Congressional Hearing

Plant Genome Science: From the Lab to the Field to the Market, Part III, before the Subcommittee on Basic Research of the Committee on Science, House of Representatives, Washington, D.C.

Tuesday October 19, 1999

[Source: Congressional Hearing: "Plant Genome Science: From the Lab to the Field to the Market, Part I-III," by the Subcommittee on Basic Research of the Committee on Science, House of Representatives; August 3, October 5 and October 19, 1999. This format was published on November 21, 2016 by Jeff Kirkpatrick, Ban GMOs Now and includes testimony from James H. Maryanski who was the Biotechnology Coordinator of the FDA at that time. Following this official documentation is the testimony of Maryanski as it is posted on the FDA's website as well as a brief comment. There are differences between the officially recorded testimony and the text that appears on the FDA's website].

The Subcommittee met, pursuant to recess, at 2 p.m., in room 2318, Rayburn House Office Building, Hon. Nick Smith (Chairman of the Subcommittee) presiding.

Chairman **SMITH.** The Subcommittee on Basic Research will come to order for the purpose of a third in a series of hearings on plant genome science. And we have entitled this series of hearings From the Lab to the Field to the Market.

At our last hearing, we heard from distinguished scientists about some of the benefits that agricultural biotechnology promises, like better tasting, healthier foods, continued improvements in crop production and quality and delivery of needed vaccines and medicines, just to name a few.

At our first hearing, we heard from the NSF, the National Science Foundation, as well as the USDA and others, about the advancement of the gene technology, and its tremendous potential for consumers. Consumers already benefit from gene modification in developing pharmaceuticals in medicines. Insulin, for example, which had to be extracted at one time, extracted and purified from pigs, now is made by bacteria genetically modified to produce it.

In agricultural biotechnology, our consumers will see the benefits of lower costs, a cleaner environment, and enhanced food with improved nutrition and taste. We will only see these promising new products, however, if there is a market for them. And this market will only exist if people believe that these products are safe.

We are now faced, I think, with a situation of the unknown to many consumers being somewhat vulnerable to the suggestion that somehow these products are unsafe. This has been happening quit

aggressively in Europe. I think it was last week that 11 organizations, a lot of the environmental organizations, gathered in Blue Mountain Lake, New York, talking about what kind of marketing strategy might be utilized to express their potential fear of these products in the United States.

I think this committee, I think this country has an obligation to make sure that any food product or any clothing product that we produce and sell is going to be safe. That is part of the reason for this hearing today. The success of these groups in Europe has the potential of stopping the kind of scientific endeavor that can add tremendous benefits to humanity.

The recent practice of certain scientific journals of printing research articles or letters that either have failed the peer review process or have not been peer reviewed at all has also created the impression that the scientific community is divided and that a debate on the safety of agricultural biotechnology is raging. It is not.

So far, in testimony before this Subcommittee and in published reports, papers, and letters, the scientific community has expressed confidence in the safety of these products. There has been genetically-modified food produced for the last 400 or 500 years. Healthy, high-quality food has been a priority in the United States and we now have the safest food supply in the world.

Here in the U.S., we place the responsibility for ensuring that agricultural biotechnology does not result in the release or marketing of unsafe products on three agencies: Department of Agriculture; the EPA, Environmental Protection Agency; and the Food and Drug Administration. In addition, there are volumes of laws within the States that try to assure that those food products that are sold or consumed in those States are safe and nutritious.

Today, representatives of these three agencies, all of whom are scientists, I might add, are here to outline their approach to evaluating agricultural biotechnology products. The traditional method of gene modification has been to bring two plants together, transferring thousands of genes from one plant to another. Under a regulatory framework developed under Ronald Reagan in 1986, products created through biotechnology would have to comply to two criteria. One, they would continue to be regulated according to their characteristics and effect, not their method of production; and two, would be regulated under the Federal Plant Test Act, the Federal Insecticide, Fungicide and Rodenticide Act, and the Food and Drug Cosmetic Act.

In conclusion, let me say that the idea that agricultural products of new biotechnology should be regulated in a manner similar to the products of the traditional method has very broad scientific support. The National Research Council, for example, has concluded in a 1989 report that ‘‘no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods.’’ And we hope to hear your comments on that today.

Does this mean my 5 minutes is up, or you don’t time it? Oh, good.

The producers we have in place, the procedures that these Government organizations have in place, are rigorous and have been shown effective. But anti-biotech activists are taking advantage of consumers’ natural tendency to be wary of products which are new and about which they may know little. I think the Administration and the agencies represented here today could be doing a much better job informing the public. I also would put that challenge to producer groups and commodity groups. Information is the best tool to understanding, and understanding is the best key, I think, to assure safety.

The benefits of biotechnology are great, and they extend far beyond our Nation's farms and supermarkets. It is possible that those who stand to benefit most from biotechnology are those in the developing world's struggling to feed growing populations because they have the potential for the greatest suffering.

I would like to quote our 39th President in conclusion, and that's of course, President Jimmy Carter, and I quote: "If imports like these biotechnology crops are regulated unnecessarily, the real losers will be the developing nations. Instead of reaping the benefits of decades of discovery and research, people from Africa and Southeast Asia will remain prisoners of outdated technology. Their countries could suffer greatly for years to come. It's crucial that they reject the propaganda of alarmist groups before it is too late." End of quote. That was Jimmy Carter.

I'd now like to recognize the Ranking Minority Member on Basic Research Subcommittee, the gentlewoman from Texas, Ms. Johnson.

Ms. **JOHNSON.** Thank you very much, Mr. Chairman.

I am pleased to join the Chairman today in welcoming you, our witnesses, to this afternoon's hearing on plant biotechnology. In two previous hearings, the Subcommittee reviewed the status of plant genome science and the state of scientific understanding of the benefits and risks associated with that biotechnology.

Today, we will consider how applications of this technology are regulated in order to protect human health and to avoid adverse environmental impacts. We have seen from our past hearings that plant biotechnology has the promise to provide many benefits for agricultural producers and consumers. Whether these potential benefits are realized ultimately will rest on the foundation of public acceptance of the technology.

How this will ultimately unfold is an open question, as is evident from the adverse reaction in many European nations to genetically-modified plants. A well-understood and effective regulatory process is essential for ensuring safety and for building public trust in the development and use of genetically engineered plants.

It is not enough that the regulatory process is effective. It must also be seen to work well. This implies a high degree of transparency in the procedures employed and in the tests and analyses that constitute the basis for regulatory action.

Today we will review the roles of the Federal agencies charged with plant biotechnology regulation. I am interested in how the agencies carry out their responsibilities and hope to learn how the agencies coordinate their activities and what requirements are placed on the companies seeking approval of their biotechnology applications.

I would appreciate having the views of the witnesses on whether the testing procedures now carried out for determining the possible effects of genetically altered plants on human health and then environment are adequate to assess risk. Also, I am interested in any recommendations our panelists might have for research that would contribute to improving the review and decision-making process for the approval of new applications of genetic engineering.

Please comment on what can be done to improve our ability to identify the potential risks of plant biotechnology, to estimate the likelihood such risks may occur, and to determine what testing procedures and analyses will provide the information necessary to quantify and manage risk.

I appreciate the attendance of our witnesses today, and I look forward to this discussion. Thank you, Mr. Chairman.

Chairman **SMITH.** We have a very distinguished group of panelists today. At this time, I would like to take a few minutes to introduce them.

Dr. Sally McCammon serves as the Science Advisor for the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture, and Dr. McCammon is also head of the delegation of the Organization for Economic Cooperation and Development, the OECD working group, on harmonization of regulatory oversight in biotechnology. She is here today to tell us about USDA's regulatory procedures for plants created using biotechnology.

And Dr. Janet Andersen is the Director of the Bio-Pesticides and Pollution Prevention Division of the Office of Pesticide Programs at EPA. Dr. Anderson will be explaining her division's role in regulating plants developed using biotechnology to produce their own insect protection system, the so-called plant pesticides.

Dr. James Maryanski is the Biotechnology Coordinator at the Food and Drug Administration's Center for Food Safety and Applied Nutrition. He will be explaining FDA's regulatory procedures for bio-engineered food products.

And Mr. Mark Silbergeld is Co-Director of the Washington office of Consumers Union, the publisher of Consumer Report Magazine. And he will be giving us CU's point of view on the regulation of foods created using agricultural biotechnology.

And finally, Dr. Stephen Taylor is joining us from Lincoln, Nebraska, where he is professor and head of the Department of Food Science and Technology and Director of the Food Processing Center at the University of Nebraska. His research is focused in the area of food allergies. And Dr. Taylor, I understand you just returned late last night from a meeting in Australia. We very much appreciate your willingness to testify today, and thank you all very much for being here and sharing with us your time and expertise on this very important subject.

And it is the tradition of the Science Committee to have the witnesses stand and take an oath. So Dr. Taylor, out in Nebraska, if you would join us for standing and raising your right hand and taking this oath.

[Witnesses stand.]

Chairman **SMITH.** Do you swear to tell the whole truth and nothing but the truth?

[Witnesses respond in the affirmative.]

Chairman **SMITH.** Let the record show that the witnesses answered in the affirmative.

And Dr. McCammon, we will start with your presentation. And let me note that we are being simulcast today, and also your total written statement will be included in the record, without objection, hearing no objection. And so if you can summarize your testimony within the 5 minute limitation, it would help us in terms of time constraints for us to ask you questions that this Subcommittee might have.

Dr. McCammon.

TESTIMONY OF SALLY L. McCAMMON, SCIENCE ADVISOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE:

Dr. **MCCAMMON.** Thank you, Mr. Chairman, and Members of the Subcommittee on Basic Research. It is a pleasure and an honor to be here on this topic, which has been of interest to me and my agency for a long time.

My name is Dr. Sally McCammon, and I am the Science Advisor for the Animal and Plant Health Inspection Service. USDA is being impacted in a lot of its agencies across the board by biotechnology. However, the marketing and regulatory programs mission area, of which I am a part, has been affected greatly. There are three agencies in MRP. One is the Agricultural Marketing Service. And they have been affected by the classification of transgenic varieties of cotton, seed testing and identification technologies, and applications for the protection of new plant varieties under the Plant Variety Protection Act.

The Grain Inspection, Packers and Stockyards Administration, or GIPSA, is currently monitoring developments to assess the effect on the official U.S. standards for grain and the official grain inspection system. APHIS, my agency, the Animal and Plant Health Inspection Service, its mission is to protect plants and livestock from diseases and pests. We have been involved in biotechnology policy and regulation since the mid-1980s.

Under our statutory obligations, we regulate genetically-engineered plants, microorganisms, and veterinary biologics, to assure safe technology transfer from the laboratory through field testing and development. We take it to the commercialization step and then determine whether the applicant is free to grow it, subject to regulatory approvals from the other two agencies, EPA and FDA.

We regulate under three statutes. The first is the Plant Quarantine Act of 1912, and the Federal Plant Pest Act of 1957. We regulate plants and microorganisms to assure that there is no plant health risk to agriculture and the environment. Also, under the Virus Serum Toxin Act of 1913, we look at veterinary biologics, which include live and killed vaccines and diagnostic kits.

Once something comes in under our regulations, it's also, and an action is taken in the environment, we're also subject to the National Environmental Policy Act. And under that, we look at a variety of other environmental issues.

I'd like to leave you with five kind of points that we think kind of encapsulates what the purpose of the regulatory system is. First and foremost is safety. That's the primary purpose that we're in business for.

Second, that this safety must be science based, that our decisions must be based on science, for the root of the word science is knowledge. And we gain this science through a variety of means, through conferences, workshops, published literature, work with the National Academy, and we have highly trained, qualified scientists that do the reviews.

This science is continually evolving and incorporated into our approvals. As new science comes on board and as new products, we have to evaluate new products.

Third, the regulatory system is predictable. Predictable in that there are time frames for permission to field test and to receive a determination that you no longer need to be regulated under APHIS, if you submit an application for that. This allows industry or researchers to plan both for the business and for doing the field research itself.

Fourth, coordination is very important. We coordinate with the States through the States' departments of agriculture. We coordinate with other Federal agencies, the EPA, FDA, and others. And we coordinate internationally through the OECD and the standard setting bodies, like the International Plant Protection Convention and the Office of International Epizootics.

And finally, we do believe that transparency is a major purpose of regulations, that public input is requested to develop the regulations and in specific decision making instances. We also provide a lot of guidance on how we do make our decisions. For example, we had a customer service meeting this spring in which both industry and other, the States and interested public, came and gave us comments on our process.

We have a web site, both for USDA and for APHIS, in which information is available.

Finally, I would just like to say that the regulations are in place to assure safe technology transfer. Thank you very much.

Chairman **SMITH.** Dr. Andersen.

TESTIMONY OF JANET L. ANDERSEN, DIRECTOR, BIOPESTICIDES AND POLLUTION PREVENTION DIVISION, OFFICE OF PESTICIDE PROGRAMS, OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY:

Dr. **ANDERSEN.** Good afternoon, Mr. Chairman and Members of the Committee. I am pleased to appear before you today to discuss the Environmental Protection Agency's role in the assessment and regulation of agricultural biotechnology products.

As I have been so kindly introduced, I am the Director of the Biopesticides and Pollution Prevention Division of EPA. My division is responsible for the regulation of all biopesticides, including the plant

pesticides. And to date, we have approved 12 plant pesticide products and granted 16 tolerance exemptions for associated plant pesticides.

The scientific and regulatory staff in the Biopesticides and Pollution Prevention Division have the technical training and expertise to thoroughly and fairly review these products before allowing them onto the market.

I believe that biotechnology applied to agricultural pest control holds real promise to reduce reliance on chemical pesticides, thereby reducing exposure to workers, to our food supply, and to the environment of these products. On the other hand, there are potential risks from these products that must be evaluated. For example, the BT protein produced in corn is essentially produced throughout the growing season. While in the microbial spray products, the microorganism lives only for a few days when it's applied in the field.

In developing our approach, EPA followed the Coordinated Framework for regulation of biotechnology which states that EPA will regulate pesticide substances under the Federal Insecticide, Fungicide and Rodenticide Act, and under the Federal Food, Drug and Cosmetic Act. EPA's proposed plant pesticide rule makes it clear that we regulate pesticidal substances, not the whole plant, that we are regulating all products of biotechnology, all the products of biotechnology—but we are not regulating all products of biotechnology, but rather exempting several categories of products where there is little or no risk. And that we are proposing to regulate pesticidal substances that are new or that have new exposures to humans and the environment.

My testimony in the written record gives several examples of the exemptions that we have proposed at EPA and how these match most of the exemptions that have been called for by a number of academic scientists. Differences in plant pesticides compared to other pesticides calls for a unique set of data requirements fitting for these products. And I've provided you with a chart listing studies that EPA requires. I'm sorry it's not able to go up on the screen today, as we thought it could.

But you can see from that that EPA does a thorough evaluation on both the potential risks to human health and to the environment. We look at acute toxicity in the diet. We consider the risks of allergenicity. We look at the possibility of introduced genes spreading to other species and to nearby plants. We look at the potential for the pesticidal substance to come into contact with other insects and animals, particularly those insects that may have benefit to the local agricultural ecology, or those that might be endangered or threatened.

And in the case of BT crops, we look at the management plants that must be in place to ensure that we have little chance of insect pests developing resistance to the BT.

In all cases, the characterization of both the gene and the substance produced are important. Questions have been raised as to why EPA includes the genetic material in our definition of plant pesticides. The genetic material is essential to the pesticidal property. Not only does the genetic material code for the protein, but it also codes for where in the plant cell that protein will be produced. It influences the tissue inside the plant in which that protein will be produced. It may influence when in the plant's life the protein will be produced. And it may determine whether that protein has the ability or the genes are able to spread to other food crops or to wild plants.

We have cases where apparently the pesticidal effect comes from both the protein and actually the direct effects of the genes, also. And I can assure the Committee that including the genetic material in the

definition has never caused a problem in making a regulatory decision. The information we require on the genetic material is part of EPA's thorough assessment that is made before these products are allowed on the market.

At the agency, we're currently addressing two major issues. The first is pesticide resistance. EPA is working on insect resistance management for BT crops. Because we believe, as others do, that it is important to maintain the viability of both BT crops and BT microbial products.

EPA requires refugias where non-BT crops are planted to maintain susceptibility to pest populations that will breed insects, if they survive the exposure to BT. The second issue is potential risks from BT corn to monarch butterflies. EPA considered the potential adverse effect from BT corn on butterflies and moths before we registered these products. Our scientists knew that BT protein is toxic to many insect pests - and in this particular order, the lepidoptera, or the butterflies and moths.

However, EPA concluded that it is highly unlikely that endangered, threatened or even highly revered species, such as the monarchs, will be significantly exposed to BT corn. If the results from field experiments being conducted this summer identify risks from exposure to BT corn, EPA will work with the scientists, the companies, and the corn growers to mitigate those risks.

I've presented an overview of EPA's activities to regulate pesticide products through biotechnology. Our biotechnology program is based on five important principles: sound science, transparency and decision making, consistency 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. It's credible, it's defensible, and it will serve to protect the environment and the public health as we address the challenges associated with biotechnology.

Thank you, Mr. Chairman. I'll be glad to answer any questions that you or the Committee have.

Chairman **SMITH.** Dr. Andersen, thank you.

What's happening right now is we have one vote on the Floor and possibly a procedural vote that will follow it. There are 9 minutes left in this vote, so this Committee is in recess until the call of the Chair or if Mr. Gutknecht returns, then the Subcommittee can be reconvened under his call.

With that, we are recessed for this vote.

[Recess]

Chairman **SMITH.** The Subcommittee will reconvene.

I believe, Dr. Maryanski, we will proceed with you.

TESTIMONY OF JAMES H. MARYANSKI, BIOTECHNOLOGY COORDINATOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION:

Dr. **MARYANSKI.** Thank you, Mr. Chairman and Members of the Committee, for giving the Food and Drug Administration the opportunity to testify today on its scientific approach for assessing food safety and the regulatory procedures that industry follows to market foods derived from new plant varieties, including bioengineered varieties.

As you have said, I'm Dr. James Maryanski; I'm the Biotechnology Coordinator in FDA's Center for Food Safety and Applied Nutrition. FDA has authority under the Federal Food, Drug and Cosmetic Act to ensure the safety of all domestic and imported foods for man or other animals in the United States market, except for meat, poultry, and egg products, which are regulated by the Department of Agriculture.

FDA relies on its authority under the Act to ensure the safety of foods and food ingredients. The Act places a legal duty on developers to ensure that foods they market to consumers are safe and comply with all requirements of the law.

In 1992, FDA published its regulatory road map policy. The policy explains FDA's views about regulating human foods and animal feeds produced from new plant varieties, including crops developed by the newest methods of molecular and cellular biology, and those developed using traditional techniques. The policy focuses on the traits and characteristics of the foods and applies to all new varieties of food crops, no matter which techniques are used to produce them.

This science-based policy was developed through careful consideration by FDA scientists of new developments in biotechnology and of the types of commercial foods and food ingredients likely to be developed by recombinant DNA techniques. We also considered scientific principles for assessing safety that had been developed and agreed upon by several prestigious scientific groups, including the National Academy of Sciences, the Food and Agriculture Organization, the World Health Organization, and others.

In our review of new bioengineered foods, we found they shared certain common characteristics. Recombinant DNA techniques are being used to introduce copies of one or a limited number of well-characterized genes into a desired food crop. In most cases, these genes produce proteins or proteins that modify fatty acids or carbohydrates in the plant. In other words, common food substances that the body handles in the same manner as the thousands of different proteins, fats, and carbohydrates that make up our diet today.

Taking these and other considerations into account, we identified several broad safety issues that should be evaluated. The need to assure that new substances, that is, newly introduced proteins, fats, and carbohydrates, are safe for consumption. The need to ensure that any changes in the food, such as the level of natural toxins and nutrients, stay within normal safe levels. The need to analyze the potential for introduced proteins to cause allergic reactions.

We incorporated these and other issues into a comprehensive guidance to industry that is central to our policy. This guidance provides a standard of care to help plant developers ensure that the products they develop meet the safety standards of the Act. It also provides guidance on those situations in which developers should specifically consult with FDA on issues such as labeling, the design of appropriate test protocols and whether a food additive petition would be required.

Under FDA's policy, bioengineered foods and food ingredients must adhere to the same standards of safety under the Act that apply to their conventional counterparts. This means that these products must be as safe as the traditional foods in the market. FDA has broad authority to initiate regulatory action if a product fails to meet the safety standards of the Act.

The policy also makes clear that labeling will be required if the composition of the bioengineered differs significantly from what is expected for that food, or if the bioengineered food contains a new allergen. FDA considers it to be prudent practice for developers to discuss products of new technology with the agency prior to marketing. FDA established an informal consultation process by which firms can inform the agency that they have completed a food or feed safety assessment. A consultation is complete when all safety and regulatory issues are resolved.

This process has worked well. Mr. Chairman, we are confident that our approach is appropriate. It allows us to ensure the safety of new food products and also to allow the use of safe new biotechnology techniques that give manufacturers the ability to produce better products, to provide consumers additional choices.

I would be happy to answer any questions the Committee may have. Thank you, Mr. Chairman.

Chairman **SMITH.** Thank you, Dr. Maryanski.

Mr. Silbergeld.

TESTIMONY OF MARK SILBERGELD, CO-DIRECTOR, WASHINGTON OFFICE, CONSUMERS UNION OF U.S., INC.:

Mr. **SILBERGELD.** Thank you, Mr. Chairman. And the Consumers Union thanks you very much for the opportunity to testify.

As best I can, I will summarize my statement in the time allotted. But first I would like to come to something that both you and Representative Johnson mentioned in your opening statements. And that is, consumer confidence and communication. I have a 14 year old son. And every weekend he comes to me and he says, Dad, can I go out with my friends. And I always say, where are you going. And he always tells me.

And the minute he says, Dad, you don't want to know, that's when I will want to know. And that's part of what's going on with the products of this new food technology. Consumer organizations, and I don't know of anyone we work with that hasn't, are calling for labeling. And the industry and the Government are saying, you don't want to know.

Mr. Chairman, consumers have not in this country raised the kind of ruckus that consumers have raised in Europe, but partly, it's because they don't know just what it is that they are eating. In a recent poll, fully 50 percent of them stated that they didn't know that there were genetically modified foods on the market, and probably in their pantries.

But when they were told that that was the case, 81 percent of them said they wanted labeling so they could make their own decisions. They don't want industry to make the decision for them, they don't want Government to make the decision for them. They want to know, and they want to make a decision for themselves.

And I think that the fear that that decision will be sometimes negative is somewhat overblown. But at any rate, it misplaces the proper working of the marketplace. Consumers need to have the information that they want in order to make the decisions on the basis that they want to make them.

I will state right up front, Mr. Chairman, Consumers Union—and I have sent a copy of the September issue of Consumer Reports, and its article, The Seeds of Change—knows of no genetically modified food now on the marketplace that presents any known risk to consumers. This is not a scare issue, we don't want to treat this as a scare issue. We believe that it is a right to know issue. We think that it is also, however, a question of whether the regulatory system is sufficiently fail-safe.

And our concern is not that the FDA has not identified the right risk concerns. They have. Our concern is that the process is so voluntary. There is a decision tree. The companies that engage in producing food with this technology need to tell the FDA that they will follow the decision tree. But they don't have to report to the FDA as to what they have done in deciding when to test, when not. There's no register, there are no record-keeping requirements. When they choose to consult with the FDA, my understanding is that they can do so on the basis of test summaries rather than hard test data.

In effect, it's a good faith process. It's not, again, the right risk factors haven't been identified. But that so much of it does depend on good faith. And in fact, these foods have a potential for presenting safety issues that are somewhat different than traditional foods.

It may be true that many applications of this technology are no different than what Luther Burbank did in his time. But Mr. Chairman, you can't cross a fish with a tomato. Fish and tomatoes don't mate. And when, as has already happened, a fish gene is put into a tomato, there should be far different requirements for testing than there is when you are crossing a squash with a tomato or a tomato with a tomato.

And so our concern is that things can in fact be done and have been done that can't be done with traditional cross-hybridization. And we think that the process should not be as voluntary for that reason, as it is today.

My testimony outlines a number of reasons, other than food safety, why consumers may want to choose traditional foods, at least in many cases. And we believe that consumers should have the right to do that.

I see that my time is up, and so I will leave the Committee with the thought that perhaps the greatest harm to consumer acceptance of the products of this technology may be a consumer suspicion that there are, and possibly unfounded consumer suspicion, that the reluctance to label is hiding something that they want to know about. We believe that labeling would go a long way toward making consumers more confident that if they choose this product, that there is nothing being hidden, and that if they choose not to choose it, they have the information with which to do so.

Thank you very much, Mr. Chairman. I would be happy to answer any questions.

Chairman **SMITH.** Mr. Silbergeld, thank you very much.

Now we move to Nebraska for Dr. Taylor. But you know, this is the most advanced technological hearing room in the United States Congress. Yet our problem today on our back screen is a light bulb burned out. So the Committee can see the monitors at each side or on the table, and I think the rest of the witnesses have a monitor before them.

So with that, Dr. Taylor, please proceed.

TESTIMONY OF STEPHEN L. TAYLOR, PROFESSOR AND HEAD, DEPARTMENT OF FOOD SCIENCE AND TECHNOLOGY, UNIVERSITY OF NEBRASKA:

Dr. **TAYLOR.** Thank you, Mr. Chairman. I assume you can hear me.

Thank you for the opportunity to participate from Lincoln, Nebraska. As you already know, I just returned from a WHO-FAO-WTO international trade conference on international trade beyond the year 2000 in Australia. So with a little time lag on my conscience here, I'll do the best I can to participate.

I was asked today to comment on the concept of substantial equivalence as part of the safety evaluation process for foods derived through genetic modification. My own major research involves food allergies and intolerances, and I can be prepared to comment upon that issue if the Committee desires, as well.

As part of the safety assessment process for GMO foods, allergenicity concerns are a key component. And so I've been involved in this process since the early 1990s in that aspect. I have also been involved in discussions of the broader safety evaluations of GMO foods. In 1996, I was privileged to serve as Chairman of the FAO-WHO expert consultation on biotechnology and food safety in Rome.

The concept of substantial equivalence has been a key part of the safety evaluation of GMOs since 1991, before any GMO foods were ready for the market. Recently, the concept of substantial equivalence was questioned in an article by Millstone and colleagues in Nature. I believe that the concept of substantial equivalence should remain as a key part of the safety evaluation of GMO foods, and that the alternative approach suggested by Millstone, et al. is ill-advised.

The concept of substantial equivalence has been recognized as an integral component of the safety assessment of GMO foods by many scientific and regulatory experts from the U.S. and other countries. The concept has been endorsed by the Organization for Economic Cooperation and Development, where it was first elaborated in 1991 by the World Health Organization, the Food and Agriculture Organization of the United Nations, and others.

Government authorities in the U.S., Canada, Japan, United Kingdom, and European Union have adopted substantial equivalence as part of the basis for the safety assessment of GMO foods. With the global endorsement of the concept of substantial equivalence, I think I am on rather sound turf to advise that this concept should be retained.

The WHO-FAO consultation that I chaired in 1996 concluded, this approach provides equal or increased assurance of the safety of foods derived from genetically-modified organisms, as compared to foods or food components derived by conventional methods.

Millstone and his colleagues assert that the concept of substantial equivalence provides an excuse for not requiring biochemical or toxicological tests. This is simply not true. In fact, foods derived from

GMOs are subjected to rather extensive testing. GMO foods are substantially equivalent to their conventional counterparts except for the introduced traits. Typically the introduced trait is conferred by the insertion of one or a few genes that result in the product of one or a few novel proteins in the transgenic food.

As a result, safety assessment is focused on a detailed molecular characterization of the introduced DNA, an analysis of the effect of the introduced DNA on its composition—including, as Dr. Maryanski indicated, key nutrients and anti-nutrients in the GMO food, as compared to its conventional counterpart—and a thorough assessment of the novel proteins, including toxicological, immunological, and allergenicity testing.

In addition, the biological aspects of the GMO crop are also always assessed. Substantial safety and testing information is submitted to the USDA, EPA, and FDA as part of the commercialization process in the United States. To claim, as many of the individuals have been doing recently, that safety testing is not conducted on GMO foods is a serious misrepresentation of the facts, in my opinion.

Millstone et al. advocate the use of extensive animal toxicology testing procedures on the whole GMO food. In my view, this simply would not work very well. It would be wasteful of laboratory animal resources and unlikely to detect any harmful substances, even if they were present. The novel proteins and the products in GMO foods are often present at very low levels and their effects, if any, would not be detected by feeding the whole GMO food to live animals.

Single, whole foods are often insufficient for adequate nutrition of a laboratory animal. That is a key reason why humans should eat a varied diet, by the way. Thus, effects might be seen in lab animal testing that would be attributable to such nutritional inadequacies of the diet. For this reason, toxicologists rarely attempt to assess the safety of whole foods, preferring instead to focus on specific components.

The concept of substantial equivalence serves as the focus of the safety assessment of GMO foods and focuses attention on the novel components contained therein. This approach is much more likely to yield helpful results, and much less likely to produce confounding and uninterpretable results.

In summary, I would recommend continued application of the concept of substantial equivalence and continuation of the focus of the safety assessment of GMO foods on the novel components. And I would add that in my view, the requirements of the Federal agencies that you have already heard from today are sufficient to assure the safety of GMO foods.

Thank you very much.

Chairman **SMITH.** Dr. Taylor, thank you very much.

Dr. Taylor, I circulated a draft bill, a piece of legislation before the other witnesses that says the Food and Drug Administration shall require that any fruit, vegetable, nut, or grain product that has not been genetically modified bear a label identifying such product as a product which has not been genetically modified.

And Dr. Maryanski, maybe this is a rhetorical question, but in your testimony you said the United States uses the term genetic modification to refer to all forms of breeding, both modern, such as genetic engineering, as well as conventional. And if that were the case, as the interpretation for genetically

modified in this law, what fruits or vegetables or nuts or grain products would be so labeled as not being genetically modified?

Dr. **MARYANSKI.** Well, that would be hard to define. From a scientific perspective, virtually all foods are modified in some way genetically. And so therefore, it would be difficult to identify a food that had not been subjected to some kind of genetic modification.

Chairman **SMITH.** So, Mr. Silbergeld, if you were going to label, what kind of law would you construct for labeling?

Mr. **SILBERGELD.** I would not want to prescribe particular language at this point. At this point, our concern is to seek wider agreement than there is at this moment on the principle that genetically-modified foods using modern technology as a modification process should be labeled as such.

And I also want to be up front in saying, I don't think that the label should have the effect of a skull and crossbones. As we said in our September Consumer Reports article, we know of no genetically-modified food, in the narrow sense, on the market today that presents any known novel or additional risk. But we believe that consumers do want to know if modern technology has been used.

Chairman **SMITH.** It was suggested by witnesses in two previous hearings that we held that they thought that the cross-breeding—where you took thousands of genes and put them into a plant, most of, you know, not having the slightest idea what the effect of those other genes might have—was much more potentially dangerous than knowing the characteristics and probably the results of particular genes that might be injected through modern biotechnology.

So it seems to me that that's also got to be a consideration, as far as being a consumer advocate. If scientists say that that's more dangerous, should they also not be labeled.

Mr. **SILBERGELD.** Well, I believe that the problem is not with the category of foods as a whole, it's with particular products, and on a product by product basis. Crossing one tomato with another tomato may not present any new risk whatever. Putting a gene from a non-food substance——

Chairman **SMITH.** Or of course, there's many—history in the last 100 years has many cases, potatoes that were cross-bred that resulted in toxicity.

Mr. **SILBERGELD.** Right, and the same thing happened, but it didn't get to market because the guidelines were——

Chairman **SMITH.** No, no, this was cross-breeding.

Mr. **SILBERGELD.** Yes.

Chairman **SMITH.** This wasn't the new modern gene breeding.

Mr. **SILBERGELD.** Yes, and they were toxically high in alkaloids, and that can happen.

Chairman **SMITH.** A comment from Dr. Andersen, and Dr. McCammon, if you'd like to, and Dr. Taylor, and then I'll give up my time and we'll move on. Did you have a comment in this whole area of labeling, distinguishing how do we do a better job, either with information or informing the public what the potential dangers are?

Dr. **TAYLOR.** Mr. Chairman.

Chairman **SMITH.** Yes, Dr. Taylor.

Dr. **TAYLOR.** I guess, speaking from Nebraska, I'd like to take the position of the farmers into consideration to some extent. I think you have to be very careful in labeling products as free of GMOs or genetically-engineered components or whatever you might want to call them. Because we haven't settled on what we mean by GMO-free and what tests we are going to use to establish that.

That would be one of the big future arguments that we will have with our European friends because there are many different tests with many different levels of sensitivity. And those farmers in the Midwest who are currently trying to segregate their grain and oil seed crops may find that they will fail some of these tests, despite their best efforts, because they contain extraordinarily low levels of GMO components.

So that would be my comment, relative to any regulatory approach to attempt to label these materials, is that you also have to come to grips with a decision about what constitutes GMO-free.

Chairman **SMITH.** The comments in the Agriculture Committee hearing this morning was that, it's very possible that there could not be an absolute guarantee, for example, that even if next year a farmer were to buy the conventional soybeans that there could be a guarantee that there weren't genetically modified soybeans in that batch of seed anyway. So I mean, we've gone a great deal down the line.

Unless Dr. Andersen, Dr. McCammon, you have a comment, we'll move on. Representative Johnson.

Ms. **JOHNSON.** Thank you, Mr. Chairman.

Dr. Maryanski, Mr. Silbergeld in his testimony takes the position that FDA has a responsibility to mandate the labeling of genetically engineered plant products, and has the necessary authority to do so. If the FDA does have that authority, why does it not require that that happens?

Dr. **MARYANSKI.** Thank you, Representative Johnson. It would be helpful if I would clarify just what the labeling policy is for the Food and Drug Administration. There is required labeling for any foods that are substantially different from their counterparts. For example, if they differ in nutritional value or if the consumer would have to know how to cook the food or store the food differently than they had previously. Or if there were a consequence to the consumer, such as there were new allergens in the food. That kind of information would have to be clearly disclosed to the consumer. The question is really whether the method by which the product has been developed should also be required in the label. We have not viewed the various methods of agricultural breeding as information that would be material to the product, which is the legal language that we have to use to determine whether information would be required.

The Food, Drug and Cosmetic Act does not have a specific provision that would require FDA to, or rather would require manufacturers, to disclose information on the basis that consumers demand that information. There's no specific authority for us to do that. Labeling is done based on the information that is material to representations made or implied about the product, implied about the product and to consequences for use.

So it is our judgment at this time that we're not aware of any information that the use of genetic engineering, per se, creates a class of products that differ in safety or quality or any other uniform way from products that are produced by other methods of plant breeding. So we don't feel that under the current statute that we can compel manufacturers to include that information.

Ms. **JOHNSON.** What is the difference between genetically engineered and organic in terms of labeling?

Dr. **MARYANSKI.** Of course, the Congress has given the Department of Agriculture the authority to establish standards for organic labeling which, as you know, that process is ongoing. Once those standards are in place, then the Food and Drug Administration will enforce those standards.

So the standards for the two are under different statutory authority.

Ms. **JOHNSON.** Thank you, Mr. Chairman.

Chairman **SMITH.** Just a follow-up. Are the organic farmers using genetically-modified seeds? I suspect they have to be, if you include traditional cross-breeding in your definition of organically modified. Can an organic farmer use a Roundup Ready soybean and still, under the current regulations, have it listed as organic? Mr. Silbergeld, do you have the answer?

Mr. **SILBERGELD.** The USDA is still in the process of developing those regulations. When it published in the Federal Register a proposal that would allow modern genetic modification technology products to be labeled as an organic product or to be included in products that were labeled as organic. In

the process, the USDA received hundreds of thousands of comments objecting to that. So, while it's true that they use traditional hybrids, the organizations that represent, I assume, most——

Chairman **SMITH.** So that hasn't been finalized, really, in USDA regs?

Mr. **SILBERGELD.** No, it has not been finalized. And the Secretary has indicated, if I recall correctly, USDA can correct me if I'm wrong, that the next draft will not include that provision, based on the comments in the public record.

Chairman **SMITH.** But your recommendation is that somehow, the cross-breeding, even though the science community says that has greater potential danger, your inclination is to leave that aside as far as the seeds that an organic farmer may use?

Mr. **SILBERGELD.** Yes.

Chairman **SMITH.** Because there aren't any [unmodified] seeds that exist, of course.

Dr. Maryanski, is it the Lenape potato? The Lenape potato was withdrawn from the U.S. market sometime in the 1960s, when it was discovered to contain high levels of those potato toxins. In the mid-1980s, there was also a variety of celery that was abandoned because of high levels of toxins, causing, I think, skin rashes. If these crops were developed today, using the modern biotechnology, would they ever make it to market?

Dr. **MARYANSKI.** In the case of the Lenape potato, of course, since that incident, potato breeders have routinely monitored for that glycoalkaloid in potatoes, and that's also been true of engineered varieties. But in the case of most conventional varieties of crops, there are relatively few analytical studies that are conducted during development. This is in contrast to what is done with engineered varieties, where there are far more tests being done for nutrients, toxins, vitamins, and minerals and so forth, as a way of providing that additional assurance that the important components of the plant are at the levels that are expected.

Chairman **SMITH.** So do I hear you say that they would be much less likely to even get to the market in the first place if they were produced through modern biotechnology and resulted in these kinds of toxins? Is that what I hear you say?

Dr. **MARYANSKI.** Well, I think that the testing that's being done is likely to cover more substances, and so therefore would be more likely to catch a problem, yes.

Chairman **SMITH.** Dr. McCammon or Dr. Andersen or Dr. Taylor, any further comments in this area?

Dr. **MCCAMMON.** I would just like to add to what Dr. Maryanski said, that the monitored biotechnology allows us to evaluate these plants much more rigorously than has been done previously. And we are able to look at the effects, because this analysis is done and you get information on the toxicants, you can also take that information and extrapolate whether there might be an effect on the environment from an increase or decrease.

Of course, we're not—anything that we approve, these toxicants fall within a range that's normally acceptable. Thank you.

Chairman **SMITH.** I have a question for the representatives of the three regulating agencies. What would each of you tell the American people to reassure them that the plants and foods produced through biotechnology today are safe for the environment and human consumption, and would you or if you would, how would you counter the possible misconceptions about the process? And then, Dr. Taylor, I'll follow up with whether or not you have any thoughts on that.

So how, are you comfortable reassuring the American people; should we have additional safeguards? Please give me your comments on how you would assure this Committee and the American people that what we're doing now as far as oversight is adequate.

Dr. **MCCAMMON.** I think one thing, the American people are not aware of the proactive nature that the Federal system has taken in this arena, and that we put regulations, we evaluated the technology from the mid-1980s, have had regulations in place, and the products evaluated since 1986. That's 13 years. That's longer than any other country in the world.

In that time, we developed an expertise across agencies and in our agencies that are very seasoned in looking at the issues of taking on new scientific issues and incorporating them. We were the ones who developed the approaches to evaluating these products in the first place.

I would say that we look at a variety of issues from crop biology, taxonomy, genotype, we look at field testing, we look at commercialization issues. We take everything from the laboratory, and this is when a variety is being developed, it will be field tested for 5 or 6 years, and this is after information is developed in the laboratory. And we are monitoring this as we go along. And in certain cases, as in some of the BT plants, we're monitoring them after they're commercialized.

Chairman **SMITH.** Dr. Andersen.

Dr. **ANDERSEN.** I would actually commend this Committee and the Agriculture Committee that we met with on the Senate side a couple of weeks ago for your efforts to get more information out. I think that that is one of the most important aspects that can happen.

What actually are the Federal agencies doing in their regulatory approaches, and then having that information as widely available as possible. And we appreciate the fact that your Committee actually puts this information on the internet. And our own agency is putting testimony, scientific reports, risk assessments, etc., on a regular basis, now, to the internet where anyone can actually see that information, not just in the United States, but of course, worldwide. I think that communication effort is real important.

Chairman **SMITH.** See what information?

Dr. **ANDERSEN.** The information that we presented today about how we regulate these products, but also the information in our actual risk assessment that we put on, of what our decisions are about the information that comes in, what we reviewed, and how we made our regulatory decisions.

Chairman **SMITH.** Dr. Maryanski.

Dr. **MARYANSKI.** Yes, thank you. Yes, we're very confident in the process that we have. That is a process for which we had a very transparent process, particularly back in the early 1990s, when there was more attention on this issue at that time, and we were looking at the first product that had been presented to us. And that process that we follow today evolved from those discussions among many scientists. So we're very confident about the science and the approach that we're taking to oversight of these products. There have been 44 products that companies have completed, food safety and nutritional assessments and discussions with FDA to date. The experience that we've had to date has shown that these products really do not raise substantial food safety questions. Obviously, we always have to be cognizant that a new product may come along that will require further scientific scrutiny than we have seen to date. But we are certainly ready for those events, also.

Thank you.

Chairman **SMITH.** Dr. Taylor, did you have a comment?

Dr. **TAYLOR.** I would simply agree that the safety process involved in the various Federal agencies is adequate and sufficient. Certainly it's stood the test of time over the past 13 years that I think it's even capable of dealing with products that will evolve in the future that may bring further issues to light.

Chairman **SMITH.** Representative Woolsey.

Ms. **WOOLSEY.** Thank you, Mr. Chairman.

I'm sorry I didn't get to hear everything. But I represent people who live north of the Golden Gate Bridge in California, the Sixth Congressional District. And I have to tell you, they are hoping that we will

follow up as a body and this Congress will do something to follow up on these good hearings you've had, Mr. Chairman.

And they want us, all of us, to err on the side of caution. And I would say that probably to a person, they support labeling. And we could use my district as a barometer, because if we can make the people in my district happy with what we do with biotechnology and with what we do along these lines, I'm sure that the rest of the world will come along. So you have to know where I'm coming from when I talk to you.

I really was delighted that Mr. Silbergeld supports labeling. And I'd like to ask you, all of you, what else besides labeling can we do to add to consumer confidence, even if its perception, I'm telling you, for us to sit here and know that it's only, it's not true and everything's okay, nobody's going to take their internet to the grocery store when they're shopping. They're going to want to know when they get to that store, people are too busy, they want to know what's safe, even if it's only safe in their own mind. They will want to know what's been done to the food that they're feeding their children.

So what else can we do?

Mr. **SILBERGELD.** Representative Woolsey, I would say that, I am hard put to think of anything that would be nearly as important as labeling. Because people want to know, and they want to make their own decisions, as you yourself indicated. I think that if the FDA, and it apparently has sent a notice to the Federal Register about some hearings to be held, will be open to a public critique of the process to see whether anything else needs to be done. And my own testimony indicates some things that we believe will improve the certainty, that nothing adverse will slip through the net. And update, if the record justifies it, its process, including, as I have indicated, some mandatory record-keeping, perhaps some identification of categories of the product that require more special attention than others, the guidelines do have some.

But we are concerned about, especially about whether non-food genes would be put into a food product, whether food genes from something that's substantially allergenic would be put into another. Separate those out for far less voluntary and far more mandatory procedures than the run of the mill product, where you're crossing one variety of tomato with another, or crossing one food that's not allergenic with another food that's not allergenic, in the substantial public health sense, I mean, that nobody anywhere has ever had a reaction, but is not identified as a food with high degree of allergenicity.

And have a special track for foods in which the transfer itself may create a greater concern than the run of the mill high-tech product. That would convince a lot of people that this is not just a way of saying, the Government's got a process and therefore you don't need to worry about it, and say, the Government process really is focused on the problems you might have. And we have a much higher degree of caution there than we do for the ordinary run of the mill new high-tech product. But that would help to convince the public that the appropriate steps are being taken.

Ms. **WOOLSEY.** Dr. Maryanski.

Dr. **MARYANSKI.** Thank you. We certainly feel that there are some ways that we can better communicate with the public. And I think that we're at the time when there are some increasing questions about technology and about our oversight and procedures relative to this technology. Back in the early 1990s, we did go through a process where there were many questions coming to us. Those seem to have been answered about 1994, after we made the decision on the first product.

And our sense has been that the American public has been comfortable with this technology and that we have not heard a number of responses coming for the past several years. Certainly there has been an increase in the number of questions we have been receiving. We are interested in ways to understand better the basis of those questions. For example, when we speak of labeling, what is really the basis of the consumer's concern about labeling? It may very well be that their concern is about the safety of these products, and that we may need to give some attention to the science that underpins the assessment. Because if the consumers are concerned about safety, then we want to make sure that we do have the soundest science, which we believe we do, but make sure that we do have that, and that that is being communicated to the public.

As Mr. Silbergeld said, we are planning to hold some public meetings across the country for the purpose of providing the public an opportunity to hear about our policy and about our approach, and also to share with the public what our experience has been for the last 5 years, because we actually now have quite a bit of experience in looking at the products of this technology. But also to hear whether there are other things that we could be doing, whether there's any new science that we should be taking into account, or other ways that we can modify our policy that would give the public more confidence in the policy.

Ms. **WOOLSEY.** Well, I'd like to suggest that one of those hearings be in my district. I think that would be, we need a cross-section of folks. And you want to talk about well-educated, caring, informed, involved, and agriculturally based community.

Chairman **SMITH.** We'd like a hearing in the district of every member of this Subcommittee.

Ms. **WOOLSEY.** I've wanted one in mine, Mr. Chairman.

Dr. **MARYANSKI.** I hope across the bay in Oakland is close enough?

Ms. **WOOLSEY.** No, it's a different group. But that's all right, my folks will be over there.

Chairman **SMITH.** The gentleman from Minnesota, Mr. Gutknecht.

Mr. **GUTKNECHT.** Thank you, Mr. Chairman, and thanks once again for this hearing. I think this is an extremely important issue.

Coincidentally, this afternoon, or at lunch, the Congressional Study Group, of which I am a member, had lunch with Hans Ulrich Klose, who is a member of the German Bundestadt, and is also the chair of their foreign relations committee. One of the issues that came up, believe it or not, was this issue. And we talked about how Europeans in general, and Germans in particular—and I don't want to misquote him—but he basically said they are not going to accept genetically-modified organisms in terms of their foodstocks coming into Europe and Germany. And I tend to think he was very candid and very sincere about that.

That raises great concerns for those of us who represent agricultural districts. Because I would guess in my district, and this would only be a guess, at least 25 percent of the corn and beans now are genetically modified organisms, GMO. And we have to at some point I think, we're going to have to figure out what we're going to do. Because before I got into this business, I was a salesman. One of the rules we always had is, the customer's always right. And if the customer says they won't buy it, then we've got to rethink.

And I want to move to another one of my maybe least favorite or most favorite subjects, and that is, one of the largest seed companies in the world is owned by a large conglomerate that also owns a baby food company. And it is incredibly disturbing to me that at the same time one arm of this company is in effect spending billions of dollars developing new seed varieties and using the latest biotechnology methods to produce that seed, on the other hand, their baby food company is saying that they won't buy GMO type products from our farmers.

Would anybody care to respond to that? I guess what it is, it comes back to something, I believe it was Jefferson said originally, that ''words are plentiful, but deeds are precious.'' And in that action, I think they spoke volumes about what they think about GMO. Any of you want to respond to that? Dr. Taylor.

Dr. **TAYLOR.** Well, I don't know if I can defend those actions, either. I have been incredulous about the same exact issue with that particular company. I suppose you'd have to take it up with the chairman of the board of that particular corporation to ask him why two different divisions within his corporation can come to such differing positions. I have no idea how that developed.

Mr. **GUTKNECHT.** Well, Dr. Taylor, I might just tell you, for your benefit, that I have suggested that he in fact be invited to testify before this Committee. And we also have the power of subpoena if he decided that he didn't want to come and tell us exactly why he did that. But whether or not we'll get to that point, we don't know.

Anybody else?

[No response.]

Mr. **GUTKNECHT.** One final question, then, or maybe comment, one of the other concerns I have, and we continue to have this debate about the monarch butterfly. And I was happy to hear—I didn't catch all of your comments, Dr. Andersen—but I would like to read for you a quote that appeared, I believe, in the Des Moines Register or at least an Associated Press article. Dr. Geoffrey Glassberg, president of the North American Butterfly Association, was quoted in the press saying, the danger of BT corn to the

monarch butterfly was overstated. He said, ''I think there are a lot more dire threats than that to the monarchs. In the Midwest, mowing roadsides and using herbicides is probably much more devastating, actually.''

Would you agree with that basic statement?

Dr. **ANDERSEN.** There are a lot of issues for the monarch butterfly that have been quite disturbing for that population as a revered insect in the United States, and actually probably around the world. There have been habitat destructions. One of the things that always made this insect especially was its ability to eat milkweed, and carry the toxins with it that kept it protected from predators. There have now been some predators that have developed an ability to eat the monarch butterfly anyway.

So it's had weather problems, it's had a variety of things that have really hurt it. Certainly mowing roadsides, if it's taking away the milkweed, is taking away a food supply for those young insects.

I think the real issue that is before me, is I must look at what the impact is from this particular aspect of BT corn pollen. Is it going to be a serious additional threat to the monarchs? And I have to put it in, do try and put it into overall context. But I also have an obligation to look at it in the specific. That's what we're intending to do.

What I did mention is that there is an extensive bit of field work going on this summer looking at those exposure questions. And there will be a major workshop in November and probably another one in December that will make these available to the public, and we will be looking at that information, deciding if there are appropriate actions we should take or not.

Mr. **GUTKNECHT.** Mr. Chairman, if I could just finally, last thought, I hope that all of you, and again we thank you for joining us in this hearing, the next round of the WTO talks are going to be extremely important to our farmers. This issue is going to be front and center as we try to work out agreements. Because you know, the truth of the matter is, we cannot eat all that we can grow here in the United States. We need export markets. And if a decision is made that we're going to move forward with GMO, and I think we have to, then we're going to have to figure out a way to negotiate.

So I hope at least the first two panelists are going to be actively involved with the Administration in developing a strategy, so that we can come out of this next round of talks with at least the opportunity to have export markets around the world, whether or not we're going to produce these new biotechnology plants and organisms.

But thank you very much.

Chairman **SMITH.** The gentleman from North Carolina, Mr. Etheridge.

Mr. **ETHERIDGE.** Thank you, Mr. Chairman.

Let me thank you also for holding this hearing.

I'm going to ask a couple of questions, and I apologize for being late, and I hope they haven't already been done. If they have, then raise a hand and we'll move to the next one.

I believe very strongly in what we're doing in the biotech area. I've been involved in it for a number of years, long before I got here. But my first question, Dr. Andersen, is to you, if you would cover it for me, if it hasn't already been covered. A lot of my folks contact me and I'll ask you to share with me, why on the one hand EPA is using assumptions, and in their case they feel they are default assumptions, in a lot of cases, worst case scenarios, to eliminate crop protection agents under FQPA, and on the other, we're seeking to make it harder for farmers to use genetically-altered crops that don't require those tools to grow crops.

And secondly, if we're going to do that, then what tools can farmers use to really remain competitive in one of the toughest environments we find our agriculture community in today?

Dr. **ANDERSEN.** I think you're asking what the agency is doing to help bring a variety of new tools to farmers that may replace those compounds that might be lost under FQPA. And if that's the question, I would say that my division is devoted entirely to bringing new biological pesticides to the market. And some of those can indeed help them. We have registered a number of these BT crops, and actually a number of replacements also that will help for insecticides that are virus protectants - because insects carry viruses to plants.

We also have a program at EPA that is looking at conventional chemical pesticides, and for ones that are less risky, or reduced risk, as we call them, they have an expected review and an excellent track record of having those products in that pipeline go through much more rapidly than they would if it was a traditional chemical pesticide.

And in that program, we have actually just recently added a provision that we will include for those expedited reviews, those products that would be alternatives to organophosphates, as they are being looked at under FQPA. So we're trying very hard to bring alternatives to those products. In fact, the agency registered 17 new active ingredients this last year that we've just completed our fiscal year.

Mr. **ETHERIDGE.** Let me move to another question before my time runs out for you, Dr. McCammon. It gets back to the question my friend from Minnesota I think just raised, when he talked with the, at lunch with the fellow from Germany. Last time I checked, most of the big companies that are now selling the seeds to our farmers through biotechnology or gene alterations are headquartered in Europe. They are multi-international corporations.

And it's always been troubling to me that they're willing to take the dollars from our farmers and sell the seed, and then they're in Europe and they don't want to talk to the leadership in Europe to buy the products that our farmers grow, and the resources they take from us. Now, it seems to me that we've got a problem. And we've got a chance to deal with it.

And I guess, Dr. McCammon, what I want to ask you is this, not that you can deal with it, but I think we can deal with it when we get in the next round of negotiations, to what extent are U.S. farmers being hurt—and I think they are—and disadvantaged, by the resistance of the European Union, and I feel very

strongly about this, because I think they are doing it. And maybe this is, I happen to believe it's more on protectionism than it happens to be on the resistance on the basis of sound science.

But would you care to make a comment on that? Certainly on the sound science side, if you don't want to get into protectionism, I really think that's what it's all about. And how do we go about dispelling this notion, if we're going to help our farmers and assure them that it is safe?

Dr. **MCCAMMON.** Well, my expertise is actually in the regulation and oversight of review of the products. However, that being said, part of our, a lot of the products that we're reviewing at this point in time are of companies that have located subsidiaries in this country. So they are, as you well know, in Research Triangle Park——

Mr. **ETHERIDGE.** I've talked to them about that.

Dr. **MCCAMMON.** They have set up businesses here, which actually has been, I think, to our advantage.

Mr. **ETHERIDGE.** Sure.

Dr. **MCCAMMON.** Okay. On the other hand, all the regulatory agencies work very hard in the international venues, the standard setting bodies at OECD, to develop approaches, work with our counterparts in the regulatory agencies, in the OECD member countries. And that includes not only the EU countries, but Japan, Australia, Canada, New Zealand, Korea, and in a variety of other countries, so that we can come to some common consensus on how to review these products based on sound science.

I think the regulatory agencies feel that science is the only thing that we can come to common agreement upon. All the countries have different laws and statutes, and those will never be the same. But the bottom line is that we would like to have the approach and the scientific review be harmonized.

Mr. **ETHERIDGE.** Mr. Chairman, if I have any more time left, would anyone else like to comment on that, whether it's based on protectionism or on sound science, the resistance?

Dr. Taylor. Dr. Taylor.

Dr. **TAYLOR.** Mr. Etheridge, I appreciate the opportunity to comment briefly. I really don't know what all the motivations might be on the European side. I do think that one of the key issues is effective communications with consumers. I think one of the things that happened in Europe was that there was a lot of concern developed before any effective communications were attempted.

And I had the opportunity to attend a consumer conference on biotechnology in Europe in late May. And I can tell you that many of the consumers in Europe are genuinely frightened of this technology, in my view needlessly. But nonetheless, they are indeed frightened of the technology and reacting as you might expect them to react in such a situation.

I'd also like to point out that this problem has the—it may affect adversely some of the smallest producers and processors in this country in an adverse way. And I hate to see that happen. We've already had an experience in Nebraska where a small microwave popcorn manufacturer with fewer than 25 employees, working in one of our rural communities, had a shipment of microwave popcorn rejected in Germany because it contained undeclared GMOs.

The only sin that this processor had was that he grew his popcorn across the road from a farmer that had GMO popcorn, or GMO corn, growing in his field. And a very small amount of pollen drifted across the road on one of our windy Nebraska days, and there was sufficient GMO pollen in his popcorn to cause them the ability to detect it. And so his shipment was rejected.

And I think that is an economic issue for that particular processor and one that I think we are going to see more of in the future. And I hate to see that kind of development occur over this issue, when there are no safety implications in my view, especially with these low levels of detection in some of the systems being used in Europe.

Mr. **SILBERGELD.** Congressman, there are two issues with the EU. One of course is variety approval, and the other is labeling. And the EU has a labeling directive which it has not implemented, because they haven't solved the threshold question.

I'll go back to what Mr. Gutknecht said, and that is, the customer's always right. If a customer won't take it, I mean, nobody told people they had to buy an Edsel. If people view this as an Edsel, you can do two things. You can try and convince them it's not, or you can put it out there and tell them what it is and see whether they want to buy it.

I think American producers are not looking for a signal that they tells them, go ahead and put all your acreage in genetically-modified crops, I think they are looking for a signal as to what they should grow according to what market they want to sell. And if there is a market for traditional varieties in Europe, we can produce that, too. I don't think this should be a policy where we're telling everybody they have to take genetically-modified, they have to eat, consumers have to accept genetically-modified product, in order that we can plant all of our acreage in it.

What we need is a clear signal. We're not going to get a clear signal if we challenge their right to label. Now, one might argue about whether the label is disparaging or not, and that's a fair question, it should not be disparaging. But they want the right to choose, and so long as we say, you don't need to worry about it, just take what we give you, you're not going to get cooperation.

If we recognize their rights to choice, based not only on the sound science questions about safety, but upon social preference as well, then I think we'll get a lot more cooperation, at least from consumers in the EU. Now, whether the Government is protecting EU producers in some way, they have a long history of that, too. And it would be foolish of me or anybody else not to recognize that.

And the approval process certainly warrants scrutiny. I have every indication that the Administration does not want to be before a WTO dispute settlement understanding panel on the labeling issue. They are willing to go to dispute over whether the approval process is being used unfairly. And I would urge you to bifurcate and understand the difference between those issues, so that consumers know what they're getting, but that all governments are making decisions about safety based upon safety considerations.

Mr. **ETHERIDGE.** Thank you.

Chairman **SMITH.** The gentleman's 10 minutes has expired.

[Laughter.]

Dr. Silbergeld, and we're going to finish in the next couple 3 minutes, but would you also suggest labeling of pharmaceutical products, vaccines, etc., that have been genetically developed?

Mr. **SILBERGELD.** I don't know what the practice has been on this, I haven't looked at those.

Chairman **SMITH.** Prescription drugs, medicines, insulin.

Mr. **SILBERGELD.** I don't know what the requirement is now. It may already be the requirement.

Chairman **SMITH.** If they're genetically modified?

Mr. **SILBERGELD.** No.

Chairman **SMITH.** That is not a requirement.

Mr. **SILBERGELD.** But those really are a different category. If you talk about prescription drugs, you have an intermediary there who is an expert, you have a physician.

Chairman **SMITH.** It's these intermediaries right here that I regard.

Mr. **SILBERGELD.** But these intermediaries don't have consumers as their patients.

Chairman **SMITH.** Dr. Maryanski, Mr. Silbergeld suggested that you go by summaries and not by the full data on the pre-market investigations by some of these companies. Could you explain that? Is that right? Do you just go by a summary of that particular producer saying, this is safe and good, or do you get the data, or if it's not enough, do you request more? It seems like a valid concern. Please explain it to us.

Dr. **MARYANSKI.** Yes, thank you, Mr. Chairman, for the opportunity to answer that. Because I think it is one of the things that's most difficult to understand about the process that we're using here. This is not a process like we approve food additives where there is an administrative process and the company submits a petition and there is a comprehensive scientific review and then a decision and then a regulation.

This is a much different process. Foods are not required under law to be approved by FDA. Nevertheless, we do believe that it is important when there's a new technology for us to know the kids of changes that are being made in the food supply. And that is the basis for the consultation procedures that we strongly recommend to companies and which they are following.

These procedures arose from our deliberations in developing the 1992 policy and our review of the Flavr Savr ™ tomato, which was the first product that was brought to FDA by a company in 1989. And the company at that time asked us to conduct a full review of that product, which we did do, working with the company, our scientists with theirs, over a period of over three years, in which we reviewed all of the data. We helped them design the studies that they would carry out and we reviewed all of the data.

And that was a very resource intensive process, and one that we felt was very useful at that point, because that was an example of the first product. It helped us in developing our policy. And when we discussed that product with the food advisory committee our food advisory committee—which is a committee of experts from outside of FDA that include academic, industry, and consumer representatives—those committee members suggested to us, including some of the consumer representatives, that that product really didn't raise substantial food safety issues, and that we should probably think about having a more abbreviated process, if there were to be similar types of products.

And we did agree with that, from a scientific perspective. And so we have established these informal procedures by which companies can consult with us prior to marketing. Part of that process is for the companies to consult with us on specific scientific issues, for example, if there is a protein that must be assessed for allergenicity, or if there is going to be some nutritional change in the food, we would want the company to specifically talk to us about those kinds of issues.

But we are not asking the companies to provide all of the data that they develop to the agency. This is a process where we do ask them, when they feel they are ready to meet their legal duty in marketing this product, to provide us a summary of their work in safety and nutritional assessment for both foods and feeds. That information gives us the opportunity to ask the question, is there anything about this product that would cause us to remove it from the market if it went to the grocery store. Are there any safety issues or regulatory issues that have not been resolved. That is the kind of process that we have been following since the Flavr Savr™ tomato on these 44 products that I mentioned to you.

Chairman **SMITH.** And for the record, has there ever been a new genetically-modified food product that's come to market without going through the FDA process?

Dr. **MARYANSKI.** We are not aware of any products, sir.

Chairman **SMITH.** I'd ask the other witnesses, maybe in 30 seconds, to give any summary comments that they'd like to give. Dr. Andersen.

Dr. **ANDERSEN.** Just in regard to that, when it is a pesticidal substance that comes to us, it does get a thorough evaluation, much more like the original process. There is a requirement for testing on rodent species. There are, we've been looking only at proteins. So we do a thorough evaluation, both on the human health side as well as on the ecological effects sides, for all the products.

Chairman **SMITH.** Dr. McCammon.

Dr. **MCCAMMON.** We look at environmental effects as well as potential effects on agronomic properties and agriculture in general. And I'd like to, I had brought some overheads, but since our visual system wasn't working, I'd like to enter three of them into the record, if I may.

Chairman **SMITH.** Without objection, they'll be entered into the record.

Dr. **MCCAMMON.** It just goes over the kinds of issues and things that we look at and evaluate.

Chairman **SMITH.** And while I'm thinking of it, I would request permission to enter into the record my letter to the Wall Street Journal on this subject, without objection.

Dr. Taylor, did you have a final comment? Or Mr. Silbergeld, did you have a final comment?

Mr. **SILBERGELD.** Yes, and I just want to comment on Dr. Maryanski's question. Dr. Maryanski said they are unaware of any instance with respect to the question you just asked. I would be a lot happier if they said no. I believe consumer confidence in the system would be much higher if these, at least the filing requirements and related record-keeping and record retention requirements, were formal instead of informal.

Chairman **SMITH.** Yes. My impression is it's sort of the way scientists sometimes talk that they are never aware of it, because in their evolvement over the years, things that they thought were true end up

not being true sometimes. I was so surprised when I when from high school chemistry to college chemistry.

Dr. Taylor.

Dr. **TAYLOR.** I really have no further comments. I think I have stated my support for the current safety evaluation process, and have heard nothing today that has changed my opinion.

Chairman **SMITH.** Representative Johnson.

Ms. **JOHNSON.** Just one quick question. We talked about the European Union and their attitude toward genetically-modified foods. Do we have protections in this country for imported foods?

Dr. **MARYANSKI.** Imported foods would be handled, whether they are genetically engineered or otherwise, like all foods that come into this country, they are subject to the requirements of the Food, Drug and Cosmetic Act. If there's a health problem with a food, then FDA has authority to remove it from the market.

But we would not necessarily know that a food was engineered. Someone would likely tell us, however, you know, the customer who is going to buy it and place it on the market is most likely going to want to know that that product is not going to be questioned by FDA.

Ms. **JOHNSON.** Conversely, why are we questioned so much by the European Union, do you think?

Dr. **MARYANSKI.** I think that one of the biggest differences between the U.S. and Europe is the openness of our system. When we began to formulate policy in the U.S. in 1984 between that time and when we made the decision that the Flavr Savr™ tomato could go to market in 1994, which was a 10-year period, the Food and Drug Administration engaged in 10 or 11 opportunities for public comment, or public meetings around these issues, often in conjunction with our sister agencies.

And so it was a very open process. In fact, the company, Celgene, when they came to us and asked us to review their product, they said, we're making all of this information available to you and to the public. So we were able to put all the information on display, there was no confidential business information at that time. And I think the openness that we have in our Government system is a very big factor in the differences.

Ms. **JOHNSON.** Does it appear that this might be more of a trade barrier than a realistic concern from the European Union?

Dr. **MARYANSKI.** Well, ma'am, my own opinion is that I think it's much more complicated than that. I think that there are many factors that are at play.

Ms. **JOHNSON.** Thank you.

Chairman **SMITH.** Mr. Etheridge, are we all set?

Mr. **ETHERIDGE.** Yes.

Chairman **SMITH.** We would like permission to send you some of the questions that haven't been asked, and if that's acceptable. The record of this Subcommittee will be held open 5 days for any additional comments by members of the Subcommittee. And again, to all the witnesses, thank you very much for giving us your time and thoughts on what I think is a very important item that we must solve in terms of consumer confidence if we're to move ahead with the kind of scientific research that can be so beneficial, not only to the health but also to our environment.

And as a farmer, I would just also like to point out that it's a well-acknowledged fact that our food supply in the United States is of the—is the safest and of the highest quality of any place in the world. So with that, I adjourn this hearing.

[Whereupon, at 4:06 p.m., the Subcommittee was adjourned, to reconvene at the call of the Chair]

This document was published on November 21, 2016 by Jeff Kirkpatrick, Ban GMOs Now. Minor changes were made to adjust for spelling and grammatical errors from the original and references to page breaks were removed.

The source that was used was: Congressional Hearing: "Plant Genome Science: From the Lab to the Field to the Market, Part I-III," by the Subcommittee on Basic Research of the Committee on Science, House of Representatives; August 3, October 5 and October 19, 1999

http://commdocs.house.gov/committees/science/hsy215140.000/hsy215140_1.HTM

This document is also available HERE. This is an electronic volume of three days of hearings that took place on August 3, October 5 and October 19, 1999. Although it can be viewed online, in order to obtain a copy, a person must pay for it. It is very strange that a document that should belong to all Americans is "owned" by a third party and that it must be purchased in order to obtain an original copy. It is also strange because other hearings at that time are still in the public domain. From that same website, Maryanski's testimony begins HERE.

This motivation for researching the original text of the hearing was because the "official" testimony of James H. Maryanski as posted on the Food and Drug Administration's website did not include the question and answer section; it was only a statement. James Maryanski was the Biotechnology Coordinator of the FDA in 1999. The FDA's website also did not provide the name of the hearing, so locating the original title of the hearing as well as the documentation itself involved a bit of research. This type of absence of readily available information is consistent across all branches of the US government where GMOs are involved. It may or may not be the case in other circumstances, but it is certainly the case with genetically modified foods and crops, etc. One example is the absence of videos of Congressional hearings from recent years: although we have access to excerpts posted by various news sources, the original videos are no longer available for public viewing. They have been removed from YouTube and from government websites. This is quite disturbing.

There are also several concerns about Maryanski's testimony, particularly with claims that the FDA is confident that GMOs are safe:

> "In conclusion, Mr. Chairman, FDA takes seriously its mandate to protect consumers in the United States and to ensure that the United States' food supply continues to be one of the safest in the world. FDA's process for evaluating bioengineered foods is one in which the public can have confidence that food biotechnology products must meet the law's safety standards. FDA's 1992 policy statement and our guidance documents make clear that premarket clearance is required if there is scientific uncertainty about the safety of food derived from bioengineered plants. The policy also makes clear that labeling will be required if the composition of the genetically modified food differs significantly from what is expected for that food, or if the genetically modified food contains potential allergens.
>
> "Mr. Chairman, we are confident that our approach is appropriate. It allows us to ensure the safety of new food products and also allow the use of safe, new biotechnology techniques that give manufacturers the ability to produce better products and provide consumers additional choices."

It has been well-established since this 1999 testimony that Maryanski's assertions are inaccurate, at best. As the result of a Freedom of Information Act request (FOIA) the public became aware of several memos and other papers. This was revealed due to a 2000 lawsuit (*Alliance for Bio-Integrity v. Shalala, et al.*, 116 F. Supp.2d 166 (2000)) where a team of attorneys, scientists, and religious leaders sued the FDA over various aspects of the legal basis regarding GMOs (including FDA's refusal to mandate labels on genetically modified foods). Those documents demonstrated that the FDA's own scientists disagreed with the assertion that there is "certainty about the safety" of GMOs; in fact, just the opposite view was expressed by the FDA's own scientists.*

> *For complete details, see: Steven Druker, *Altered Genes, Twisted Truth - How the Venture to Genetically Engineer Our Food Has Subverted Science, Corrupted Government, and Systematically Deceived the Public*, Clear River Press, (2015); distributed by Chelsea Green Publishing; also see: Marie-Monique Robin in *The*

> *World According to Monsanto - Pollution, Corruption, and the Control of the World's Food Supply*, The New Press, New York, (2010). For a brief summary, see: "Why The FDA's Policy on Genetically Engineered Foods is Unscientific, Irresponsible, and Illegal," by Steven M. Druker, Alliance for Bio-Integrity; 2015 (5 pages)

In other words, according to documents that were produced later, Maryanski's testimony - at best - misrepresents the truth. To bluntly state it another way: he lied. Additionally, the entire basis for the FDA's approach to regulating GMOs was ***not based on science***, but rather, on politics – this is directly from Maryanski himself. In her book (*The World According to Monsanto - Pollution, Corruption, and the Control of the World's Food Supply*), Marie-Monique Robin documented an interview with Maryanski; the following is an edited excerpt from that interview:

> **Maryanski**: "Basically, the government had taken a decision that it would not create new laws."
>
> **Marie-Monique Robin**: "But this decision that GMOs should not be submitted to a specific regulatory regime wasn't based on scientific data, it was a political decision?"
>
> **Maryanski**: "Yes, it was a political decision. It was a very broad decision that didn't apply to just foods. It applied to all products of biotechnology," he said hesitatingly.

This an excerpt from her book is on page 146 (Marie-Monique Robin in *The World According to Monsanto - Pollution, Corruption, and the Control of the World's Food Supply*, The New Press, New York, (2010)). Additionally the book was made into a movie where he stated this on camera. An excerpted sound file from that movie scene is available HERE.

In Maryanski's 1999 testimony he clearly asserts that this is a "science-based policy" when it was clearly a politically motivated policy. For an extensive report on this specific topic, see: "Politically Corrected Science - The Early Negotiation of U.S. Agricultural Biotechnology Policy," by Mary Ellen Jones, a Doctoral Dissertation in Science and Technology Studies at Virginia Polytechnic Institute; November 1999 (404 pages).

According to many critics, scientists, and layman alike, this politically motivated policy is the very antithesis of science-based. It is considered fraudulent for Maryanski to suggest otherwise.

It is worth noting that Maryanski's "official" testimony as posted on the FDA's website differs "substantially" from the actual recorded testimony. Although the version on the FDA's website may possibly be sourced from a written testimony submitted as supplemental material, the FDA gives no indication that this is the case; if it is, the written document is much different than the verbal testimony. It has clearly been "cleaned up" and is not an accurate reflection of the actual words that were spoken by Maryanski in his verbal testimony on October 19, 1999.

Maryanski's "official" testimony, as copied and pasted verbatim (on November 21, 2016) from the FDA's website is as follows:

Genetically Engineered Foods

Statement of

James H. Maryanski, PhD
Biotechnology Coordinator
Center for Food Safety and Applied Nutrition
Food and Drug Administration

before

the Subcommittee on Basic Research
House Committee on Science

October 19, 1999

INTRODUCTION

Mr. Chairman and members of the Committee, thank you for giving the Food and Drug Administration (FDA or the Agency) the opportunity to testify today on its regulatory program for foods derived from new plant varieties, including genetically engineered varieties. I am Dr. James Maryanski, Biotechnology Coordinator, in FDA's Center for Food Safety and Applied Nutrition (CFSAN).

FDA believes it is very important for the public to understand how government is overseeing the new foods being introduced into the marketplace and to have confidence in that process. To that end the Agency appreciates this opportunity to describe its processes and procedures to the Committee and to the public, and to clarify what bioengineered food products are and how FDA regulates them.

For almost two decades FDA has been studying genetic modification techniques for drug-biologic development, as well as the development of new foods, and the Agency has carefully developed policies to accommodate the changing and evolving world of biotechnology. The evidence shows that we are meeting our goal of ensuring that these new products meet the same safety standards as traditional foods.

Mr. Chairman, I will describe our legal authority and the regulatory procedures that industry follows to market a bioengineered food product. Before addressing those topics specifically, I would like to provide some background on food biotechnology.

FOOD BIOTECHNOLOGY

First, let me explain what we mean when we refer to food biotechnology or genetically engineered foods. 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 are genetically altered peaches), and tangelos (which are a genetic hybrid of a tangerine and grapefruit) are all examples of such breeding and selection. Food products produced through modern methods of biotechnology such as recombinant DNA techniques and cell fusion are emerging from research and development into the marketplace. It is these products that many people refer to as "genetically engineered foods." The European Commission refers to these foods as Genetically Modified Organisms. The United States uses the term genetic modification to refer to all forms of breeding, both modern, i.e. genetic engineering, and conventional.

The new gene splicing techniques are being used to achieve many of the same goals and improvements that plant breeders have sought through conventional methods. Today's techniques are different from their predecessors in two significant ways. First, they can be used with greater precision and allow for more complete characterization and, therefore, greater predictability about the qualities of the new variety. These techniques give scientists the ability to isolate genes and to introduce new traits into foods without simultaneously introducing many other undesirable traits, as may occur with traditional breeding. This is an important improvement over traditional breeding.

Second, today's techniques give breeders the power to cross biological boundaries that could not be crossed by traditional breeding. For example, they enable the transfer of traits from bacteria or animals into plants.

In conducting its safety evaluations of genetically engineered foods, FDA considers not only the final product but also the techniques used to create it. Although study of the final product ultimately holds the answer to whether or not a product is safe to eat, knowing the techniques used to create the product helps in understanding what questions to ask in reviewing the product's safety. That is the way FDA regulates both traditional food products and products derived through biotechnology.

LEGAL AUTHORITY

Turning now to FDA's legal authority over genetically engineered foods, FDA has authority under the Federal Food, Drug, and Cosmetic (FD&C or the Act) Act to ensure the safety of all domestic and imported foods for man or other animals in the United States market, except meat, poultry and egg products which are regulated by the United States Department of Agriculture (USDA). Pesticides are regulated primarily by the Environmental Protection Agency (EPA), which reviews safety and sets tolerances (or establishes exemptions from tolerance) for pesticides. FDA monitors foods to enforce the tolerances set by EPA for pesticides. Bioengineered foods and food ingredients (including food additives) must adhere to the same standards of safety under the Act that apply to their conventional counterparts. This means that these products must be as safe as the traditional foods in the market. FDA has broad authority to initiate regulatory action if a product fails to meet the safety standards of the Act.

FDA relies primarily on two sections of the Act to ensure the safety of foods and food ingredients:

(1) The adulteration provisions of section 402(a)(1). Under this post-market 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 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 (section 409). Under this section, substances that are intentionally added to food are food additives, 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).

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 exempt from the requirement for premarket review, for example, there is a long history of safe use in food. Generally, whole foods, such as fruits, vegetables, and grains, are not subject to premarket approval because they have been used for food for lengthy periods of time.

Under FDA policy on foods derived from new plant varieties, a substance that would be a food additive if it were added during traditional food manufacture is also treated as a food additive if it is introduced into food through genetic modification of a food crop. For example, a novel sweetener bioengineered into food would likely require premarket approval. Generally, under Agency policy, 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.

In our experience to date, we have not seen substances of that type. The substances intentionally added to food via biotechnology to date have been well-characterized proteins, fats, and carbohydrates, and are functionally very similar to other proteins, fats, and carbohydrates that are commonly and safely consumed in the diet and so will be presumptively generally recognized as safe. Importantly, our authority under section 409 permits us to require premarket approval of any food additive and thus, to require premarket review of any substances intentionally introduced via bioengineering that are not generally recognized as safe.

FDA's authority under current law, both pre- and post-market provisions, is sufficient to ensure the safety in the marketplace of foods derived from new plant varieties.

SYSTEM OF REGULATIONS

Because FDA determined that bioengineered foods should be regulated like their conventional counterparts, FDA has not to date established any regulations specific to bioengineered food. In 1992 FDA published its "regulatory roadmap" policy document, the "Statement of Policy: Foods Derived from New Plant Varieties." The statement explains FDA's views about regulating human foods and animal feeds produced from new plant varieties, including crops developed by the newest methods of molecular and cell biology (such as recombinant DNA methods and somaclonal variation) and those developed using traditional techniques. The policy focuses on the traits and characteristics of the foods, and applies to all new varieties of food crops, no matter which techniques are used to develop them.

This science-based policy was developed through careful consideration of new developments in biotechnology. FDA scientists had carefully followed the developments in research over the previous several years to determine the types of commercial foods and food ingredients likely to be developed by recombinant DNA techniques. We also considered scientific principles for assessing safety that had been developed and agreed upon by several prestigious scientific groups, including the National Academy of Sciences (NAS), the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the Organization for Economic Cooperation and Development (OECD) in developing FDA's policy.

In formulating FDA policy, we reviewed new foods under development through biotechnology, and found they shared certain common characteristics: (1) Recombinant DNA techniques are being used to introduce copies of one or a limited number of well-characterized genes into a desired food crop. The introduced gene or genes then become integrated in the plant and are passed to successive generations of plants by the natural laws of genetics; (2) In most cases, these genes produce proteins, or proteins that modify fatty acids or carbohydrates in the plant, in other words, common food substances; and (3) The proteins, fatty acids, and carbohydrates introduced into food crops are well- characterized and not known to be toxic and they would be digested to normal metabolites in the same manner that the body handles the thousands of different proteins, fat and carbohydrates that make up our diet today.

Since newly introduced substances in foods derived using recombinant DNA techniques would be proteins, fats or carbohydrates, we then examined the safety questions that should be addressed before products reach the market. We identified four broad safety issues that should be evaluated: (consumption; (2) the need to ensure that the changes in the food, such as the level of natural toxins in the food, if any, stay within normal safe levels; (3) the need to ensure that significant nutrients stay within normal range; and (4) the need to analyze the potential for introduced proteins to cause allergic reactions. We incorporated these and other issues into a comprehensive guidance to industry that is central to our policy.

The guidance in our policy statement provides a "standard of care" to help plant developers ensure that the products they develop meet the safety standards of the FD&C Act. It also provides guidance to industry on those situations in which developers should specifically consult with FDA on issues such as labeling, design of appropriate test protocols, and whether a food additive petition would be required.

I would like to highlight some activities that we have engaged in following publication of our 1992 policy. In response to comments we have received regarding potential allergenicity of foods derived from bioengineered plants, we hosted a "Conference on Scientific Issues Related to Potential Allergenicity in Transgenic Food Crops" in 1994. We hosted this conference in cooperation with the EPA, and USDA. The goal of the Conference was to foster a dialogue among scientists on food allergy and new varieties of food crops developed by gene transfer to assess current information regarding what makes a substance such as a protein a food allergen and what means are available to assess allergenic potential. FDA has gained valuable insights on these issues from this conference.

Also in response to comments we received to the 1992 policy, FDA sought to develop sound scientific principles regarding the safety of the use of antibiotic resistance marker genes in the development of bioengineered plants intended for food use so as to provide sound scientific guidance to crop developers regarding the safe use of antibiotic resistance marker genes. We consulted with outside experts having expertise in relevant fields including gene transfer and antibiotic resistance. The purpose of the consultations was to determine whether circumstances exist under which FDA should recommend that a given antibiotic resistance gene not be used in crops intended for food use, and if so, to delineate the nature of those circumstances. Based on these consultations, FDA issued in September 1998, guidance on the use of antibiotic resistance marker genes in bioengineered plants intended for food use and requested comments on that guidance.

Finally, we should point out that the 1992 policy is not static. The policy was based on our research with respect to products that were in the development pipeline at the time. Since the statement was developed, we have not seen any products we did not anticipate, but it is important to point out that we are keeping abreast of new developments in this rapidly evolving technology and will modify the policy if necessary.

GETTING A BIOTECH PRODUCT TO MARKET

Finally, let me describe the procedures industry follows to get a biotech food product to market. In 1994, for the first bioengineered product planned for introduction into the market, FDA moved deliberately, following the 1992 policy. We conducted a comprehensive scientific review of Calgene's data on the Flavr Savr™ tomato and the use of kanamycin resistance marker gene, and also held a public meeting of our Food Advisory Committee (the Committee) to examine applicability of the 1992 policy to products such as the Flavr Savr™ tomato. The Committee members agreed with FDA that the scientific approach presented in the 1992 policy was sound and that questions regarding the Flavr Savr™ had been addressed. The Committee members also suggested that we develop a more expedited process for FDA and the

industry to reach decisions on the marketing of other bioengineered foods that do not raise substantive scientific issues.

Subsequently, FDA established an informal process by which firms can inform the Agency that they have completed a food or feed safety assessment. FDA requests that firms submit a summary of their assessment to the Agency. It is our expectation and experience that all firms have complied with this request for all plant varieties that have been commercialized to date. This process has worked well to date and permits the Agency to identify and resolve any safety or regulatory issues before products reach the market.

The goal of FDA's evaluation is to ensure that human food and animal feed safety issues or other regulatory issues (e.g. labeling) have been addressed prior to commercial distribution. Agency scientists evaluate the available information to determine whether any unresolved issues exist, regarding the food variety that would necessitate legal action by the Agency if the product were introduced into commerce. Examples of such issues may include the potential for significantly increased levels of plant toxicants or anti-nutrients, reduction of important nutrients, new allergens, or the presence in the food of an unapproved food additive. FDA considers a consultation to be complete when all safety and regulatory issues are resolved. In 1994, FDA discussed this consultation process during a joint public meeting of the Agency's Food Advisory Committee and its Veterinary Medicine Advisory Committee. The committee members agreed with FDA that, based on the types of bioengineered foods and feeds under development, the consultation procedures provide an appropriate level of government oversight.

The Agency encourages developers to consult early in the development phase of their products, and as often as necessary. When a firm has accumulated the information that it believes is adequate to ensure that the product complies with the relevant provisions of the FD&C Act, the Agency recommends that the developer inform FDA about the bioengineered foods intended to be introduced into commercial distribution by providing a summary of the company's safety and nutritional assessment which Agency scientists review for unresolved safety or regulatory issues.

The safety and nutritional assessment summary should normally contain sufficient information for Agency scientists to understand the approach the firm has followed in identifying and addressing relevant issues. Some examples of this information would 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;
- 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;
- 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.

I would like to briefly go back to one of the items I just mentioned that we consider, and one that is a frequently raised concern about bioengineered food - - food allergens.

As we have described in our policy, foods derived from new plant varieties are regulated by FDA under the existing framework of the FD&C Act. Labeling, by law, is limited to identifying significant changes in a food's composition, and it must not mislead consumers. Thus, for example, if a tomato had a soybean gene introduced into it, labeling would be needed to alert consumers to the presence of the potential allergen, unless it could be demonstrated scientifically that the soybean allergen was not present. It is also possible that if the Agency concluded that labeling alone would not adequately protect consumers, FDA would object to the marketing of the product.

Similarly, if a copy of a new gene introduced into a carrot produces a protein that significantly changes the composition of the vegetable, the name "carrot" may no longer accurately describe the product and a new name would be required.

CONCLUSION

In conclusion, Mr. Chairman, FDA takes seriously its mandate to protect consumers in the United States and to ensure that the United States' food supply continues to be one of the safest in the world. FDA's process for evaluating bioengineered foods is one in which the public can have confidence that food biotechnology products must meet the law's safety standards. FDA's 1992 policy statement and our guidance documents make clear that premarket clearance is required if there is scientific uncertainty about the safety of food derived from bioengineered plants. The policy also makes clear that labeling will be required if the composition of the genetically modified food differs significantly from what is expected for that food, or if the genetically modified food contains potential allergens.

Mr. Chairman, we are confident that our approach is appropriate. It allows us to ensure the safety of new food products and also allow the use of safe, new biotechnology techniques that give manufacturers the ability to produce better products and provide consumers additional choices. I would be happy to answer any questions the Committee may have.

Page Last Updated: 08/06/2009

Source: FDA's website: "Testimony of James H. Maryanski, Biotechnology Coordinator of the FDA: Genetically Engineered Foods - Plant Genome Science: From the Lab to the Field to the Market," before the Subcommittee on Basic Research of the Committee on Science, House of Representatives; October 19, 1999