which that issue could be looked at without going into great detail, without trying to figure out every aspect, all "t"s crossed and "i"s dotted, compensation funds, indemnification agreements, insurance products. All of that needs to be part of an extended conversation that we need to have in this country so that everybody can do what they want without worrying about necessarily being economically damaging to their neighbor or being damaged as a result of something somebody else does. And this is not picking sides. This is trying to figure out how do we have all aspects of agriculture be able to prosper in this country.

And we would be happy to work with folks who want to look at any of those options, or there may very well be a better fourth option or fifth option or sixth option. The point of this is, let's at least

have a discussion about it to see what works, what doesn't work, what is a good idea, what is a bad idea. And that is essentially where this is, Congressman. It is not a well——

Mr. CONAWAY. Let me set the record straight. I didn't intend to make light of the seriousness of this issue by correcting your statement. That was not my intent. If you want to put us on that kind of a footing, we can. While the discussions go on, *ad infinitum,* while your processes go on, *ad infinitum,* I understand, you are saying all the right things. You are saying exactly what everybody wants said, except the farmers are out there waiting on a decision. We have a batch of Roundup Ready® alfalfa seed that will go bad, I am told, before too much longer, while we have these discussions, these extended discussions on these issues. So I agree, we need to get this done. But sooner rather than later, and let's don't use the constant conversation of delay from making a decision and moving forward.

Secretary VILSACK. Representative, as you know, there is a 30 day review period, and we are still in that period. So we have——

Mr. CONAWAY. But the conversation you were proposing would seem to me to be much, much longer than 30 days in terms of third, fourth, fifth and sixth options.

Secretary VILSACK. Well, that is a conversation that is larger than one crop.

Mr. CONAWAY. Right.

The CHAIRMAN. Both gentlemen's time has expired. I turn now to the gentleman from Pennsylvania, Mr. Thompson, for his 5 minutes.

Mr. THOMPSON. Thank you, Mr. Chairman. Thank you, Mr. Secretary. It is always good to see you. Thanks for joining us for this forum.

As you know, I have been following the issue of Roundup Ready® alfalfa for some time. I spearheaded two Congressional letters on the SU. One I sent, actually going back to November 2009, asking you and your agency to prioritize the completion of the Environmental Impact Statement for the Roundup Ready® alfalfa. And I sent a second letter in July of 2010, asking you to issue a partial deregulation of the crop as a result of the Supreme Court case in favor of the alfalfa. And a partial deregulation would have put the crop back on the market while the USDA completed the EIS process.

Now it is 2011 and we are still talking about getting this product back on the market. The EIS process took 46 months to complete. And in the middle of extremely low dairy prices, this product obviously would have been helpful to my farmers and dairy farmers all across the nation, many who grow alfalfa on their farms.

We have had historically low milk prices during the last few years. Many dairy farmers grow their own alfalfa for use for their dairy, and alfalfa growers have self-reported $100 increase in profits an acre when using Roundup Ready® alfalfa because of the increased yields as a result of the decreased weed pressure.

And I think it is important that we look at this toll for farmers and we think of the dairy industry specifically and how we must commit our resources that help them during this crisis.

Now I understand that lawsuits are certainly one of the reasons we don't have that product available to farmers. And one of the reasons some groups are successful in their cause to oppose the introduction of biotech crops is because USDA has been slow to respond to the rulings of these court cases. This technology obviously will no doubt have a positive impact on dairy farms, and I am very concerned that many dairy farms may not be able to reach their demand if Roundup Ready® alfalfa is not deregulated in time for planting season.

Actually, it is—I guess the fact I represent Punxsutawney, it is appropriate to say this feels like Groundhog Day to me. I mean, November 2009 that was my letter, preparing for the purchase of seed for the 2010 planting season, and here we are in 2011.

Has USDA—and I know you reflected a little bit on the economic impact already. But just to clarify, has USDA been taking economic impacts like this into account when coming to their decision?

Secretary VILSACK. The decision we have to make, Congressman, is consistent with the Plant Protection Act. There are two different issues here. There is the Plant Protection Act, which is really designed and directing our decision making process. There is the, in this case, the court-ordered EIS under NEPA which is a completely different process. We were trying to comply with the court order in terms of completing the EIS in a way that was comprehensive enough that didn't lead necessarily to yet more litigation and more delay. I am certainly sympathetic with your concerns about the dairy industry. That is the reason why we put a dairy council together. It is the reason why we took steps in 2009 to help that industry out, and we are looking forward to the diary council's recommendation in March of this year, working with this Committee to make sure that we create greater stability in that industry.

There are a variety of things that probably need to be done in order, and that may be a subject of another conversation between the two of us and this Committee, and I look forward to that.

Mr. THOMPSON. The court challenges, I haven't looked in great detail with that, that raised these red flags and delayed this process. Were they specifically related to the questioning of the science or the safety, or was it more market issues and competing market issues?

Secretary VILSACK. It was compliance with NEPA, whether or not an Environmental Assessment was adequate; and, if not, requiring and directing that an Environmental Impact Statement, which is far more extensive and comprehensive, needed to be done. That is what we have done. That is what we recently filed.

Mr. THOMPSON. Okay, one other last question. It seems to me that if the third option is put into place, it would create a regulatory nightmare for USDA. Maybe that is just my projection. But how do you see USDA actually administering such a policy? And frankly, how much time do you project would be required to fully implement the third option, which that time for implementation I see just as additional delay and financial burden on our dairy farmers, or farmers in general, from accessing this scientifically proven, safe technology.

Secretary VILSACK. Congressman, any decision we make, we will be prepared to fully and appropriately implement and do in a way

that will not interfere with the capacity of folks to farm on a timely basis. We are well aware of the time constraints that we are under relative to seed. You know, the reality is, as you well know, the safety of these products has never been under question and it isn't under question at all. And in my opening statement I made that, and I want to make that, clear. The safety of this product has not been questioned in the lawsuits. It has been a process and a procedural set of issues.

Mr. THOMPSON. Thanks, Mr. Secretary. I appreciate your time. Thank you, Mr. Chairman.

Mr. CONAWAY [presiding.] The gentleman from Indiana, Mr. Stutzman, 5 minutes.

Mr. STUTZMAN. Thank you, Mr. Chairman. And thank you, Mr. Secretary, for being here.

I am new to Washington and it is good to be here, and I enjoy the conversation so far. But I am getting up to speed on this particular issue. But just listening to the conversation today, I guess I just have a couple of questions more on practice.

Being a practicing farmer in northeast Indiana, we actually were raising organic crops, but also raised seed corn. And so, I definitely understand that there is a push for raising organic crops. And I believe that and I think it is good practice. But I know for our particular operation, it got to the point where it became an economic decision as well.

And I guess my question would be, more towards some of the proposals that have been tossed out, and maybe you could comment on them, maybe in particular with genetic seeds, modified seeds, that there be buffer zones potentially. Could you touch on that a little bit and where that conversation is going, because we have had a lot of those conversations back at the state legislative level about CAFOs and setbacks. And it really does create a lot of problems.

Secretary VILSACK. Well, the industry itself, within the industry, has had these conversations. And initially, the industry focused on alfalfa on best management practices and with a contractual relationship between the provider and the producer. Over time, it evolved into something beyond best management practices, or in addition to best management practices, which are stewardship contracts which reflect sort of the unique nature of alfalfa and the pollination that takes place and the type of pollinators you use. And in some cases, set-back distances or zones, if you will, were created in some areas. In some states there are actually areas where there has been agreement that no GE crop will be grown because of the potential impact.

So those conversations were taking place, have taken place. And what is taking place now is an extension of those conversations in which those who were not necessarily party initially to the conversations are now talking to each other. And what we know is that there is now a real desire to ensure that there will always be seed available for whatever production system you want to embrace. What prompted a lot of concern was, as GE alfalfa is utilized and as its use is expanded, will we get to a point where that will, at some point in time, today or tomorrow, jeopardize the ability to have seed to produce organic or non-GE? That is a constructive

conversation to have, because it informs USDA in terms of the tools we might be able to bring to bear in terms of germplasm and seed purity that might reassure folks that we are not going to lose our capacity, whatever choice you might want to make as a farmer. So that has sort of been the nature.

And the question then is, if you have a stewardship arrangement, the design of it, the verification of it, the industry is in the process verifying and auditing, is that sufficient? Is it adequate? Some folks say yes, some folks say no. But there has been a conversation about that and there has been a good exchange of information, and I think the beginning of a trusting relationship in terms of certain elements have been brought together that weren't together before all of this.

Mr. STUTZMAN. So did I catch you right that there are several states that already have taken action in setbacks or——

Secretary VILSACK. There are areas. California is one area, one state where there are areas that have been designated as sort of off limits. But there are also stewardship contracts where producers agree to operate under a certain set of conditions.

Mr. STUTZMAN. Privately?

Secretary VILSACK. This is a private arrangement, a contractual arrangement. And that raises the issue of, okay, how was that designed, is that adequate given the pollination system that you use? Is that adequate? Is it 3 miles, is it 5 miles, is it 900 yards? What distance is appropriate? And what supports that, and how do you verify that that is being done?

And that then gets you into a whole complicated discussion of tolerance levels and the like. It is a set of complicated questions, complicated issues, that I think people are taking very seriously.

Mr. STUTZMAN. Well, I know in our operation we are starting to move out of some of the organic production just because of weed pressure and because of rotation in crops and things like that. And I know that if we were starting to deal with setbacks, it would definitely limit our flexibility in the crops that we would be raising on certain land. So that is always a fear of mine, that you start talking setbacks or buffer zones, it would——

Secretary VILSACK. I think every area of the country, every operation is, in a sense, somewhat the same and somewhat unique at the same time. And that is what makes this so complex is the tremendous diversity and opportunity we have in this country to actually be able to do all of this. And the question is how do we do it all, successfully, without interfering with each other.

Mr. STUTZMAN. Thank you, Mr. Chairman.

Mr. CONAWAY. The gentleman's time has expired. The gentleman from Iowa, Mr. King, 5 minutes.

Mr. KING. Thank you, Mr. Chairman.

Mr. Secretary, I thank you for your testimony. And I did hear most of it. I didn't hear all the exchange between some of the Members so I don't want to go over new territory. But I wanted to ask you if you would speak to the issue of the message that comes out of here with the position that seems to be shaping with the USDA and GMO products. How does that echo through Europe where we are constantly seeking to export our products over there? And I have charged them myself with using that as trade protectionism.

In your discussions with the U.S. Trade Representative, could you give us a sense of how that sounds and what that looks to you from where you sit, Mr. Secretary?

Secretary VILSACK. Well, Congressman, obviously the decision we make, if it is within a—if it is justified by the science and it is within the rules that we have, I think that is very consistent with the positions we have taken on the international scene. The conversation that we are having today, the conversation that has been taking place in various places throughout the last 30 days, is very helpful in the sense that it allows us to begin to; A, celebrate the diversity of American agriculture; and, B, also gives us another opportunity to reinforce the positive aspects of biotechnology, which we need to do more of on the international stage.

Mr. KING. Do you see the Europeans starting to perhaps back away a little bit from their relatively hard line on GMOs?

Secretary VILSACK. I want to be optimistic about that, Congressman. The resistance has been pretty consistent and pretty longstanding. I think everyone in this world who is serious about agriculture sees what we all see, which is six billion, seven billion, eight billion, nine billion people. How are we going to feed them? And we can't feed them unless we make the best use of all of our resources and that we do it in a way that doesn't necessarily overtax our capacity, our water resources, which is also an issue, and doesn't compromise our ability to have clean water with pesticides and chemicals. So biotechnology is part of the answer.

Mr. KING. Well, Mr. Secretary, let me say something and it is perhaps better that I say it, and I am not seeking to put words in your mouth, just my own. But as I observe what has gone on in Europe with the GMO protectionism there, it looks to me like it started out to be a political movement that wasn't based on sound science, that got some foundation there, and it penetrated through the politics of Western Europe, and now it becomes a trade protectionism tool that was spawned by a political movement. I won't ask you to respond to that, but I wanted to put my view into the record.

Then I would ask you if the Department has examined the loss of economic growth or the economic impact of not having a clear-cut, I will say, approval for GMO alfalfa in particular, Roundup Ready.

Secretary VILSACK. Well, we have had a conversation about this before, and I want to make sure I am clear about this. There is an indication and an understanding that what is being done in the industry today and what is proposed in Option 3 could very well result in some areas of the country not being conducive to the growing of a certain type of alfalfa.

On the other hand, there is also a recognition of the economic impact that if we don't do this well, that those who are producing non-GE crops for export, those who are producing organic crops for domestic and export consumption may also be harmed. So it is a process where there are economic analyses on all three areas.

Mr. KING. Do you happen to have a number that would tell us that if there was no conflict between GMO alfalfa and organic alfalfa, if there happened to just be no conflict, what is the potential economic improvement that we would have from the increased pro-

duction in the GMO alfalfa, if it could be raised any place where it were chosen, without an impact on the organic?

Secretary VILSACK. I don't have that number. And I know that, I don't know that it is—I don't know how easy it would be to calculate that, because of the fact that people are making decisions every year to change their operation.

Having said that, here is what I can say with certainty; that we need the biotechnology and we need the GE crop production. I can say with certainty that there is going to continue to be interest on the part of U.S. agriculture in adopting and embracing biotechnology. At the same time that is happening, there is also a very robust market being created, both domestically and abroad, for non-GE crops and for organic crops, which creates great opportunities and options for farmers. And that is a positive thing for this country.

Mr. KING. I thank you, Mr. Secretary.

And then just in conclusion, you will be aware of press reports of Deputy Secretary Kathleen Merrigan and her record and the way she is viewed as having been instrumental in obstructing the approval of bioengineered veterinary drugs and also in preventing the inclusion of genetically engineered crops under the organic rubric. That I take from *Forbes Magazine.*

And you understand our concern when we have an individual with all of that influence in that position and this subject that affects all of the agriculture across the country.

Secretary VILSACK. I would understand that concern on every Member of this Committee with the exception of two, you and Congressman Boswell, because you both know me. This decision, at the end of the day, is the Secretary's decision.

Mr. KING. Thank you, Mr. Secretary. I appreciate your testimony and particularly your response to that final question. Mr. Chairman, I yield back the balance of my time.

Mr. CONAWAY. Mr. Schilling from Illinois is recognized for 5 minutes.

Mr. SCHILLING. Thank you, Mr. Chairman. Mr. Secretary, good to see you, being from Illinois.

Actually, the questions, like Mr. Stutzman, I am also new to this arena, so I just really look forward to serving on this Committee. The questions that I did have have already been addressed, so I really just appreciate being here and hope to be effective on this Committee.

Mr. CONAWAY. Does the gentleman yield back?

Mr. SCHILLING. I yield back.

Mr. CONAWAY. The gentleman from Arkansas, Mr. Crawford, is now recognized.

Mr. CRAWFORD. Thank you, Mr. Chairman.

Mr. Secretary, thank you for being here today. I represent the First District of Arkansas which, if you know anything about Arkansas, we refer to that area as the Delta. And in the Delta we have large economies of scale primarily geared toward rice, cotton, and soybean production, so this is a sensitive issue for my constituents.

But let me ask you this. If I were a large-scale alfalfa producer and one of my neighbors decided to plant organic alfalfa, neighbor

adjacent to me, who is responsible for implementing that buffer zone?

Secretary VILSACK. It would depend on the arrangement that you had with the producer of the seed. It could very well be that there is a contractual arrangement that you have that creates some responsibility. It could very well be that your neighbor needs to know what you are doing and needs to understand the impact. I mean, you could reverse that question. And that is why we are having this conversation, so that there is a clear path and a clear way to know how to respond to that question.

It kind of depends on the circumstances, Congressman. I am not trying to be evasive, but it really does depend on your contractual relationship and also what your neighbor knows about your operation and what decisions your neighbor makes relative to the distance that he or she locates, and it depends on pollination. I mean, it depends on a lot of issues. So it is very hard to answer that question.

Mr. CRAWFORD. Okay. With regard to Roundup Ready technology, glyphosate-tolerant plants have been on the market for a number of years. Is it safe to say, then, the USDA and the FDA have deemed that these products are safe for the environment and for human health?

Secretary VILSACK. There is no question, Congressman, about the safety of these products.

Mr. CRAWFORD. And then final question, has there been a calculation that you are aware of how much land would be taken out of production to accommodate the needs for buffer zones?

Secretary VILSACK. Well, obviously that depends on the degree to which folks accept this technology, but there has been at least an estimate that roughly 20 percent of the land might not be amenable under Option 3. That is obviously not true under Option 2.

Mr. CRAWFORD. And so in those buffer zones that land is taken out of production, does that become a conservation program?

Secretary VILSACK. No, it could very well be other products. It could be other crops or it could be other types of—other types of crops, it could be livestock or it could be whatever other options are available. It is not that you would have to take the land out of production totally. It is that you would not be able to plant certain types of crops relative to alfalfa in that zone. You wouldn't be able to plant GE alfalfa in that zone, as is the case already in some parts of the country. We have some areas of the country today where that is the case, where producers understand that they cannot use certain technologies because of the impact it may have on surrounding crops.

Mr. CRAWFORD. Okay. I misspoke, and I do have one final question. We talk about the economic impact as it applies to farmers, but what about the economic impact as it applies to the investment and biotechnology? If these products become less appealing to farmers and therefore their value goes down, are we going to see a disruption in investment in the biotechnology community?

Secretary VILSACK. This chart reflects, Congressman, all the pending regulations.

If you could put the other chart up. Despite all the difficulties we have talked about today, you can see the number of petitions

for deregulation that have escalated over the course of the last several years. One of the great things about American agriculture, as I said in my statement, is how innovative it is. One of the under appreciated aspects of American agriculture is its innovation. It is one of the reasons why it is productive and I think it is one of the reasons why we are seeing some success today.

So I am confident that we are going to be able to figure out ways in which we can enhance innovation. That is what this whole process at the end of the day ought to be about, and it certainly from my perspective what it is about, how do we create innovation, how do we foster innovation, and how do we make sure that farmers have choice.

Mr. CRAWFORD. Thank you, Mr. Secretary. I yield back.

Mr. CONAWAY. Mr. Secretary, have there been any organic certifications lost as a result of biotech plants crossing over?

Secretary VILSACK. Let me check with the staff on that.

We don't know of any. I am going to go back to the office and double-check that and make sure.

Mr. CONWAWY. If you wouldn't mind providing that. You do those certifications, your shop does, right?

Secretary VILSACK. Yes.

Mr. CONWAWY. So if you would provide that for the record, I would appreciate it. I yield back to the real Chairman. Thank you for being here.

Secretary VILSACK. No. While the National Organic Program Regulation (7 CFR Part 205 *et seq.*) excludes the use of products resulting from genetic modifications, USDA–AMS does not consider inadvertent trace presence in itself to be a violation.

NOP regulations do not require withdrawal of crops or land in the case of inadvertent GE contamination, but some producers have reportedly done so voluntarily.

The CHAIRMAN [presiding.] Secretary, once again thank you for coming and sharing your insights and your observations with us. Obviously we have a good many conversations that lie ahead and I look forward to that and I hope do you too.

Secretary VILSACK. Thank you, Mr. Chairman. Thank you.

The CHAIRMAN. Since our next panel is coming to the table we would like to welcome them, the Honorable Charles F. Conner, President and CEO of National Council of Farmer Cooperatives, in Washington, D.C.; and accompanied by Bernice Slutsky, Ph.D., Vice President, Science and International Affairs, American Seed Trade Association, in Alexandria, Virginia. Whenever you are ready.

STATEMENT OF HON. CHARLES F. CONNER, PRESIDENT AND CEO, NATIONAL COUNCIL OF FARMER COOPERATIVES, WASHINGTON, D.C.; ACCOMPANIED BY BERNICE SLUTSKY, PH.D., VICE PRESIDENT, SCIENCE AND INTERNATIONAL AFFAIRS, AMERICAN SEED TRADE ASSOCIATION

Mr. CONNER. Thank you, Mr. Chairman, for the opportunity to be here today. I know the hour is late. I have provided a full statement to the Committee, and I would ask that that be distributed to Members of the Committee for this forum, and I will attempt to summarize those remarks very briefly.

I am here today on behalf of 3,000 farmer owned cooperatives and a broader coalition of very diverse agricultural industry groups with an interest in this issue, Mr. Chairman, and we thank you for holding this forum today. This is especially timely, given the Department of Agriculture's pending decision relative to herbicide tolerant alfalfa, and the long reaching effects of that decision.

I noted earlier Mr. Schrader's remarks, Mr. Chairman, about the importance of biotechnology in terms of meeting future food needs of this country. I would take that a step further, Mr. Chairman, and say that, as I said to Secretary Vilsack at our meeting on December 20th, without biotechnology our country would be in some very difficult straits relative to our current supply and demand estimates already today. We need this technology, Mr. Chairman, and we should be encouraging it.

The development and adoption of these products and the promise of new products will make possible the continued availability of safe food, feed, and fiber products to consumers to the U.S. and worldwide. With 23 biotech crops, Mr. Chairman, in the regulatory pipeline and more on the way, it is clear that USDA's pending decision relative to alfalfa will have broad implications going forward in the future.

The acceptance of biotech crops would not have been possible without a strong risk-based regulatory approval process that has been in place since 1986, and has been based solely on sound scientific principals. It has served us well.

In 2005, Mr. Chairman, APHIS prepared an Environmental Assessment for Roundup Ready® alfalfa, as required by the National Environmental Policy Act, NEPA, and deregulated the crop under the Plant Protection Act. The crop was grown by U.S. farmers quite successfully, I might add, for 2 years before a NEPA court suit reversed that APHIS decision. I would add for the record, Mr. Chairman, that when I say successful I am talking about successful from the producers' standpoint. And some of our data suggests that farmers producing Roundup Ready® alfalfa were as much as $110 an acre better off as a result of growing that Roundup Ready® alfalfa. Again, this is technology that we need and need quickly.

In 2007, the U.S. District Court of the northern region of California, San Francisco, required APHIS to prepare a full Environmental Impact Statement, due only, Mr. Chairman, to procedural concerns over APHIS meeting its NEPA obligations. I want to be clear, there was no finding of any deficiency under the Plant Protection Act and there was certainly no risk in health or safety identified, and I think Secretary Vilsack has echoed that point today.

In December of 2010, USDA announced the completion of the court-ordered EIS and said it would make a final regulatory decision under the Plant Protection Act possibly later this month. However, in preparing this EIS, USDA did choose in an unprecedented way, Mr. Chairman, to include an option referred to as Alternative 3, that of deregulating Roundup Ready® alfalfa. Alternative 3 includes a series of unprecedented conditions such as isolation distances of up to 5 miles, other geographic restrictions that would not allow farmers to plant, we estimate, on as much as 20 percent or more of the current alfalfa acres in this country, and that acreage

is as high as 50 percent in the western part of this country with the restrictions that are suggested under Option 3.

Having made the latter determination, it is clear that USDA is obligated, in our opinion, to unconditionally deregulate the crop, the alfalfa crop, and has no authority to impose these arbitrary restrictions as suggested under their preferred Option 3, in their words. Combined with broader policy statements in the EIS, the imposition of the conditions on a crop that poses no plant risk sets a dangerous precedent for the continued safe development, availability, and marketability of new biotech tools. Therefore, we fully support alfalfa growers having access to Roundup Ready® alfalfa for this spring's planting without conditions posed by the USDA or any government agency.

I certainly can appreciate Secretary Vilsack's commitment to address some of the roadblocks that have been placed in the path of valuable biotech crops. We all understand that. Where I respectfully disagree with the Secretary is on the proper means of removing those roadblocks.

In addition to my experience with the Roundup Ready® alfalfa lawsuit while I was at the Department, I happened to be Acting Secretary during another lawsuit filed with regard to Roundup Ready sugarbeets. It is my belief that attempting to mediate disputes between interest groups in conjunction with a specific regulatory decision for a biotech product would set a precedent that is in direct conflict with the longstanding adherence and the rule of law relative to science-based regulation for biotech crops in the United States. In fact, the U.S. Government has continually supported and defended science-based regulatory regimes. And we discussed that plenty already this morning. But it is fair to say we are the standard for the world and we continue to press the world to move to our standard of safety and safety and soundness.

One of the terms we have heard a lot over the last several month is "coexistence." Coexistence with respect to biotech's crops, as has been stated, Mr. Chairman, is indeed a marketing issue. It is absolutely not a safety issue. Despite claims to the contrary, Alternative 3 will hurt the ability of growers to choose what they want to plant, in this case, as I have pointed out, impact their bottom line, profitability.

Market needs, communication, and workable solutions by the industry and growers, not government mandates, are the key to ensuring the multiple production systems can continue to exist side by side as they have for so long already.

It has been suggested that extraordinary regulatory action is needed to address the burdens that have been imposed by recent NEPA lawsuits challenging APHIS's decision making. Those who are totally opposed to biotechnology, Mr. Chairman, have sought relief in Federal courts under NEPA for nearly 30 years and more recently have challenged regulatory actions taken by APHIS. In those very few cases where their suits have been successful it has always been based upon the court finding of procedural violation and no court has ever held that the biotech crops present any kind of health or safety risk to the environment, and certainly APHIS has never been directed by any court to regulate coexistence as has been proposed under this so-called Option 3.

In closing, we urge the Administration and this Committee to maintain the integrity of this regulatory process for the benefit of U.S. growers and our consumers. We must remember that we are working towards the use of biotechnology in a manner that promotes continued opportunity, profit making opportunities for all of our farmers and for better marketing opportunities for consumers around the world.

We look forward to working with you, Mr. Chairman, and this Congress and Secretary Vilsack on these issues, and I thank you for the opportunity to appear here today.

[The prepared statement of Mr. Conner follows:]

PREPARED STATEMENT OF HON. CHARLES F. CONNER, PRESIDENT AND CEO, NATIONAL COUNCIL OF FARMER COOPERATIVES, WASHINGTON, D.C.

Chairman Lucas, Mr. Peterson and Members of the Committee, thank you for holding today's forum on the biotechnology product regulatory approval process. I am Chuck Conner, President and Chief Executive Officer of the National Council of Farmer Cooperatives (NCFC). NCFC represents the nearly 3,000 farmer-owned cooperatives across the country whose members include a majority of our nation's more than two million farmers. These farmer cooperatives allow individual farmers the ability to own and lead organizations that are essential for the vitality of the agriculture sector and rural communities.

I applaud the Committee for holding this forum in recognition of the need to gain insight, provide transparency and highlight the concerns of America's farmers. This is timely given the U.S. Department of Agriculture's pending decision on herbicide-tolerant alfalfa and the long-reaching effects of that decision. These are the very reasons so many grower groups and related organizations urged the Committee to host this session. Additionally, NCFC is a member of a broad coalition of agriculture and related industry groups on biotechnology—that group will submit additional comments for the record.

My comments today will focus on three issues:

- First, the USDA regulatory process for agricultural biotechnology approvals to date;
- Second, the regulatory status of Round up Ready alfalfa and "co-existence" issues; and
- Third, litigation and court cases over biotechnology product approvals.

American agriculture has long been at the forefront of meeting the world's ever expanding needs for food, feed and fiber. The availability of corn, cotton, soybeans, sugarbeets, canola, alfalfa, and other crops enhanced through biotechnology will continue to assist the U.S. farmer in providing for the world's growing population.

In addition, crops enhanced by biotechnology currently on the market bring value to agriculture, consumers and the environment. For example, some of these plants have been engineered to allow the application of herbicides such as glyphosate over the top of crops growing in the field, reducing tillage and runoff. Others have been protected against harmful insect pests and diseases, thereby reducing the need for chemical spraying.

The development and adoption of these products, and the promise of new products, makes possible the continued availability of safe food, feed and fiber products to consumers in the U.S. and worldwide. With 23 crops in the regulatory pipeline, and more on the way, it's clear that USDA's pending decision on herbicide-tolerant alfalfa will have a far-reaching impact.

The acceptance of biotech crops would not have been possible without the existence of a risk-based regulatory process based on sound scientific principles. That process has been in place since the adoption of the Coordinated Framework for Regulation of Biotechnology by the United States was announced in 1986. Every biotechnology crop on the market today has successfully completed review under the Framework and has been found to be safe. We support the integrity of the U.S. regulatory requirements for biotechnology-derived crops.

Under the authority of the Plant Protection Act implementing regulations, USDA's Animal and Plant Health Inspection Service (APHIS) is the agency that reviews all biotechnology crops before they can be field tested or commercialized. APHIS has overseen tens of thousands of field tests that have made it possible for

over 70 biotechnology crops to reach the market through its deregulation process. In making deregulation decisions under the Plant Protection Act, APHIS has consistently relied upon its independent evaluation of the potential for new products that could pose a plant pest risk. Under its authority it considers factors that are relevant to a plant pest risk determination. Though the National Environmental Policy Act (NEPA) must be addressed in making a deregulation decision, it is important to remember that NEPA is a procedural statute. NEPA directs APHIS to assess potential environmental impacts of its actions, but that is where NEPA's jurisdiction ends. NEPA does not give USDA any authority beyond the Plant Protection Act and APHIS's implementing regulations.

In 2005, APHIS prepared an Environmental Assessment for glyphosate-tolerant alfalfa and made a deregulation decision. The crop was on the market and successfully grown by U.S. farmers for 2 years before a NEPA law suit reversed APHIS' decision. In an order issued by the United States District Court for the Northern District of California in San Francisco in 2007, APHIS was required to prepare a full Environmental Impact Statement (EIS) because the court found that APHIS failed to follow the proper procedures in meeting its NEPA obligations. There was no finding of any deficiency under the Plant Protection Act or of any risk to health or safety.

In December 2010, USDA announced the completion of the court-ordered EIS. In subsequent meetings, the Secretary has indicated he will make a final regulatory decision by late January 2011. In preparing the EIS, USDA chose to include the option, referred to as "Alternative 3," of deregulating glyphosate-tolerant alfalfa with unprecedented regulatory conditions in an attempt to address concerns between growers planting glyphosate-tolerant alfalfa and those planting conventional and organic alfalfa. USDA designated this as one of its "preferred options." The conditions include isolation distances of up to 5 miles and other geographic restrictions that would not allow farmers to plant glyphosate-tolerant alfalfa on an estimated 20 percent of alfalfa acres (50 percent of the alfalfa acreage in the western states); limitations on harvest periods and equipment usage; seed bag labeling; seed coloration; and the listing of seed production field locations on a national database.

The EIS for glyphosate-tolerant alfalfa states USDA's conclusion that it does not pose a plant pest risk. Having made that determination, USDA should immediately deregulated glyphosate-tolerant alfalfa without additional regulatory conditions. Combined with broader policy statements in the EIS, the imposition of conditions on a crop that poses no plant pest risk sets a dangerous precedent for the continued safe development, availability and marketability of new biotechnology products. Broad policy changes related to how USDA makes regulatory decisions on new biotechnology crops should not be made in the context of an environmental review for a specific crop. Attempting to mediate disputes between interest groups in the context of a specific regulatory decision for a product such as glyphosate-tolerant alfalfa would set a precedent that is in direct conflict with the long-standing adherence to science-based regulation of biotechnology crops in the U.S. as well as this Administration's commitment to upholding the public's trust in the integrity of the scientific process.

Now that an EIS has been prepared and APHIS has found, for the second time, that there is no plant pest risk, we fully support alfalfa growers having access to glyphosate-tolerant alfalfa for planting this spring. The best way to ensure production of this valuable crop is for USDA to grant full deregulation without further delay. We urge the Secretary to fully deregulate glyphosate-tolerant alfalfa, and hope that the U.S. Government will vigorously defend that action in any court challenge. The alfalfa industry, with its partners, has demonstrated it has stewardship measures in place that meet all requirements of the re-deregulation that does not require additional regulatory oversight.

We appreciate Secretary Vilsack's commitment to address some of the roadblocks that have been placed in the path of valuable new biotechnology crops including herbicide-tolerant alfalfa and sugarbeets by NEPA litigation. Where we respectfully disagree with the Secretary is on his approach to removing these roadblocks.

One of the terms we've heard most over the last several months is "coexistence." The ability of growers to choose what they want to plant cannot be achieved through the process laid out in the alfalfa deregulation decision if the Department adopts Alternative 3. The ability of multiple production systems to exist side-by-side is based on market needs, communication, and workable solutions developed by industry and growers. Growers have always worked closely with the seed industry and state seed certifying agencies to meet their respective stewardship obligations through contractual agreements and other mechanisms.

Characterizations of disputes between farmers with different cropping systems may have been overstated in the last several months. Farmers, processors and mar-

kets have been and are managing potential conflicts with best practices and private contractual agreements. Where the terms of private contracts call for the exclusion of safe, deregulated biotechnology crops, those contracts should not be the basis for the imposition of regulatory conditions on the production of those biotechnology crops. Coexistence of all crops is a marketing issue, not a safety issue.

It has been suggested that extraordinary regulatory action is needed to address the burdens that have been imposed by recent NEPA lawsuits challenging APHIS's decisions. Those who are opposed to biotechnology have sought relief in the Federal courts under NEPA for nearly 30 years and more recently have challenged regulatory actions taken by APHIS. In those few cases where their suits have been successful, it has always been based on the court finding a procedural violation—no court has ever held that a biotechnology crop presents a risk to health, safety or the environment, nor has any court ever directed APHIS to regulate coexistence. The answer is to take whatever steps are needed to adequately address APHIS's procedural responsibilities under NEPA so that, when and if a decision is challenged, it can be successfully defended with little or no adverse impact on agricultural production or innovation. We look forward to discussing these issues with the Secretary and the Administration further.

APHIS has already implemented a number of key reforms to address the court's concerns with its NEPA compliance. This ability to learn, evolve and improve is one of the great strengths of the U.S. regulatory process for biotechnology. The best insurance for mitigating the adverse effects of the current round of NEPA court cases will be the continued preparation of enhanced Environmental Assessments for biotechnology crops and, where circumstances warrant, an Environmental Impact Statement. We continue to support efforts to secure adequate resources for the continued enhancement of APHIS's regulatory program and the defense of its decisions.

The U.S. Government has consistently supported and defended science-based regulatory regimes. In many international forums, U.S. policy is the standard for science- and risk-based regulation. The U.S. successfully argued against the European Union in a World Trade Organization dispute over the approval of biotechnology products. The interests of growers, businesses and consumers depend on trade agreements with countries that import commodities and products that we produce. The injection of non-science-based criteria into our government's regulatory process will only serve to undermine those international efforts.

As former Acting Secretary and Deputy Secretary at USDA, I am very familiar with the biotechnology product regulatory approval process. We were threatened by lawsuits when I was at USDA—in fact, the alfalfa case was filed while I was Deputy Secretary. I believed then and I believe now in science-based risk assessments for the regulation of all crops.

In closing, we urge the Administration and this Committee to maintain the integrity of the regulatory process for the benefit of U.S. growers and our consumers. We must remember that we all are working toward the use of biotechnology in a manner that promotes continued opportunities for all farmers and consumers around the world. We look forward to working with the Secretary on this issue.

Thank you again for convening this forum and for your continued interest in this matter.

The CHAIRMAN. Thank you, Mr. Conner.

In 2006, the World Trade Organization dispute settlement body ruled in favor of the United States, Canada, and Argentina in the EU biotech case, upholding the principle of regulating based on sound science.

How does the current debate with respect to coexistence affect similar cases that the U.S. may be a party to in the future?

Mr. CONNER. I don't think there is any question, Mr. Chairman, that we are concerned about the precedent that would be set under this so-called Option 3 should the Department choose to go anywhere near that direction in their final determination relative to alfalfa. Our WTO case was won very strongly against the EU on the basis that these are decisions based upon safety and soundness, based upon environmental impact, not based upon in any way a precautionary principle of any kind, not based in any way upon consumer preferences of any kind, based upon safety and soundness. And we won that case, we won it strongly. I think it is hard

to back up that case if indeed we go in that direction in some of our regulatory procedures going forward, and I think Option 3 takes us down that path and should not.

The CHAIRMAN. Mr. Conner, the EU has long been an advocate for including the so-called precautionary principle in international agreements.

Are there similarities, as you see it, to be drawn between the debate about coexistence and the precautionary principle?

Mr. CONNER. I think so, Mr. Chairman. The precautionary principle is really a manifestation, if you will, of policies where politics trumps science in a regulatory decision-making process. That is not the system we want to go to. We want to emphasize that we think USDA should stick to a science-based regulatory process.

The CHAIRMAN. So I guess, Mr. Conner, the question then becomes in your opinion—and you have been around this process a little bit.

Mr. CONNER. A long time.

The CHAIRMAN. You have an little understanding, a little history of observation. If USDA decides on deregulation with conditions under the so-called Option 3, will the United States in effect be defending the precautionary principle in the future? Will we be defending what we have argued against for decades, I guess is really the point?

Mr. CONNER. I don't think there is any question, Mr. Chairman, that a decision to move forward with Alternative 3 is going to have significant consequences, no question about it. It will send a message we believe to our trading partners that the United States has shifted its policy away from promoting sound science relative to these decision making processes and now including politics in that decision making process. And the precedent that that sets, the future of that for these pending biotech products, as well as everything that is going to come down the pike that we don't even know about yet, but that are going to be absolutely necessary in order for us to meet our food and fiber needs on the planet in the future is going to be threatened if we go in this direction.

The CHAIRMAN. The U.S. Government invests significant resources towards outreach in developing countries to assist them in developing functional science-based regulatory systems.

What impact do you anticipate in countries that are beginning to see the value in agricultural biotechnology if the USDA regulates biotechnology products based on, I guess the polite phrase would be, socioeconomic concerns rather than plant pest basis?

Mr. CONNER. Mr. Chairman, there is no question that agricultural biotechnology is not just a thing for the United States of America. It has been widely accepted all over the planet, it is now grown we believe in 25 countries. I am advised over 335 million acres of biotech crops are planted on the globe this year. I am further advised that most of the majority of those countries planting biotech crops are what we would refer to as developing countries. So this is not a developed country issue either. Most are in developing countries.

Why is this happening? It is simple. They see biotechnology as the means by which they feed their people, and I think that is the right assessment, that is the right call, and we again are going to

need these products grown all over the planet in order to meet the future food needs of the population that I think everyone acknowledges is going to be here in the not too distant future.

The CHAIRMAN. One last question, Mr. Conner, and my time is about to expire, you have been a part of the process on all sides. You have observed everything, you have been subject to these lawsuits in the past. Earlier the question was asked about whether the legal framework with which it is possible for these kind of procedural lawsuits to take place is occurring.

Is there some structural change here we need to be addressing in the way the law works as opposed to implementing the law perhaps?

Mr. CONNER. It is a great question, Mr. Chairman, if I could answer it perhaps this way. I don't think I would favor at this stage a change in the Plant Protection Act, at this stage in the process. I say so because I believe that USDA has the authority and the flexibility under that Act to regulate accordingly. I think one thing I would point out to the Committee is the fact that perhaps you have been left with the notion that we are regulating the approval of new biotech plants the exact same way we did perhaps a decade or 2 decades ago, and that is not the case. APHIS has put in place a number of reforms over the last decade relative to the approval of these plants. I personally believe many of those reforms will help expedite this process, probably not as fast as it should be, but I think it does provide them again the flexibility to make those kind of changes, make the call, make the determination ultimately of safety of those products.

And I will say as well, Mr. Chairman, this was a problem when I served at USDA, I think it continues to be a problem. APHIS is an agency where we probably need to focus a little bit upon their resources. They are called upon to do a great deal with very, very limited resources. I think I would propose leaving the Act alone, giving APHIS some additional resources that they need to see these approval processes move forward more quickly, before I would consider legislative changes.

The CHAIRMAN. If my colleagues will tolerate me for one more moment in this forum environment. The question about Environmental Assessment *versus* Environmental Impact Statement, could you shed some light on that?

Mr. CONNER. Well, one the changes that APHIS has made to the current approval process is they have altered what are called the Environmental Assessments for approval of products. And they have also altered the means by which then they determine whether Environmental Assessment is necessary, sort of lower impact situation, or whether they need to go to the full blown Environmental Impact Statement. Again that is not to say that all the problems have been solved, but they have recognized that some of these issues need to be addressed. They have made those changes. The Act provides them with that authority.

If I could, if you would indulge me, Mr. Chairman, Mr. Peterson raised earlier the notion of why didn't we just simply make the decision to do the EIS on all of these products, going forward. And again there has probably been circumstances where we should have initiated the EIS from the very beginning I suspect, but I would

just note that when you look at the 75 or 76 plants that have been approved and are used again widely in so many crops across America today, there is absolutely no way that we would have the resources or have had the resources to do a full EIS on all 76 of those plants. And as I told some folks informally earlier, there is probably not enough plant scientists in our entire university system in America to do that kind of analysis.

So we need to continue to focus upon those times when Environmental Assessment is necessary and all that is needed *versus* those times when we need to go up to that next level and make that call, and I again I think APHIS is getting much better and more tuned into when one of those is appropriate.

The CHAIRMAN. Thank you, Mr. Conner. I now turn to my colleague from Iowa, Mr. Boswell.

Mr. BOSWELL. Thank you, Mr. Chairman. Mr. Conner, welcome back.

Mr. CONNER. Mr. Boswell, thank you.

Mr. BOSWELL. You have been in this room a few times.

Mr. CONNER. A few times, yes, indeed.

Mr. BOSWELL. And our association with you in the co-op business, as I served as a very activist Chairman of the local through the farm crisis and so on, I appreciate what you are doing today. Thank you for your efforts.

Listening to this conversation between you and Chairman Lucas I guess leads me to the question, in your mind does the Secretary have the authority to implement the partial deregulation, do you think?

Mr. CONNER. I am not a lawyer, Mr. Boswell.

Mr. BOSWELL. I am not either.

Mr. CONNER. Well, we may be able to communicate with each other then. I will just tell you having served in the capacity as one who oversaw the regulatory process for this and many, many other products I think it is my view, and the one that I currently share, that once they have completed all of the process in terms of the assessment of the safety of these products—which they have on Roundup Ready® alfalfa—I do not believe that they have the regulatory authority to do anything other than just simply deregulate the product, which is the so-called Option 2 that the Department has presented and is under consideration through January 24th.

Mr. BOSWELL. Okay. Thank you. You heard my earlier statement that I am a long time supporter of science and biotech. I actually believe, as I have heard you state, that to feed this hungry world, growing population I don't know how else we do it. At the same time across the country in my state and other places the farmer's market, the interest in organic foods, and so on, has really exploded. And it is a great opportunity for jobs and giving people what they want. And so I kind of maintain the idea with this grand need we have that there is room for both. And I do believe that. I think we need to work with both, get them to communicate together and so on. And I know when I go to my towns, my medium sized cities, my capital city, the interest in the organic food is a big item, it is very big. At the same time as I have been exposed to the world, kind of like you have and some of the rest of us, and

this population growth, I just think we have to continue the science and so on.

I guess I ask do you share my hope and belief that they can work this out and coexist and everybody do well? Do you share that feeling?

Mr. CONNER. I do, Mr. Boswell. I share it wholeheartedly and I will tell you many of the farmer owned cooperatives that I represent are engaged in conventional as well as organic production and they have seen tremendous growth in both. I think there has been coexistence in the past and it is a testament to our farmers, to the agriculture system we have in this country that when you walk into a grocery store today and no matter what you are looking for it is there and available in just about every shape and size imaginable. It is a remarkable system, it really is.

Mr. BOSWELL. Well, I appreciate that. I thought you probably did. Mr. Chairman, I just wonder if we see a need here. It seems like that we almost see people developing sides. I don't think—maybe there needs to be a side. Maybe we need to figure out how to facilitate communication because it seems like everybody on the Committee feels that we have to do science and at the same time just this exchange that I have had with Mr. Conner, there is a desire and need and a use out there for organic side. And a lot of our co-ops, I think you have had reminders, they do do it. Is there a role that we can play to help the communication on that to realize there is room for both?

The CHAIRMAN. The gentleman is always full of wisdom and good ideas and that is a part of our agenda on this Agriculture Committee is to address the needs of all agriculture.

Mr. BOSWELL. Well, anyway, thank you for your time and we will move forward. That is all we can do.

I yield back.

The CHAIRMAN. The gentleman yields back. We now turn to the gentleman from Texas, Mr. Conaway.

Mr. CONAWAY. Thank you, Chairman and Mr. Conner, for being here. As I heard discussion on Option 3, or Alternative 3, I can see this monster bureaucracy coming together to try to set back standards or buffer zones or all these other things for every single product that is on that list. Aren't those decisions as to whether or not local land use, aren't those decisions really better left to the states and local municipalities and local entities rather than some effort on the part of USDA to try to figure out that rule for the entire country?

Mr. CONNER. Well, Mr. Conaway, I think we would say that private party interests should be the ones in charge of this, because there is precedent for private party interests looking after these issues of coexistence, quite successfully I might add. In the case of alfalfa, in particular, I know some of the members I represent are quite anxious out there to fulfill a market for organic alfalfa seed, a market that exits, a market that I think they are prepared to be there in a big way and believe that through private contractual arrangements they can more than fulfill that market to the benefit of the co-op as well as the producers that are growing that high value crop.

Again, one of the problems, the rub here is, and I go back to Secretary Vilsack's statement, I think virtually the last sentence that he made here, and I just read from this: "I look forward to our discussion here and I hope you share my belief that farmers, ranchers, growers are in the best position to decide what is best for their operations." And so I concur with that statement.

Mr. CONAWAY. Right. I do, too.

Mr. CONNER. I think there is not a role for the Federal Government to be stepping in the middle of these private contractual arrangements relative to coexistence, and I believe they will take care of themselves.

Mr. CONAWAY. Well, the interesting thing is that the Secretary said all the right things, and very political about everything, and hugged all sides and those kinds of things. But at the end of the day if he pulls the trigger on Option 3 then that last statement is inaccurate.

Mr. CONNER. It is inaccurate. That is correct.

Mr. CONAWAY. Because that is not how you would go about that. How much of this is a definitional issue? In other words, from a scientific standpoint is the milk coming out of a cow that is fed organic alfalfa *versus* Roundup Ready® alfalfa, are there any minute differences chemically in that milk that is discernable, measurable?

I see Dr. Slutsky is shaking her head. It is hard for the stenographer to record that.

Mr. CONNER. Why don't you go ahead on that? You are more of the science person here.

Dr. SLUTSKY. No. I mean from a chemical point of view, no. From the point of view of the organic standard, which is a process-based standard, I think that there might be some issues if you could call that milk organic, but from a safety, chemical perspective, no, there is no difference.

Mr. CONAWAY. Okay. So USDA sets the standards for what is or is not organic, correct?

Dr. SLUTSKY. Yes.

Mr. CONAWAY. So I would expect that 100 years from now genetically engineered seeds, as an example, will be the new organic, given the strains that everybody talks about, growing populations, shrinking land mass, those kinds of things. Should there be a suggestion that USDA look at the standards for organic given it is just really a marketing issue and not a health and safety issue, that USDA should look at those standards to see if it really does make sense given the growth in population of the world, given the impact that in this instance Roundup Ready® alfalfa has on the ability to produce more of it on less land or the same land? Are we hung up with just the phrase *organic* meaning something that we grew ourselves in the backyard with whatever? Is there an opportunity to have that conversation at some point?

Mr. CONNER. I will say, Mr. Conaway, from our standpoint we have no problem with those current organic standards and again farmer-owned co-ops are in the business of meeting those standards and doing so to the benefit of their own farmer owners, whether that is milk, fruit and vegetables, no matter what.

Mr. CONAWAY. Mr. Conner, in the meantime talk continues and you have guys out there who are really spring loaded to plant

Roundup Ready® alfalfa who aren't going to be able to do that as it currently stands. So we can continue to have these conversations at 10,000 feet and you have guys out there who really need to make some decisions on the ground and so we will keep up the conversation.

I yield back, thank you, sir.

Mr. CONNER. And again our point of view is that is a different statement than USDA making a regulatory decision under the Plant Protection Act, favoring one of those over another. We don't believe there should be any favoring one way or the other. Let the commercial interests solve those issues as they have in the past.

The CHAIRMAN. The gentleman's time has expired, all time has expired. I would like to thank the panel for their participation and their insights also. Clearly we have a lot of work ahead of us in the coming season on a variety of topics, and I suspect we will look at this one many more times. Thank you very much.

The forum is adjourned.

[Whereupon, at 12:45 p.m., the Committee was adjourned.]

[Material submitted for inclusion in the record follows:]

SUBMITTED LETTER BY JAMES C. GREENWOOD, PRESIDENT AND CEO, BIOTECHNOLOGY INDUSTRY ORGANIZATION

Hon. FRANK D. LUCAS,
Chairman,
House Committee on Agriculture,
Washington, D.C.;

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

Dear Chairman Lucas and Ranking Member Peterson:

The Biotechnology Industry Organization (BIO) wishes to express its appreciation to the U.S. House of Representatives Committee on Agriculture for the January 20, 2011 public forum to review the agricultural biotechnology regulatory authorization process. Like the participants in the forum, BIO strongly believes that science-based decisions by the U.S. Department of Agriculture (USDA) are critical for agricultural biotechnology products to meet future food production challenges. While BIO is pleased that USDA ultimately decided to fully deregulate glyphosate-tolerant alfalfa, we are concerned that USDA previously considered imposing restrictions as a means to regulate coexistence even though the product did not present a risk to health, safety or the environment. We further continue to be concerned that coexistence is mentioned specifically in the Record of Decision as one of USDA's purposes in the context of regulating agricultural biotechnology products.

BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,100 members worldwide. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology. Corporate members range from entrepreneurial companies developing their first product to Fortune 100 multi-nationals. We also represent state and regional biotechnology-derived associations, service providers to the industry, and academic centers.

USDA's regulatory system has helped demonstrate the safety and acceptance of biotech-derived crops. The Plant Protection Act (PPA) has provided USDA with the scientific basis for regulating and deregulating biotechnology-derived crops. Based on its authority under the PPA, USDA has overseen tens of thousands of field tests of biotechnology-derived plants and deregulated over 70 of these crops. This system has brought significant benefits to farmers, consumers and the environment without any evidence of adverse effects to health, safety or the environment.

The National Environmental Policy Act (NEPA) also requires USDA's Animal and Plant Health Inspection Service (APHIS) to consider potential environmental impacts. Under the NEPA process, USDA prepares an environmental assessment (EA) to identify whether there is the potential for significant impacts on the human environment. A draft EA is released for public comment before it is finalized by the agency. If the EA concludes there is no significant impact, no further environmental review is necessary. If the EA concludes that there is the potential for significant environmental impacts, then the agency is to undertake a full Environmental Impact Statement (EIS). The agency prepares a draft EIS for public comment prior to finalizing it. The process of drafting, receiving public comment and finalizing an EIS can take two to three years or more.

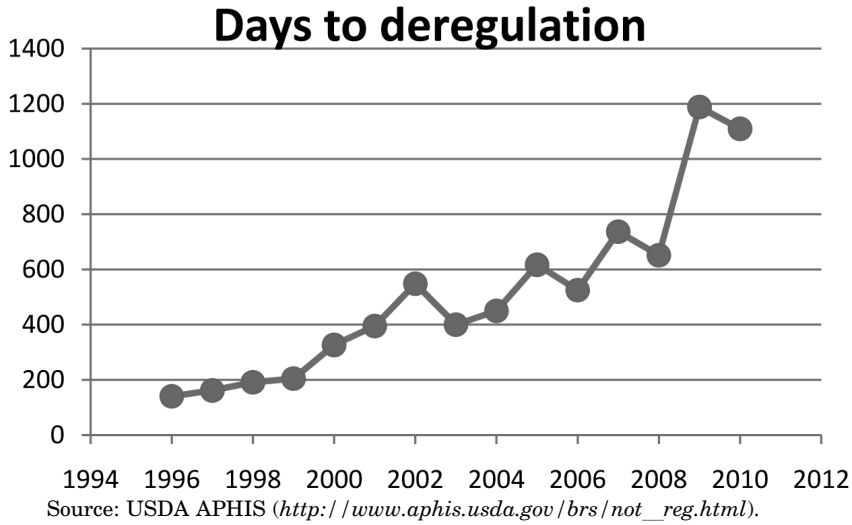
In each case, USDA has made an independent, science-based evaluation of the potential environmental impacts of its deregulation decision as required by NEPA. Any USDA movement away from the scientific justifications used in America's agricultural biotechnology policy would set a dangerous precedent for blocking future agriculture technologies, create legal uncertainty for pre-existing regulatory decisions, and undermine the United States' commitment to defend our exports from non-tariff barriers.

Fortunately, USDA's January 27, 2011, announcement and Record of Decision authorizing full deregulation of glyphosate-tolerant alfalfa followed science-based conclusions under the PPA and complied with USDA's NEPA responsibilities through the issuance of an EIS. BIO appreciates that USDA has amplified its NEPA compliance efforts in response to a handful of recent Federal Court decisions and, in the case of glyphosate-tolerant alfalfa, complied with the Court's order to prepare an EIS. However, we are still concerned that USDA considered using the EIS as a means to regulate coexistence for alfalfa, which would have been inappropriate since no plant risks were identified and therefore USDA would have exceeded the statutory authority under the PPA. To be clear, no court has ever directed USDA to regulate coexistence or change its coexistence policy, nor has any court held that a biotechnology-derived crop has presented a risk to health, safety or the environment. We are relieved that USDA did not issue restrictions, based on NEPA, to the deregulation of glyphosate-tolerant alfalfa.

BIO supports coexistence in American agriculture. American agriculture has an impressive track record of successfully addressing the economic and market-based issues associated with coexistence, whether neighbor-to-neighbor or through state seed certifying agencies or other local, state or regional initiatives. The Federal Seed Act and National Organic Program, both administered by USDA's Agricultural Marketing Service, currently provide measures for addressing seed production, handling and commingling. In the field of agricultural biotechnology, growers have worked closely with the seed industry to meet their respective stewardship obligations through contractual arrangements and other mechanisms. That is where matters of coexistence and stewardship are addressed most effectively and efficiently.

We also would like to take this opportunity to clarify another point for the record. If the United States is to reap the benefits of agricultural biotechnology, we need more timely and science-based authorizations of the innovative biotech products that are in the technology pipeline. When the plant biotechnology industry submitted its first products for authorization in 1995, USDA granted authorizations in a relatively expedient fashion—141 days, on average, in 1996 (see *Figure 1* below). Since then, the length of time for authorization has increased on average by more than 700 percent. And the delays for achieving authorization are increasing at a time when we know even more about the safety of this technology and the benefits it holds.

Figure 1: Average Number of Days to Achieve Authorizations by Year, 1996–2010



Source: USDA APHIS (*http://www.aphis.usda.gov/brs/not__reg.html*).

In addition, delays have increased in the permitting process. While the specified time period for the approval of permit applications by regulation is 120 days, the fact is, many permits are taking as long as 400 days to approval. Overall, 23 permits have taken more than 250 days for approval, or two times the target time of 120 days (2003–2009). Any additional delays and unpredictability to the authorization process will cause U.S.-based biotech companies to lose investment, hinder public research and innovation, and cause American producers to lose out on new technologies that can help enhance their production capabilities while producers in other countries are gaining a competitive advantage. Efficiently and sustainably increasing global agricultural production, including through the development and adoption of new technologies, will be paramount to meeting future population needs for food, feed, fuel and materials.

Again, we thank you for the Committee's public forum highlighting the need for USDA to maintain a science-based regulatory system and evaluation process that demonstrates the safety and acceptance of biotech-derived crops.

Sincerely,

JAMES C. GREENWOOD,
President and CEO.

SUBMITTED QUESTIONS

Questions Submitted by Hon. Collin C. Peterson, a Representative in Congress from Minnesota

Response from Hon. Thomas J. Vilsack, Secretary, U.S. Department of Agriculture

Question 1. Please explain in detail the public comment process that lead to the exclusion of genetically modified traits from food products certified under the Organic Foods Production Act.

Answer. The Organic Foods Production Act of 1990 (OFPA) does not prohibit genetic engineering. In some measure, this was because Deputy Secretary Kathleen Merrigan, at the time, was working for the U.S. Senate Committee on Agriculture, Nutrition and Forestry. While the Deputy is widely known for her work in drafting OFPA, she also has a history of advocacy for biotechnology.

The Organic Foods Production Act of 1990 (OFPA) does not prohibit genetic engineering. In some measure, this was because Deputy Secretary Kathleen Merrigan, at the time, was working for the U.S. Senate Committee on Agriculture, Nutrition and Forestry. While the Deputy is widely known for her work in drafting OFPA, she also has a history of advocacy for biotechnology.

When the first proposed rule to implement OFPA was published in 1997, it did not prohibit genetic engineering and, instead, USDA asked the public to provide guidance on this topic. USDA received a record-breaking 275,603 public comments, the vast majority demanding that USDA prohibit "GMOs." Deputy Secretary Merrigan became Administrator of the Agricultural Marketing Service in 1999, after these comments were received, and she was responsible for overseeing the development of the second proposed and final rule. Working with Secretary Glickman at the time, they concluded that because the organic standard is not a safety-based standard, but rather is a process-based marketing claim, and because existing state, private, and international standards prohibited genetic engineering, USDA would follow suit. The prohibition is defined under the term "excluded methods" and the final rule has been in full force since October 1, 2002.

Question 2. As biotech traits evolve from field crops to industrial processes to perhaps those that do not require the insertion of a plant pest gene, what are the limitations of the current regulations and statues in ensuring an effective and efficient regulatory structure?

Answer. At USDA we continue to examine the issues and weigh the options available to revise our regulations to ensure an effective and efficient, science-based regulatory structure. This will require conversations and partnerships with a wide range of stakeholders, including other Federal agencies such as the Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and other agencies with interests in agricultural biotechnology.

Question 3. Is the option for ordering Environmental Impact Statements for each pending trait under consideration? If so, how feasible is that option given the current workload at APHIS?

Answer. We do not anticipate preparing an environmental impact statement for each deregulation decision. That will continue to be determined on a case-by-case basis.

Question 4. It took roughly 46 months for your agency to complete the final EIS on glyphosate-tolerant alfalfa. Is this the same amount of time it will take to complete the EIS on glyphosate-tolerant sugarbeets, or for any other trait for which an EIS would be ordered? Have you taken steps to shorten this process, if possible?

Answer. USDA is currently working on the EIS for GE sugar beets, and we expect to have it complete by May 2012, which would be less than the 46 months for the GE alfalfa EIS. Where possible, we have taken steps to shorten the process for completing the EIS for GE sugar beets, while satisfying applicable law.

Question 5. When do you expect to come to a decision on Alpha-Amylase Maize Event 3272, also known as corn amylase?

Answer. USDA announced its decision to deregulate alpha-amylase corn on February 11, 2011.

Question 6. Option No. 3 in the final EIS for glyphosate-tolerant alfalfa proposed planting and growing restrictions that do not show up in the draft EIS, plus appeared to be more restrictive than industry practices. Can you explain from where you drew your conclusions on the restrictions presented in that option?

Answer. In developing the restrictions we considered:

- Comments received on the draft EIS.
- The restrictions and best management practices recommended in the petition for partial deregulation submitted by Forage Genetics.
- The Association of Official Seed Certifying Agencies (AOSCA) Alfalfa Seed Stewardship Program (ASSP).

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