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TO REVIEW THE BENEFITS AND FUTURE DEVELOPMENTS IN AGRICULTURE AND FOOD BIOTECHNOLOGY

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

JUNE 14, 2005

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TO REVIEW THE BENEFITS AND FUTURE DEVELOPMENTS IN AGRICULTURE AND FOOD BIOTECHNOLOGY

TUESDAY, JUNE 14, 2005,

U.S. SENATE,,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,,
Washington, DC.

The committee met, pursuant to notice, at 2 p.m., in room SR–328A, Russell Senate Office Building, Hon. Saxby Chambliss, chairman of the committee, presiding.

Present or submitting a statement: Senators Chambliss, Lugar, Harkin, and Salazar.

STATEMENT OF HON. SAXBY CHAMBLISS, A U.S. SENATOR FROM GEORGIA, CHAIRMAN, COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

The CHAIRMAN. The hearing will come to order, and I welcome you this afternoon to this hearing to review the benefits and future developments in agriculture and food biotechnology. I appreciate our witnesses and our members of the public being here, as well as those who are listening through our website.

This year marks the tenth anniversary of the commercialization of agriculture biotechnology. The dramatic adoption rate of biotechnology crops has changed U.S. and global agriculture. I know of no other modern technological development in agriculture that has had such a profound impact on farm operations and food production as biotechnology. I have heard biotechnology described as the single largest influence changing agriculture since the introduction of the cultivator. In my home State of Georgia alone, 94 percent of the upland cotton acres were planted this year with biotech varieties. Nationally, crops enhanced through biotechnology accounted for 76 percent of the cotton acres, 85 percent of the soybean acres, 45 percent of the corn acres. By all accounts, biotech crops have produced real gains for growers by raising incomes and promoting more environmentally friendly farming.

According to a 2003 study released by the National Center for Food and Agriculture Policy, U.S. farmers who planted biotech crops earned an additional $1.9 billion over what they would have earned planting conventional varieties. Globally, during the 9–year period from 1996 to 2004, planted acreage of biotech crops increased more than 47–fold, from 4.2 million acres in 1996 to over 200 million acres in 2004, with an increasing proportion grown by developing countries.

The estimated global area of approved biotech crops in 2004 was 200 million acres, up from 167 million acres in 2003. I appreciate that despite the strong growth and commercial success of biotech crops, the technology and its application elicits strong opinions from many sides. The American public has accepted agriculture and food biotechnology and has a high level of confidence in Government agencies responsible for its oversight. However, we recognize that it is important to institute science-based systems in other countries that do not enjoy the same level of confidence in their government or their regulatory systems.

One of the purpose of this hearing is to review the current regulatory framework governing agriculture biotechnology and to learn about new policies that are being instituted based on the lessons we have learned. It is important that sound science remains the cornerstone of our efforts when regulating this technology. A strong science-and risk-based system that ensures products are safe for the environment and human and animal health must be the underlying premise of U.S. Government policy.

The U.S. Government agencies responsible for oversight of agriculture biotechnology include the Department of Agriculture, the Environmental Protection Agency, and the Food and Drug Administration. Sound regulatory oversight of agriculture and food biotechnology ensures public confidence and is essential to present and future acceptance of the technology worldwide.

I believe that protection of our food and feed supply is our highest priority, and I look forward to hearing how our regulations are currently working and what efforts are being made to update them.

We will also hear about current innovations and future uses. Just as biotechnology is revolutionizing the medical field, its application to agriculture is no less exciting. The past 10 years focused on agronomic input traits that improved yields, reduced pesticide costs, and improved soil conservation and water quality. In addition to building on these benefits, the next 10 years promise innovations that will allow consumers to derive benefits through healthier foods and new crops that will help alleviate world hunger.

We are also already developing industrial products in our crops that promote a cleaner environment through renewable fuels and biodegradable plastics. No other technology in agriculture is transforming the way our Nation farms quite like this. The testimony we hear today will help further explain what is being done to ensure we continue to have confidence in the technology and how future innovations will impact our daily lives.

Now, Senator Harkin has already let us know that he is going to be getting here a little bit late. We will certainly allow him to make any comments when he does arrive. Senator Lugar, we are glad to have you here this afternoon. If you have any opening comments, we will be happy to hear from you at this time.

STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA

Senator LUGAR. Well, Mr. Chairman, I just thank you for having this hearing. You have excellent witnesses, and this is very, very

important, just as you have indicated. But I look forward to hearing the testimony.

The CHAIRMAN. Great. Thank you very much.

We have two panels this afternoon. The first panel will include the Honorable Chuck Lambert, Deputy Under Secretary, Marketing and Regulatory Programs, United States Department of Agriculture. Mr. Lambert we are certainly pleased to have you here.

Dr. Clifford Gabriel Director, office of Science Coordination and Policy, from the Environmental Protection Agency. Dr. Gabriel, welcome. We are glad to have you here.

And Dr. Robert Brackett, Director, Center for Food Safety and Applied Nutrition, from the Food and Drug Administration. Dr. Brackett, we are pleased to have you, and I cannot help but note that we know you are an expert because you taught at the University of Georgia, and everybody from the University of Georgia is an expert.

[Laughter.]

The CHAIRMAN. Gentlemen, we are pleased to have you here. We look forward to your testimony and to your responding to our questions. And, Dr. Lambert, we are going to start with you, and we welcome hearing your comments.

STATEMENT OF CHUCK LAMBERT, DEPUTY UNDER SECRETARY, MARKETING AND REGULATORY PROGRAMS, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC

Mr. LAMBERT. Thank you, Mr. Chairman. I am pleased to be here to provide the committee an overview of USDA's role in regulating ag biotech. I understand that my full comments will be in the record, so I will just try to hit the high notes here.

Biotech is rapidly evolving, and as Federal regulators, it is critical that we keep pace with the technology. Since we began regulating biotech in 1986, we have deregulated more than 60 genetically engineered agricultural products and overseen more than 10,000 biotech field tests. It is the responsibility of USDA to thoroughly evaluate genetically engineered organisms to verify that they are safe for agriculture and the environment.

This is a responsibility that we share with the EPA and the Food and Drug Administration. Under the Coordinated Framework, we work in concert to ensure that biotech crops are safe not only for agriculture but also the environment.

APHIS' primary focus is regulating the interstate movement, importation, and field release of plants under the Plant Protection Act through a permitting and notification process. To a lesser degree, we also regulate biotech-derived veterinary biologics under the Virus-Serum Toxin Act. And we are currently evaluating our role in the regulation of genetically engineered animals and other pathogens and pests under the authority of the Animal Health Protection Act that was in the 2002 farm bill.

In the last 3 years, the program has made a number of changes to address the latest advances in biotech. We created the Biotech Regulatory Services, or BRS, in June of 2002. Cindy Smith, here behind me, is the Deputy Administrator for BRS, as is John Turner.

APHIS' field testing requirements for regulated plants are designed to prevent the unintentional environmental introduction, either through pollen movement or seed or grain commingling or other means, of a protein produced in these plants that could present a potential risk to agricultural crops or the environment.

Anyone who wants to field test such crops must submit a permit for applications and inform us of the confinement conditions to prevent the escape of pollen, plants, et cetera.

I would add that we are committed to ensuring that State interests are fully considered in the field test permit and notifications, and before any product can be field tested, we address and work with the State officials to address their concerns to ensure that the tests can be conducted safely. And the agency has never approved a field test permit over the objections of our State counterparts.

Regarding pharmaceuticals and industrials, although there has been much attention given to these in reality, the hype exceeds reality. We have approved about 90 permits for field tests out of the total 10,000 field tests. But this is a growth area, and we have modified and imposed stringent confinement measures with increased isolation distances and fallow zones and other measures to assure that there is no commingling of these pharmaceuticals and industrials with commercial production.

The Biotech Regulatory Services established a new Compliance and Enforcement Unit to ensure further adherence to permit conditions, and inspectors conduct at least five inspections during the growing seasons and another two inspections in the year following the growing season in the case of industrials and pharmaceuticals.

As I have indicated, we are seeing a lot of change in the biotech industry, and we recognize the need to modify. In January of 2004, we announced plans to renew and strengthen our current biotech regulations. We are currently conducting an Environmental Impact Statement to evaluate our regulations, and we are looking toward moving away from the current notification and permit process to more of a science-based evaluation or a tier-based evaluation where the products that we know and are most familiar with would receive the least regulation; those new and unknown products we would subject to further scrutiny and closer evaluation prior to release. We are anticipating that that EIS would be published sometime this fall or early winter. It will be out for notice and comment and will invite a wide range of public comments. We have worked with our counterparts here and obviously will keep the folks here on the Hill posted as well.

So we are continuing to work on communication and outreach. We are working closely with our sister agencies at FDA and EPA, and we are confident that we are ready for the future of agricultural biotech.

So thank you again for the opportunity to be here, and I look forward to answering any questions. Thank you.

[The prepared statement of Mr. Lambert can be found in the appendix on page 39.]

The CHAIRMAN. Dr. Lambert, thank you very much.

Dr. Gabriel.

STATEMENT OF CLIFFORD GABRIEL, DIRECTOR, OFFICE OF SCIENCE COORDINATION AND POLICY, U.S. ENVIRONMENTAL PROTECTION AGENCY, WASHINGTON, DC

Mr. GABRIEL. Thank you very much. Good afternoon, Mr. Chairman, Senator Lugar. I am pleased to be here before you today to discuss EPA's role in the administration and regulation of agricultural biotechnology. I welcome the opportunity to participate along with my colleagues from FDA and USDA to explain what the agency is going in this area.

The agency believes that biotechnology has great potential to reduce our reliance on some older, more risky chemicals and to lower worker and ecological risk. Regulation of these products is designed to manage and mitigate any risk posed by these products to ensure protection of public health and the environment.

Under the Coordinated Framework for the regulation of biotechnology products, the responsibility for oversight is shared by three Federal agencies: the USDA, EPA, and FDA. Efforts in this administration have been aimed at strengthening the coordination among these agencies.

Under the Coordinated Framework, products of biotechnology are regulated under existing statutes in a manner similar to the regulatory approach used for products developed through other techniques. EPA currently uses three statutes to regulate certain classes of biotechnology products. Products of biotechnology that are intended for use as pesticides would be regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA, and sections of the Federal Food, Drug, and Cosmetic Act that address pesticide residues for food and feed. Under the Toxic Substances Control Act, or TSCA, EPA reviews novel microorganisms that are products of biotechnology.

Because TSCA specifically excludes pesticides, foods, feeds, and pharmaceuticals, this biotechnology program sees few products with agricultural applications. The one exception to date is nitrogen-fixing bacteria, for example, for increased alfalfa or soybean yield.

Under FIFRA, regulated products include genetically engineered microbial pesticides, as well as pesticides produced by plants that act within the living plant to protect it from pests. The most well-known agricultural biotechnology products are crops engineered to contain highly specific insecticidal proteins derived from the bacterium Bacillus thuringiensis, or simply Bt. Such pesticidal substances produced and used in living plants along with the genetic material to produce these substances are called plant-incorporated protectants, or PIPs.

EPA has built numerous opportunities for transparency into its review procedures. EPA's Biopesticides Pollution Prevention Division has been working with companies and individuals developing PIPs since the mid–1980's. EPA has held numerous public meetings with scientific experts and with interested stakeholders, and EPA makes data submitted concerning human health and the environment available for review through a public docket. Every new PIP is announced in the Federal Register with an invitation for public comment.

For the PIPs EPA has registered to date, we review data in five categories. Those are product characterization, toxicology, non-target organism effects, exposure and environmental fate, and resistance management.

One of the challenges that lie ahead is formalizing data requirements and testing guidelines specific to PIPs. Currently these requirements are determined on a case-by-case basis by EPA scientists. Currently, EPA has 12 active registered PIP products. A list of those is attached to my written testimony. Eleven of these products are Bt proteins, and crops include potatoes, cotton, field corn, sweet corn, and popcorn.

Mr. Chairman, we at EPA think that these are promising times for advancing better, lower-risk solutions to pest control needs. We believe that these products have great potential, but we are not simply accepting industry claims as to their safety. We are proceeding cautiously to ensure the protection of our citizens and the environment while at the same time recognizing the potential benefits.

In closing, I would like to emphasize that EPA's biotechnology program is based on five important principles. Those are sound science, transparency in decisionmaking, consistent and fairness, collaboration with regulatory partners, and building public trust. EPA believes that our regulatory system is based on the most rigorous scientific information available, and is credible, defensible, and will serve to protect the environment and public health as we address the challenges associated with biotechnology in the future.

Thank you for the invitation to appear before your committee this afternoon, and I will be happy to answer any questions you may have.

[The prepared statement of Mr. Gabriel can be found in the appendix on page 44.]

The CHAIRMAN. Thank you very much.

Dr. Brackett.

STATEMENT OF ROBERT E. BRACKETT, PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROCKVILLE, MARYLAND

Mr. BRACKETT. Good afternoon, Mr. Chairman and Senator Lugar. I am Robert Brackett, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration, and I would like to thank you for the opportunity to testify today about how FDA regulates genetically engineered foods, or bioengineered foods, as we like to call them, and I am pleased to be here today with my colleagues from USDA and EPA.

FDA is the Federal agency that regulates everything we eat except for meat, poultry, and egg products, which are regulated by our partners at USDA. FDA's Center for Veterinary Medicine oversees animal feed and products used to improve the health and productivity of animals. My shop, the Center for Food Safety and Applied Nutrition, oversees the rest, including plant-derived bioengineered food. FDA is confident that the bioengineered foods on the market today are as safe as their conventional counterparts. Both

the Government Accountability Office and the National Academy of Sciences have issued reports agreeing with this assessment.

For years, scientists have been improving plants by changing their genetic makeup through cross-breeding and hybridization in which two related plants are cross-fertilized and the resulting offspring have characteristics of both parent plants. In the breeding process, however, many undesirable traits can often appear in addition to the desirable ones. Some of these undesirable traits can be eliminated through additional breeding, but this is time-consuming. Breeders can then further select and reproduce the offspring that have the desired traits.

All of our major food crops have been extensively genetically modified through conventional breeding and continue to be improved through various breeding methods. Breeders have also developed new food varieties through breeding. Nectarines, for example, are genetically altered peaches, and tangelos are a genetic hybrid of the tangerine and grapefruit. Today, by inserting one or more genes into a plant, scientists are able to produce a plant with new, advantageous characteristics but with greater precision. The new techniques give scientists the ability to isolate genes and introduce new traits into foods without simultaneously introducing undesirable traits. This is an important improvement over the traditional breeding methods. Bioengineering expands the range of new proteins and other substances that can be introduced into plants, and this is of enormous utility to breeders.

Are there risks? Any genetic modification technique, including both traditional breeding methods and bioengineering, could change the composition of a food in a manner relative to food safety. But because of the increased precision offered by bioengineering, the risk of inadvertently introducing detrimental traits is actually less likely to occur with bioengineering.

The agencies have well-established procedures for establishing the safety of such new substances. In a 1992 policy statement on bioengineered foods, FDA announced that the agency was "not aware of any information showing that the foods derived by these new methods differ from other foods in any meaningful or material way, or that as a class, foods developed by the new techniques present any different or greater safety concerns than foods developed by traditional plant breeding." The 1992 statement and its scientific underpinnings still reflect FDA's thinking about bioengineered foods.

Bioengineered foods and food ingredients must adhere to the same standards of safety under the Federal Food, Drug, and Cosmetic Act that apply to their conventionally bred counterparts. This means that these products must be as safe as traditional foods on the market. FDA has broad authority to initiate regulatory action if the product fails to meet the requirements of the FD&C Act. FDA has established a consultative process to help companies comply with FD&C Act requirements for bioengineered foods that they do intend to market. Companies have used this consultative process more than 60 times as they sought to introduce genetically altered plants representing 16 different crops into the U.S. market, and there is a list of these products on our website.

We are confident that the bioengineered foods that have been subject to the consultations with FDA over the past 10 years are no different in terms of safety than their conventional counterparts. FDA is participating in the interagency Agricultural Biotechnology Working Group, which includes the Office of Science and Technology Policy, EPA, USDA, and others. FDA, in cooperation with the working group, will continue its oversight of new and emerging food biotechnology products and will be vigilant in ensuring the safety and integrity of the food supply.

I thank you again for the opportunity to address these issues, and I am happy to answer any questions that you might have.

[The prepared statement of Mr. Brackett can be found in the appendix on page 50.]

The CHAIRMAN. Thank you very much.

Let me address this to all three of you. One of the challenges for the Federal Government is to ensure all three agencies responsible for the regulatory oversight of agricultural biotechnology are communicating effectively and are coordinating action together. While each has distinct and separate authorities, if any one agency is not working with the others, oversight is compromised. Public confidence in the safety and integrity of the food supply will diminish, compromising the agricultural sector and food export markets.

Can you please explain the procedure—and I would like for each one of you to briefly do this—for coordinating among your respective agencies to ensure that biotechnology policy issues are being address in a consistent and coordinated and efficient manner?

Specifically, can you walk through your individual roles related to the approval of Roundup Ready soybeans and how the agencies have worked together to address regulatory issues that have arisen?

And how is the administration coordinating to assure appropriate oversight on future products that may or may not be intended for introduction into the food supply?

Dr. Lambert, would you start us off, please?

Mr. LAMBERT. Thank you, Mr. Chairman. There is a coordinated process. The Office of Science and Technology Policy coordinators the interagency process to make sure that we are all three on the same page, especially on big decisions. There are monthly calls among the three agencies, and we confer on scientific issues at the staff level on a routine basis.

At USDA, our primary role, first, we would control the importation or the interstate movement of the proposed event. We would handle the notification or permitting and notification process for the confined field releases and field tests of the event, and to make sure that that event is confined from the commercial product. As more information becomes available, then we would go through the deregulation process. We would evaluate the scientific data to make sure it is as safe as traditionally bred varieties or counterparts. Then any proposal to deregulate would be published in the Federal Register for notice and comment to allow for broad-based input into that proposal to deregulate that event.

The CHAIRMAN. Dr. Gabriel?

Mr. GABRIEL. I am afraid as this goes down the panel, you will be hearing some of the same things since we are a coordinated group.

The CHAIRMAN. I hope so.

[Laughter.]

Mr. GABRIEL. Actually, 5 months ago I was at the Office of Science and Technology Policy at the White House and was the principal staff person responsible for coordinating the Ag Biotech Working Group, so I have a lot of experience with managing that structure. But as Dr. Lambert said, there is a higher policy level working group that includes OSTP, OMB, all the relevant agencies, including State Department, Department of Interior, basically all agencies that have an interest in either regulating or basically marketing the product overseas or domestically.

This group has worked very well. Usually the way it works is an issue would surface, whether it is, say, something to do with, pharmaceuticals from plants, there would be a smaller working group, usually consisting of the technical experts. The regulatory agencies would get together, develop proposals, bring them to the larger working group for further discussion with basically clearance through that process, and then the agencies would go back and sort of work on implementing whatever agreement was reached through that working group process.

There are also opportunities to coordinate up and down the chain. There are technical-level discussions with folks that actually have the deep science experience, trying to make sure that the programs are coordinated, so that happens as well.

In terms of Roundup Ready soybeans, that is an area where EPA would be responsible for looking at the herbicide application as a new use to the product. You are not looking at a PIP, as I mentioned in my testimony. This is not a plant-incorporated protectant. But it is a potential new use for a herbicide, and we would look at all the ramifications of expanding the label for a new herbicide on soybeans.

The CHAIRMAN. Dr. Brackett?

Mr. BRACKETT. Well, Mr. Chairman, I, too, am going to emphasize how closely we do coordinate things, but in addition to the higher-level coordination that Dr. Gabriel just mentioned, it is important to point out that the working-level scientists are in pretty much constant communications between the three agencies on any new issues that are arising. So even though it may not necessarily on the surface appear to be the responsibility of one agency, we all know about it.

With respect to FDA's role, we are responsible for making sure that any introduced proteins that are a result of biotechnology are, in fact, safe. So, in particular, we will look at any potential toxicity or allergenicity effects of a particular protein, and then on the final product, for instance, in the Roundup Ready soybeans, to make sure that there are not any unintended consequences that would have affected, for instance, the nutritional status of that product as well. And so our role goes to affirming the safety of those products together with what USDA and what EPA have done.

The CHAIRMAN. Does there come a point in time—and I use the example of the Roundup Ready soybeans because of its more recent

action. But is there a point in time when the three of you or at least a representative from all three agencies sit down and sort of digest what is going on in other agencies relevant to a product like that so you make sure that everything that needs to be covered has been covered?

Mr. LAMBERT. I would say yes, we do that on a routine basis.

The CHAIRMAN. OK. Dr. Brackett, the FDA first published policy regarding the voluntary premarket consultation for new bioengineered food in 1992. With the acceleration of new biotechnology food product commercialization during the 1990's, consumer groups and foreign export partners began expressing concern that the FDA policy is voluntary and have urged a mandatory system be put in place to review bioengineered food products before they are marketed.

In January of 2001, FDA proposed a rule for the premarket notification of bioengineered foods. The proposed PBEN establishes a mandatory procedure for the submission and review for bioengineered food. I have been informed that FDA has delayed finalizing that proposed rule.

Can you please provide us with the agency's current thinking on the finalizing of this rule?

Mr. BRACKETT. Yes, Mr. Chairman. When we proposed that rule, that was earlier in the consultative process. In the intervening years, we have found that the consultation process has worked so well that actually trying to finalize that rule was actually put to a lower priority, and we are focusing on the consultative process at this time.

The CHAIRMAN. OK. Senator Lugar?

Senator LUGAR. Well, thank you very much, Mr. Chairman. I appreciate your organization of the hearing with each of these agencies, ask the question you have just asked, and that is, are they visiting with each other, are they coordinating policies, and they have responded that they are—in fact, in preparation for the hearing, I suspect have made sure everybody is on track because this has been a regular and appropriate line of questioning in these hearings over the years on biotech.

The integrity of the products really depends upon the efficiency and efficacy of the agencies that are represented here, plus others you may identify. And that is extremely important as we talk about biotech to the rest of the world. And this hearing is important, once again, to establish the integrity of the process, that users of biotech products in this country not only are safe but, as we will hear from the distinguished additional panel, have resulted in extraordinary gains in income for American farmers as well as for those abroad, as well as extraordinary changes in yield which have made life-saving differences, especially in other countries.

All of those things would be very dramatic as they were, but if you taking a chance in the process, why, the downside would be obvious, too; that in return for the money and for the life-saving, you also are putting at risk in products that are deficient people who are also involved in farming and production.

I make that point because throughout the years in these hearings, we have been trying to explore why there is such resistance

in Europe. I don't center entirely the criticism there, but this has been a major bone of contention.

As one of the witnesses in the second panel points out in testimony, it says, "Even in Europe, things are happening." Quite apart from other continents where a lot of things are happening. We have had Dr. Borlaug before the committee several times, and we appreciate and hope that he gets well now because his contribution, just as has been suggested, has been magnificent in terms of life-saving. Some have suggested that he has been responsible really for the longevity of more people on this Earth than any other one individual through the breakthroughs, first of all, in the Mexico projects and the Philippines and moving through India and now into Africa. And this is exciting work.

But I mention the second panel. They will speak for themselves because their testimony is truly thoughtful and informative. Many people of common sense have reasoned, if all of this is true, if literally you are going to be saving hundreds of thousands of lives, why the resistance? And so it is important we do our homework back here so there is no academic reason whatsoever for anyone in Europe, Asia, or anywhere else to question the safety and efficacy of the products that are involved in biotech.

So this is useful, I think, as a benchmark always to just check our own findings, our own regulatory procedure to make sure it as sound as you have testified.

Now, having said that, let me ask: Do the regulatory agencies in any way get into the diplomacy of the spreading of the good word or the good products? In other words, if, in fact, there are the income gains that are evident from biotech, plus the fact that people, because the yields are higher and because the crops work better in various other climates, manage to change really the quality of life, I suspect it is not your portfolio to advertise these effects. But, on the other hand, this is such good news that it would be hard for you to suppress it.

I am just curious. At what point does either the marketing or the diplomacy of these situations become a part of your responsibilities, or do you stick strictly to the regulatory functions to make certain as the products come through? Can you describe even more, in other words, your mission as you perceive it?

Mr. LAMBERT. We do from a standpoint of communication and outreach talk about the regulatory process, the safeguards that we have in place, the additional measures that we have taken, share our experiences and changes in the regulatory process. So through communication and outreach, not only domestically but to our trading partners, I think we foster that climate where the technology——

Senator LUGAR. Do you visit with regulators from other countries? Are they interested in what you are doing?

Mr. LAMBERT. We do, and through the Codex, there is a working group that is working on biotechnology as well.

Mr. GABRIEL. There are multiple international fora for us to interact with our counterparts. There is the Codex, as was just mentioned. There is also the Organization for Economic Cooperation and Development, OECD, a lot of good interaction there, especially with our European colleagues, and others. We have fora in

Asia, a lot of bilateral interactions. So, you know, the opportunities are many and we certainly try to take advantage of all those opportunities.

I think probably the very best way for us to instill confidence in the consuming public, I think, is by sticking to the science, by having a transparent process that puts the cards on the table and people can see how we are making our decisions. And as long as we can do that, I think that takes us a long way to making the kind of inroads into the pockets of skepticism, perhaps, that you mentioned in your comments.

Senator LUGAR. Do you have any interaction with the World Food Program of the United Nations? I ask this because essentially this is a group of people that are really on the forefront of trying to stop starvation. And I know from my own visits with some of these people that they have been frustrated often in Africa because some statespersons there have gotten word from Europeans that these biotech situations are unsafe and are likely to cause great harm to the ecosystems of their countries. This is why I am a bit curious whether there is any interaction with those people.

Mr. LAMBERT. Not that I am aware of, Senator.

Mr. GABRIEL. Same here.

Senator LUGAR. Thank you, Mr. Chairman.

The CHAIRMAN. That is interesting that you raise that issue, Dick, because I was sitting here thinking about this hearing this morning, and as we move toward going to Hong Kong for the WTO Round in December, certainly we are going to have a lot of formal discussions. But what I have found is that a lot of the information that you get comes more from the informal discussions than the formal.

So I think we probably want to coordinate with you folks maybe a sit-down before that. There is a large delegation from this committee going. We ought to sit down with you all to glean from you what you have learned from your counterparts, so when we talk with our counterparts across the table in Hong Kong, it would be very beneficial to know kind of their thought process so we can hopefully remove some of these impediments and answer some of these arguments that they have got or that we will hear about.

Senator Salazar?

Senator SALAZAR. Thank you very much, Chairman Chambliss, for holding this hearing on this very important subject.

I want to follow up just on the question from Senator Lugar, regarding what we do to try to get more into these pockets of skepticism that we face in other countries. My question is whether or not we are doing enough and whether there are more specific things that we ought to be doing here in America, including out of this Congress. For many of us on this committee, we very much want to open up markets in other places of the world for our agricultural products, whether that be in Japan or South Korea or China. We are always working on that agenda to try to provide new opportunities to sell our agricultural products. Yet, when you hear about the skepticism that we find in Europe as well as in other places around the world with respect to our biotech products, it just raises the same question for me in my mind that Senator Lugar asked: What more can we do to try to get rid of some of the

skepticism? We have gotten rid of it, I think, here in this country pretty well, but we still face it so clearly in Europe and other places.

So are there things that we ought to be doing as a Congress to try to address that issue?

Mr. LAMBERT. From my viewpoint, it is just continue dialog and discussion, Senator. We have explained to the U.N. about the safety of genetically engineered products with respect to food aid to Africa and tried to have broader understanding there. I have been in some APEC forums. There are many Asian countries that have biotech developments in channel, but for whatever reason have been able to commercialize those. And we have seen in China they are beginning to bring many of those onlines, and I think possibly as China goes, so may go the rest of Asia. But we are beginning to see, I think, reduced resistance in some of these regions, where there is a growing awareness of the importance of adopting this technology for a variety of reasons.

Mr. GABRIEL. One of the components in a lot of these discussions is the whole area of capacity building. A lot of developing countries are reluctant to take on some of these products if they don't have their own, you know, in-house ability to make these safety assessments for themselves. They don't want to be seen as accepting a rubber stamp from any other country. It is important that they have their own capabilities. And we certainly are looking at the possibility, not so much the EPA but certainly across the Government, on ways to improve our capacity building, ways to target the resources that we have to help countries develop their own regulatory apparatus, making sure that they are comfortable with the products. So that's another important part of the puzzle there.

Senator SALAZAR. I would just make a suggestion. Most of us will have meetings, as I have within the last week, with the Ambassador from China to the United States, the Director from Taiwan, the Ambassador to the United States, to talk about trade in these countries. I think for us to have a set of talking points in terms of how those countries could have confidence in the bioengineered products coming from this country is something that would be helpful to us as we try to be good Ambassadors for the work that you do.

A question just for Dr. Brackett. I understand that we do not have legislation to address this issue. For us this hearing is simply a hearing to learn more about what is going on and to see whether or not there are any issues that we ought to be concerned about. I noted in your testimony, on page 6 you talk about the authorities of the FDA. You talked about how the authority of the FDA gives you the power to remove food from the market if the food poses a risk to public health. My question to you is: Has that power ever been exercised on the part of the FDA? Or have we never had a product that has essentially triggered the use of that authority on the part of the FDA?

Mr. BRACKETT. For bioengineered products specifically?

Senator SALAZAR. Yes.

Mr. BRACKETT. No, we have never had to exercise that. It has all been safe.

Senator SALAZAR. Thank you very much.

The CHAIRMAN. Thank you.

Gentlemen, recently Syngenta notified all three agencies that seed distributed by the company contained an event known as Bt10, which had not undergone full regulatory clearance. APHIS has since completed its investigation, and FDA released a statement regarding its presence in food and feed. Last week, Syngenta announced it has applied to the FDA for marketing approval.

For all three of you, how have all three agencies coordinated on the Bt10 issue, particularly on the investigation and how you came to the conclusions on safety? And to Dr. Brackett, how long should the process take to complete the review of Syngenta's packet? And in your opinion, does this incident highlight the need for a more comprehensive adventitious presence policy that identified an appropriate level of safety for intermittent, low levels of products in development that have not completed all regulatory reviews?

Mr. BRACKETT. We did just receive a packet from Syngenta to evaluate that. Based on our initial consultations with the other agencies, we realize this is probably an instance where the gene product itself was safe because it is similar to one that was—or it is the same protein that was approved before.

With the current full packet that we have received, we have moved that to the very top of our evaluations, and so we are going to be moving forward with that as quickly as we can. We will not know exactly how long it will take until we actually get into the materials and see how much or what of the materials are there that we might need.

With respect to the second part of your question, this does not necessarily, we do not think, say anything against the current policy for early protein review. That policy or that guidance is meant, very early in the research and development stage for companies who anticipate they might have a product going into commercial food production, to meet with FDA early and often to sort of get an idea of what problems we might see down the line. In this case, we would likely not have seen any problems there.

So with respect to any other sort of adventitious presence, this was a laboratory error, basically, one in which the sample was never meant to get out into the commercial supply. And so that is something that the guidelines were really not meant to address.

The CHAIRMAN. How about as far as the coordination between all three agencies relative to the safety issue on Bt10?

Mr. GABRIEL. The agencies have worked very closely on this, as you might imagine. Since Syngenta came to the three agencies at the end of last year, probably not a week goes by that there is not some conference call, face-to-face, or some other interaction between all the agencies that are involved in this topic.

In terms of how the agencies worked to determine the safety of the product, very early on we requested information from Syngenta about the nature of the genetic construct within Bt10. And based on sequence information, based on other information that Syngenta was able to provide, EPA scientists primarily were able to confirm that the proteins that are expressed in Bt10 are, in fact, the same proteins that are expressed in another biotechnology product, Bt11, which has an exemption from the requirements of tolerance. Therefore, we are able to determine that should Bt10 be found in feed

or food, the existing exemption from the requirements of tolerance would apply; therefore, those products would not be considered adulterated. So that was basically the thought process that we went through.

In terms of the investigation, we were able to work very closely, EPA with USDA, and I am sure we will hear from USDA on their process. But to the extent that we work together, under different statutes, different requirements, it could not be exactly on the same track. In fact, EPA's investigation is still open. We are still in, I believe, the final stages of that. But the agency has worked very closely together, shared resources, shared information. And, again, it was a fairly seamless operation.

One of the things that we have been talking about doing—and we will be doing that very soon—is looking basically at lessons learned. Even though the process worked very well in our estimation, we think that there probably are places that we could make this process more efficient, improve the types of interchanges that we had to have to deal with something like this.

Mr. LAMBERT. USDA APHIS used the following framework to evaluate whether there were safety issues involved with Bt10: The first question we asked was how similar is this corn line to lines that have been deregulated and deemed to be safe. And the fact is that this is the exact same protein that is deregulated in Bt11.

And we asked then is there any reason to believe that these genes or gene products could pose safety risks if they were produced in other corn lines, and the answer is no, because they are already deregulated in some other corn lines.

Is the undefined cultivation of Bt10 likely to present any plant risks or would this become considered a weedy species? And, again, the answer was no.

And are there ways which this corn could be likely to cause direct or indirect damage to other plants? And, again, the answer was no.

So we did have daily, in some instances, interagency meetings and calls. The general coordination and communication was very good, and, in fact, this was, I think, the first time that EPA and USDA conducted a joint environmental investigation or a joint investigation of this event.

Regarding adventitious presence, we do support addressing that, and that is one issue I failed to bring up when I was discussing the EIS, the Environmental Impact Statement. We plan to come with the need for establishing thresholds for adventitious presence. Whether that would have helped in this case given that it was a laboratory issue I think is open for discussion. But we have at APHIS conducted an internal evaluation of how we handled this and important things to learn. And one of the things as we go into the interagency discussion and process that we intend to bring to the table is that in other areas we have used the incident command system—in Veterinary Services, Plant Protection Quarantine, Forest Service, and other governmentwide agencies—to understand and we probably did not really understand how complex this issue is, so recommending to our fellow agencies that we work and plan to coordinate and work through an incident command system. As

we move on future issues, this is something that at least might warrant consideration.

The CHAIRMAN. Thank you.

Senator Harkin?

STATEMENT OF HON. TOM HARKIN, A U.S. SENATOR FROM IOWA

Senator HARKIN. Mr. Chairman, thank you very much, first of all, for having this hearing.

I have just a couple of opening comments. I just wanted to welcome two prominent Iowans who will be on the next panel, they are, Ambassador Ken Quinn, who is president of the World Food Prize Foundation; and Mr. Ron Heck, who is Chair of the American Soybean Association. I will have more to say about those two and about the World Food Prize Foundation when their panel comes up.

I will just ask that my opening statement be made a part of the record.

The CHAIRMAN. Without objection.

Senator HARKIN. Thank you, Mr. Chairman.

[The prepared statement of Senator Harkin can be found in the appendix on page 36.]

Senator HARKIN. There is a lot of talk about the controversial aspects of recombinant DNA, but I think we have to keep in mind, as I tell people a lot, that biotech has been with us a long time. This is not something new, whether it is hybridization or whether it is—I always say you go back to whenever it was in history that people first used yeast to make their bread rise, thath was biotech. And so we have been using it for a long time.

But in the case now where we are looking at recombinant DNA and we are sort of collapsing timeframes here in many cases, we have to be, I think, pretty cautious in how we proceed. We have a set of regulations basically in place that were there for conventionally produced and conventionally bred precursors to some of these. Now, the fundamental question we need to ask is whether those regulations are sufficient for the new challenges that are arising. Again, I say that sometimes we have to proceed with some caution and to make sure that we have wise regulations. That is why I liked the last question that our chairman asked about the coordination that is being done.

I would also say at the outset that we need to focus more on research, Mr. Chairman. In the 2002 farm bill, we put in there a goal of doubling agricultural research over 5 years, but 3 years later, viryually none with inflation, we have only had an increase of 4.3 percent. And with all of the problems that confront us in terms of global hunger, food safety, biotech and using biotech not only for food but for energy and other things, it would seem to me that this is where a dollar of investment pays off greatly.

Having made those statements, there is one question I wanted to ask this panel, and it has to do with the regulatory scheme that we have now. FDA currently has a premarket consultation process whereby biotech seed companies submit all safety data related to the product. They discuss safety considerations with the FDA before the product is marketed. If FDA has questions about the safety

data, the company may be asked to conduct additional studies to provide more detailed answers.

Now, this process is voluntary, and although it is voluntary, all bioengineered products, I understand, have undergone this consultative process. And no biotech food product has been commercialized without FDA's evaluation of their safety data. So, Dr. Brackett, my question is: Does an independent company or FDA conduct studies on the safety of the products at hand, or does FDA rely solely on the company-provided data?

Second, has there ever been a case where FDA does not approve of a company's safety data and rejects the company's request to market a product?

Mr. BRACKETT. With respect to the first part—could you repeat the first part again?

Senator HARKIN. The first part is: Does an independent company or does FDA itself conduct studies on the safety of the products at hand, or do you just rely upon the studies provided by the company that is trying to market this product?

Mr. BRACKETT. We would rely on the packet provided by the company and look at a very broad base. First of all, the most important thing is the gene product itself and the safety of that product, and the main problems one would see would either be potential toxicity from that product or allergenicity. So that we could tell based on what the company submitted to us and based on our experience with those gene products, whether they were likely to be.

In a broader issue——

Senator HARKIN. Wait a minute. You ask the companies if they would like to have further studies done? Is that what you are saying?

Mr. BRACKETT. We would ask them for more data in some cases, yes.

Senator HARKIN. If you want to, you would ask them for more data.

Mr. BRACKETT. Right.

Senator HARKIN. But there is no other independent company that would examine this.

Mr. BRACKETT. No, there are no others.

Senator HARKIN. Well, then, the second part is: Has there ever been a case where the FDA does not approve of a company's safety data and rejects the company's request to market a product? Has there ever been a case?

Mr. BRACKETT. There have been cases, yes.

Senator HARKIN. And could you supply those for us?

Mr. BRACKETT. Yes, we would be happy to provide them for you.

Senator HARKIN. I would like to take a look at those myself.

Now, my last question. What are the arguments for or against making this consultative process—which is voluntary now, making it mandatory?

Mr. BRACKETT. Well, the case is—of course, if it is mandatory, it has a bit more clout. But the case against it, actually, is that the voluntary process has worked very, very well. We cannot really find a way to—there are always ways to improve it, but there are no major flaws. And, really, as a practical matter, the reason that the products have not been commercialized is that the consultative

process, the letter that the company gets from FDA has enough clout with the customers of that product that a company who does not go through the consultative process would not even be able to market, no one would really want their product unless they could be assured that it had gone through an investigation or an evaluation.

Senator HARKIN. Thank you very much, Dr. Brackett.

That is all I have, Mr. Chairman.

The CHAIRMAN. Gentlemen, thank you all very much. We appreciate your being here and appreciate very much your testimony and your input.

The CHAIRMAN. Our second panel will consist of a long-time good friend of mine, former House colleague, the Honorable Jim Greenwood, who is now the Chief Executive Officer, Biotechnology Industry Organization; Mr. Ron Heck, Chairman of the American Soybean Association; Ambassador Kenneth Quinn, President of the World Food Prize Foundation.

Gentlemen, welcome. We are pleased to have you here, and we look forward to your testimony.

Mr. Greenwood, I will have to tell you that one of the advantages of being a former Member during the quiet period is that you get discriminated against. We have to ask you to stand and let's put you under oath. Would you raise your right hand, please? Do you swear or affirm that the testimony you are about to provide is the truth, the whole truth, and nothing but the truth, so help you God?

Mr. GREENWOOD. I do.

The CHAIRMAN. Thank you very much.

Gentlemen, again, we welcome you here to discuss this critically important issue, and particularly as to what is going on out there outside the Government sector. And, Jim, we will start with you, and, Mr. Heck and Ambassador Quinn, we will come that way. So we look forward to your comments.

STATEMENT OF JIM GREENWOOD, PRESIDENT AND CHIEF EXECUTIVE OFFICER, BIOTECHNOLOGY INDUSTRY ORGANIZATION, WASHINGTON, DC

Mr. GREENWOOD. Well, thank you, Mr. Chairman. It is the first time I have been on that end of the swearing-in process. I have been on the other end many a time, and it feels a little different. But I thank you, Mr. Chairman, for holding this hearing, and I welcome the opportunity to testify before Senator Harkin and Senator Lugar as well.

My name is Jim Greenwood. I am the President of the Biotechnology Industry Organization, otherwise known as BIO. Our membership includes over 1,100 member companies and research institutions in North America and around the world. These members are actively involved in research and development of new medicines, foods, and industrial products to benefit the lives of people and the environment.

I would to thank Senator Saxby Chambliss for the opportunity to be with you today.

The industry celebrates two important milestones this year: first, the tenth anniversary of commercialized biotech crop plantings; and, second, the planting of the one billionth acre of biotech crops.

Agricultural biotechnology is the most rapidly adopted technology in the history of food production. Its widespread use demonstrates a shift from chemically based agriculture to biologically based agriculture.

According to the International Service for the Acquisition of Agri-Biotech Applications, in 2004, 8.25 million farmers in 17 countries planted biotechnology crops, 90 percent of whom were in developing countries.

In the United States, in 2004, 85——

The CHAIRMAN. Jim, excuse me. Would you state that again, those numbers?

Mr. GREENWOOD. In 2004, for the first time, biotech—excuse me. Let me say that again. According to the International Service for the Acquisition of Agri-Biotech Applications, in 2004, 8.25 million farmers in 17 countries planted biotechnology crops, 90 percent of whom—that is, the farmers—were in developing countries.

In 2004, for the first time, biotech crops acreage in developing countries grew faster than in developed countries. In the United States in 2004, 85 percent of soybeans, 76 percent of cotton, and 45 percent of corn were biotechnology crops. We expect these gains to continue. By 2010, ISAAA projects that up to 15 million farmers will grow biotech crops on more than 370 million acres in as many as 30 countries. Biotechnology enables farmers to reduce input costs and improve yields. It is also used to increase the health of farm animals, enabling the production of safer and more nutritious meat, milk, and eggs.

Pest-resistant and herbicide-tolerant biotechnology crops reduce the need for ag chemicals. Biotechnology crops have been attributed to reduction of ag chemicals by significant amounts, increasing farmers' incomes by $1.9 billion per year and boosting crop yields by 5.3 billion pounds.

Benefits to the farmer also translate into benefits to the environment. Growing more food on less land reduces the need to clear forested lands to create more farmland. This will be increasingly important as global population grows. Reducing the number of times farmers spray chemicals also reduces the consumption of fuel and greenhouse gas emissions. Further, the reduction in the need to plow to control weeds leads to better conservation of soil and water and decreases soil erosion and ag chemical runoff.

The development and subsequent adoption of this technology could not have been possible without a strong regulatory system to ensure the safe use of these products for both human health and for the environment. We recognize that strong regulatory systems are essential to consumer confidence, and we work closely with the U.S. Department of Agriculture, the Food and Drug Administration, and the Environmental Protection Agency, all of whom play important roles in providing science-based assessments of our products. We recognize that this dependence on a strong regulatory system will only increase as we move to the development of what is often referred to as second-generation biotechnology products.

While research and development in agronomic traits like the ones discussed above will continue, significant research is under way in the second generation of products which will address a wide range of societal concerns.

Biotechnology offers great promise to provide more nutritious foods. Researchers are working to create oils with reduced levels of harmful trans fat and saturated fats. Foods are in development which will have higher levels of nutrients, protein, and essential amino acids, as well as extended shelf life. And we can look forward to foods that are allergenic to certain segments of the population today being non-allergenic in the future because of the use of biotechnology in food production.

Another promising avenue of research is the development of plant-made pharmaceuticals, which will allow companies to manufacture novel biologics and therapeutics in plant cell systems. The technology has the potential to reduce the costs of producing pharmaceuticals to enable increased access to life-saving drugs.

In closing, biotechnology has a long track record for using innovative techniques to solve long-standing problems. Our industry is investing heavily in research and development which will provide products which will promote human, animal, and environmental health.

Thank you for giving us the opportunity to provide this information to you today, and I will try to answer any questions that you may have.

[The prepared statement of Mr. Greenwood can be found in the appendix on page 70.]

The CHAIRMAN. Thank you very much.

Mr. Heck, welcome.

STATEMENT OF RON HECK, CHAIRMAN, AMERICAN SOYBEAN ASSOCIATION, PERRY IOWA

Mr. HECK. Good afternoon, Mr. Chairman. I believe you will find our remarks to be very consistent with your opening remarks earlier this morning.

I am Ron Heck, a soybean and corn farmer from Perry, Iowa. I serve as Chairman of the American Soybean Association, and I am appearing today on behalf of the American Farm Bureau Federation, the National Corn Growers Association, and the National Cotton Council, as well as ASA. We thank you for the opportunity to testify before the committee.

2005 marks the tenth anniversary of the introduction of biotech crops for commercial production. Our organizations recently recognized the planting of the billionth acre of biotech-enhanced agricultural crops. Since 1996, and in each successive year, American agriculture has been the world leader in the adoption of agricultural biotechnology. In 2004, the United States accounted for half of the world's total planting of biotech crops. U.S. plantings of the three major biotech crops continue to expand. For example, in 2004, 86 percent of total soybean plantings were modified to be herbicide-resistant, up from 81 percent in 2003; 76 percent of the upland cotton plantings were biotech cotton, up from 73 percent in 2003; and 46 percent of corn plantings were biotech corn, up from 40 percent in 2003.

American farmers have seized the opportunity offered by biotechnology to improve their production efficiency. They recognize that the adoption of new technologies is essential in maintaining a competitive advantage for U.S. agricultural exports. The benefits

of biotech crops include lower pesticide usage, decreased soil erosion, increased yields, disease resistance, and fuel savings. The future of this technology is bright: new biotech plant varieties are being developed that will produce crops within enhanced nutrient and health profiles, as well as crops tolerant to drought, salty soil, cold, and disease.

Crop biotechnology has led to reduced tillage practices, saving 1 billion tons of topsoil annually, reducing by 309 million gallons the amount of fuels used by farmers, and decreasing greenhouse gas emissions by 1 billion pounds. Biotechnology has decreased pesticide applications by 46 million pounds and is saving U.S. consumers $3.5 billion a year in water treatment and management costs.

While the United States is the world leader in the production of agricultural crops enhanced through biotechnology, other countries are also expanding their biotech crop production. In 2004, global biotech crop acreage increased by 20 percent to a total of 200 million acres—the ninth consecutive year of double-digit growth. The global value of total crop production from biotech crops in 2003 was estimated at $44 billion.

Market development for these crops is dependent on public policy that does three things: maintains an unbiased, science-based regulatory system that inspires consumer confidence; two, works to ensure market access for biotech crops and products domestically and internationally; and, three, creates an environment conducive to the development of new biotech crop varieties. I would like to elaborate on each of these three points.

First, the U.S. regulatory system does not require any specific labeling or traceability for biotech crops and ingredients that have been determined to be substantially equivalent in safety and nutrition to conventional crops. This science-based regulatory approach should continue.

Some countries have adopted or are considering regulatory regimes that stigmatize biotech crops by requiring mandatory labeling and traceability of foods containing ingredients derived from biotech commodities. These policies have the effect of nullifying the regulatory system in place.

Unfortunately, countries with mandatory labeling and traceability laws for biotech commodities are trying to internationalize their systems by pushing for adoption of similar requirements by the Codex Alimentarius Commission. The U.S. Government must continue its efforts to prevent adoption of non-science-based and discriminatory standards on a worldwide basis.

Two, regarding market access, it is critical to ensure open access to world markets for the products of biotechnology. The European Union's current approach to require the labeling and traceability of food and feed derived from biotech commodities is inconsistent with its own risk assessments and also inconsistent with the widespread practice by the EU's own food industry, where they use biotech-derived processing aids in the product of food products that are not then required to be labeled.

Our organizations, along with 17 other major U.S. ag organizations, have requested that the U.S. Government file a WTO complaint against the European Union challenging non-scientific bar-

riers to market access for biotech-derived crops. We also support the current WTO case against the EU's moratorium on approvals of new biotech varieties.

Third, it is important that we foster an environment conducive to innovation and the adoption of new technologies. Government and private sector research centers must be assured that the United States is working to ensure that there will be a market, domestically and internationally, for approved products derived from biotechnology.

In developing countries, adoption of suitable biotechnology traits has the potential to deliver increased efficiency in ag production, a driver of economic growth. Biotechnology is an important tool for tackling world hunger.

In conclusion, American agriculture has enthusiastically embraced the benefits that biotechnology provides in enhancing production efficiency and the competitiveness of U.S. agricultural commodities on world markets. As we recognize this tenth year of commercial biotech production, we look forward to continuing our work with Congress to support this important agenda. U.S. farm organizations are committed to ensure broader acceptance of these products internationally and continued consumer confidence at home. We will work with Congress and the administration to address unnecessary trade barriers implemented by other countries for biotech commodities.

Thank you for the opportunity to testify, Mr. Chairman.

[The prepared statement of Mr. Heck can be found in the appendix on page 78.]

The CHAIRMAN. Thank you, Mr. Heck.

Ambassador Quinn, welcome.

STATEMENT OF AMBASSADOR KENNETH M. QUINN, PRESIDENT, WORLD FOOD PRIZE FOUNDATION, DES MOINES, IOWA

Ambassador Quinn. Thank you very much, Mr. Chairman. I wanted to say at the outset that we do not know each other, but I was part of an Iowa-Georgia initiative to increase exports in 1979, and I visited the University of Georgia and had dinner at the wonderful President's House, the antebellum home there, and so I hope that gives me at least a little credibility and——

The CHAIRMAN. That qualifies you as an expert.

[Laughter.]

The CHAIRMAN. You went to heaven while you were in Athens.

Ambassador Quinn. It certainly felt like that. Thank you very much, Mr. Chairman.

Dr. Borlaug asked me to convey his greetings to you, his apologies that he could not be here today, and his hope that you would understand his medical necessity keeping him away. I may seem like a strange substitute for him being a political science major who worked in the State Department for 32 years, but he and I had the same experience of working in poor villages, and we saw and learned the lesson that the things that can uplift people out of poverty were the same things that uplifted our own country, whether it is in Iowa or Indiana or Georgia. It was rural roads and agricultural technology, particularly that which came from our land

grant and agricultural colleges. And so he and I are kind of soul mates and kindred spirits on this subject, and that is why I am so pleased to be the President of the World Food Prize, where our mission is to inspire similar kinds of breakthrough achievements.

Dr. Borlaug created the World Food Prize to be the Nobel Prize for food and agriculture. He went to the Nobel Committee and tried to convince them to create one, and they turned him away—nicely, of course, since he was a Nobel Peace Prize winner. So he went out and started one on his own—The World Food Prize— and for the last 19 years, every October on or around World Food Day, we give a quarter-million-dollar prize to an individual who has made a breakthrough achievement.

We also hold a symposium with speakers talking about cutting edge issues in food and technology. Senator Lugar, I know that before I was President, you were there. Thank you so much for that. Senator Harkin has also been at many of our events. Then we have a Youth Institute. We get 100 high school kids and 100 high school teachers, and we throw them in the room with all these laureates and experts. And it is amazing what rubs off and the inspiration for careers in food and technology and biological sciences come out of that experience.

Dr. Borlaug created the World Food Prize to inspire those achievements necessary to feed the world in the 21st century. And if he were here today, he would tell you that it took 10,000 years to expand world food production to its current levels of over 5 billion tons a year. But by 2025, the world will nearly have to double that current production just to feed the growing world population. And there are only two ways to do it: Either we grow more food on the land that is in production now; or we will have got to cut down more forests, jungles, or bring fragile land into production with all the environmental consequences that entails.

And so the World Food Price seeks to reach out and inspire and to touch and urge those people working in this field to find ways, not only through biotechnology but certainly including biotechnology, to increase productivity, reduce the use of pesticides, increase the nutritional content of food. Malnutrition, of course, affects people both in developed countries and underdeveloped countries. We tend to think of it just of hunger and poverty, but it also involves obesity. And so our leading companies now are looking at how can food be changed to make it more nutritional and more healthful. And our symposium this October will highlight that, whether it is through the school lunch programs that Catherine Bertini,our 2003 laureate was advocating, or promoting similar programs of Senator Dole and Senator McGovern. We were one of the first to have a symposium on the importance of food in Africa in countering HIV/AIDS or highlighting the work of golden rice and its promise.

Also, the World Food Prize wants to promote conservation, conservation tillage, reduced soil erosion, and ways to resist plant disease. Dr. Borlaug's dream is someday a scientist will find a way to take from rice that gene that allows it to be immune to rust disease and plant it into soybeans or corn others to stave off those kinds of diseases. He also stresses that biotechnology can help plants better deal with cold and heat and arid conditions, or reduce the time

for breakthrough achievements. It took 70 years to figure out from beginning to end, how can you put more lysine and tryptophan into corn to make it more nutritious and healthy. It finally, has two World Food Prize. But if biotech procedures had been used, that time could have been cut in half or more. Of course, as Dr. Borlous said, we are running out of time for making these kind of advances in bringing food and medicine closer together.

One of the lessons I learned as an American ambassador and as a young diplomat in the Mekong Delta in Vietnam during the war was that biotechnology can also be a crucial weapon in countering terrorism. The only time America has ever totally destroyed a terrorist organization was in Cambodia, the Khmer Rouge. More than 200,000 Vietnamese troops could not get the job done the 10 years that they were there. But we put in place an effort—we built roads into every Khmer Rouge base area, and we brought with it new agricultural technology and education and human rights, all the things that followed just as they did in our country going down the road into our small towns. In 9 years, the Khmer Rouge went from 25,000 people who controlled two-thirds of the country to the last general surrendering and the organization being obliterated. And it was the roads and new agricultural technology that did the job.

Mr. Chairman, Dr. Borlaug would tell you that the things we need to do in the future are: promote the primacy of science; support our land grant colleges and institutions with more money for research; and also make visas more readily available for foreign students. I was with a group of 300 officials last night from all the agricultural and land grant colleges. What they talked about were how visas and lack of funding were cutting back their institution's, the ones that produced the individuals who in the last 60 years led the greatest period in agricultural achievement and hunger reduction the world has ever seen. We have 24, if you count Dr. Borlaug, World Foof Prize laureates who were in the forefront of that effort, the greatest achievers during the greatest period achievment. Fifteen of these Laureates, including those from abroad came from America's land grant colleges and agricultural institutions. Dr. Borlaug would also tell you that we need an event that can bring everybody together from around the world. We are trying to create that with our World Food Prize symposium. We want to have the single most significant observance of World Food Day anywhere around the world, and that is what we are seeking to build. With the support of Senator Harkin, we also are working to have a Norman Borlaug Hall of Laureates, which would serve as the pantheon of these heros. Just as the Nobel Laureates are honored in Stockholm and in Oslo, there ought to be a place to honor the heros of Agriculture, and it ought to be in the heart of America where the greatest agricultural achievements have come, so that people can come and visit there.

This October 13th we have our Laureate ceremony in our Iowa State capitol. There will be more life-saving achievement gathered at that place than at any other place around the world. Indeed, it will feature Dr. Borlaug, and I guess if he were there alone, you could say that as well, along with all of the other laureates. We will have people from 62 countries. We will have 100 people who are from other countries who are with the Iowa and Nebraska Corn

Promotion Boards and the biotech seminar. We take these foreing officials all around the State. We will also have people from the U.S. soybean organizations who will be there as well. And we are enormously pleased to work with them.

I apologize for running over time, Mr. Chairman. Thank you.

[The prepared statement of Ambassador Quinn can be viewed in the appendix on page 82.]

The CHAIRMAN. You are very inspirational, Ambassador, and you are certainly welcome to whatever time you need to talk about the great things that you are doing. Thank you very much.

Ambassador Quinn. Thank you.

The CHAIRMAN. Mr. Heck, I want to ask you a question that is somewhat related to biotech but somewhat related to the 2005 farm year. This issue of rust and soybeans, what kind of apprehension has been raised and anxiety has been developing among farmers across America relative to this issue this year? And where do you think we are headed short term?

Mr. HECK. Well, there is great apprehension. Rust left untreated will devour 80 percent of our yields. However, on the other hand, with proper warning systems and proper preparation, the damage can be limited to mostly the financial damage caused by the necessity to spray the fungicides.

Certainly we are in for a few years of being very nervous about our soybean crop all throughout the country. It may well get to Iowa this year. It may not. We do not really know. That depends on the weather. Certainly it is already in Georgia, and it is certainly a problem there already and will be every year because of the over-wintering problem.

We would like to have a biotech solution for that. We know that is at least several years away, and in the meantime, we have to use fungicides. But the only real answer to totally protect ourselves would have to be within the plant itself.

The CHAIRMAN. I have heard from some of my farmers that there is conversation and thought about the fact that kudzu actually attracts that rust. I hope that is the case. Maybe we will finally find some good use for kudzu.

[Laughter.]

The CHAIRMAN. Congressman Greenwood, you note in your testimony global adoption rates for biotech crops and the rapid rise in planted acres, especially in developing countries. It is fascinating to hear those numbers. That is why I asked you to repeat that to make sure I understood exactly what you were saying. You also note that food and fiber production will need to double in order to keep pace with population growth by 2025.

What do you see as the biggest challenges and impediments regarding biotech crop development and acceptance, both domestically and internationally?

Mr. GREENWOOD. Mr. Chairman, I think it is mythology and misunderstanding. Biotechnology has been around, as has been noted, for some time now, and Americans have been eating biotech products for a very long time. And there really is no evidence whatsoever of a safety concern, and yet in some quarters the resistance is pretty strenuous.

If you look at the European resistance, which is not universal but it is intense in some quarters, I think we have to consider that there are multiple agendas at work. First off, the Europeans have had some tough times with regard to the credibility of their food safety organizations, with mad cow disease and so forth, so they are perhaps in some regards more skeptical there than we are.

One has to consider the green politics in Europe, which is party politics that is very different than it is here and how that affects the decisionmaking.

I think there is a fair amount of protectionism, frankly, that plays into this issue as well. There is some anti-U.S. sentiment. There is some anti-capitalist sentiment.

But when you go to the issue of the Third World, I think it might lend some—the notion as to how this resistance may ultimately dissipate, and that is, as long as the world sees this as a U.S. phenomenon with U.S. products entering European markets, those sentiments that I have just addressed will persist. But the more the world sees this as an issue for developing countries to help lift poor farmers from poverty so that they can educate their children and live in higher standards, so that they can feed their people with more levels of protein so that they can overcome issues like Vitamin A deficiency from rice, I think particularly in Europe, where there is a great deal of sympathy and empathy with the Third World, perhaps that part of the world will begin to view biotechnology more favorably.

But we have a big responsibility to act constantly at the highest standards of ethics, to have the best regulatory regime in the world so that we can set the standard.

The CHAIRMAN. Senator Harkin?

Senator HARKIN. Just following up on that, I remember when we met several years ago with the President of the European Union, Romano Prodi. The problem was that they did not have in place an FDA type of an organization for the European Union, and they were going to set that up. I believe they have established an agency.

Mr. GREENWOOD. I believe they have. It is not a mirror image of ours, and I don't think it has the credibility and the rigor of ours.

Senator HARKIN. Does it even have the authority that ours does? Does it cut across national lines?

Mr. GREENWOOD. It does not have—individual nations can still stop approval.

Senator HARKIN. That was a big problem before, and it is still a problem over there, that they have not set up the type of an agency, and they said they were going to try to set up one that would mirror our own FDA. But to the best of my knowledge, that still has not happened.

Mr. GREENWOOD. They have some distance to travel in that regard, Senator.

Senator HARKIN. I think that is right.

Mr. Heck, I just wanted to ask you briefly—and then I wanted to ask Ken Quinn a question—about the soybean rust coming in. I may have missed the answer to Chairman Chambliss' question,

but is there some thought that with biotech we can actually do something about this?

Mr. HECK. Yes, we have talked——

Senator HARKIN. What is the latest you have heard about it?

Mr. HECK. We have talked about it extensively for a number of years, and the two alternatives are a solution through the seed, through the plant itself, where it becomes resistant to rust, or fungicides. Fungicides are expensive and there is a difficulty of application. And you still have loss of yields with a fungicide, so that is a stop-gap measure that we will be using for a number of years, and I hate to say it, but, you know, rather than leave it open, like 5 years or 10 years before we have a solution through the seed with biotechnology, where the plant itself is resistant to rust. First you have to find the proper genetics and then transfer it into soybeans and then transfer it into commercially adopted varieties.

Senator HARKIN. So again, in terms of the immediacy of the soybean rust, it probably might not be helpful right away.

Mr. HECK. It certainly will not be helpful right away. It will be at least a period of a handful of years.

Senator HARKIN. Sometime down the road.

Ambassador Quinn, thank you for being here. Thanks for a very passionate statement about the need for us to be more aggressive in our whole research agenda and, in fact, being the promoter of a worldwide effort to bring scientists and others together to really solve this problem of feeding the additional people that are going to be on this planet in the next 20, 30 years, without resorting to cutting down all the forests and depleting all the water and other resources.

A big question that comes up on biotech is that a lot of poor people around the world, a lot of the smaller farmers who want to grow crops that will yield more, yield better, be more disease resistant, pest resistant, that type of thing, there is a fear that some of these farmers may save the seed, and if they save the seed, two things happen: one, obviously is a market loss for the producers of seed who have invested in the genetus; second, it may destroy or replace some of the indigenous heirloom type varieties that might be there that might be lost forever.

I don't know that much about it to talk any more than that, but I hear that a lot, and I am just wondering if your foundation is looking at that and asking scientists and others about how we might deal with of those hurdles.

Ambassador Quinn. Yes, absolutely, we are. Last year, one of our laureates was Dr. Monty Jones, the first African scientist from south of the Sahara to win such a prize, probably the highest scientific honor ever accorded to a scientist from Africa south of the Sahara. And Dr. Jones, working with conventional methods, figured out how he could marry Asian rice and African rice. The Asian rice, you know, it just yields incredibly. And you have got the African rice, which is tough and it has learned how to survive in these tough soils and incredible heat and arid conditions. It stays alive, but it cannot produce much.

Dr. Jones went into the seed banks which had been preserved by his research center, despite the fact that there were terrible wars going on around them in Cote d'Ivoire, they had to pick up and

move to Ghana with the seed banks. But they had preserved a great, great many, in fact thousands of ancient African seeds. A crucial thing to do. Dr. Jones went back in there and found some of these oldest African seeds and brought them out and had an arranged marriage with the Asian rice. Now when they take these new seeds out to the fields, they can get—if they put enough fertilizer on it, they can get 150–percent increases in yields. It has incredible potential for what can be done to feed West Africa.

But it is crucial. It is crucial to save those seeds and not let them be obliterated. Dr. Jones example is as much one to other scientists in Africa as it is to what can be done for farmers. And so it is exactly the kind of thing, the World Food Prize seeks to do: to find somebody who needs to be honored somebody who needs to be brought before the world. And the example of what he has done needs to be shared so that his work can be the model to be followed.

Senator HARKIN. Mr. Chairman, the World Food Prize Foundation, as Ambassador Quinn has talked about, gives this award every year. It is the brain child of Dr. Borlaug. It has been said that he saved more human lives than any single person in the history of the world because of his Green Revolution that he had developed, a farm kid from Cresco, Iowa. As you can see, we are very proud of him.

The history of the prize involves going to the Nobel committee to try to get them to establish a prize like this, But, no, they had their set-up and that is it, they were not going to add a new prize. John Ruan and his family have stepped to the forefront to fund the World Food Prize. It is an incredible gathering of scientists every year at the awarding of this prize.

Now, not too many Americans know about it, but I tell you, you go to Africa, you go to Southeast Asia, and they know about it. I mean, this is a big deal to them. Food is so crucial to them. We Americans may not think that much about food. It is cheap and so plentiful in America. Go to the local grocery store and the shelves are stocked, and you can buy whatever you want at a very cheap price. In these countries where food is just in a delicate balance all the time, it is so crucial to them. So the World Food Prize is a momentous thing, and the fact that it is America that is doing it and leading the charge is something that strengthens our leadership in so many parts of the world.

I wanted to add that little editorial comment on the World Food Prize and thank you for your leadership, Ambassador.

Ambassador Quinn. Thank you, Senator.

Senator HARKIN. And the Ruan family and Norman Borlaug. I am sorry he could not be here. Al is 91 years old, and I tell you, he would outpace us any day of the week. He is very energetic and travels all over the world. Why I thought it would be appropriate, to have Ambassador Zuinn here at this hearing on biotechnology is because what the World Food Prize Foundation is about is really getting the best minds in the world to figure out how we can both save the planet ecologically and how we are going to feed these additional 3 billion people coming along. When you see what they have already done and what some of these scientists have done and you think about the promise of biotechnology and what it can do

in terms of genetically engineering plants to be more drought resistant, for example, to save water, to hold it when they need it instead of just evaporating it off, to be able to even use brackish water for growing. I have wondered why is it that there are certain plants that can grow in sea water, the most popular being mangroves, for example. Coconut palms, I don't know how many people know this, tolerate sea water. You can grow them with sea water. How can they do that and we cannot do it with soybeans or corn or rice?

Well, just think of all of the parts of the world where they have bad water or brackish water, coastal plains. If we can do that kind of genetic engineering, my goodness, what we could do to increase the production of edible crops and food supplies around the world.

That promise is out there, and that is what is down the road that we can do, and that is why I feel so strongly about supporting biotechnology, making sure we have the regulatory structure to reassure people that it is safe, to make sure that we have the processes to go through and everything, but to really push ahead on this. Otherwise, we are going to have a big problem here not only in America but globally. I just want to make those comments and, again, to thank all of the witnesses and especially Ambassador Quinn and all that you have done for the World Food Prize Foundation. These two marry together, what we are trying to do through the World Food Prize and what we are trying to do through biotech and leading the world in that area, too.

So thank you very much, Mr. Chairman, for letting me editorialize.

Ambassador Quinn. May I add just one comment?

Senator HARKIN. Sure.

Ambassador Quinn. In 2002, we had our symposium on global water insecurity, and we brought several Israeli water engineers and water experts. We had a Palestinian water expert. We had one from Egypt. We had somebody from the World Bank who works in arid conditions in Syria and researchers from the UAE and others working exactly, Senator Harkin, on what you ere talking about. How can you use biotechnology to take brackish water and to have productive plants that can survive in that kind of situation? And we see it not only about feeding people, but it is about building peace.

You know, the other great legacy of Dr. Borlaug is that he went to India and Pakistan when they were virtually at war with each other in the middle 1960's, one of the few people who could go back and forth, and he dealt with the top leaders and convinced them to change their whole approach to agriculture. But it saved, you know, hundreds and hundreds of millions of people from famine, starvation, and death. And that is another part of what food can be in the World Food Prize. It ought to be this is a place where you can bring people together, whether it is Israelis and Palestinians, people from other parts of the Middle East, and because they are talking about food and alleviating human suffering, it can be a place where they can come together, put those other differences aside, and work together on this.

The CHAIRMAN. Senator Lugar?

Senator LUGAR. Mr. Chairman, I would like to follow on Senator Harkin's questioning. This is sort of a good session in a way for personal counseling. I have got three parts on my farm, about 200 acres of hardwood trees, 200 acres in soybeans, and 200 acres in corn. On the tree front, the ash bore has been giving problems in Michigan. It is approaching Indiana. And at Purdue, with money really provided by the Congress in terms of agricultural research and trees, why, they believe that they are going to mount a defense against the ash bore, which will capture the bore or at least eradicate the problem before it gets to Indianapolis. It is moving rapidly in that direction. So this is somewhat reassuring. But I am not so reassured about soybean rust.

Now, here we are talking about several years, and what other farmers—and, Mr. Heck, you are right in the middle of this and have been for years in your own life, but are contemplating is should we change our planting situation a little heavier in corn or heavier in something else other than beans, and are sort of in the whirlwind of this. It is not reassuring that somehow or other the Lord will provide ingenuity. You know, just picking up on Ambassador Quinn's thought, maybe if the World Prize were devoted at this point as a high profile for the person that solves the soybean rust problem, we might find somewhere on this Earth—and that is the beauty we are talking about today. It is not just American ingenuity, but somebody who has done at least some basic work with regard to that problem that might contribute to a much more rapid solution. Because if, in fact, the soybean rust problem is as fierce as has been suggested—and it could well be—this is going to alter American agriculture very significantly for several years while we are working our way through the various permutations of the research.

I don't know that there is any such place on Earth or anybody who has ever thought of the problem, but they must have. Soybean rust has been around for a while. It has not bothered us. But, nevertheless, somebody somewhere may know something. And so I just highlight, the virtue of the hearing, again, is that we started correctly with our parochial concerns. Are we doing our homework in terms of regulation? Is the integrity of the process working? Are we talking to each other? Well, we found we are, and admirably so.

So if we can go to the rest of the world with not only clean hands but even beyond that the idealism of this process, but then from the rest of the world, we need to extract some solutions that may be tremendously helpful here. The prize may be helpful in highlighting, as you pointed out. But so may be the American Soybean Association or others who may have some allies out there in the world who have done this sort of thing before.

The reason I am excited about the hearing is that not only do we have sort of a first panel that established the ground rules, but the second panel, we are really thinking big. It is so big that it is sort of beyond our comprehension. When Senator Harkin mentions—and you do, I think, Ambassador Quinn—that maybe as many as a billion lives were saved because of the Green Revolution, this is so far beyond comprehension. We have hearings day by day in which we lament the fact that tens of persons are being killed in combat, that other persons are at risk of being killed perhaps

from some terror disaster in the United States. And horrible as these things may be, we are talking tens, hundreds, at the worst maybe thousands of people that might be involved. But a billion is almost beyond our comprehension.

This is the enormity of the subject matter here, and, furthermore, as you pointed out, if something does not happen within the next 50 years to feed 3 billion more people that are prophesied to be a part of our world, either we will have had the growth in yields, and safely so, or we will have chopped down a good part of the rest of the rain forests with ecological consequences for humanity for the rest of time that are incalculable. So the stakes are extremely high in terms of what is occurring here.

I liked Congressman Greenwood's point that even as we are thinking very, very big about the world, just in a parochial sense back home here soybean farmers had $1.2 billion more net income last year, 2004, because of the subject matter we are talking about. There are very few things we do in farm bills that could have an increase of that amount of money, 200–some million for corn farmers, and ditto for cotton farmers, and what have you, adding up to 1.9, I think you calculated. This is big money now, not in the hereafter or collectively historically. These are for real farmers who are out there farming now and who are utilizing these biotech methods, and hopefully hoping for more to come, as well as prevention of soybean rust, altering the scheme.

What I am wondering from any of you, is there any hope that somebody has done something in soybean rust, just to take that topical example, that may accelerate the process here? Because if so, this would be great news to a lot of farmers who are very anxious, including myself, about the whole process. If not, then we need to try to think through why will it take several years, sort of explain the process of science. And there are a lot of reasons. It takes time to grow whatever it is in terms of you have the ideal plant to check out whether it does have all the qualifications. But any reassurance at all on soybean rust or any of the rest of this?

Mr. HECK. Well, there has been a great of activity on it, and the U.S. Government has been very helpful on some of the activity in the land grant college/university system. Virtually all the known soybean varieties and types have been screened for rust resistance. It seems to me like that was a number like 20,000 different kinds. A few genes of resistance were identified, again, with the help of private industry, the University of Illinois, the Ag Research Service. Those genes are being placed in soybean varieties and seeing how they react.

I think you can be assured that everyone in the soybean world knows that this is the biggest one, the biggest one there ever was, and there is an enormous financial prize for the company that can come up with a solution through the seed. There is a great deal being done, and we would be happy to discuss with you in detail some other avenues that could be explored with congressional funding with extra pushes, because there are areas that could be done where a relatively small investment of a few million dollars could make billions of dollars of difference in the damage control and save many, many lives by solving this problem sooner rather than later. It does just take time, though.

Senator LUGAR. Mr. Chairman, I just would be prompted to say this might be very well worthwhile of the committee or the staff's time to explore what these means are, what kind of investment you are talking about. You mentioned land grant colleges and some private firms, and that is the genius of the American system, both of these. But this is so urgent, this is probably something that needs to be hopped on if you have ideas and so forth. And I hope that you will share them with the chairman and with the committee because these could be action steps for us.

Mr. HECK. We would be happy to do that.

Mr. GREENWOOD. May I comment?

Senator LUGAR. Sure.

Mr. GREENWOOD. Far be it from me to talk more about soybeans than the soybean guy, but in the category of thinking big, Senator, today is the first day in 6 months that I stepped foot in the Capitol, and I admit that when I did, I looked up at the dome and I had a moment of wondering whether I made the right step in leaving the Congress. The reason that I know that I did is because I believe that biotechnology will be and is now the most transformational human endeavor in our history. It will dramatically change our health care system, our food supply, and our environment like nothing else has before, because it is giving us the tools to look into the secrets of life and use them with our God-given brains to the benefit of our fellow humans.

On the food side, we have heard here many times today a fixed amount of arable soil, a growing population, and the potential devastating consequences of that. There is much that can be done on the yield side to make plants more productive and more nutritious. But if you look at where the margin is, it is on what it is that destroys plants. It is on the diseases. It is on the insects. It is on the drought. It is on the other climatic conditions. And these are precisely the areas where biotechnology is offering tremendous hope because we can find out what it is that makes plants, agricultural plants, susceptible to this damage, find out what genetic materials and proteins exist to resist that and make them stronger, and reduce the loss. And if we can reduce the loss in agriculture around the world, therein lies tremendous hope for mankind.

Ambassador Quinn. And there is the promise of looking at rice and seeing if you can find, what it is about the genomic makeup of rice that prevents it from getting rust disease. We had last year as our co-winner of our prize a man named Yuan Longping, a very simple man from Hunan Province in China who is, I think, without doubt the single greatest rice producer and expert in all history, because he developed hybrid rice. And he has rice that is producing such incredible yields of grain, it is almost beyond comprehension. And I have been at some of the biotech labs that are working on rice, the Chinese Academy of Agricultural science. We brought the leading genetic engineer from China to our symposium in the year 2000. And in all of that, there may be a remarkable opportunity here for a U.S.-Chinese interaction on this problem of rust disease that could be of great benefit to both counties.

Senator LUGAR. Well, Mr. Chairman, I thank you again for the hearing. I am a true believer in the situation. Getting back to my trees, out on our farm there is a small acreage that is fenced off

by Purdue, and they are grafting year by year onto these specimen trees, whether they are black walnut or oak or ash or what have you, they are trying to find the genomes of the very best oak tree that ever happened and is resistant to disease, but likewise has growth possibilities and fewer infirmities. It is an exciting process to watch. My agreement with them is not to touch their trees for 15 years or so, so I am, of course, going to abstain from touching them. I am just watching them.

Ambassador Quinn. When I was in China, we were given a briefing about oak disease, and with maps and overlays of where this kind of oak rot is located —rot that just causes the oak trees to suddenly collapse without any warning. And it was—it actually was showing on the map—you will be happy to hear, Senator, that the center of this disease was going to be in Des Moines and not in Indianapolis. And it looked from the map that it was pretty close to my backyard. So I left with great trepidation, but not knowing quite what to do.

Senator LUGAR. Thank you.

Mr. GREENWOOD. Mr. Chairman, if I can end with a commercial, June 19th through 22nd is BIO 2005 in Philadelphia; 18,000 people will come and learn what is new in biotechnology. And the Senators and all their staffs are welcome to come. It is quite a fascinating opportunity.

The CHAIRMAN. Well, thank you, and we will make sure that some of our folk from here are there. This is a fascinating subject, and I cannot tell you how much we appreciate both panels being here. We could stay here all afternoon and dialog about what the future of agriculture and what the future of food production is going to be and how that translates into solving problems relative to world hunger and any number of other issues. I just cannot tell you how fascinating it is to me personally.

But we do appreciate your being here. Thank you for your testimony and your input here. The record will remain open for 5 days for any additional comments.

Ambassador Quinn. Could I leave one final thought about Dr. Borlaug, Mr. Chairman?

The CHAIRMAN. Certainly.

Ambassador Quinn. That is that his powers go beyond biotechnology. His desire in life was to play second base for the Chicago Cubs.

[Laughter.]

Ambassador Quinn. Last year, on June the 9th, he was invited to Fenway Park to throw out the first pitch. And while some may think that the trades that sent Garciaparra away or brought Schilling there is what got the Red Sox their first world championship, I believe it was Dr. Borlaug's visit there. Finally, the curse of Babe Ruth was confronted with another Babe Ruth, the Babe Ruth of food production. I think Dr. Breaus drove it out and exorcised that demon and let the Red Sox win.

Now, those who are not Red Sox fans may not be so happy with him, but I just wanted to share that.

The CHAIRMAN. That sounds like pretty good reasoning.

[Laughter.]

The CHAIRMAN. Thank you very much.

[Whereupon, at 3:57 p.m., the committee was adjourned.]

APPENDIX

JUNE 14, 2005

Senator Tom Harkin
Hearing to Review Future Agriculture and Food Biotechnology Developments
Committee on Agriculture, Nutrition and Forestry
United States Senate
June 14, 2005

Chairman Chambliss, I appreciate your holding these hearings, to review both the benefit and regulation of agricultural biotechnology. I look forward to hearing from our witnesses on issues facing the biotech industry. I am particularly pleased to have two prominent Iowans on the panel today: Ambassador Kenneth Quinn, President of the World Food Prize Foundation, and Ron Heck, Chair of the American Soybean Association.

The World Food Prize is the most prestigious prize in agricultural research, and gives vital recognition to agricultural achievement in increasing the quality, quantity and availability of food in the world.

Some 200 million acres of genetically engineered crops are grown worldwide, and about 60% of that is in the United States. Biotechnology holds the promise of improving yield, disease and pest resistance, nutrition, and creation of beneficial compounds from many different crops. Products like Bt corn and cotton are helping the environment by reducing the need for pesticide spraying. Drought resistant varieties are being developed to improve production in places where food scarcity is a serious problem, like Africa.

Biotechnology is a broad topic – though the most controversial aspects are in the area of recombinant DNA, biotech is as old as the first people who used yeast to make their bread rise. Biotechnology is also being used to trace genetic markers in conventionally developed hybrids, speeding up the process of cross breeding. It's

improving the characteristics not just of food, but of fiber and plants grown for industrial production.

And even more advances are on the horizon. Just last week, I hosted a Capitol Hill showcase of biobased products manufactured from raw materials like soybeans and corn. Everything from plastic drinking cups and carpet backing to cleaning fluids, to industrial lubricants are being manufactured from renewable sources, and more will be done in the future. Bioengineering is developing new varieties of these commodities that would be particularly suited to these manufacturing processes, making them more efficient. It is even possible to produce pharmaceuticals within a plant. But these commodities not intended for human or animal consumption raises challenging regulatory issues – how to ensure that the genetic manipulation does not spread to conventional crops in the field, or get intermixed with food crops in commerce.

With the great promise of biotechnology comes a need for caution and regulation. Testing and strong controls are important to ensure the safety of genetically modified organisms introduced into the food supply and the environment. Recombinant DNA is being regulated under a network of laws originally created for other purposes. This is based on an assumption that bioengineered crops are essentially the same as their conventionally bred precursors. The fundamental question we need to address is whether that assumption is correct – are bioengineered crops properly regulated under existing statutory and regulatory authority, or are there challenges associated with these commodities that would require new authority?

Our committee is involved not just in regulating biotechnological products, but also in promoting biotech research. In the 2002 farm bill, we set the goal of doubling

agricultural research over the six years that the bill is in effect. Unfortunately we are far below that figure. In 2002 when the current farm bill passed, combined research spending for the two largest ag research programs, the Agriculture Research Service and the Cooperative State Research, Education and Extension Service, was some $2.04 billion. Three years later, it has risen to $2.13 billion in inflation-adjusted dollars, an increase of just 4.3%. Obviously, only a fraction of the funding to these programs goes directly to biotechnology research.

I strongly support research currently being funded by the National Science Foundation to map the corn genome, which promises tremendous benefits when this basic science is available for commercial application. The soybean genome is also being explored, which has become more important now that we desperately need to quickly develop varieties that are tolerant of Asian soybean rust.

Again, thank you, Mr. Chairman.

Testimony of Dr. Chuck Lambert
Deputy Under Secretary for Marketing and Regulatory Programs
U.S. Department of Agriculture
Before the Senate Agriculture, Nutrition and Forestry Committee
June 14, 2005

Thank you for the opportunity to be here today. I am pleased to provide the Committee with an overview of the Department of Agriculture's (USDA) role in regulating agricultural biotechnology.

This is a science that is rapidly evolving, and as Federal regulators it's critical that we keep pace with this new technology. Here at USDA, we're committed to meeting not only the challenges that we can see ahead on the horizon but also those that science has yet to discover. Since USDA first began regulating biotechnology in 1986, we have deregulated more than 60 genetically engineered (GE) agricultural products. In that time, we have also overseen more than 10,000 biotech field tests. It's the responsibility of USDA to thoroughly evaluate GE organisms to verify that they are just as safe for agriculture and the environment as traditionally bred crop varieties, which have been the cornerstone of American agriculture.

This is a responsibility that we share with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), who are also here today. Under what is known as the Coordinated Framework, we work in concert to ensure that biotech crops are safe not only for agriculture and the environment, but also the food supply. This coordinated effort is critical for reassuring industry, consumers, and other groups—both here in the United States and, increasingly, abroad—that biotechnology-derived crops, animal vaccines, and other products are rigorously regulated for safety.

Regulatory Overview
For its part in this coordinated effort, USDA's Animal and Plant Health Inspection Service (APHIS), under the Plant Protection Act, regulates the interstate movement, importation and field release of GE plants, insects and microorganisms through permitting and notification procedures. In other areas, APHIS regulates biotechnology-derived veterinary biologics under the Virus-Serum toxin Act. The Agency is also evaluating its role in the regulation of GE animals, pathogens and pests under the authority of the Animal Health Protection Act, which was passed as part of the 2002 Farm Bill.

The regulation of GE plants, however, is where APHIS has the most regulatory focus. The Agency has long recognized that plant-derived biotechnology research was increasing and becoming much more complex. In order to ensure that the Agency remained at the forefront in developing appropriate regulatory policies to address the latest advances in the technology, APHIS created Biotechnology Regulatory Services (BRS) in June of 2002. The program, which started with 25 employees, has grown to a staff of more than 50. In the last 3 years, the program has made a number of changes to review and further strengthen USDA's existing biotechnology regulations. During this

time, BRS has also made a concerted effort to reach out to stakeholders interested in biotechnology, including industry, non-governmental organizations, States and others to make sure that they fully understand the important regulatory changes that have taken place.

In general, APHIS' field testing requirements for regulated plants are designed to prevent the unintentional environmental introduction, whether by pollen movement, seed or grain commingling, or other means, of a protein or trait produced in these plants that would present a risk or potential risk to agricultural crops or the environment.

Companies, universities and other researchers that wish to field test such crops must submit permit applications, with information about the plant variety being tested, the purpose of the test, how it will be conducted, as well as the specific confinement conditions taken to prevent the escape of pollen, plants, or plant parts from the field test site. Applicants must also detail how the site will be destroyed once the field test is complete to prevent persistence in the environment. The planting conditions detailed in the application must meet or exceed the stringent requirements set forth by APHIS. These requirements are specific to each plant variety, and we continually evaluate them to ensure that the latest scientific evidence is taken into account.

APHIS also has a streamlined permitting process, called notification, in place. Most of the field tests carried out in the United States are authorized under the notification process. The notification process expedites approvals for field testing for certain types of low-risk plants that APHIS has considerable experience in regulating. Under the notification procedure, the regulated article to be field tested must be a plant, and the genetic modifications to that plant must meet established criteria. During the permitting and notification process, APHIS also takes into account the requirements of NEPA.

I want to emphasize that APHIS is committed to ensuring that State interests are fully considered and accommodated in the Agency's biotechnology field test permit and notification review processes. Before any field test can be undertaken in a given State, APHIS officials provide detailed information pertaining to the proposed field test to their counterparts in that State for review and concurrence. If a particular State has science-based concerns about the confinement measures described in the documentation, APHIS works with that State to address the outstanding concerns and add any additional conditions the State deems necessary to ensure that the field test can be conducted safely. The Agency has never approved a field test permit over the objections of State counterparts.

Pharmaceuticals and Industrials

Science is moving rapidly for crops producing pharmaceuticals and industrial, and APHIS has taken a proactive approach to safely regulating these types of field tests. APHIS' recent efforts to strengthen regulations have provided additional assurances to States that field trials are safe for agriculture and the environment. In 2003, APHIS imposed new measures for all crops genetically engineered to produce pharmaceuticals and industrials.

Developers are producing pharmaceutical and industrial compounds using rice, corn, barley, tobacco, and safflower. These crops are grown to produce research chemicals, vaccines, human antibodies, and human blood proteins. Although there has been much attention on these products, relatively few pharmaceutical and industrial field tests have actually taken place. About 90 permits to field test pharmaceutical and industrial crops have been issued since 1991 in about 15 States. In comparison, we've approved thousands of field tests for GE crops as a whole. This is an area of research, however, where we expect to see more growth and that's why we've made changes in our regulatory process to make clear that pharmaceutical and industrial crops are evaluated rigorously.

APHIS issues permits for pharmaceuticals and industrials on a case-by-case basis. The Agency also conducts environmental assessments, which include public comment periods, whenever required under the National Environmental Policy Act and based on established safety criteria. APHIS further imposes stringent confinement measures requiring increased isolation distances and fallow zones, dedicated farm equipment, and restrictions on planting food or feed crops on land used to produce pharmaceutical and industrial crops. For example, the isolation distance for open-pollinated corn is 1 mile. This means that such a field test cannot be planted within 1 mile of other corn crops.

To ensure that these permit conditions are being met, APHIS inspectors conduct at least 5 inspections during the growing season for all pharmaceutical and industrial crops. These inspections coincide with key times during the growing season: pre-planting, after planting, just prior to harvest, at harvest, and post harvest. After the field test is complete, Agency inspectors follow up with two additional inspections to ensure that the plot was completely destroyed and no left over plants remain. These volunteer plants, if detected, must be immediately destroyed.

Compliance

Compliance with APHIS' stringent permit conditions is high, and that is due in large part to the Agency's efforts to work with researchers to ensure that they understand our requirements and can implement them in the field. Given the growing scope and complexity of biotechnology, now more than ever, APHIS recognizes the need for scientifically sound, effective safeguards and greater transparency of the regulatory process to ensure that all those involved in the field testing of GE crops understand and adhere to the regulations set forth by BRS. This need is echoed by the biotech industry, stakeholders, and consumers. To that end, in 2003, APHIS' Biotechnology Regulatory Services established a new Compliance and Enforcement unit to further ensure adherence to permit conditions. In addition to ensuring that permit conditions and recordkeeping requirements are met by researchers, APHIS has also instituted new training programs for inspectors who inspect and audit field trials of GE crops. This ensures inspectors know what to look for in the field and that they handle each inspection with consistency and uniformity. The unit also encourages self-reporting by researchers should they identify a potential infraction. Under APHIS regulations, companies, universities and other researchers are immediately required to report, verbally and in writing, any potential

problems, so that the issue can be resolved as quickly as possible in order to confine the transgenic organisms.

Deregulation
After successfully completing the field-testing and data collection stage of a new plant variety's development, a permit holder can petition APHIS to deregulate the biotechnology crop. In support of this petition, the permit holder must submit further information on the results of the field-testing, in addition to information documenting that the plant poses no risk to agricultural crops or the environment. In considering the petition, APHIS carefully reviews the data submitted by the permit holder, and also weighs other pertinent scientific studies and information. When APHIS deregulates a biotechnology-derived plant, it does so because the plant poses no pest risk to other crops or plants. After submission of a complete petition, deregulation process requires that APHIS publish a *Federal Register* notice thereby making the documents available to the public and providing the public with an opportunity to comment. Once APHIS deregulates a particular biotechnology product, the company must still comply with applicable FDA or EPA requirements prior to marketing. In addition, APHIS can bring a product back under regulation at any time if the Agency becomes aware of evidence indicating that the product may pose some sort of plant pest risk.

Environmental Impact Statement
Efforts to further strengthen our regulations and improve compliance and enforcement have improved our ability to protect agriculture and the environment while allowing for the safe field testing of GE crops. However, as I've mentioned throughout my testimony, we recognize that the science of biotechnology is going to continue to evolve and we must be prepared to keep pace with those changes. That is why in January of 2004, APHIS announced plans to review and strengthen APHIS' current biotechnology regulations. As a result of that announcement, APHIS is currently conducting a programmatic Environmental Impact Statement to evaluate our biotechnology regulations. The decision to undertake this EIS is the result of inter-agency discussions, which included our sister agencies, EPA and FDA.

The EIS, which is currently being drafted, evaluates environmental issues associated with potential revisions to existing regulations. Under the Plant Protection Act of 2000, APHIS has broad authority to safeguard American agriculture and protect the environment. The EIS will look at expanding APHIS' regulatory scope beyond GE organisms that may pose a plant pest risk to include GE plants that may pose a noxious weed risk and GE organisms that could be used as biological control agents.

As part of the EIS, APHIS is also evaluating the benefit of developing new criteria, based on risk, familiarity, and intended use for reviewing applications to conduct GE crop field tests. Under the proposed approach, APHIS would move away from our current system of permits and notifications in favor a multi-tiered permitting system. This new system would utilize the knowledge we've gained about biotechnology in the last 19 years to help streamline the permit process for familiar field tests, so we can focus our resources and attention on new requests with which we have less experience. Over time, this

science-based approach would reduce the regulatory burden and allow APHIS to concentrate oversight on new GE products based on science and potential risk.

The EIS will also consider the environmental effects of exempting, from regulation, the low-level and intermittent occurrence of certain GE organisms that have not completed all applicable review, provided they meet safety criteria and there has been adherence to regulatory requirements. This issue is known by many as adventitious presence.

While I've briefly highlighted some of the main issues, the EIS is much more broad in scope. In fact, the current programmatic review of BRS' existing biotechnology regulations is USDA's largest effort of its kind since the Coordinated Framework for biotechnology regulations was first established in 1986. We've established an ambitious timeline for completing the comprehensive draft EIS and hope to publish the document in the Federal Register this fall. Throughout this initiative we will continue to coordinate with our interagency partners and communicate with the public to hear their views and ensure that they understand what it is that we're considering. As a result of the initial scoping process we've already received more than 2,000 public comments. APHIS also held several days of meetings to hear from interested stakeholders, including industry, non-governmental organizations and others. As a follow up to that process, BRS will again be reaching out to the public this summer by holding open forums once a month to hear from anyone interested in our regulatory review. These comments will all be considered as we continue to move forward in this process.

Finally, I'd like to close by saying that our emphasis on communications is part of an on-going effort to be more transparent regarding the regulatory process. The easier it is for people to understand our regulations, the more confidence we believe they will have in APHIS' ability to protect agriculture and the environment. We're very excited about the regulatory changes that have already occurred as well as those that are on the horizon. In partnership with our sister Agencies FDA and EPA, we're confident that we're ready for the future of agricultural biotechnology.

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

Testimony of
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U.S. Environmental Protection Agency
before the
Committee on Agriculture, Nutrition and Forestry
United States Senate

June 14, 2005

Introduction

Good afternoon, Mr. Chairman and members of the Committee. I am pleased to appear before you today to discuss the Environmental Protection Agency's (EPA) role in the assessment and regulation of products produced through biotechnology. I welcome the opportunity to participate on this panel and explain what the Agency is doing to regulate biotechnology products and our plans for the future. We work closely with our partner agencies, the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) to ensure that crop plants created using biotechnology, and food from such plants, are safe to both people and the environment.

Biotechnology holds great promise. For example, it can reduce our reliance on some older, potentially more risky pesticides, while also reducing potential risks to farm workers and the environment. Given these and other potential benefits, we are committed to ensuring that this technology is used appropriately. The Agency's regulatory decisions are based on rigorous scientific information, high scientific standards, and transparency to promote public understanding and oversight. By following these principles, our program strives to ensure the protection of public health and the environment. Biotechnology is a rapidly evolving field. The federal government's regulatory program must similarly advance to ensure the continued protection human health and the environment. Given our intellectual and scientific investment in regulating biotechnology, the Agency stands ready to meet the future challenges.

Coordinated Framework

In the 1980s, it became clear that companies would soon begin to apply the techniques of genetic engineering to agriculture and that biotechnology products for use in agriculture would soon become available for widespread commercial use. Also at that time, the Federal government began to evaluate its options for regulating commercial products created using biotechnology. In 1986, the federal government, under the auspices of the Office of Science and Technology Policy, released the "Coordinated Framework for Regulation of Biotechnology", which laid out the broad outlines of its approach to regulating biotechnology products. In general, the Framework established an approach to regulating the products of this new technology based on use, not the process used to create them. Rather than seek new legislative authority, these products are regulated using existing laws.

Under the Coordinated Framework, the oversight responsibility for agricultural biotechnology products is shared by three Federal agencies: the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA). Efforts in this Administration, as in previous Administrations, have been aimed at making the coordination between EPA, FDA, and USDA on biotechnology issues even stronger, while ensuring a comprehensive and seamless regulatory system.

Under the Coordinated Framework, products of biotechnology are regulated under existing statutes and in a manner similar to the regulatory approach used for products developed through other techniques. Thus, products of biotechnology intended to be used as pesticides are regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the sections of the Federal Food, Drug and Cosmetic Act (FFDCA) that address pesticide residues in food and feed. Under the Toxic Substances Control Act (TSCA), EPA reviews novel microorganisms that are products of biotechnology.

Coordinated Framework and Pesticides

Within the Coordinated Framework, EPA regulates all biotechnology products that meet the definition of a pesticide under FIFRA; this includes genetically engineered microorganisms with pesticidal action as well as pesticidal products produced by plants that act within the living plant to protect the plant from pests. The second category is referred to as plant-incorporated protectants, or PIPs.

To fully understand EPA's current regulatory approach to PIPs, some basic information may be helpful. EPA's jurisdiction under FIFRA is limited to pesticides. For example, the sale of a PIP engineered into a plant to assist the plant to resist insect damage would be subject to FIFRA, whereas a plant engineered to resist drought would not. The former comes under EPA authority because the substance produced by the plant is intended to function as a pesticide by "preventing, destroying, repelling, or mitigating" a pest. A plant bioengineered to resist drought, through for example deeper root growth to access water, would be subject to USDA authorities, and any food or feed produced would be subject to FDA authorities.

Up until the end of the 20th Century, plant breeders have supplied farmers with hardier and more disease-resistant crop varieties through conventional breeding. This is done primarily by mating a crop plant with a wild or related plant and selecting offspring with the desired trait, or by inducing mutations in a plant and mating that plant with others while selecting desirable traits. It is in this way that we got bigger roses and more robust tomatoes.

In the early 1980s, scientists began to move genetic information selectively between organisms through biotechnology techniques. The transfer of desired traits could now be accomplished more broadly and more rapidly, including between unrelated species. In the case of PIPs, scientists move genetic material encoding the information to produce pesticidal substances from any source into plants. Information can be moved into a plant, for example, from another plant, a bacterium or virus, an insect or an animal. One of the best known biotechnology product is based upon genetic information from the bacterium *Bacillus thuringiensis*, or simply "Bt". This bacterium, when sprayed on plants, is toxic to certain types

of pest insects that feed on the plant. Through biotechnology, scientists can take the genetic material encoding the information to make the pesticidal protein from the bacterium and place it in, for example, a corn plant. The corn plant can now synthesize its own Bt protein and ward off pests on its own. No external spraying for the target pest is necessary.

Pesticide Registration

In developing our approach for an appropriate risk assessment for these products, EPA has held numerous public meetings with extramural panels of scientific experts; e.g., the FIFRA Scientific Advisory Panel, the Office of Pesticide Programs' Pesticide Program Dialogue Committee, and with interested stakeholders at a number of public hearings and workshops throughout the country. Additionally, EPA makes all of the submitted data concerning human health and environmental effects available for inspection and review through a public docket. Every new PIP is announced in the Federal Register with an invitation for public comment. Scientific Advisory Panel meetings are open meetings, and comments from interested parties are accepted either in person or in writing. Through this open participatory process the Agency has developed a risk assessment approach for products going through the registration process.

A potential registrant typically comes in for a meeting with our scientific staff, at which time we decide upon the appropriate data requirements to support the Experimental Use Permit (EUP), the tolerance or tolerance exemption, or for the full commercial approval and registration. The studies done under the EUP are used to obtain the data necessary to support the application for the full registration. Under the Pesticide Registration Improvement Act (PRIA), the decision times for such applications are mandated between 18 and 24 months. All PIP decisions have been completed within PRIA timeframes so far.

For the PIPs products EPA has registered to date, we review data in five categories: product characterization, toxicology, non-target organism effects, exposure and environmental fate, and resistance management. Product characterization includes reviewing the source of the gene and how the gene is expressed in a living organism, the nature of the pesticidal substance produced, modifications to the introduced trait as compared to that trait in nature, and the biology of the recipient plant.

For toxicology, an acute oral toxicity test of the pesticidal substances on mice is required. At times, it has not been possible to make enough of the substance for testing purposes in the plant itself so EPA has allowed the exact same protein to be produced by bacteria as long as there are sufficient data to show that the protein produced by the bacteria are identical to that produced by the plant. It should be noted that to date, all of the PIPs reviewed by EPA are proteins. For protein PIPs, EPA requires a digestibility test where the amount of time it takes for the protein to break down in gastric and intestinal fluids is determined. This information is relevant to a simulated determination of the potential of the protein to be an allergen. Determination of whether an introduced protein is likely to be an allergen is one of the major challenges for the Federal agencies. EPA and FDA are working on this issue together. For allergenicity assessment, EPA requires in addition to the digestibility test, tests for heat stability, and a comparison of the structure of the protein to the structures of known food allergens.

For ecological effects, EPA examines the exposure and toxicity of the PIPs to non-target organisms, such as wildlife and beneficial insects. These tests are unique to the crop and pests involved. For example, during the review of the Bt-potato, a test of potential effects of the introduced protein to lady beetles was conducted and showed that there were no adverse effects to these beneficial insect predators because they are related to the target pest, the Colorado potato beetle. For Bt-corn, tests were conducted on the potential effects on fish because field corn may be manufactured into commercial fish food. No effects were observed in the tests. Monitoring of potentially affected organisms in fields planted with PIPs is also required. EPA also has evaluated the degradation rates of the proteins in soil and plant residues.

If adverse effects or potential adverse effects are observed in the testing, a second or higher tier of testing is required to allow EPA to evaluate the risks. EPA routinely consults with USDA and FDA on data reviews of these PIPs. EPA, USDA, and FDA have frequent contact to insure cooperation and open communication between the agencies.

Currently, EPA has twelve active registered PIP products (see the attached list). Eleven of these products are for a Bt protein. The crops have included potatoes, cotton, field corn, sweet corn, and popcorn. There have also been Experimental Use Permits for Bt tomatoes and Bt soybeans. The Agency has also established tolerance exemptions for pesticide proteins from viruses that have been moved via recombinant DNA technology to plants like watermelon, cucumber, potato, and papaya. In 1998, EPA registered a PIP based on the potato leaf roll virus (PLRV) and a Bt protein. The Bt protein and the PLRV protein were combined to provide virus and insect protection.

In 2001, EPA completed a reassessment of all of the then existing Bt PIP registrations, to make sure that all uses were up to current regulatory and scientific standards. All stakeholders were encouraged to participate and the FIFRA Science Advisory Panel was convened to peer review EPA's findings. As a result, those Bt PIPs that continued to be registered are supported by the latest scientific data requirements and are being used under updated regulatory conditions.

Biotechnology Products under the Toxic Substances Control Act

The Biotechnology Program in EPA's Office of Pollution Prevention and Toxics administers regulatory oversight over the commercial introduction of new microorganisms and the significant new uses of existing microorganisms under its Toxics Substances Control Act (TSCA) authority.

This law gives EPA the authority to take action on "chemical substances" which may present an unreasonable risk of injury to health or the environment. TSCA authorities generally cover all new and existing chemical substances, except for certain products, including: pesticides, tobacco products, certain nuclear material, food, food additives, drugs, and cosmetics.

Under this framework, EPA has established procedures for the regulation of microorganisms that are products of biotechnology as "new chemical substances." The rule is designed to ensure that EPA can adequately identify and regulate potential risk associated with microbial products of biotechnology without unnecessarily hampering this important technology.

Under Section 5 of TSCA, if a person wishes to commercialize a new microorganism, or plans to introduce such microorganisms into the environment for commercial research purposes, EPA requires a notification at least 90 days prior to commercialization and the submission of certain information. EPA reviews the information to determine whether the intended activity may present an unreasonable risk to health or the environment. Decisions on what action to take for each submission are based upon reviews by a multi-disciplinary team of scientists.

International Activities

EPA is working on several international fronts in an effort to share data and foster collaborative relationships in the field of biotechnology. EPA, in conjunction with USDA and FDA, was instrumental is establishing two working groups within the Environment Policy Committee of the Organization for Economic Cooperation and Development. The two groups are the working Group on Harmonization of Regulatory Oversight in Biotechnology and the Task Force for the Safety of Novel Foods and Feeds. These groups provide information useful to EPA as it performs risk assessments on genetically modified organisms, including plant and microorganisms under three of its jurisdictional statutes, FIFRA, FFDCA, and TSCA.

The U.S. has also been active in negotiating a workable implementation of the Cartegena Protocol on Biosafety and the EPA has played a role in those activities. We have also been involved in standard setting activities under the International Plant Protection Convention, as well as many bilateral exchanges of information and expertise.

EPA participated as part of the U.S. delegation to the Codex Task Force to develop guidelines and principles for assessing foods derived from biotechnology. This international effort by regulators and scientists sets forth a set of principles and guidelines any country can use to assess these products. These guidelines reflect the U.S. approach to assessing biotechnology products. EPA will be part of the U.S. delegation to the anticipated second round efforts in Codex addressing other biotechnology food and feed issues.

Conclusion

We appreciate the opportunity to present an overview of EPA's activities to regulate products produced through biotechnology. Five important principles guide EPA's biotechnology program: sound science, transparency in decision making, consistency and fairness, collaboration with regulatory partners, and building public trust. EPA is committed to a regulatory program based on the most rigorous scientific information available so that our decisions are credible, defensible, and protective of the environment and public health as we address the challenges associated with biotechnology.

Thank you for the invitation to appear before your committee this morning. I will be glad to answer any questions you may have.

Current FIFRA Section 3 Registrations of Pesticidal Plant Incorporated Protectants

PLANT-INCORPORTED PROTECTANT	REGISTRANT	DATE REGISTERED	DATE EXPIRES
Bt potato Cry 3A	Monsanto 524-474	May, 1995	no expiration date
Bt corn 11 Cry 1Ab (field and sweet corn--no refugia for sweet corn-+)	Syngenta field corn 67979-1 sweet corn 65269-1	August, 1996; February, 1998	October 15, 2008
Bt corn Mon 810 Cry 1Ab	Monsanto 524-489	December, 1996	October 15, 2008
Bt cotton Cry 1Ac	Monsanto 524-478	October, 1995	September 30, 2006
Replicase for potato leaf roll	Monsanto 524-474	November, 1998	no expiration date
Bt corn POCry1F	Dow/Mycogen 68467-2	May 2001	October 15, 2008
Bt corn POCry1F	Pioneer/Dupont 29964-3	May 2001	October 15, 2008
Bt cotton Cry2Ab2	Monsanto 524-522	December 2002	September 30, 2006
Bt corn Cry3Bb1	Monsanto 524-528	February, 2003	February 24, 2006
Bt corn stack Cry3Bb1 + Cry1Ab	Monsanto 524-545	October 31, 2003	February 24, 2006
Bt cotton Cry1Ac + Cry1F (WideStrike)	Dow AgroSciences 68467-3	September 30, 2004	September 30, 2009
Bt corn MOCry1F Event DAS-06275-8	Dow AgroSciences 68467-4	May 27, 2005	October 15, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

ROBERT E. BRACKETT, PH.D.

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CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

UNITED STATES SENATE

JUNE 14, 2005

FOR RELEASE UPON DELIVERY

Introduction

Mr. Chairman and Members of the Committee, I am Robert Brackett, Director, Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to testify today on FDA's regulatory program for foods derived from bioengineered plants, also known as genetically engineered, or bioengineered, foods.

Background

Within FDA, the Center for Food Safety and Applied Nutrition (CFSAN) oversees bioengineered plant-derived food and ingredients intended for human consumption. Our Center for Veterinary Medicine (CVM) oversees bioengineered plant-derived products used as animal feed or as ingredients in animal feed, as well as bioengineered products used to improve the health or productivity of animals. My testimony this morning focuses on bioengineered plant-derived foods. Let me also clarify that in the Federal Food, Drug, and Cosmetic (FD&C) Act, food is defined as food for man or other animals. So, when I talk about food, it also encompasses animal feed unless stated otherwise.

We believe it is very important for the public to understand how FDA is regulating the bioengineered foods being introduced into the marketplace and to have confidence in that process. Therefore, I appreciate this opportunity to describe our policies and procedures.

First, let me state that FDA is confident that the bioengineered foods on the United States market today are as safe as their conventional counterparts. This conclusion has been echoed in recent reports by the National Academy of Sciences (NAS) and the Government Accountability Office, and most recently in a 2004 report from NAS's National Research Council and Institute of Medicine entitled, "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects." Over the last ten years, FDA has reviewed the data on more than 60 bioengineered food products, ranging from herbicide resistant soybeans to a modified canola oil. To date, the evidence shows that these foods are as safe as their conventional counterparts.

In a 1992 policy statement on bioengineered foods, FDA announced that the Agency was "not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or material way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding." This 1992 statement and its scientific underpinnings still reflect FDA's thinking about bioengineered foods.

Crossbreeding, Hybridization, and Bioengineering

The selection and genetic improvement of plants for agricultural use has been going on for thousands of years, although plant breeding as a science only began in the late 1800s. Typically, plant breeding has involved crossbreeding and hybridization, in which two

related plants are cross-fertilized, and the resulting offspring have characteristics of both parent plants. In the breeding process, however, many undesirable traits often can appear in addition to the desirable ones. Some of those undesirable traits can be eliminated through additional breeding, which is time-consuming. Breeders can then further select and reproduce the offspring that have the desired traits. Many of the foods that are already common in our diet are obtained from plant varieties that were developed using conventional genetic techniques of breeding and selection. Hybrid corn, nectarines (which could be considered genetically altered peaches), and tangelos (which are a genetic hybrid of a tangerine and grapefruit) are all examples of such breeding and selection.

Today, by inserting one or more genes into a plant, scientists are able to produce a plant with new, advantageous characteristics. The new gene splicing techniques are being used to achieve many of the same goals and improvements that plant breeders historically have sought through conventional methods. Today's techniques can be used with greater precision and allow for more complete characterization and, therefore, greater predictability, of the qualities of the new variety. They give scientists the ability to isolate genes and introduce new traits into foods without simultaneously introducing undesirable traits. This is an important improvement over traditional breeding. Any genetic modification technique, including both traditional methods and bioengineering, could change the composition of a food in a manner relevant to food safety. But because of the increased precision offered by the bioengineered methods, the risk of inadvertently introducing detrimental traits is actually likely to be lessened. Bioengineering does

expand the range of new proteins and other substances that can be introduced into plants. However, the agencies have well-established procedures for determining the safety of such new substances.

FDA has found no evidence to indicate that deoxyribonucleic acid (DNA) inserted into plants using bioengineering presents food safety problems. The small amounts of the newly expressed proteins are generally unlikely to change the safety profile of the plant. If safety concerns should arise, however, they would most likely fall into one of three broad categories: allergens, toxins, or anti-nutrients. FDA has extensive experience in evaluating the safety of such substances in food.

As to potential allergens, foods normally contain many thousands of different proteins. While the majority of proteins do not cause allergic reactions, virtually all known human allergens are proteins. Since genetic engineering can introduce a new protein into a food plant, it is possible that this technique could introduce a previously unknown allergen into the food supply or could introduce a known allergen into a "new" food. FDA's guidelines help developers to identify this issue and address any concern prior to marketing.

A second possible problem is the introduction of toxins into the food crop. It is possible that a new protein could cause toxicity. A third possible issue is the introduction of anti-nutrients, such as molecules like phytic acid that binds essential dietary minerals such as phosphorus.

Breeding, whether bioengineering or otherwise, can cause unintended changes in the composition of the food. For example, it might result in a reduction of Vitamin C or an increase in the concentration of a naturally occurring toxin in the food. Developers of bioengineered foods analyze the composition of the foods from their new crop varieties to ensure that they do not market foods whose composition differs from conventionally-derived counterparts.

It is important to note that the kinds of food safety testing typically conducted by developers of a bioengineered food crop to ensure that their foods meet all applicable requirements of the FD&C Act address these potential concerns. In the event that something unexpected does occur, this testing provides a way to detect such changes at the developmental stage and defer marketing until any concern is resolved.

Legal and Regulatory Background

The overall Federal regulatory structure for biotechnology products, known as the Coordinated Framework, was adopted by Federal agencies in 1986 (51 FR 23302, June 26, 1986). Under the Coordinated Framework, FDA regulates bioengineered plant-derived food in conjunction with the United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). FDA has authority under the FD&C Act to ensure the safety of all domestic and imported foods for man or other animals in the U.S. market. The exceptions to this are meat, poultry, and processed egg products,

which are regulated by USDA. The safety of animal drug residues in meat and poultry, however, is regulated by FDA's CVM. Pesticides, including those bioengineered into a food crop, are regulated primarily by EPA, which reviews safety and sets tolerances (or establishes exemption from tolerance) for pesticides. FDA enforces the pesticide tolerances set by EPA. USDA's Animal & Plant Health Inspection Service (APHIS) oversees the agricultural and environmental safety of planting and field testing of bioengineered plants.

Bioengineered foods and food ingredients must adhere to the same standards of safety under the FD&C Act that apply to their conventionally bred counterparts. This means that these products must be as safe as the traditional foods on the market. FDA has broad authority to initiate regulatory action if a product fails to meet the requirements of the FD&C Act.

FDA relies primarily on two sections of the FD&C Act to ensure the safety of foods and food ingredients that are produced using biotechnology:

(1) The adulteration provisions of section 402(a)(1). Under this postmarket authority, FDA has the power to remove a food from the market (or sanction those marketing the food) if the food poses a risk to public health. It is important to note that the FD&C Act places a legal duty on developers to ensure that the foods they market to consumers are safe and comply with all legal requirements.

(2) The food additive provisions in section 409. Under this section, a substance that is intentionally added to food is a food additive, unless the substance is generally recognized as safe (GRAS) or is otherwise exempt (e.g., a pesticide, the safety of which is overseen by EPA). Unapproved food additives are subject to the adulteration provisions in 402 (a)(2)(c) of the FD&C Act.

The FD&C Act requires premarket approval of any food additive, regardless of the technique used to add it to food. Thus, substances introduced into food are either: (1) new food additives that require premarket approval by FDA; or (2) GRAS, and are therefore exempt from the requirement for premarket review by FDA. Generally, foods such as fruits, vegetables, and grains are not subject to premarket approval under the FD&C Act because they have been safely consumed over many years. Other than the food additive system, there are no FDA premarket approval requirements for foods generally.

In 1992, recognizing that bioengineered products were on the horizon, FDA published a policy explaining how existing legal requirements would apply to products developed using the tools of biotechnology (57 FR 22984; May 29, 1992; "Statement of Policy: Foods Derived from New Plant Varieties"). The 1992 policy was designed to answer questions about these products and to assist developers prior to marketing to meet their legal duty to provide safe and wholesome foods to consumers. The basic principle of the

1992 policy is that the traits and characteristics of the foods should be the focus of safety assessment for all new varieties of food crops, no matter which techniques are used to develop them.

Under FDA policy, a substance that would be a food additive if it were added during traditional food manufacturing is also treated as a food additive if it is introduced into food through bioengineering of a food crop. Our authority under section 409 permits us to require premarket approval of any food additive and, thus, to require premarket approval of any substance intentionally introduced via bioengineering that is not GRAS.

Examples of substances intentionally introduced into food that would be reviewed as food additives include those that have unusual chemical functions, have unknown toxicity, or would be new major dietary components of the food. For example, a novel sweetener bioengineered into food would likely require premarket approval. In our experience with bioengineered food to date, however, we have reviewed only one substance under the food additive provisions, an enzyme produced by an antibiotic resistance gene (kanamycin), and we granted approval as a food additive. In general, substances intentionally added to or modified in food via biotechnology to date have been proteins and fats that are, with respect to safety, similar to other proteins and fats that are commonly and safely consumed in the diet and, thus, are presumptively GRAS. Therefore, they have not needed to go through the food additive approval process.

In 1994, following the 1992 policy, FDA conducted a comprehensive scientific review for the first bioengineered product planned for introduction into the market. FDA reviewed Calgene's data on the Flavr Savr™ tomato and the use of the kanamycin resistance marker gene. Calgene submitted food additive petitions for the enzyme product of the marker gene for use in food and feed. We subsequently approved the petitions. FDA also held a public meeting of our Food Advisory Committee to examine applicability of the 1992 policy to products such as the Flavr Savr™ tomato. The Advisory Committee members agreed with FDA that the scientific approach presented in the 1992 policy was sound and that the questions regarding the Flavr Savr™ had been addressed. The Advisory Committee members also suggested that we provide an expedited decision process for the marketing of bioengineered foods that do not raise substantive scientific issues.

In response, FDA established a voluntary consultative process to help companies comply with the FD&C Act's requirements for the bioengineered foods that they intend to market. The results of our consultation are public information and are available on our website. Since the consultation process was created, companies have used the consultative process more than 60 times as they sought to introduce genetically altered plants representing more than 16 different crops into the U.S. market. We are not aware of any bioengineered plant-derived food intended for commercialization that is subject to FDA's jurisdiction that has not been evaluated by FDA through the current consultation process.

Typically, the consultation begins early in the product development stage, before it is ready for market. Company scientists and other officials meet with FDA scientists to describe the product they are developing. In response, the Agency advises the company on what tests would be appropriate for the company to assess the safety of the new food. After the studies are completed, the data and information on the safety and nutritional assessment are provided to FDA for review. The Agency evaluates the information for all of the known hazards and also for potential unintended effects on plant composition and nutritional properties, since plants may undergo changes other than those intended by the breeders. For example, FDA scientists evaluate data and information to assure that the newly expressed compounds are safe for food consumption, and that there are no allergens new to the food, no increased levels of natural toxicants, and no reduction of important nutrients. They also determine whether the food has been changed in any substantive way such that the food would need to be specially labeled to reveal the nature of the change to consumers.

Some examples of the information reviewed by FDA include:

- The name of the food and the crop from which it is derived;
- The uses of the food, including both human food and animal feed uses;
- The sources, identities, and functions of introduced genetic material and its stability in the plant;
- The purpose or intended technical effect of the modification and its expected effect on the composition or characteristic properties of the food or feed;

- The identity and function of any new products encoded by the introduced genetic material, including an estimate of its concentration;
- A comparison of the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties with special emphasis on important nutrients, anti-nutrients, and toxicants that occur naturally in the food;
- Information on whether the genetic modification altered the potential for the bioengineered food to induce an allergic response; and
- Other information relevant to the safety and nutritional assessment of the bioengineered food.

If a plant developer used a gene from a source whose food is commonly allergenic, FDA would presume that the modified food may be allergenic. The developer, however, is allowed the opportunity to demonstrate that such food would not cause allergic reactions in persons allergic to food from the source.

If FDA scientists have questions about the safety data, the company may, for example, provide more detailed answers or conduct additional studies. Our experience has been that no bioengineered product has gone on the market until FDA's questions about the safety of the product have been answered.

Labeling

Section 403 of the FD&C Act sets labeling requirements for all foods. All foods, whether derived using bioengineering or not, are subject to these labeling requirements. Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular way. Section 201(n) of the FD&C Act provides additional guidance on how labeling may be misleading. It states that labeling is misleading if it fails to reveal all facts that are "material in light of such representations (made or suggested in the labeling) or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."

Although the legislative history of section 201(n) contains little discussion of the word "material," there is precedent to guide the Agency in its decision regarding whether information on a food is in fact material within the meaning of 201(n). Historically, the Agency has generally limited the scope of the materiality concept to information about the attributes of the food itself. FDA has required special labeling on the basis of it being "material" information in cases where the absence of such information may: (1) pose special health or environmental risks (e.g., warning statement on certain protein diet products); (2) mislead the consumer in light of other statements made on the label (e.g., requirement for quantitative nutrient information when certain nutrient content claims are made about a product); or (3) in cases where a consumer may assume that a

food, because of its similarity to another food, has nutritional, organoleptic (i.e., affects taste, color, odor, or feel), or functional characteristics of the food it resembles when in fact it does not (e.g., reduced fat margarine may not be suitable for frying).

FDA does not require labeling to indicate whether a food or food ingredient is a bioengineered product, just as it does not require labeling to indicate which conventional breeding technique was used in developing a food plant. Rather, any significant differences in the food itself have to be disclosed in labeling. If genetic modifications materially change the composition of a food product, these changes must be reflected in the food's labeling. This would include its nutritional content (for example, more oleic acid, or greater content of the amino acid lysine) or requirements for storage, preparation, or cooking, which might impact the food's safety characteristics or nutritional qualities. For example, one soybean variety was modified to alter the levels of oleic acid in the beans. Because the oil from this soybean is significantly different when compared to conventional soybean oil, we advised the company to adopt a new name for that oil, a name that reflects the intended change.

If a bioengineered food were to contain an allergen not previously found in that food, information about the presence of the allergen would be material as to the potential consequences of consumption of the food. If FDA determined that labeling would be sufficient to enable the food to be safely marketed, the Agency would require that the food be labeled to indicate the presence of the allergen.

FDA has received comments suggesting that foods developed through modern biotechnology should bear a label informing consumers that the food was produced using bioengineering. We have given careful consideration to these comments. However, we do not have data or other information to form a basis for concluding that the fact that a food (or any of its ingredients) was produced using bioengineering is material within the meaning of 201(n) and, therefore, constitutes information that must be disclosed as part of a bioengineered product's labeling. Hence, we believe that we have neither a scientific nor a legal basis to require such labeling. We have developed, however, draft guidance for those who wish voluntarily to label either the presence or absence of bioengineered food in food products.

The Agricultural Biotechnology Working Group

The interagency Agricultural Biotechnology Working Group, which includes the Office of Science and Technology Policy (OSTP), FDA, EPA, USDA, and others, has addressed regulatory issues related to the potential for low, intermittent levels of materials from bioengineered food crops to inadvertently get into food or feed.

In August 2002, OSTP published a Notice in the *Federal Register* (67 FR 50578) which proposed coordinated actions by FDA, EPA, and USDA aimed at strengthening controls over field trials to address the potential of material from field trials to inadvertently get into food or feed. As part of this OSTP initiative, on November 24, 2004, FDA issued a draft guidance document entitled, "Guidance for Industry: Recommendations for the

Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use." This draft guidance outlines procedures to address the possible intermittent, low-level presence in food and feed of new non-pesticidal proteins from biotechnology-derived crops under development for food or feed use but that have not gone through FDA's premarket consultation process. Under this guidance, FDA encourages developers to submit protein safety information once field testing reaches a stage of development such that there could be concerns that new non-pesticidal proteins produced in the field-tested plants might be found in food or feed. FDA's focus would be on proteins new to such plants because FDA believes that any potential risk from the low level presence of such material in the food supply would be limited to the possibility that it would contain or consist of a new protein that might be an allergen or toxin. FDA would still expect developers to conduct a complete consultation with FDA prior to marketing food or feed from the plant, consistent with current practices. The comment period for the draft guidance closed on January 24, 2005. FDA is reviewing the approximately 3000 comments received and expects to complete the final guidance by the end of the calendar year.

The Agricultural Biotechnology Working Group is also working on the issue of pharmaceutical crops. FDA has the authority and responsibility for regulating pharmaceuticals, including human biologics, whether they are produced in traditional manufacturing facilities or from crops in the field. Regulations found in parts 210 & 211 of Title 21 of the Code of Federal Regulations outline practices that must be followed by pharmaceutical manufacturers as part of good manufacturing practice. These regulations

are general in nature and apply to all pharmaceutical manufacturing methodologies, including plant-made pharmaceuticals. For crops in the field, however, there are particular issues to be addressed, for example, the disposition of the residual crop left over after a pharmaceutical is extracted. The interagency working group is working to clarify authorities for regulating genetically engineered crops ordinarily used to produce food (e.g., corn), whether they are intended for food, pharmaceutical, or industrial use, and to make sure there are no gaps in protecting human health and the environment. We are evaluating ways to help keep pharmaceutical and industrial compounds out of food when they are not supposed to be there. We are looking at ways that would be science- and risk-based, enforceable, complementary with the USDA-APHIS regulatory scheme, and that would not pose too high a barrier to development of these products.

In September 2002, FDA and USDA jointly published the Draft Guidance for Industry on the use of bioengineered plants or plant materials to produce biological products, including medical devices, new animal drugs, and veterinary biologics. This draft guidance, which contains sections on FDA oversight and sections on APHIS oversight, outlines the important scientific questions and information that should be addressed to FDA by those who are using bioengineered plants to produce medical or veterinary drug products. FDA and USDA are working to finalize this guidance document.

Other Activities

FDA has made a commitment to ensuring that consumers have access to information about new bioengineered food products in a timely fashion and has made more information about these foods available on FDA's website.

To ensure that FDA has the best scientific advice on issues related to bioengineered foods, we have added experts in this field to our foods and veterinary medicine advisory committees and created a Food Biotechnology Subcommittee of the Food Advisory Committee.

In addition, NAS has formed a standing Committee on Agricultural Biotechnology, Health and the Environment. FDA, EPA and USDA requested that the committee assess the potential for unintended effects of genetically engineered foods and how to evaluate their impact on human health. The committee's report, "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects," was published in July 2004. According to the committee, all evidence evaluated to date indicates that unexpected and unintended compositional changes arise with all forms of genetic modification, including conventional methods and genetic engineering techniques. The committee noted that a "policy to assess products based exclusively on their method of breeding is scientifically unjustified." The committee recommended that compositional changes that result from any method of genetic modification in food, including genetic engineering, undergo an appropriate safety assessment. The committee presented an

approach to scientifically assess whether unintended effects that result from the genetic modification could lead to adverse health concerns. The approach suggested by the committee is generally consistent with FDA's approach.

FDA provided international leadership in the work of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, a task force established for a four-year time span by the Codex Alimentarius Commission (Codex). The work of this task force was especially important because it developed internationally accepted principles and guidelines for the evaluation of the safety of bioengineered foods. Those principles and guidelines were adopted by Codex in 2003, at the conclusion of the life of the task force. These principles and guidelines are the international standards for ensuring the safety of genetically engineered foods, and they are consistent with FDA's approach. Codex recently re-established the task force for another four-year span. It will have its first meeting this coming September, when it will decide on new work.

FDA also is actively participating as a member of the Organization for Economic Cooperation and Development's Task Force for the Safety of Novel Foods and Feeds. This task force is in the process of writing scientific/technical consensus documents aimed at compiling current information that is important in food and feed safety assessment. These consensus documents serve as references to Codex and regulatory bodies.

Mr. Chairman, FDA, in cooperation with EPA and USDA, will continue its oversight of new and emerging food biotechnology products and will be vigilant in ensuring the safety and integrity of the food supply. I thank you again for the opportunity to address these issues. I am happy to answer any questions you might have.

WRITTEN TESTIMONY
JIM GREENWOOD
PRESIDENT AND CHIEF EXECUTIVE OFFICER,
BIOTECHNOLOGY INDUSTRY ORGANZATION

BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
UNITED STATES SENATE

REGARDING BENEFITS AND FUTURE DEVELOPMENTS IN
AGRICULTURE AND FOOD BIOTECHNOLOGY

JUNE 14, 2005

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Good morning Mr. Chairman, Senators, Ladies and Gentlemen. I am Jim Greenwood, President of the Biotechnology Industry Organization (BIO). I am privileged to be here this afternoon on behalf of BIO. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in 31 other nations. BIO members are actively involved in the research and development of new medicines, foods, and industrial and environmental products to benefit the lives of people and the environment.

I would like to thank Senator Saxby Chambliss (R-GA) and members of the committee for the opportunity to be with you today, and for organizing this hearing.

The agricultural segment of our industry is celebrating two significant milestones in 2005. First, this year marks the 10th anniversary of commercialized biotech crop plantings, and second, last month we marked the planting of the one billionth acre of biotech crops. These two points help to demonstrate that agricultural biotechnology is the most rapidly adopted technology in the history of food production.

Today's farmers want these new crops to help solve their big "E" challenges: Protecting the Environment, conserving Energy, improving the agricultural Economy, Enhancing crop benefits and improving crop Endurance in the face of disease, pests, and weather. A biologically based agricultural system is a renewable method to conserve our farmland providing opportunities for future generations of America's farm families to remain as stewards of their land, and leaving a softer footprint on the environment which we all share.

In this tenth year of growing crops enhanced through biotechnology, global acceptance continues to increase at a rapid pace. According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), in 2004, global biotech crop plantings continued to grow at a sustained double-digit rate of 20% compared with 15% in 2003. The estimated global area of approved crop plantings was more than 200 million acres in 2004.

These crops were grown by approximately 8.25 million farmers in 17 countries, up from 7 million farmers in 2003. But most notably, 90% of the beneficiary farmers were resource-poor farmers from developing countries, whose increased incomes from biotech crops contributed to the alleviation of poverty. This is an unwavering and resolute vote of confidence in the technology. Farmers are masters of risk aversion, and have consistently chosen to plant larger acreage of biotech crops year, after year, after year.

For the first time, biotech crop acreage in developing countries grew faster than developed countries, further increasing the important economic, health and societal benefits realized by these small farmers. Eleven developing countries grew biotech crops in 2004, nearly double the number of industrialized countries (six) growing the crops. In fact, five key developing countries – China, India, Argentina, Brazil and South Africa, are expected to have a significant impact on the adoption and acceptance of biotech crops globally.

We expect these gains to continue at a high rate of momentum well into the future. By 2010, ISAAA projects up to 15 million farmers will grow biotech crops on more than 370 million acres in up to 30 countries.

Closer to home, the United States is the world leader in the development and planting of these crops. In 2004, American farmers chose to plant 85% of soybeans, 76% of cotton and 45% of corn with seeds improved through biotechnology that allow the plants to protect themselves from insects and disease and promote better weed management. The United States has also approved for commercial planting biotech varieties of canola, chicory, flax and linseed, melon, papaya, potatoes, rice, squash, sugar beets, tobacco and tomato. The annual R&D investment of the six largest companies in the sector is $2.7 billion, or 10.8 percent of sales.

The rapid adoption of this technology by U.S. farmers is a testament to the solutions it provides to problems on the farm. Biotechnology enables farmers to reduce input costs

and improve yields. And by freeing farmers from the chore of constantly spraying and tilling their fields to remove weeds, biotech improved crops not only reduce the use of chemical inputs, reduce soil erosion, and reduce the use of fossil fuels; they increase the amount of time farmers have to spend with their families.

A study from the National Center for Food and Agricultural Policy (NCFAP) measured the impact of six biotech crops (corn, canola, cotton, papaya, soybeans and squash) on grower incomes and the environment in the United States. NCFAP found that, compared with conventional crops, the biotech varieties lifted grower incomes by $1.9 billion, boosted crop yields by 5.3 billion pounds, and reduced agricultural chemical use by 46.4 million pounds in 2003.

The growers who gained the most economically were those in the corn and soybean heartland of the Upper Midwest: Iowa, Illinois and Minnesota. But 42 states in total enjoyed some economic benefit from biotech crops. Of the six crops studied, biotech soybeans produced the greatest economic return for growers—an additional $1.2 billion in income.

Biotech corn produced the highest yield gains generating an additional $258.4 million for farmers. Farmers growing biotech cotton gained an extra $413 million in income; biotech canola growers earned $9 million more. Compared to a similar NCFAP study performed in 2002 (based on 2001 data) yield gain resulting from biotech crops was up 41%, production costs fell 25%, and the crops produced a 27% higher economic return.

Biotechnology also contributes to increasing the health of farm animals enabling the production of safer and more nutritious meat, milk and eggs. It also keeps our family pets healthy. There are over 100 licensed vaccines and diagnostic tests developed through biotechnology that significantly reduce disease in both farm and companion animals.

Biotechnology can be used to detect desirable genes in livestock populations. This new tool can improve breeds, help select the healthiest animals for feedlot management and provide consumers with a certification of meat quality. DNA sequencing technology can be used to create advanced animal identification methods to track meat products from birth to plate in a very short time frame (24 hours) thereby protecting consumers from both accidental and intentional contamination of the food supply. Livestock cloning accelerates the reproduction of the healthiest and most productive livestock, allowing farmers and ranchers to breed top quality animals for food production.

The development and subsequent adoption of this technology could not have been possible without a strong regulatory system to ensure the safe use of these products for both human health and the environment.

We recognize that strong regulatory systems are essential to consumer confidence and we work closely with the U.S. Department of Agriculture, the Food and Drug Administration and the Environmental Protection Agency, all of whom play important roles in providing science-based assessments of our products.

We recognize that this dependence on a strong regulatory system will only increase as we move to the development of what is often referred to as "second generation" biotechnology products.

We also urge the U.S. government to continue to require our trading partners to adhere to international treaties that support science-based regulatory regimes and the intellectual property rules that fuel the innovation engine that drives our industry.

Agricultural biotech research is showing increasing global acceptance. There is research now underway in 63 countries and on every continent except Antarctica according to a December 2004 report by C. Ford Runge, an economist and director of the Center for International Food and Agricultural Policy at the University of Minnesota. According to

Runge "the most significant single potential actor in Asia is China, which is aggressively engaged in biotech adoption and research."

A number of biotech crops are approved and could be launched commercially at any time, including rice, soybeans, and corn in China. But it's worth noting that 20 academic institutions in India are researching 16 crops; Indonesia reports planting approvals, field studies and basic research. South Korea has approved corn and soybeans and undertaken a 20-year program of biotech research. Japan has given import approval to six biotech crops and is conducting research in biotech fruits, vegetables and grains. Malaysia in 2004 approved a Biotechnology Agenda, and in Thailand, field studies on cotton, rice and vegetables are under way along with research on cassava, papaya and long beans.

Even Europe is showing forward movement in the adoption of biotech crops. European Union countries were host to 1,849 field trials between 1991 and August 2004. By country, the number of field trials conducted was: 520 in France, 270 in Italy, 263 in Spain, 199 in the United Kingdom, 138 in Germany, 129 in Belgium, 68 in Sweden, 38 in Denmark, 19 in Greece, 16 in Finland, 11 in Portugal, 50 in Ireland, and three in Austria.

Our product pipeline is rich and offers great promise to provide more nutritious and safer foods. More than a dozen agricultural firms are spending millions of dollars to research ways to make our milk, meat and poultry products safer through improved animal health products and diagnostic tools. These products will greatly reduce the number of Americans affected by food borne illness such as salmonella, Listeria and *E. coli.*

Biotech companies are developing soybean and canola varieties with healthier fat content profiles, reducing or eliminating harmful trans-fat and saturated fat. Foods are in development which will have higher levels of nutrients, protein and essential amino acids as well as extended shelf-life. And because biotechnology researchers have identified the allergenic proteins in many foods and are developing varieties that delete or disable those proteins, we can look forward to allowing those with allergies to enjoy a fuller diet without fear of an allergic reaction.

Foods that contain vaccines could potentially save hundreds of thousands of lives in regions with frayed or nonexistent health care infrastructures. Products in development include bananas and potatoes that contain a vaccine for human papillomavirus, one of the most prevalent sexually transmitted diseases and the cause of almost all cervical cancer.

Another promising avenue of research is the development of plant-made pharmaceuticals which will allow companies to manufacture novel biologics and therapeutics in plant-cell systems. The technology has the potential to reduce the costs of producing pharmaceuticals to enable increased access to life saving drugs.

New vaccines will reduce food borne pathogens from livestock and poultry on the farm, to further assist in reducing food borne illness in consumers. Cattle resistant to mad cow disease (BSE) are being developed. Pigs are being produced with leaner pork; milk and eggs with increased content of heart-healthy fatty acids are in development.

The greatest challenge of the 21st century will be to feed and clothe nearly 10 billion people in an environmentally responsible fashion. This will require a delicate balance of preserving space and land use for wilderness and wildlife, with agricultural food and fiber production. Nobel Laureate Norman Borlaug has noted that "It took some 10,000 years to expand food production to the current level of about 5 billion tons per year. By 2025 we will have to nearly double current production again."

Many of the current constraints on sustainable production can be overcome with biotechnology, as our increasing understanding of agricultural genetics opens new doors for advancements in yield, quality, and preservation of the environment. This has never been more urgently needed -- in the past decade we've seen a marked decline in the steady productivity gains from traditional plant breeding as the genetic potential of the older production methods reaches its limits.

Biotechnology isn't the only answer to these daunting challenges, but it certainly is a major part of the solution.

The first green revolution is over. Biotechnology opens the door to the second, and necessary agricultural revolution.

Biotechnology will serve this essential role, to allow us to produce more and more healthful foods, on a fixed amount of arable land, in a more efficient manner. The breakthroughs provided by biotech agriculture will reduce soil tillage, fossil fuel use, and runoff of agricultural pesticides into our lakes, streams and oceans.

In closing, biotechnology has a long track record for using innovative techniques to solve long standing problems. Our industry is investing heavily in research and development which will provide products which will promote human, animal and environmental health.

Thank you for giving me the opportunity to provide this information to you today. I look forward to answering any questions that you may have.

STATEMENT BY RON HECK
CHAIRMAN, AMERICAN SOYBEAN ASSOCIATION
BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
UNITED STATES SENATE
REGARDING
AGRICULTURE BIOTECHNOLOGY

June 14, 2005

Good afternoon, Mr. Chairman and Members of the Committee. I am Ron Heck, a soybean and corn producer from Perry, Iowa. I serve as Chairman of the American Soybean Association. I am appearing today on behalf of the American Farm Bureau Federation, the National Corn Growers Association, and the National Cotton Council, as well as ASA. We thank you for the opportunity to testify before the Committee today.

As you know, 2005 marks the tenth anniversary of the introduction of biotech crops for commercial production. Our organizations recently recognized the planting of the billionth acre of biotech-enhanced agricultural commodities. Since 1986, and in each successive year, American agriculture has been the world leader in the adoption of agricultural biotechnology. In 2004, the United States accounted for 50 percent of the world's total plantings of biotech crops. U.S. plantings of the three major biotech crops continue to expand. For example in 2004:

- 86 percent of total soybean plantings were modified to be herbicide-resistant, up from 81 percent in 2003;
- 76 percent of upland cotton plantings were biotech cotton, up from 73 percent in 2003, and;
- 46 percent of corn plantings were biotech corn, up from 40 percent in 2003 (ASCII prospective planting report March 2004).

American farmers have seized the opportunity offered by biotechnology to improve their production efficiency. They have recognized that the adoption of new technologies, including biotechnology, is essential in maintaining a competitive advantage for U.S. agricultural exports on the world market. The advantages of biotech crops include the environmental benefits of lower pesticide usage and decreased soil erosion, increased yields, disease-resistance and fuel savings. The future of this technology is bright – new biotech plant varieties are being developed that will produce crops with enhanced nutrient and health profiles, as well as crops tolerant to drought, salty soil, cold, and disease.

Crop biotechnology has led to reduced tillage practices across all crops with biotech traits. These reduced tillage practices are saving one billion tons of topsoil annually, reducing by 309 million gallons the amount of fuels used by farmers, and decreasing greenhouse gas emissions by one billion pounds. Biotechnology has decreased pesticide applications by 46 million pounds and is saving U.S. consumers $3.5 billion in water treatment and management costs.

American production of crops utilizing biotechnology is expected to continue to rise. The approval of new varieties of biotech crops will play an important part in this increase. New varieties of biotech corn, cotton and soybeans are being developed that address a wider range of production limiting factors. In the future, wheat, rice, sugar beets, alfalfa, apples, bananas, lettuce and strawberries can be expected to move into the biotech era. Currently, over 50 agricultural biotech products are on the market and many more are being developed. In addition, 63 developing countries are conducting plant biotech research across 57 different crops.

While the United States is the world leader in the production of agricultural crops enhanced through biotechnology, other countries are also expanding biotech crop production. In 2004, global biotech crop acreage increased 20 percent to a total of 200 million acres – the ninth consecutive year of double-digit growth. In 2004, a total of 8.25 million farmers in 17 countries planted biotech crops, up from 7 million farmers in 2003. During the period from 1996 to 2004, a cumulative total of 951 million acres of biotech crops were planted globally. The global value of total crop production from biotech crops in 2003 was estimated at $44 billion.

The increase in production of biotech crops in the United States and abroad has raised the importance of developing and maintaining markets, both domestically and internationally for products derived from biotechnology. Market development is dependent on public policy that:

1. Maintains an unbiased, science-based regulatory system that inspires consumer confidence;
2. Works to ensure market access for biotech crops and products domestically and internationally; and,
3. Creates an environment conducive to the development of new biotech crop varieties.

I would like to elaborate on each of these points.

1. Maintaining an unbiased, science-based regulatory system that inspires consumer confidence

Biotechnology in the United States is regulated by several federal agencies, including the Food and Drug Administration (FDA), the Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). These government agencies play an important role in providing unbiased, science-based evaluations concerning the human, animal, and environmental safety of biotech commodities. The U.S. regulatory system does not require any specific labeling or traceability for biotech crops and ingredients that have been determined to be substantially equivalent in safety and nutrition to conventional crops. This science-based regulatory approach should continue.

Some countries have adopted or are considering regulatory regimes that stigmatize biotech crops by requiring mandatory labeling and traceability of foods containing ingredients derived from biotech commodities. These policies have the effect of nullifying the regulatory system in place. If the science-based regulatory system concludes that a product is safe for human consumption, it becomes unnecessary to label it as "genetically engineered" or "genetically modified."

If consumers, either domestically or internationally, demand products free from biotech ingredients, the market will respond by developing brands that meet this criterion, and make them available through a voluntary labeling system. Why should all consumers be forced to pay the cost of a mandatory traceability and labeling system when the biotech-enhanced product in question has been approved as safe for human consumption?

Unfortunately, countries with mandatory labeling and traceability laws for biotech commodities are trying to "internationalize" their systems by pushing for adoption of similar requirements by the Codex Alimentarius Commission. Codex is responsible for setting international food safety guidelines based on sound scientific principles. The U.S. Government must continue its efforts to prevent adoption of non-science based and discriminatory standards on a worldwide basis.

2. Working to ensure market access for biotech crops and products

Biotechnology is so critical to U.S. agriculture as a production tool that ensuring open access to world markets is imperative. This is not possible unless science-based approvals and traceability and labeling requirements for biotech commodities are the international standard. The European Union's (EU) current approach to require the labeling and traceability of food and feed derived from biotech commodities is inconsistent with its own and other countries' exhaustive risk assessments undertaken on products of agricultural biotechnology. It is also inconsistent with the widespread practice by the EU's own food industry of using biotech-derived yeasts, enzymes, and other processing aids in the production of beer, cheeses, and other food products that are not required to be labeled.

The international acceptance of products derived through biotech enhancement, once they have been approved as safe for humans, animals, and the environment according to internationally accepted, scientific principles, must be a high priority of U.S. government policy. We must not allow non-scientific, discriminatory, and trade restricting laws and regulations to negatively affect U.S. commodity and food exports. Our organizations, along with 17 other major US agriculture and food organizations, support these principles, and have requested that the U.S. government file a WTO complaint against the European Union challenging non-scientific barriers to market access for biotech-derived crops. We also support the current WTO case against the EU's moratorium on approvals of new biotech commodities. While we appreciate that the focus of this hearing is on our experience with existing biotech crops and emerging technologies, we look forward to discussing these critical issues with the Committee in the near future.

3. Creating an environment conducive to the development of new biotech crop varieties

If U.S. agriculture is to maintain its place on the technology frontier, it is imperative that we foster an environment conducive to innovation and the adoption of new technologies. Government and private sector research centers must be assured that the United States is working to ensure that there will be a market, both domestically and internationally, for approved products derived from biotechnology.

There are many agricultural commodities which could benefit from this technology. Our organizations applaud the efforts of the Administration to establish an organization whose objective will be to facilitate the development of biotechnology-derived specialty crops.

American agriculture has now experienced first-hand the benefits of this technology for a decade. Today, 16 other countries have also had experience with biotechnology, but its full potential is yet to be realized. In developing countries, where agriculture is often a dominant sector, adoption of suitable biotechnology traits has the potential to deliver increased efficiency in agricultural production – a driver of economic growth. In addition, biotechnology is an important tool for tackling the problems of world hunger. The global population is expanding while the amount of arable land continues to shrink. Technologies like biotechnology offer an opportunity for increasing yield and reducing crop losses.

In conclusion, American agriculture has enthusiastically embraced the benefits that biotechnology provides in enhancing production efficiency and the competitiveness of U.S. agricultural commodities on world markets. As we recognize this tenth year of commercial biotech production, we look forward to continuing our work with Congress to support this important agenda. U.S. farm organizations are committed to ensuring broader acceptance of these products internationally, and continued consumer confidence at home. We will work with Congress and the Administration to address unnecessary trade barriers implemented by other countries for commodities enhanced through biotechnology.

Thank you for this opportunity to testify on this important issue. I would be happy to answer any questions.

BIOTECHNOLOGY: THE ROLE OF THE WORLD FOOD PRIZE IN INSPIRING FURTHER BREAK-THROUGH ACHIEVEMENTS

TESTIMONY OF

AMBASSADOR KENNETH M. QUINN

PRESIDENT OF THE
WORLD FOOD PRIZE FOUNDATION

BEFORE

THE SENATE AGRICULTURAL COMMITTEE

JUNE 14, 2005

Mr. Chairman,
Senator Harkin,
Members of the Committee:

At the outset let me emphasize that it was our hope that Dr. Norman E. Borlaug, the founder of the World Food Prize and one of America's leading proponents of biotechnology, would be able to be here to testify as part of this panel. However, Dr. Borlaug is today undergoing minor surgery and was thus unable to appear. At age 91, he is still going strong traversing the globe in an effort to bring the benefits of the "Green Revolution" to Africa, to inspire the next generation of young scientists and to convey the importance he attaches to the role of science in providing the additional food required to feed the burgeoning world population in the 21st century.

There is probably always some cause for trepidation when a former diplomat with a degree in political science appears to testify before the Senate Agriculture Committee, especially when the topic is biotechnology, and even more so when he is standing in for Dr. Borlaug the man of whom it is said, "He has saved more lives than any other person who has ever lived, in all human history." On second thought, however, it may not be so surprising to have someone with a Foreign Service background here today. Last Friday, June 10, a ceremony was held in the marvelous Benjamin Franklin Diplomatic Reception Room at the State Department presided over by AID administrator Andrew Natsios. At that time it was my privilege to announce that the $250,000 World Food Prize for 2005 will be presented to a scientist from India, Dr. Modadugu Gupta, for his accomplishment in bringing the benefits of small scale fish farming to over a million of the most poor people in

South and Southeastern Asia and expanding that capability in Africa through pioneering efforts in genetic transfer. The room was filled to overflowing with an array of diplomats, government officials, representatives of development agencies such as the World Bank, people representing food companies, producer groups and others deeply involved in biotechnology. They were there because of the increasingly central role food production is playing in international relations, and because the World Food Prize is increasingly seen as the foremost national and international award recognizing exceptional breakthrough achievements in increasing the quality, quantity and availability of food. And after all, that is exactly what biotechnology is all about.

As you no doubt are aware, Dr. Borlaug has been directly involved in the task forces and special committees the US Government has established to have exchanges with Europe and other parts of the world regarding the acceptance of genetically modified foods. In this capacity, and in his individual speaking and writing, Dr. Borlaug has emphasized several points which I feel sure he would be pleased if I repeat for you here.

First and foremost, Dr. Borlaug is a passionate advocate for the primacy of science. In his long life, he has seen firsthand the impact of the application of science to increases in productivity and nutrition. Dr. Borlaug still recounts the stories of his encounters, as a young man, with Henry A. Wallace and how Wallace helped change the face of American agriculture through the application of science he learned at Iowa State University and from the brilliant African-American pioneer Dr. George Washington Carver. Although Dr. Borlaug usually adds that then Vice President Wallace was chagrined to find Borlaug working on wheat in

Mexico and said to him "Why isn't a good Iowa boy like you working on corn?" It is Dr. Borlaug's fear that political and other considerations are coloring the debate and dialogue over biotechnology and that the world risks losing the power of this new science to help feed and an increasing hungry world.

Dr. Borlaug also sees the potential power of genetic modification in dealing with plant diseases that have plagued our country and others such as rust. As we watch the current spread of rust affecting soybeans in the United States, it may be well to recall what Dr. Borlaug, who has spent his entire career of 60 years as a plant pathologist, sites as one of his fondest dreams. He notes that the one cereal that has an apparent immunity against rust diseases is rice. "Imagine the benefits," Dr. Borlaug wrote, "if the genes that provide immunity against rust in rice could be transferred into wheat, barley, oats, millet, maize and sorghum," and I am sure he would add soybeans. "The world could finally be free from the scourge of the rusts which have lead to so many famines over the course human history."

Dr. Borlaug has also emphasized the power of genetic engineering to improve the nutritional quality. For example, had genetic engineering techniques been available, the 40 year period it took to develop a means to increase the levels of lycene and tryptophane in maize could have been cut in half or even more.

Another crucial point to Dr. Borlaug, if biotechnology is to flourish, is the importance of maintaining funding for research at our US and international public research centers. Our Land Grant Colleges and Universities, and the CGIAR centers of the World Bank are essential

elements, along with the research done by commercial agribusiness firms, in maintaining America's leading role in agricultural innovation.

Finally, Dr. Borlaug consistently points out the crucial importance of biotechnology to preserving our environment and biodiversity on our planet. When all other arguments are put aside, the bottom line question Dr. Borlaug poses is this: In the next 50 years there will be an addition three billion people to feed on our planet. The additional food necessary to accomplish this task will be found in one of two ways. Either we will develop techniques which permit us to achieve increased yields on the land currently in production; or we will be forced to cut down significant parts of the remaining rainforests and animal habitats to make more land available to grow this additional food. This will be the most important issue to be addressed as we move from the "Green Revolution" to the "Gene Revolution," he concludes.

In this regard, it is important to recall that Dr. Borlaug's break-though achievements in the 20th Century are credited with saving a billion people from famine, and keeping an estimated one billion hectares of forest and rainforest from being cleared for agricultural production.

Perhaps Dr. Borlaug's most important and longest-lasting contribution to the effort to address food production and hunger in the 21st century will be his creation of the World Food Prize. The origins of the World Food Prize can be traced back to the mid 1960's when Dr. Borlaug was asked by the United Nations Food and Agriculture Organization to go to India and Pakistan as those two countries faced the prospect of severe food shortage. Working on the basis of equality and mutual respect, Dr. Borlaug partnered with senior officials and young scientists in both

countries to introduce a new rust resistant wheat variety he had developed during two decades of research in Mexico which tripled the yield. This new approach to agriculture staved off a pandemic famine and lead to both countries becoming self-sufficient in wheat in very few years.

For this achievement, in 1970 Dr. Borlaug was presented the Nobel Peace Prize as the "Father of the Green Revolution." But it bothered Dr. Borlaug that so many others, who were equally deserving of recognition, were not honored in the same way. So when the Nobel Committee advised him that it could not accede to his proposal that they establish a new Nobel Prize for food or agriculture, Dr. Borlaug, in 1986, created the World Food Prize. And with the financial support of the Ruan family this award has been presented annually each October over the last 19 years to individuals who have made exceptional Nobel-like breakthrough achievements in increasing the quality, quantity and availability of food in the world.

In conjunction with the presentation of this award in the magnificent Iowa State Capitol building on or around World Food Day, Dr. Borlaug believed that there needed to be a place where officials and experts can come together to address the crucial issues facing world agriculture, recognize and inspire individual achievements in developing new technologies and inculcate in our young people their importance in being involved in agricultural and biological science.

For the past 19 years the World Food Prize has been this vehicle. The creation of the World Food Prize is an inspiring story of how two men both born in small towns in Iowa in 1914 came together in the belief that

they could create something that might change the world. Norman Borlaug and John Ruan are those two men. I was greatly pleased when in 1999 they invited me to join with them in this endeavor. When Dr. Borlaug and I first met in 1999 we talked about our experiences of working in very poor villages, we discovered that we had a common perception about how to bring dramatic change to poorer societies. I had grown up in eastern Iowa not far from the "Field of Dreams" and had ended my diplomatic career as Ambassador to Cambodia, the site of the Killing Fields. But the connection between these two is not as distant as it may seem. Like many young officers entering the State Department, my first thought was of an assignment to some European Capital where I might attend diplomatic receptions in chandeliered ballrooms. Instead, I found myself assigned in the Mekong Delta at the height of the Vietnam War. I ended up staying for six years. And it was there that I learned one of the most important lessons of my life about the power of agricultural technology and rural roads in transforming societies and defeating terrorism.

In 1968, new "miracle rice" had just been developed in the Philippines and was being introduced into the villages where I served as the district senior advisor as part of the Military Assistance Command. The rice had been developed following Dr. Borlaug's model of improved wheat, using new, high yielding seeds and an integrated set of support mechanisms such as fertilizer and irrigation. The payoff was enormous. Whereas families had at best been able to produce one crop of traditional rice, barely enough to sustain their family, with the new seeds they could get two or three crops a year, each with much higher yields. In the area where this new rice was planted, family incomes increased dramatically. A drive through those villages showed children with better clothes and

better nutrition living in homes that were bigger and stronger. And those families now had extra income with which they could buy a motor bike or some other desired item. The most instructive aspect of this process was that the new seeds and this new approach to agriculture were adopted only in villages reached by the improved road. So when we drove through the first four villages with the upgraded road and new bridges, life seemed transformed with children easily able to get to schools in nearby hamlets and thus able to remain in school longer. At the same time, security in these villages improved exponentially. Terrorist cells, which had been in regular operation, seemed to evaporate with the improved economic prospects in the villages. However, when you came to the end of the improved road and crossed the canal by sampan, life in the other four villages seemed unchanged from what it had been 100 years ago. Houses looked rundown; children seemed poorly dressed, thinner and poorly nourished; families were forced to subsist on only one rice crop; and security remained elusive. It was necessary to have an armed escort during the day and one did not venture in the villages at night because of the ongoing presence of the Vietcong. The lesson I learned from this experience was the lesson that Dr. Borlaug and everyone in his generation had seen growing up. The way America transformed its rural society, whether in Iowa or any another state, was by building rural roads and by spreading new agricultural technologies being developed at our land-grant colleges and by its graduates. I carried this lesson with me through the rest of my diplomatic career and finally to Cambodia as Deputy Assistant Secretary and then Ambassador. In 1990 there were still approximately 25,000 Khmer Rouge in control of large parts of that devastated country, whom even 200,000 Vietnamese troops could not dislodge and destroy. With the coming of the UN brokered peace agreement and democratic

elections I worked with the new Cambodian government to put in place a program to de-mine and upgrade rural roads into Khmer Rouge areas and to bring new agriculture technology with it. This accomplished what all the air strikes and artillery barrages could not. Wherever the roads were built and new technology introduced, it destroyed the Khmer Rouge by undermining support for them in the most remote areas, bombarding them with economic progress, human rights, more access to health care, and educational opportunities. Nine years later, just as I was about to depart Phnom Penh, the last Khmer Rouge general surrendered, thus totally eliminating that terrorist organization.

It should be instructive as we confront terrorist organizations in many other places in the world, that biotechnology (the current equivalent of that Miracle Rice) and rural roads may be among our most valuable and potent weapons in the struggle between freedom and terrorism.

The assignment I was given by Dr. Borlaug when I arrived in Iowa in 1999 was to build the World Food Prize into the Nobel Prize for Food and Agriculture. For the past six years we have been endeavoring to achieve that objective through a three-fold approach. Each October, on or near October 16, World food Day, we hold a ceremony in our magnificent Iowa State Capitol building that will rival, if not exceed, those in Oslo and Stockholm at which the Nobel Prize is presented.

In October 2004 we had representatives of 62 different countries in the chamber of the House of Representatives as Dr. Borlaug presented our $250,000 Prize. Also assembled there was more life-saving achievement in terms of the work of our laureates than is assembled any other place around the globe.

It is Dr. Borlaug's goal to have the most significant observance of World Food Day, anywhere around the globe, take place in Des Moines each October. And so, in addition to this ceremony, with Dr. Borlaug's lead, we hold a two day symposium on a cutting edge topic in the food and development. We emphasize two points: First that addressing issues of hunger and human suffering can be a way to transcend the most divisive political issues, just as Dr. Borlaug did in the 1960's when he led the effort to bring about change in Pakistan and India. Secondly, more than ever before, issues of food production are directly tied to national security.

In 2000, when the debate about biotechnology was largely confined to environmental concerns being stressed by Europe, the World Food Prize Symposium addressed the critical role biotechnology could play in feeding developing countries.

In 2001, we put Agroterrorism on our conference agenda six months before the tragic events of 9/11. As a result, we had seven of the world's leading experts on bioterrorism speaking in Des Moines, at the first meeting anywhere to highlight the vulnerability of our food supply in the post 9/11 era.

A year later, global water insecurity was the topic addressed, with special emphasis on Israel and the Middle East. Iowa proved to be an exceptionally good place to bring together Israelis and Palestinians along with experts from Egypt, Syria and the UAE. Again, biotechnology was front and center, as the research being done to adapt crops to extreme arid conditions as well as to salt water intrusion was featured. We were

particularly pleased that Dr. Saul Arlosoroff, Chairman of the Israeli Water Engineers Association, said of this symposium:

> "During the past 45 years, I have never participated in a symposium, conference, or seminar that could match your organization and the quality of the presentations."

This October the World Food Prize will have another first. Our symposium will address the twin challenges of confronting malnutrition and hunger in the developing world and overnutrition and obesity in our country and other parts of the developed world. Senior officers at HHS tell us no one has put these two groups of experts together in the same room. And again, biotechnology will be in the forefront.

The leaders and senior officials of four of America's foremost agribusinesses are all on the program, as are the leading researchers in the area of biofortification and enhancing nutrition. We will also be stressing the potential for agriculture to play a leading role in countering HIV/AIDS. There could be, perhaps, no greater use of biotechnology than if it could impact those with compromised immune systems.

Dr. Borlaug's and my goal is to build the World Food Prize International Symposium into the DAVOS of food and agriculture, a conference once a year that draws the top officials, scientists, business leaders, researchers from across America and around the world together for a dialog on the most crucial issues facing the world of food and agriculture.

Dr. Borlaug's presence each year at this event has drawn such policy officials and experts from all over the globe to participate. With strong support from Senator Harkin, the World Food Prize is undertaking the restoration of a magnificent 100 year old building which will be known as the Norman E. Borlaug Hall of Laureates. Not only will it be a stunning tribute to Dr. Borlaug, but it will also recognize the great agricultural innovations and humanitarian achievements of persons like Herbert Hoover, Henry Wallace, George Washington Carver and Jessie Field Shambaugh (the woman who founded 4-H). But most importantly it will be a building that will inspire those meeting in it to reach for the type of achievements that Dr. Borlaug made. It will be the place in which the great discussions about biotechnology can take place and which will draw leading proponents and experts to an annual summit in Dr. Borlaug's honor, and to witness the presentation of "The Nobel Prize for Food and Agriculture."

This process is already beginning. This year, for the third year in a row, the US Grains Council and the American and Iowa Corn Promotion Boards will bring one hundred foreign officials, with responsibility for biotechnology in their countries, to the World Food Prize celebration and symposium and to see biotechnology at work on U.S. farms.

The World Food Prize events have also received special legislative endorsement. Both Iowa and Minnesota claim Dr. Borlaug as a favorite son, and both have made October 16th a statewide day of recognition for the World Food Prize in his honor. Last year, the U.S. Senate also approved a resolution making October 16th, World Food Prize Day in America in honor of Dr. Borlaug.

Dr. Borlaug would probably resist the dichotomy that your committee has imposed on these hearings by dividing them into domestic and international. To him, the research and dialogue reaches across that divide. During the past 40 years, arguably the most prolific period in agricultural research in all history, there was a thread that ran from America's colleges and universities, to the World Bank and its network of CGIAR Centers, to large research foundations to ministries of agriculture. It is no accident that more than half of the foreign recipients of the World Food Prize either studied or taught at US Land Grant colleges. It is crucial that we strengthen that thread and maintain that research connection that Norman Borlaug and others spent so many decades putting in place.

Mr. Chairman, in 2006 we will celebrate the 20th anniversary of Dr. Borlaug's founding of the World Food Prize. There could no greater anniversary present for Dr. Borlaug than for us to work together to fulfill his dreams. Together, I believe we could gather several hundred of the leading figures in the world for a special dialogue on biotechnology with Dr. Borlaug. Perhaps you and Senator Harkin could bring the entire Senate Agricultural Committee. To that we would add 100 high school students and 100 teachers, who are part of our World Food Prize Youth Institute.

It would be, without doubt, "The most significant observance of World Food Day anywhere around the Globe."

And through this World Food Prize Symposium and our Laureate Award Ceremony, together we can help inspire these next break-through

achievements that will be so crucial to the future of American agriculture and reducing world hunger, poverty and malnutrition.

DOCUMENTS SUBMITTED FOR THE RECORD

JUNE 14, 2005

A H E A D
Alliance for Health Economic and Agriculture Development
6220 30th Street NW Washington DC 20015
Tel: 202 686-8898 Fax: 202 244-0698

April 20, 2005 SUBJECT: Tobacco

The Honorable Saxby Chambliss, Chairman
Senate Committee on Agriculture, Nutrition and Forestry
Room 328-A Russell SOB
Washington DC 20510

The Honorable Tom Harkin
Ranking Minority Member
Senate Committee on Agriculture, Nutrition and Forestry
Room 328-A Russell SOB
Washington DC 20510

Dear Chairman Chambliss and Senator Harkin;

Last year Congress took the important step in providing assistance to tobacco growers that will allow them to receive the equity that Congress provided them under the 1938 tobacco program. We first and foremost want to thank you for supporting the industry-funded buyout. In providing such assistance Congress also repealed many other important provisions of the 1938 tobacco program leaving virtually nothing in place. As was noted in a letter to one of our Steering Committee members from the House Agriculture Committee Chairman, 'enactment of FETRA effectively ends *all* aspects of the federal tobacco marketing quota and price support loan programs. The United States government will no longer play a role in the marketing or setting the supply of domestically grown tobacco'. While the buyout was urgently needed and obviously supported by the tobacco growers and many in the public health community, that action has left many tobacco producing communities in a continued state of uncertainty and instability and will have significant consequences (intended or otherwise) on the health, welfare, and safety of millions of Americans. No one disagrees that the 1938 tobacco program had outlived its usefulness but it makes no sense to 'throw the baby out with the bathwater'.

As you also probably know, an informal but strong coalition had been developed by tobacco growers, their communities, public health interests and some responsible tobacco manufacturers to work cooperatively on reforming this country's national tobacco policies. This coalition of interests and people that had worked for more than 10 years to

effect meaningful change in the way in which tobacco is produced, processed, manufactured, labeled, sold, and marketed was, in the end, virtually ignored for what many believe were political goals and objectives.

We cannot turn back the clock to the 108th Congress but we can make some important inroads into effecting fair and meaningful changes in the 109th Congress.

Visionary reforms surrounding the agricultural production of tobacco can make a significant impact on the health and welfare of many Americans and must be pursued. Congress must recognize that:

- Tobacco and tobacco products are responsible for significant public health problems. In fact the use of tobacco has long been the leading preventable cause of disease and death in the United States. In addition, during times of historic budget deficits the use of tobacco is costing this country billions of dollars in health care costs and lost productivity.

- New technological advancements in the production and curing of tobacco exist and must be maintained and expanded. This will not only benefit tobacco producers in the US and make them more competitive in the world markets but, if effectively implemented, also help reduce the risks caused by the use of tobacco products.

- With the removal of geographical limitations on where tobacco is grown we can expect to see more tobacco not only being grown elsewhere in the US but an increase of foreign tobacco coming into the US -- all unchecked and unmonitored. Cheap foreign cigarettes are rapidly gaining market share. With the elimination of all inspections of imported tobacco and cigarettes there are no controls over chemicals and pesticides that can be used on that tobacco. In addition there is evidence that some foreign tobacco is grown using child labor and under conditions that do little to protect the workers. These unfair practices hurt U.S. growers who play by the rules and further jeopardizes public health and the consumers' right to know where the tobacco originated and under what conditions it was produced.

- Ongoing technological innovations in tobacco research, production and manufacturing hold great promise for new forms and uses of tobacco, that not only reduce the use of toxins and pesticides in tobacco leaf and tobacco products but also in the development of medicines and industrial enzymes.

We therefore ask that the Senate Agriculture Committee convene a series of oversight hearings both in Washington and in the field in order to begin to address the future of tobacco in the 21st century and to begin to develop policy initiatives to meet the needs of tobacco producers, public health objectives, responsible manufactures, and our national security. Such oversight hearings should include:

- The critical need to ensure that **all** tobacco (domestic and foreign) is being properly and effectively monitored and tested to ensure quality, health, and safety of the leaf.

- The need for having tobacco and tobacco products labeled to provide consumers of tobacco with as much information about the product as is necessary to allow consumers to make a fully 'informed choice' about what products they use.

- The unintended effects of removing all production controls on the trafficking, and smuggling of tobacco and tobacco products in interstate and foreign commerce, including the impact on homeland security.

- Incentives that should be given to growers, and responsible manufacturers designed reduce the risks and relative risks of tobacco to health.

- The potential of technological advances (including GMO tobacco) in developing both lower risk products as well medicines and industrial enzymes.

The Alliance is not asking for or suggesting a 'handout' from Congress. But we are suggesting that Congress do its part in providing the leadership that is needed to reshape tobacco policy in this country. And that includes leadership from the Senate Agriculture Committee. What Congress has done (or failed to do) with respect to tobacco would be tantamount to removing all oversight, monitoring, health, and safety controls over all of the food supply- something that does not serve producers, public health, responsible manufacturers, or even homeland security.

We are also writing to several other Senate Committees, including the HELP Committee and the Committee on Homeland Security and Governmental Affairs, both of which have key roles to play in establishing more effective and integrated national policies for tobacco (letters attached).

We appreciate your long standing commitment to US agriculture and look forward to working with you and other members of the Senate Committee on Agriculture in ensuring that Congress does its part in establishing the parameters under which tobacco is produced, processed, manufactured, distributed, labeled and marketed. We will be contacting your offices in the near future to ask for a personal meeting with you to discuss these important issues.

Steering Committee

Rod Kuegel
Former President Burley Tobacco Growers Cooperative
Tobacco Farmer

Andrew Shepherd
Virginia Representative to Flue Cured Tobacco Stabilization Corporation
Tobacco Farmer

Jeff Nesbit
Former Chief of Staff to FDA Commissioner David Kessler
Former Communications Director to Vice President Dan Quayle

Keith Parrish
National Tobacco Growers Association
Tobacco Farmer

Johnny Shelley
President South Carolina Tobacco Growers Association
Tobacco Farmer

Rich Hamburg
Former Senior Policy Advisor
American Heart Association

Henry West
President Burley Tobacco Growers Cooperative
Tobacco Farmer

Ridge Schuyler
Former Legislative Director to Senator Charles 'Chuck' Robb (VA-Rtd)

Rebecca Reeve
Former Director, Southern Tobacco Communities Project
Public Health Advocate

Scott Ballin
Former VP and Legislation Counsel for the American Heart Association
Former Chairman, Coalition on Smoking OR Health (AHA, ALA, ACS)

Statement from the
Alliance for Health Economic and Agriculture Development

Submitted for the Record

To the Senate Committee on Agriculture, Nutrition, and Forestry

Concerning the Future of Biotechnology, Agriculture and Tobacco

June 21, 2005

The Alliance for Health Economic and Agriculture Development (AHEAD) respectfully submits the following statement and attachment to be included as part of the hearing record on biotechnology and agriculture held on Tuesday, June 14, 2005.

Earlier this year the Alliance wrote to Chairman Saxby Chambliss and Ranking Minority Member Tom Harkin, requesting that the Committee convene oversight hearings on the future of tobacco agriculture in the 21st century, including on how production relates to the manufacturing, public health, and the illegal trafficking and smuggling of tobacco and tobacco products (letter attached as part of this submitted statement). We noted that in its efforts to assist US growers with a tobacco buyout last year, (which the Alliance supported and appreciated), Congress may have not given adequate thought and consideration to the intended or unintended consequences that the termination of the 1938 tobacco program would have. In our letter, we outlined a number of important areas that we believed the Committee needed to address. One area that we noted was the importance of the development of new technologies (including biotechnologies) in the production of tobacco. Specifically we noted that:

> **New technological advancements in the production and curing of tobacco exist and must be maintained and expanded. This will not only benefit tobacco producers in the US and make them more competitive in the world markets but, if effectively implemented, also help reduce the risks caused by the use of tobacco products.**
>
> **On going technological innovations in tobacco research, production and manufacturing hold great promise for new forms and uses of tobacco, that not only reduce the use of toxins and pesticides in tobacco leaf and tobacco products but also in the development of medicines and industrial enzymes.**

As in many areas of agriculture, biotechnological advancements related to tobacco hold great promise to society on a number of fronts. Tobacco has often been referred to as the 'white rat' of the plant world. Extensive research using tobacco is now under way in many academic research institutions as well as private companies. Many believe that

genetically modified tobacco not only holds great promise for the development of new, more *traditional* tobacco products that may one day be shown to substantially lower the risks of using tobacco and produced with fewer pesticides, but also for the development of pharmaceutical products and industrial enzymes as well. As was noted in the preliminary report of the President's Commission, **Tobacco Communities at a Crossroad**, released in January of 2001;

> **Looking ahead, however, the United States could firmly establish itself as the world leader in this area with only relatively small additional investments of public and private funds. In addition, the existing structure and oversight of tobacco production in the US – including the production adjustment and price support program, the tobacco cooperatives, and USDA oversight – provide an ideal infrastructure for the safe and constructive production and regulation of bioengineered or transgenic tobacco.**
>
> **More broadly, producing tobacco for non-harmful uses may be an area where the public health community, tobacco farmers, the biotechnology industry, and governmental agencies such as USDA, FDA and the National Institutes of Health can work together to develop and administer a coordinated plan to protect and benefit both public health and tobacco producing communities.**

However, it is also important to acknowledge that there are some in the United States, and many in other countries, especially in Europe who are concerned and cautious about the development of any genetically modified products and the potential risk that the use of such products may have on society. It is therefore important that the proper oversight of the development, manufacture, and marketing of these products is maintained.

Several important findings and conclusions concerning genetically modified tobacco were presented as part of a symposium at the 53rd Tobacco Science Research Conference held in Montreal, Quebec Canada in 1999, entitled, Recent Advances in Tobacco Science – Genetics and the Future of Tobacco. These include that:

- Opportunities now exist to explore the possibilities using this technology to produce genetically modified tobacco with improved agronomic traits, enhanced quality traits, and alternative uses.

- The increased speed and the extreme breadth of change possible with biotechnology make this a particularly unsettling time. Now, as never before, there is a need for industry, academia, and consumer interests to cooperate in the identification and management of issues generated by this new technology. We must deal with new laws and regulations, new products and industry practices, and entirely new agricultural uses that will emerge as the potential of biotechnology is realized. Tobacco is no exception.

- The science of biotechnology has been one of the major achievements of the twentieth century and will significantly impact mankind's progress in the next century. Biotechnology has the potential to affect many aspects of life. But as with any great scientific advance that has the potential to make major contributions and changes to the world, anxiety and fear of this technology and its application may develop. The use of biotechnology has resulted in often heated and ongoing debates over the pros and cons of this technology. The debates have included the "person on the street", scientists, consumer activists, business officials, and regulators. A proliferation of information and misinformation has resulted in these debates (and include toxicological, environmental, regulatory, public acceptance, and business issues).

- Tobacco with enhanced quality traits has the potential to address issues held by manufacturers and consumers of tobacco products and may add value to the grower or seed producer in the form of premium pricing. Products with improved processing characteristics, novel flavor(s), and modified product chemistry would fall within this category. Specific traits could include higher yield of leaf per unit area of land (photosynthesis and shade avoidance, sugar metabolism and partitioning); flavor metabolism, reduced accumulations of metals, reduced alkaloids, reduced tobacco-specific nitrosamines; and enhanced processing properties.

- Since tobacco is relatively easy to grow and transform in the laboratory, it had been used as the model system in many biotechnology studies. This has resulted not only in the advancement of biotechnology but also has increased the knowledge base on tobacco. With this increase in knowledge, it is now possible to genetically modify tobacco to improve agronomic traits, to enhance quality traits, and for use as an important component of molecular farming. However, much remains to be learned (e.g. there is no complete map of the tobacco genome), and the opportunity exists for basic research in such areas as gene regulation and identification of structural genes.

- The consumer acceptance of genetically modified crops is likely to hinge, at least in part, on whether or not the benefits outweigh any perceived risks. It would therefore seem reasonable that tobacco that has been genetically engineered to address consumer issues is likely to be well received by the public.

- Tobacco, being one of the first plants to be genetically engineered, has played a vital role in the development of this technology. Comparatively little use has been made of the wealth of information available on genetically modified tobacco to make technological contribution to the quality of tobacco as a crop. This may be due in part, to the various issues and concerns that have been raised regarding the use of genetically modified organisms. Acceptance is likely to increase provided these safety issues are adequately addressed and as consumers become more knowledgeable about this technology.

- The opportunities available through the use of biotechnology are enormous. The full potential of its application for the agriculture community has not yet been realized. The design and development of plants with almost any characteristic(s) that can be described in biochemical and genetic terms are theoretically possible. Basic research and industrial application have merged to produce commercialized products. It may be time that the tobacco world seriously considers the advantages that could be realized with the use of this new and powerful technology.

Conclusion

Tobacco remains at a crossroads. Opportunities and challenges exist to reform this nation's tobacco policies --- reforms that will require leadership from Congress and several key Committees in Congress, including the Senate Committee on Agriculture, Nutrition and Forestry. How tobacco and tobacco products are produced, manufactured, distributed, sold, labeled and marketed in interstate and foreign commerce will require that governmental agencies work more closely together and that the public health community, growers, manufacturers, consumers, researchers, and others engage in a more active *transparent* discussion about opportunities for reducing harm caused by tobacco. Such collaborations have the potential of benefiting public health, assisting US tobacco farmers, and protecting the environment. The development and implementation of tobacco- related biotechnologies will be an important component and determinant in the future of tobacco.

At the Committee's recent hearing many of the witnesses indicated the need for a strong and effective regulatory system. As Jim Greenwood, President and CEO of BIO noted in his testimony, "We recognize that strong regulatory systems are essential to consumer confidence and we work closely with the USDA, the Food and Drug Administration, and the Environmental Protection Agency, all of who play important roles in providing science-based assessments of our products".

We again hope that the Senate Committee on Agriculture, Nutrition and Forestry will hold hearings to hear views and comments about the future needs and opportunities for tobacco production in this country-including those related to biotechnology.

QUESTIONS AND ANSWERS

JUNE 14, 2005

Hearing to review the Benefits and Future Developments in Agriculture and Food Biotechnology
June 14, 2005
SENATOR TOM HARKIN
Questions for the record

Question for FDA, Dr. Brackett

The accidental or inadvertent presence in the food supply of materials from biotech crop varieties unapproved for food can cause major disruptions in the marketplace, putting branded food companies and export markets for US farmers at risk. Given the nature of growing and handling crops, there is a real likelihood that small and unintended levels of unapproved biotech varieties will be detected at times in the food supply in the future.

In August of 2002, the White House Office of Science and Technology Policy published a Federal Register Notice directing EPA, FDA and USDA to address concerns associated with low levels of unapproved varieties, primarily from field tests of new crops.

In November of 2004, FDA published a proposed guidance, "Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use". This guidance partially addresses the possibility that material from a new plant variety intended for food use might inadvertently enter the food supply before its sponsor has fully consulted with FDA. This is a voluntary early food safety assessment process for some new biotech crops. It covers crops intended for food or feed, but does not cover biotech plant varieties developed for non-food uses of crops, such as plant-made pharmaceuticals. This proposed guidance, which is in addition to FDA's premarket consultation process, only partially addresses the issues of adventitious presence of unapproved new plant varieties in the food supply.

What additional steps has FDA taken to fulfill the 2002 White House directive?

Are there tolerance levels set for the adventitious presence of approved, or unapproved, biotech crops in non-biotech crops?

Should crops that produce pharmaceutical and industrial products have to meet the same food safety criteria as food crops, even though they will not be marketed as food, as a precaution in the event of adventitious presence of these crops in non-biotech crops?

As the variety and quantity of biotech crops increase, will FDA work with EPA to determine the risks of cross-pollination from unapproved biotech crops to non-biotech and to establish a tolerance or threshold for cross-pollination in these instances?

Senator Tom Harkin

Question for EPA, Dr. Gabriel

Pollen drift from biotech crops to conventional and organic crops is a concern for some consumers and producers. One issue is cross-pollination from approved biotech varieties to conventional and organic crops, while another is cross-pollination of conventional and organic crops by unapproved biotech crops during field trials.

In August of 2002, the White House Office of Science and Technology Policy published a Federal Register Notice directing EPA, FDA and USDA to address concerns associated with low levels of unapproved varieties, primarily from field tests of new crops.

Has EPA set standards for pollen drift from approved biotech crops to conventional and organic crops?

What are EPA's recommendations regarding pollen drift from unapproved biotech crops from field trials to conventional and organic crops? What are the regulations in place to minimize pollen drift?

As the variety and quantity of biotech crops increase, what is EPA doing to determine the risks of cross-pollination between unapproved biotech crops and conventional and organic crops?

In what manner does EPA work with USDA's APHIS to incorporate recommendations on minimizing pollen drift in field trials?

Senator Tom Harkin

Question for USDA, Dr. Lambert

The accidental or inadvertent presence in the food supply of materials from biotech crop varieties unapproved for food can cause major disruptions in the marketplace, putting branded food companies and export markets for US farmers at risk. Given the nature of growing and handling crops, there is a real likelihood that small and unintended levels of unapproved biotech varieties will be detected at times in the food supply in the future.

In August of 2002, the White House Office of Science and Technology Policy published a Federal Register Notice directing EPA, FDA and USDA to address concerns associated with low levels of unapproved varieties, primarily from field tests of new crops.

What steps has USDA taken to fulfill the 2002 White House Directive?

Are there tolerance levels set for the adventitious presence of approved, or unapproved, biotech crops in organic crops?

As the variety and quantity of biotech crops increase, will USDA work with EPA to determine the risks of cross-pollination from unapproved biotech crops to non-biotech during field trials and to establish a tolerance or threshold for cross-pollination in these instances?

Senator Tom Harkin

Question for USDA, Dr. Lambert and FDA, Dr. Brackett

Although biotech crops have been widely adopted by farmers, few genetically engineered animals are ready for regulatory approval and commercialization.

One food application, Aquabounty's fast-growing biotech salmon, is pending approval at the FDA. Most of research on biotech animals for use as food and biological "factories" for producing human pharmaceuticals purified out of milk is being conducted by academics, government researchers, and small start-up companies. TransOva, a small company working on biotech animals, is located in Iowa.

There is currently no formal government policy outlining how biotech animals will be regulated, so companies seeking to commercialize biotech animals (or find investment capital) have no clear pathway to the market. Statutory authorities at FDA, USDA and EPA could all be invoked to cover some aspects of biotech animals. However, the federal government has not publicly indicated how it will use those authorities, by themselves or in combination with any of their other existing authorities, to regulate genetically engineered animals.

The White House Office of Science and Technology Policy was coordinating an interagency review of this issue, but its efforts seem to have slowed down to a stop. In general, there has been a relatively clear, understandable process in place to evaluate the safety of new crops for human consumption and the environment. To my knowledge, there is no such process in place for new biotech animals.

Is there any formal policy for how the federal government intends to review genetically engineered animals? And if not, can you tell me how and when you will develop that policy?

Question for the Department of Agriculture

1. Our committee is very concerned regarding the ability of the federal government to safeguard the nation's food supply from vandals and terrorists. We understand that USDA has taken steps to prevent the contamination of the food supply with potentially harmful substances.

APHIS is responsible for the oversight of the development and field testing of experimental and non-food crops, as well as new (novel) traits for food and feed use, which have not completed regulatory reviews that deem them safe for human health and the environment.

We understand that location of these field trials is currently considered confidential business information. Is it possible that current litigation, under the Freedom of Information Act, which could potentially reveal location of these experimental sites to activists and terrorists, would threaten the safety of the food supply?

Secondly, could these groups use this type of information in a way that would cause economic harm to farmers and biotechnology developers?

Question for the Department of Agriculture

2. In the case of crops that are evaluated and found to be safe by USDA does the Department/Federal Government have the authority to ensure availability of these crops and products to consumers regardless of the actions by local or state government action?

What options are available for the USDA to ensure that local governments cannot require additional restrictions on products that have been authorized for testing or food or feed use by the federal government?

Question for the Department of Agriculture

3. Current authorities exist in the US Grains Standards Act and the Plant Protection Act to ensure that products that do not meet federal regulatory requirements can be prohibited from being placed on the market. Can you please provide information regarding how these authorities have been used to ensure the safety of the food and feed supply?

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