THE REGULATORY APPROVAL PROCESS FOR GENETICALLY MODIFIED PRODUCTS

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Good morning. It's a pleasure to be here with you today to take part in this Agricultural Outlook Forum and to bring you an update on biotechnology processes. For the next few minutes, I would like to offer a broad perspective on our commitment to regulating agricultural biotechnology in a flexible, straightforward, and science-based manner.

USDA'S REGULATION OF PLANT BIOTECHNOLOGY

In developing USDA's first plant biotechnology regulations in 1987, the Animal and Plant Health Inspection Service (APHIS) dedicated itself to making the regulatory structure for these commodities flexible and customer-oriented. At the same time, we at USDA have remained steadfastly committed to ensuring that plant health in the United States is protected while allowing the safe field testing or release into the environment of genetically modified plants. Long ago, we recognized that biotechnology is evolving rapidly and that oversight structures should be able to assure safety while still facilitating technology development and use. After all, as in many other high-tech industries, regulations are a critical determinant of the time and the cost involved in bringing a genetically modified product to market. For agricultural biotechnology, innovative and risk-based regulations mean less burdensome costs for producers and more competitive positioning in the marketplace.

Moreover, if structured and administered properly, regulations can actually facilitate rather than impede the commercialization of agricultural biotechnology products by providing potential consumers with the assurances they need to accept such products. At the same time, such regulations are able to prevent or at least mitigate risks without inhibiting innovation and product development. To this end, our goal in USDA has been to develop regulations that neither over-regulate nor under-regulate.

In doing so, we have worked to ensure that our regulatory structure adequately considers health and environmental safety issues as biotechnology products are transferred from the laboratory, to the field, to the marketplace. Toward this end, we have used statutory authorities that already existed for protecting plant and animal health--rather than adding additional laws to the U.S. Government's books. We have also exercised oversight for biotechnology on a product-by-product basis--rather than evaluating all genetically modified products in the same manner regardless of what is being modified or the type of modification. This type of regulation enables

us to consider each product individually and to develop safeguards that are specialized to its individual risks.

Our rational and science-based approach also incorporates the use of performance standards, rather than design standards. In USDA, we have recognized their application to biotechnology for many years. Simply put, performance standards focus on results. For biotechnology, this means setting specific safety standards that biotechnology producers must meet before we will allow their products to be imported, moved interstate, or field tested.

Biotechnology developers must certify to APHIS that they have met these requirements. However--unlike design standards that stipulate in detail how developers must meet the requirements--performance standards let producers decide the best way to achieve compliance with the regulations. Accordingly, developers are given the flexibility needed to reduce their costs while still meeting our regulatory requirements, and--perhaps more importantly--safety is not compromised.

A major feature of the regulatory process has been our cooperative relationship with other Federal agencies as mandated by Federal policy under the coordinated framework for biotechnology regulation. We value our ability to consult with officials at the U.S. Environmental Protection Agency and the Food and Drug Administration on issues of joint concern and we continue to discuss common issues with these agencies.

These are the basic principles of USDA's regulatory program. With that overview let me describe the regulatory process in practice. In brief, we use three separate but interconnected processes: a permit process, a notification process, and a petition process. Each of these processes offers applicants with alternatives in conducting their research and still ensure the safety of plant health in the United States.

The permit process is the oldest of our regulatory procedures--it dates back to the development of APHIS' original biotechnology regulations in 1987. Under this process, applicants provide us with extensive information on their product and the safeguards they will take to ensure that the product is safe for movement or field testing. APHIS officials, in turn, review this information and determine whether to approve the proposal. In doing so, they may prepare environmental assessments or risk assessments, if necessary. Accordingly, when a permit is granted for the movement or field testing of a genetically modified organism, we are assured that the proposed release of the organism does not present a risk to agriculture or the environment.

As I noted earlier, regulations should adapt--as necessary--to increased experience about a given technology. As we learned more about the movement and field testing of certain genetically modified plants, such as tomatoes, we realized that it might not be necessary to subject these products to the extensive review of the permit process. Accordingly, we developed the notification process in 1993.

The notification process currently applies to only six plants: tomatoes, potatoes, corn, cotton, tobacco, and soybeans--all of which have been tested extensively since the late 1980's and about which we obtained a large body of knowledge. As a result, we do not require applicants to submit their research protocols or other documents pertaining to the way in which they will ensure the safe movement or field testing of these products. Rather, the applicants certify that they have met our established eligibility criteria for the type of modification to the plant, as well as our performance standards for the confinement of the crop plants.

We also reserve the right to inspect the applicants' facilities and records if necessary to ensure they are operating within the law. In doing so, we ensure the continued safety of U.S. plant health while offering biotechnology companies and other researchers with more freedom in bringing new products into the marketplace.

As I noted, the basis for the notification process was increased knowledge and experience with regard to the movement and field testing of certain genetically modified products. To aid in moving products forward based on increased knowledge, APHIS also formalized the petition process in 1993. Under the petition process, we make decisions on whether to deregulate genetically modified products. Accordingly, we require petitioners to submit, among other things: a biological description of the plant being modified and the changes that have been made to it, and also extensive data from their experiments. In addition, we always require petitioners to supply any unfavorable information, that is, any information that indicates that the regulated article may pose a greater plant pest risk than its nonmodified counterpart.

We announce receipt of petitions to the public and allow time for any interested party to comment. In turn, we review all the information, prepare an environmental assessment, and make an official determination as to whether the product should be deregulated. We wish to be certain that the plant poses no risks to plant health and is as safe to grow as nonengineered varieties of the same plant. If we decide that a product should be deregulated, we also publicly announce our decision, making sure that the views of all concerned parties are addressed.

We have also deregulated 23 products, and we are currently considering 6 more for deregulation. Some of these products are fairly well known, such as Calgene's Flavr Savr tomato, which was genetically modified for delayed softening. The Flavr Savr tomato was the first product approved for deregulation in late 1992.

With these three separate processes, we feel our regulatory oversight system adequately protects agriculture and the environment while creating a strong regulatory framework for the development and application of biotechnology. However, we never stop looking for ways to make our regulations more flexible and customer-oriented.

Accordingly, in August 1995, we published a proposal that would extend the notification process to most plant species. The proposal, if finalized, would also streamline the review process for deregulating certain genetically modified products that significantly resemble other previously

deregulated products. For example, if a genetic modification were put into "big boy" tomatoes, and we deregulated them, we would simplify the process of deregulating the same change when put into "beefsteak" tomatoes.

In addition, the proposal would lessen the paperwork requirements for certain applicants and would enable us to develop guidelines that would provide helpful information to developers of genetically modified plant products. Such guidelines could pertain to research protocols and practices or other matters. However, they would all be aimed at helping developers comply with our regulations--not to hinder their research activities.

We are still considering the comments we received on this proposal to determine how to proceed. In the meantime, we continue to review applications for permits and notifications--as well as petitions to deregulate genetically modified products.

INTERNATIONAL HARMONIZATION EFFORTS

In this regard, we have established three broad goals for the international harmonization of regulations for genetically modified products. First, we will seek to ensure the integration of compatible national approaches. This means we will work with other countries to identify the common aspects of our regulatory systems. In doing so, we can build confidence in each other's review processes and work to extend existing regulatory approaches for traditional plant products to new, genetically modified products.

Second, we will work with other countries to ensure that our different national regulatory approaches are coordinated. Toward this end, we will work in bilateral and multilateral forums, such as the Organization for Economic Cooperation and Development (OECD) and the Asia Pacific Economic Cooperation (APEC), to exchange information on how reviews of genetically modified plants are being conducted and on products being researched.

We will also continue to make important information about our regulatory system and about U.S. biotechnology developers available on APHIS' homepage on the Internet. Among other things, APHIS lists information on products that are currently being field tested and products that have already been deregulated. We believe that all of these information-exchange efforts provide an essential, informal "early warning system" on global issues that may arise regarding products nearing commercialization.

Third, we will work to ensure that scientific principles are used in evaluating genetically modified products. As I noted earlier, we have strived to base our review system on rational, science-based regulations. Under recent trade agreements, this regulatory approach has been further supported at the international level. Accordingly, we will continue to make sound science the basis for our international negotiations.

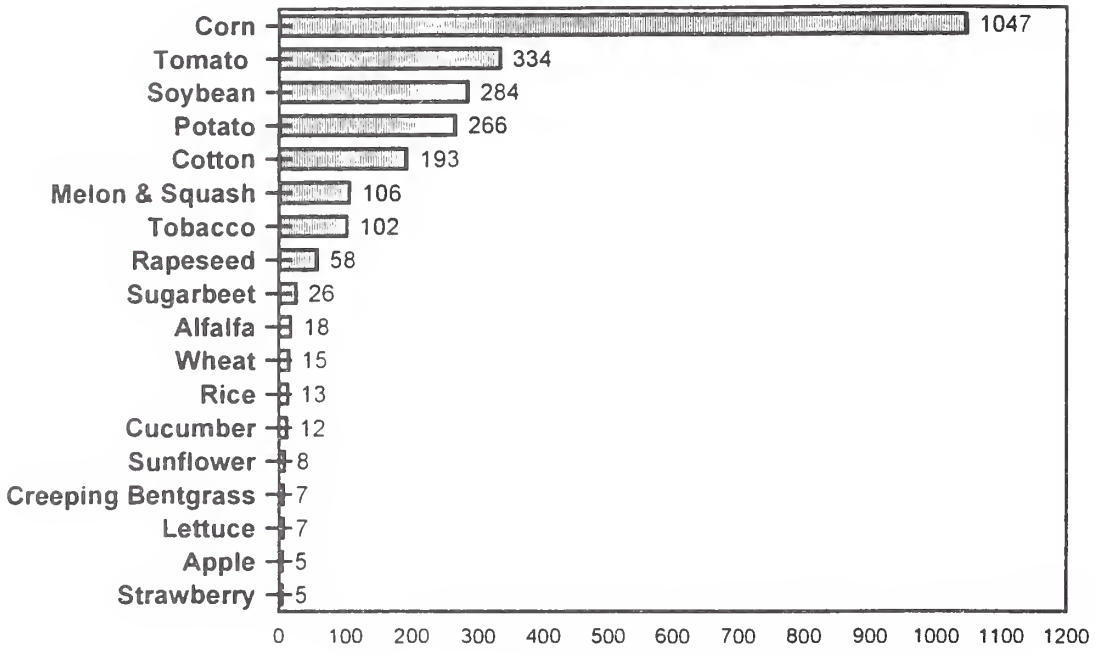
In the future, we will continue to work with OECD, APEC, and other international organizations--as well as individual nations--to promote the concepts of compatible regulatory approaches, coordination of such approaches, and reliance on sound science. We believe these principles are essential to moving genetically modified products safely in international commerce.

CONCLUSION

This morning, I have presented USDA's approach to regulating biotechnology, and I have spoken about our commitment to developing and enforcing rational, science-based regulations. I have also discussed how these regulations fit into the broader context of our efforts in the international arena and our efforts to make the regulations more flexible, efficient, and results-oriented. In doing so, I have sought to demonstrate how we constantly look for new and innovative ways to enable our biotechnology oversight system to protect U.S. agricultural health without impeding progress. Safety has and will continue to be our top priority in regulating this industry. We are confident, however, that safety can be achieved, while allowing important new agricultural products to come to the marketplace.

Thank you.

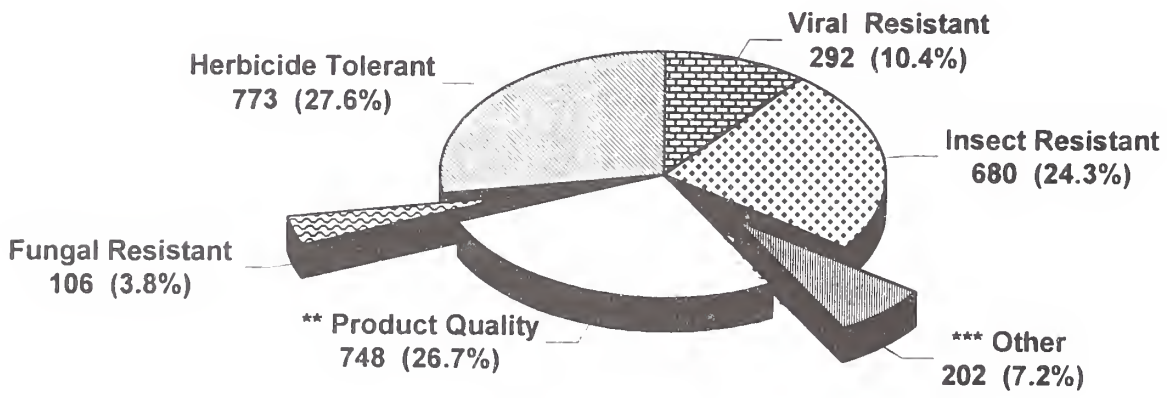
Field Releases* : Most Frequent Crops
1987 to 1/31/97



** Permits and Notifications*

2/7/97

Field Releases* : Most Frequent Categories
1987 to 1997 (1/31/97)



** Permits Issued and Notifications Acknowledged*

*** = Agronomic Properties*
**** = Marker Genes , Selectable Markers, Bacterial Resistant and Nematode Resistant*

2/7/97

Petitions: Determination of Non-Regulated Status Approved 1992 - 1995 : (1 of 2 Slides)

Approved Date	Applicant	Crop	Phenotype
10/19/92	Calgene	Tomato	Fruit npening
02/05/94	Calgene	Cotton	Herbicide Tolerant
05/19/94	Monsanto	Soybean	Herbicide Tolerant
10/31/94	Calgene	Rapeseed/Canola	Oil profile
12/07/94	Upjohn	Squash	Virus Resistant
1/17/95	DNA Plant Technology	Tomato	Fruit npening
3/02/95	Monsanto	Potato	Insect Resistant
5/17/95	Ciba-Geigy	Corn	Insect Resistant
6/06/95	Zeneca & Petoseed	Tomato	Fruit npening
6/22/95	AgrEvo	Corn	Herbicide Tolerant
6/22/95	Monsanto	Cotton	Insect Resistant
7/11/95	Monsanto	Cotton	Herbicide Tolerant
8/22/95	Monsanto	Corn	Insect Resistant
9/27/95	Monsanto	Tomato	Fruit npening
12/19/95	DeKalb	Corn	Herbicide Tolerant

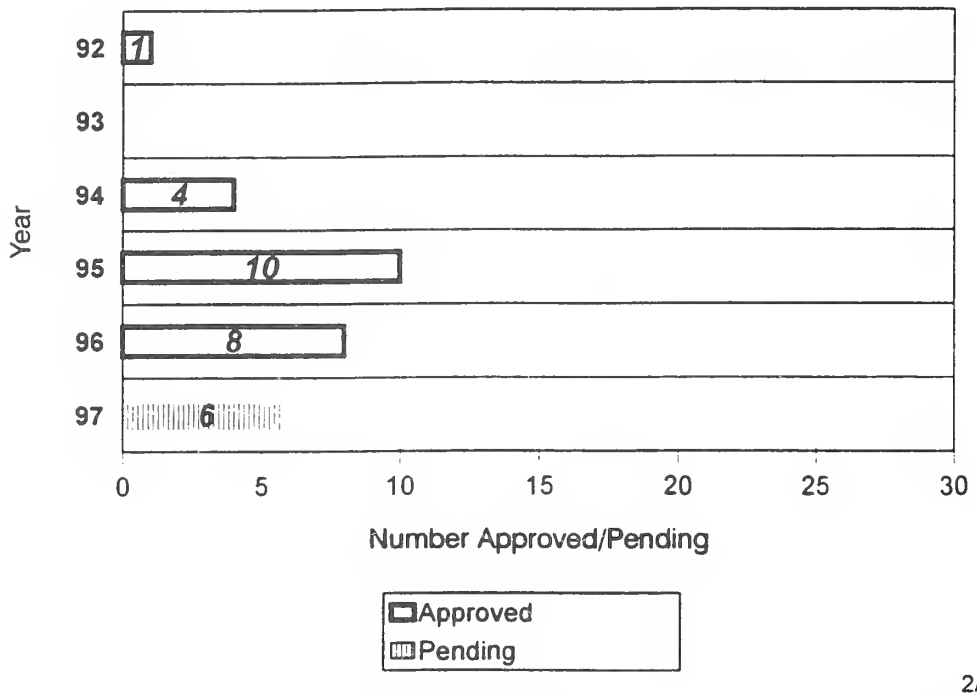
2/7/97

Petitions: Determination of Non-Regulated Status Approved 1996 : (2 of 2 Slides) as of 1/31/97

Approved Date	Applicant	Crop	Phenotype
1/18/96	Northrup-King	Corn	Insect Resistant
1/26/96	Du Pont	Cotton	Herbicide Tolerant
2/22/96	Plant Genetic Systems	Corn	Male sterility + Herbicide Tolerant
3/27/96	Agritope	Tomato	Fruit npening
5/3/96	Monsanto	Potato	Insect Resistant
6/14/96	Asgrow	Squash	Virus Resistant
7/31/96	AgrEvo	Soybean	Herbicide Tolerant
9/5/96	Cornell U & U of Hawaii	Papaya	Virus Resistant

2/7/97

Petitions: Determination of Nonregulated Status approved and pending: as of 1/31/97



2/7/97

Petitions: Determination of Non-Regulated Status Pending Status : as of 1/31/97

Received Date	Applicant	Crop	Phenotype
9/3/96	*Calgene*	*Tomato*	*Fruit Ripening*
10/17/96	*DeKalb*	*Corn*	*Insect Resistant*
11/12/96	*Monsanto*	*Corn*	*Herbicide Tolerant & Insect Resistant*
11/12/96	*Monsanto*	*Corn*	*Herbicide Tolerant*
1/08/97	*DuPont*	*Soybean*	*Oil Profile*
1/13/97	*Calgene*	*Cotton*	*Insect Resistant & Herbicide Tolerant*

2/7/97