TESTIMONY OF
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BEFORE
THE SUBCOMMITTEE ON RISK MANAGEMENT,
RESEARCH AND SPECIALTY CROPS
AND
THE SUBCOMMITTEE ON DEPARTMENT OPERATIONS, OVERSIGHT,
NUTRITION AND FORESTRY
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INTRODUCTION

Good morning. I am Jim Aidala, the Associate Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances. The Office of Prevention, Pesticides, and Toxic Substances is the Office at the U.S. Environmental Protection Agency (EPA) responsible for drafting the rule on plant-pesticides. I welcome the opportunity to appear before you this morning to describe the proposed rule as well as what we are considering for the final rules. The EPA proposed the rules in 1994 and hopes to finalize it this year. In issuing your invitation, you specifically mention the scope and scientific merit of the rule, the benefits and consequences of this regulatory action on agricultural biotechnology, and the effect this regulation might have on the position of the United States (U.S.) in international trade negotiations. I will briefly describe the primary results of issuing the rule, the philosophy EPA adhered to in developing the rule, and address the concerns you mention in your invitation.

DESCRIPTION OF RULES

Why Does EPA Have a Role?

Our primary mission at EPA is to ensure that pesticides are safe and to protect human health and the environment.

The definition of pesticide in FIFRA is broad; the term pesticide means (1) any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant, and (3) any nitrogen stabilizer.

FIFRA section 2 defines "pesticide" to include any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest.

Substances plants produce for protection against pests are clearly pesticides under the FIFRA section 2 definition of pesticide when humans intend to use such substances for "preventing, destroying, repelling, or mitigating any pest." Pesticides are subject to FIFRA and pesticide residues are subject to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA's 1994 Federal Register notice (59 FR 60495 November 23, 1994) does not propose that substances plants produce for protection against pests be considered pesticides. Rather, the 1994 Federal Register notice recognizes that these substances meet the FIFRA section 2 definition of pesticide. The primary proposals of the 1994 Federal Register notice are: exemption of several categories of plant-pesticides from FIFRA and FFDCA section 408 requirements, clarification that plants used as biological control agents are exempt from FIFRA requirements, and creation of a new part in the Code of Federal Regulations (CFR). The 1994 Federal Register notice used the term "plant-pesticide" to distinguish these substances, produced and used in living plants, from other types of pesticides. The term "plant-pesticide" includes the substances produced and used in living plants, and the genetic material necessary to produce them.

Primary Results of Implementation of Rules

The primary results of implementation of the rule EPA proposed in 1994 would be:

* exemption of several broad categories of plant-pesticides from the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA)

* confirmation that plants used as biological control agents are exempt from FIFRA requirements

* establishment of a new part in the Federal Code of Regulations (CFR) specifically for plant-pesticides, to consolidate plant-pesticide regulations and thus facilitate ease of use.

Why These Exemptions?

In 1994, EPA proposed certain exemptions because the Agency recognized that, although some plant-pesticides require regulation under FIFRA, many qualify for exemption from such regulation. Similarly, although some residues of plant-pesticides would require the establishment of a tolerance under FFDCA section 408, many would qualify for exemption from such regulation. The millennia of human cultivation and breeding of certain plants provide a base of experience of safe use which EPA believes is sufficient to justify exempting certain plant-pesticides from FIFRA and FFDCA section 408 requirements.

None of the exemptions EPA hopes to establish with this rulemaking are based

on the mechanism by which the plants acquired the plant-pesticide. The rules are "process-neutral." Rather, the exemptions are based on the characteristics of the plant-pesticides and the probability of exposures to plant-pesticides with unknown toxicological profiles. The exemptions, thus, are based on risk considerations.

I would now like to briefly describe the proposed exemptions, and would like to do so in terms of some recently-appearing reports suggesting that EPA exempt or exclude several categories of plant-pesticides from regulation. For example, the Institute of Food Technologists (IFT) suggested five categories for exclusion. The Agency's three proposed exemptions are remarkably similar to these suggested exclusions. One, IFT suggests EPA should exclude "naturally-occurring and heritable traits derived for plants of the same or sexually compatible species (i.e., gene transfers from one potato species to another)." EPA advanced such an exemption in the 1994 proposed plant-pesticide rule. Two, IFT suggested that "inherited pest-defense traits" "new to the plant species and its sexually compatible relatives which results in changes in physical structure or form (i.e., leaves with hairs to prevent or discourage insect attack)" should be excluded. EPA agrees and proposed such an exemption in 1994. Three, IFT suggested that inherited pest-defense traits "involved in defense mechanisms expressed as a cascade of biochemical and genetic events triggered by incompatibility between the pest and the plant (i.e., hypersensitive reaction or programmed cell death)" should be excluded. EPA agrees and one of its proposed exemptions includes these types of actions. Four, IFT suggested that inherited pest-defense traits that are "responsible for pest defense effects that are widely known and common within the plant, animal and microbial kingdoms, and are not characteristic of pesticides, such as enzymes" should be excluded. What is included in this category is not clear because the description is very general. However, it may well be that some of the traits that IFT would place in this grouping may be within the proposed exemptions that EPA put forth in 1994. Other compounds in this grouping, however, could pose risks to humans or the environment, a number of enzymes are already regulated as biochemical pesticides, and probably would not be exempt. Five, IFT suggested that inherited pest-defense traits derived from pest genes, such as a viral coat protein" be excluded. EPA proposed in 1994 to exempt plant-pesticides based on viral coat proteins.

Potential for Additional Exemptions

EPA recognizes that as we gain additional experience with these types of products, we may very well find that we can safely exempt other categories of plant-pesticides in addition to those that would be exempted by the final rule. EPA is working with other Federal agencies, in particular the U.S. Department of Agriculture (USDA), to develop an expedited exemption process, which EPA will publish at the same time as the final rule. This process could also be used to exempt other categories of plant-pesticides that can be shown to pose a low probability of risk and are not likely to cause unreasonable adverse effects in the absence of regulation.

Is EPA Regulating Plants?

No. EPA's approach would exempt plants. EPA would only review the plant-pesticides within plants. EPA believes this approach would give the Agency greater flexibility to grant broad categories of exemptions for plant-pesticides, independent of the process used to introduce the plant-pesticide into the plant. This approach would allow us to focus on any risk issues associated with non-exempt plant-pesticides while avoiding disruption of traditional procedures used in the development and commercialization of plant varieties.

Why Create a New Part in the CFR?

Establishment of a new part allows EPA to consolidate regulations specifically applicable to plant-pesticides in one part of the CFR. EPA believes the consolidation will benefit the public by providing greater focus, enhanced clarity and ease of use, because all the regulations specific for plant-pesticides would be in one part of the CFR. The new part would list, for example, exemptions from FIFRA regulation, and exemptions from the requirement of a tolerance or tolerances, issued under section 408 of the FFDCA, specifically for plant-pesticides.

Why Call These Substances "Plant-Pesticide"?

EPA uses the term "plant-pesticide" to distinguish these substances, produced and used in living plants, from other types of pesticides. A distinctive name facilitates creation of a new part in the CFR. However, in response to comment that the term "plant-pesticide" may have a negative connotation and raise concerns with consumers, EPA will ask for comment on the advisability of changing the name in the Federal Register package containing the final rule.

EPA PHILOSOPHY IN DEVELOPING RULES

EPA's philosophy is guided by several considerations. First, EPA believes it should fulfill its obligations under the policy choice made by the Reagan Administration in 1986 that existing laws would be used to regulate products of modern biotechnology. It is in the best interests of all stakeholders to ensure that all products developed using modern biotechnology be safely commercialized. Secondly, sound science is very important to EPA in the development of its approach to products of biotechnology. Thus, for this rule, in addition to relying on its own scientific expertise, EPA sought the advice of knowledgeable, independent experts. Third, the EPA believes that biotechnology can provide societal and environmental benefits.

Fulfilling Obligations of Reagan Administration Policy Choice

In the early 1980s, scientists began to apply the new techniques of biotechnology to produce products in medicine and agriculture. Anticipating the arrival of these new products in the marketplace, the Federal government evaluated whether the existing regulatory framework could be used to regulate such products. In 1986, the Reagan Administration concluded that existing laws could be used, and published the "Coordinated Framework of Biotechnology" (51 FR 23302 June 26, 1986) which laid out the basic approach to regulating these products. The Coordinated Framework established that rather than seeking new legislative authority, Federal Agencies would use existing laws, promulgating new regulations as necessary to address novel product categories.

This approach not only offered more immediate statutory coverage, but also had the advantage that like products would be regulated under the same statutes. Thus, the Coordinated Framework anticipated that pesticides made through the new techniques of biotechnology would be regulated by the Agency with the most experience with pesticides, EPA. EPA already had significant experience with the regulation of biotechnology products. The first biological pesticide was registered in 1948. Since then, EPA has registered hundreds of products created using the older techniques of biotechnology, and several created using the newer techniques.

The advantages of the Coordinated Framework in providing a level playing field in pesticide regulation became increasingly apparent from the mid 1980s to early 1990s. At that time, scientists began using the new techniques of biotechnology to introduce into plants the ability to produce substances, that, were the substances sprayed on the plant, would be regulated by EPA as pesticides. Logically, if EPA regulates these pesticidal substances when they are sprayed on the plant, it would also regulate these same pesticidal substances when the plant is engineered to produce them.

EPA's 1994 proposal is one in a series of Federal government actions aimed at clarifying how Agencies would use existing authority to address issues raised by new categories of agricultural products as originally envisioned by the 1986 Coordinated Framework. For example, in 1987 (52 FR 22891 June 16, 1987), in 1993 (58 FR 17044 March 31, 1993) and 1997 (62 FR 23945 May 2, 1997), United States Department of Agriculture (USDA) issued regulations under the Plant Pest Act. In 1992 (57 FR 22984 May 29, 1992), the Federal Food and Drug Administration (FDA) issued guidance to food companies seeking to market foods derived from new plant varieties. In 1994, EPA issued regulations under FIFRA for the testing of microbial pesticides (59 FR 45600 September 1, 1994) and in 1997 under the Toxic Substances Control Act, regulations addressing new microbial products of biotechnology (70 FR 17910 April 11, 1997).

The rule EPA intends to issue in 1999 is a consequence of the Reagan

Administration policy choice, which was maintained by the Bush Administration and subsequently reaffirmed by the Clinton Administration. Experience shows that countries that have chosen to use existing statutes to regulate products of biotechnology are getting products to market far more rapidly than those that have elected to seek new legislation. Consumers also appear to be more willing to accept these products when they are regulated by agencies they know.

Employing Sound Science

Making regulatory decisions using sound science and the best available expert advice is very important to EPA. EPA sought to ensure that the rule is based on sound science. The 1994 proposal was drafted with input from scientists in EPA's Office of Research and Development and with frequent consultation with recognized experts in relevant scientific disciplines through the FIFRA Scientific Advisory Panel and the Biotechnology Scientific Advisory Committee. EPA requested the advice of outside experts, from universities and agricultural research stations across the country, in three public meetings. In developing its rule, EPA also coordinated with the U.S. Department of Agriculture and the Food and Drug Administration. EPA also sponsored, or cosponsored with the U. S. Department of Agriculture and the Food and Drug Administration, three conferences on the application of modern biotechnology to plants. EPA believes that information and advice generated through these public fora allow for a more transparent rulemaking process and has significantly enhanced the scientific basis for our proposal. EPA has also discussed the rule, in particular the scientific rationale underlying the proposed exemptions, with EPA's Scientific Advisory Board.

EPA Position on Biotechnology

EPA believes that products of biotechnology, including plant-pesticides, can provide societal and environmental benefits. These benefits could include, for example, reduced reliance on synthetic chemical pesticides, thereby reducing worker exposure to chemical pesticides and other potential problems associated with use of conventional chemical pesticides, such as groundwater contamination. In support of this thesis, information received from Monsanto Company indicates that since cotton seed, engineered to express a plant-pesticide isolated from the microorganism *Bacillus thuringiensis*, became available to farmers in 1996, the use of chemical pesticides on cotton has been reduced by one million gallons. Associated benefits also included reduction in the number of containers that had to be disposed of, less water contaminated by rinsing pesticide containers and application equipment, and less fossil fuel burned to apply the pesticide.

EPA recognizes that the future of pest control is increasingly moving towards biological pesticides, including plant-pesticides. For example, half of the active ingredients registered over the past five years have been biological. Recognizing the importance of biological pesticides, EPA created in 1994 a new division, the

Biopesticides and Pollution Prevention Division, specifically to review these products. This division houses the expertise needed to address biological pesticides, including plant-pesticides. The Biopesticides and Pollution Prevention Division has extensive experience in working with biological pesticides and with the companies, both large and small, and the universities developing and registering biological pesticides.

Benefits to Agricultural Biotechnology

EPA believes this rule would provide a number of benefits to agriculture. The primary result of the rule will be the establishment of exemptions for several broad categories of plant-pesticides. These exemptions will minimize EPA's effect on agricultural biotechnology, and represent cost savings to companies, breeders and researchers. Publication of the rule will provide benefits to companies and researchers by clarifying the status under FIFRA and FFDCA section 408 of numerous plant-pesticides.

Even though EPA believes that the use of modern biotechnology in agriculture holds real promise, we cannot say that there is never going to be any risk associated with the novel products that may result. Those plant-pesticides not exempted by the pending rule may, for example, be isolated from novel sources (e.g., scorpions, spiders, snakes, microorganisms), and thus have a higher probability of presenting novel and unknown toxicological profiles. The IFT in its recent guidance also recognized that some substances should be subject to EPA regulation. Included in that group would be "plants with pest-defense substances that act as pesticides when extracted from their hosts and tested *in vitro* and in the environment, such as nicotine, scorpion toxin, spider venom, and crystalline Bt endotoxin."

EPA has established a good record for those plant-pesticides we have regulated. Since March of 1995, EPA has registered eight plant-pesticides representing 10 pesticide products. Nine of these products were for endotoxins isolated from the microorganism, *Bacillus thuringiensis* (Bt). These plant-pesticides were registered for use in various crops including potatoes, cotton, field corn, sweet corn, and popcorn. Late in 1998, EPA registered another gene from a plant virus, the replicase gene, from the potato leaf roll virus (PLRV). The replicase gene will be combined with the Bt endotoxin to control both the Colorado potato beetle and the PLRV virus in potatoes. Seed potato is expected to be available for the 1999 growing season. In addition, EPA has approved FFDCA exemptions from the requirement of a tolerance for residues of these plant-pesticides and for seven viral coat proteins. The cost of registering these plant-pesticides was a fraction of the costs associated with registering a conventional chemical pesticide. Time required for registration is approximately 12 months. Increasingly large acreage are being planted with varieties containing these registered plant-pesticides. For example, 10 - 12 million acres of Bt corn were planted in 1998, out of a total 70 - 80 million acres of corn planted. In 1998, 2.3 million acres of Bt cotton were planted, out of a total of 13 million acres of cotton planted. In 1998, 50,000 acres of Bt potatoes were planted, out of a total of 1.4 million acres of potatoes planted.

Those plant-pesticides that have been registered have been enthusiastically embraced by growers, and have been a boon for the biotechnology industry. Since their introduction in 1995, the adoption of these products has increased significantly each year. Sales were estimated to reach the $9 million mark for 1998 and are predicted to reach $20 million in 1999. EPA believes that such user demand will result in the development and use of new pest resistant crop varieties expressing novel plant-pesticides. If experience of the past few years is an indicator, the profits associated with sale of such varieties will outweigh the costs imposed by EPA requirements.

EPA believes that consumers, both in the U.S. and abroad, are reassured by EPA's continued involvement. The Agency's evaluation of non-exempt plant-pesticides will serve to encourage public confidence in the safety of plants and foods containing these products, thereby facilitating consumer acceptance. Many in industry indicate that review and approval by EPA of plants and foods containing plant-pesticides prior to commercial distribution is important from a marketing (public acceptance) standpoint, as well as reassuring global markets. EPA personnel, under the aegis of the U.S. trade agencies, have participated in numerous meetings with representatives of other governments to assure these officials that products cleared for use and consumption in the U. S. are safe.

Effect on Trade

Since EPA explained in 1994, that substances that plants produce for protection against pests are pesticides if these substances are intended to be used for preventing, destroying, repelling or mitigating any pest, the U.S. has continued to ship numerous foods containing residues of plant-pesticides to foreign markets. The fact that EPA terms these substances plant-pesticides appears to have no detectable negative effect on sales of these products.

A related issue raised by those who are concerned that EPA's approach might have adverse effects on trade is how EPA will apply its labeling authorities for plant-pesticides. EPA is not planning to require labeling of any type for those plant-pesticides that would be exempted by EPA rulemaking. Even for those plant-pesticides not exempted, labeling will be limited. For non-exempt plant-pesticides, the label issued as part of a registration remains on file with the developer. This is the only label required by EPA. The farmer purchasing seed containing a registered plant-pesticide will be provided information by the developer informing the farmer that the seed contains a registered plant-pesticide. The primary purpose of this information is to prevent unnecessary spraying of chemical pesticides. EPA assumes that it would be in the sellers' interest to provide such information, as the pesticidal characteristic is one of the reasons sellers of seed may charge a premium price for the seed.

No label or information would subsequently be associated with the plant-pesticide. The farmer would not be required to label plants containing the plant-pesticide, nor the produce of the plants. This approach is consistent with EPA's

approach to other types of pesticides, e.g., chemical pesticides, which are not labeled as to the pesticides present in food commodities.

There is no current requirement and EPA is not planning to require that produce or commodities containing plant-pesticides, either exempt or not exempt, be segregated in any way, either by the farmer or in the food distribution networks.

Effect on Research

Some scientists have expressed concern that EPA's pending rule will restrict their research. As mentioned earlier, the primary result of the rule would be exemption of broad categories of plant-pesticides from FIFRA and FFDCA, and reconfirmation that plants used as biological control agents are exempt from FIFRA requirements. These actions will not restrict research. Indeed, these actions should facilitate research. For those plant-pesticides that would not be exempted by the rule, researchers need not contact EPA until their activities are pursued on 10 acres or more of land or 1 surface acre of water. At 10 acres of land or 1 surface acre of water, an EPA-issued experimental use permit (EUP) is needed. The presumption that an EUP would not be required for testing on 10 acres or less of land or 1 surface acre of water or less is part of the EUP regulations (40 CFR 172.3) and applies to plant-pesticides as well as to synthetic chemical pesticides. As with chemical pesticides, a tolerance or exemption from the requirement of a tolerance under FFDCA is needed if the produce is going to be sold in interstate commerce.

It is EPA's experience with many biological pesticides that, when testing gets to the 10 acre level, researchers typically have either turned the product totally over to a pesticide company or are working in cooperation with a pesticide company who has experience marketing agricultural products. There are only a handful of registrations held by universities, the US Forest Service, or USDA. The Biopesticides and Pollution Prevention Division at EPA also has extensive experience working with small pesticide companies and the few universities which register products because most, if not all of these, are biological pesticides. We recognize that EPA needs to make special efforts to assist seed companies in understanding and complying with pesticide regulations. The Biopesticides and Pollution Prevention Division is assisting several small entities developing plant-pesticides.

Is There Duplication of Oversight Efforts Between Federal Agencies?

Since Congress has made EPA the Agency responsible for regulation of pesticides and given EPA statutory tools specifically written to address the risks associated with pesticides, duplication between EPA and FDA and between EPA and USDA is minimal.

With regard to potential duplication between FDA and EPA, since its creation in 1970, the FFDCA responsibility for setting tolerances for pesticide residues in food has

been under EPA's jurisdiction, while the FFDCA responsibility for regulating all other substances in food is under FDA's jurisdiction. In general, Agency jurisdiction under the FFDCA is based on whether or not the substance in question is a pesticide. FDA and EPA agree that pesticides fall under EPA's jurisdiction. There is, therefore, no duplication of responsibility between EPA and FDA. FDA and EPA do, however, share information and work closely on developing solutions to generic issues (e.g., allergenicity of food).

With regard to USDA and EPA, USDA uses several laws to regulate biotechnology products. USDA primarily relies on two of these laws to address risk issues potentially associated with plants, the Plant Pest Act and the Plant Quarantine Act. These two laws do not address food safety concerns. Thus, there is no duplication of authority with USDA in this sphere. In the area of ecological effects, EPA regulates the plant-pesticide, USDA on the other hand, regulates the plant. The USDA and EPA have worked together sharing information and using their regulatory authorities appropriately to ensure the safe use of the product. For example, in recent reviews of crop plants engineered to express a plant-pesticide (Bt), EPA used information from USDA's analysis of the ability of the plant to disseminate Bt to other varieties and to wild relatives, while USDA, in its review used information from EPA's analysis of Bt. As part of the interagency review process and the ultimate implementation of this rule, EPA and USDA will continue to work on eliminating redundancies and improving information sharing.

This type of cooperation and coordinated use of statutes was envisioned as a key part of the Coordinated Framework. Through its approach to plant-pesticides, EPA is meeting its statutory and Coordinated Framework obligations under FIFRA and FFDCA to protect human health and the environment against any unreasonable adverse effects from pesticides.

Why Not Delay Publication of the Rule?

The primary effect of publishing the rule we are considering would be the finalization of exemptions for several categories of plant-pesticides. This rule would also reconfirm that plants are exempt from regulation when used as biological control agents. Delaying finalization of the rule would mean that the regulatory status of most plant-pesticides would remain unclear. Publication of the rule will provide benefits to companies and researchers by clarifying the status under FIFRA and FFDCA section 408 of numerous plant-pesticides. Because of this uncertainty, companies may delay projects until the status of their plant-pesticides becomes clear, potentially delaying important benefits to agriculture and consumers. EPA plans an extensive outreach program once the rule is final to provide additional guidance on what types of products are exempt.

MISCONCEPTIONS CONCERNING WHAT THE RULE WOULD DO

EPA acknowledges that some members of the academic community have raised concerns about EPA's proposed rule. We believe that many of the objections raised may be due to simple misunderstanding of the proposal's provisions. In an attempt to help shed some light on these controversies, we would like to address directly some of the issues that have been raised.

FIFRA Applies to Biological as well as Chemical Pesticides

The first concern is that the pesticide statutes EPA administers apply only to inanimate chemicals and not to living organisms, and that applying these laws to plant-pesticides is a radical change in the use of the pesticide statutes. This is not so. In 1948, the first pesticide based on a living organism was registered. Hundreds of pesticides based on living organisms have been registered since then. Indeed, the language of the statute contains specific reference to biological pesticides (7 U.S.C. 136a(c)(10)(B).

EPA Does not Propose to Regulate Plant Varieties

The second concern is that EPA proposes to regulate plants and that each variety of plant would have to be registered. This is not so. In 1994, EPA confirmed that plants *per se* are exempt from FIFRA requirements. EPA intends to reconfirm this exemption in the final rule. An approach which exempts all plants from FIFRA regulation while addressing plant-pesticides, in addition to allowing the Agency to create broad categories of "process-neutral" exemptions, also allows the Agency to avoid requiring registration for plant varieties. Rather, EPA registers plant-pesticides for use in a given crop. The plant-pesticide can then be moved into any variety of that same crop without having to contact EPA. USDA has the responsibility for regulating plants.

EPA's Approach is not Based on Process

The third concern is that EPA considers to be pesticides only plants into which have been introduced, through genetic engineering, genes encoding pest resistance. As noted above, EPA's proposal would exempt plants. A related misconception is that EPA would determine which plant-pesticides are exempt based on the process by which the plant-pesticides were introduced into plants. This is not so. EPA's approach is process neutral. The exemptions that EPA proposed in 1994 are independent of the way in which the substance becomes a part of the plant. The proposed exemptions are only based on the characteristics and/or the probability of exposure to unknown toxicological profiles. Whether the plant-pesticides are introduced into the plant through evolution, genetic engineering or traditional breeding is immaterial to the exemption.

EPA and Herbicide Tolerant Plants

Another concern is that EPA will regulate the ability of a plant to tolerate (or resist) an herbicide. EPA regulates the use of the herbicide, as it would any other application for a new use of a herbicide. The herbicide tolerant plants themselves would not be subject to any EPA review.

CONCLUSION

In closing, let me assure you that EPA recognizes the potential benefits that products created through modern biotechnology may bring to U.S. agriculture. We believe that the exemptions that would be established by the rule we are currently considering, and our reconfirmation that plants *per se* are exempt from FIFRA requirements, will minimize EPA's effect on all aspects of agricultural biotechnology. We also believe that consumer acceptance will be key to the ultimate success of products of modern biotechnology, and that consumer acceptance is strongly influenced by confidence that the regulatory agencies will ensure the safety of the products. EPA believes its activities will contribute to the long-term viability of agricultural products created using modern biotechnology.