USDA/APHIS Forest and Fruit Tree
Biotechnology Meeting/workshop
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My name is Rachel Lattimore, and I act as outside counsel to the Biotechnology Industry Organization (BIO). BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and in 33 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

On behalf of BIO and its members, I'd like to thank USDA, and APHIS specifically, for providing this important public forum for the discussion of necessary data and other issues surrounding this area of research and development. As a lawyer, my comments today will focus not on the scientific issues, but rather on the legal framework that governs the research, development and commercial production of these trees, along with all other plant products of biotechnology.

The Coordinated Framework for Regulation of Biotechnology was developed by the U.S. government almost twenty years ago following extensive public debate and comment. Under the Coordinated Framework, federal agencies review biotechnology-derived plants before they are commercially planted, sold or consumed, ensuring that these plants are safe to grow and, where applicable, safe to eat. Regulators also have broad enforcement authorities that can be applied either pre-market or post-market. Since the mid-1980s, thousands of field tests involving plants produced through biotechnology have been conducted, and over 50 plants have been cleared by

two and sometimes three federal agencies. These plants have been placed into commerce without a single confirmed instance of adverse health, safety or environmental effects.

The Plant Protection Act provides USDA/APHIS broad authority for the regulation of plant-based biotechnology, including forest and fruit trees, in a manner that protects health, safety, the environment and agriculture. Together with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), where appropriate, these agencies have the necessary authority to ensure that trees and tree products produced through this technology are appropriately regulated, while fulfilling their potential to improve the lives of both forests and people.

The U.S. Department of Agriculture (USDA) is typically the first stop for any company developing a biotechnology-derived plant, including trees. The Plant Protection Act, enacted in 2000, grants USDA the authority to regulate any plant that could damage crops, public health or the environment. Under this authority, USDA administers a comprehensive permit system to ensure that data on biotechnology-derived plant varieties are reviewed before the plants are tested in the field and again before they are commercially grown. Even after a plant is cleared for sale, if new information indicates that it presents a risk, USDA is authorized to take extreme measures to contain that risk, including quarantine and destruction.

Through modern biotechnology, researchers have developed plants that are better able to protect themselves from insects, viruses or other pests. Where conventional plant breeding has been used for this purpose in the past, biotechnology provides a more efficient way to produce plants that benefit agriculture and the environment. As discussed during our meeting here, that technology may be applied to trees.

EPA regulates the pesticidal substances produced in such plants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a comprehensive licensing statute governing the sale, distribution and use of pesticides. EPA also regulates residues of pesticidal substances anticipated in food or feed under the Federal Food, Drug, and Cosmetic Act (FFDCA). In order for a food-use pesticide to be approved for sale, EPA must review the available data and determine that the pesticide meets strict safety criteria, in terms of health, safety and the environment. As I will discuss in a few minutes, FDA conducts a broader safety review on the food as a whole.

EPA's regulation of all pesticides begins with large-scale field testing. While smaller-scale field tests are conducted under USDA oversight, these larger-scale field tests are overseen both by USDA and EPA. EPA typically imposes additional monitoring requirements and permit conditions addressing the unique aspects of pesticidal substances expressed in plants. If the field trials are successful, the developer will submit extensive health and environmental safety information in an application to EPA.

Assuming EPA finds that the information supports commercialization, the producer has an ongoing responsibility to comply with any conditions imposed by the agency. One condition that applies to all pesticides approved by EPA requires the producer to inform the agency of any adverse effects that may be associated with the product. EPA has imposed additional restrictions on the first generation of plant-produced pesticides, including a reassessment requirement for pest-resistant corn and cotton originally approved in 1996. The crops satisfied EPA's strict criteria and their approvals were renewed in 2001. FIFRA and the FFDCA provide broad post-market authority for EPA to take action against a pesticide that may be associated with adverse

health or environmental effects. These actions may include requests for additional data, imposition of additional use restrictions, and suspension or cancellation of approvals if needed.

Some trees produced through biotechnology may be used to produce food or food ingredients that will be subject to FDA authority. The FFDCA provides FDA with broad regulatory authority over food and food ingredients, including food produced through biotechnology. In 1992, FDA published a comprehensive policy statement for foods derived from new plant varieties, including those produced through biotechnology. Developers follow a decision-tree approach to assessing any potential dietary risk that might be associated with the food crop under review, share data summaries with FDA scientists and consult with the agency prior to market entry. The goal is to demonstrate that the new food is as safe as its counterparts already in the food supply.

The FFDCA requires that FDA approve any food additive prior to its use in food, with the exception of a substance that is "generally recognized as safe" by the scientific community, a concept known as "GRAS." All new food ingredients must meet this test regardless of how they are produced. The FDA's 1992 policy declared that foods produced through biotechnology would be regulated under this food additive construct. If a biotechnology-derived food differs significantly from its counterparts in the food supply, it may not be GRAS and may require food additive regulation. FDA also has the authority to require labeling of such a significantly different food.

The biotechnology-derived food producer receives a letter from FDA acknowledging completion of the pre-market review and, if successful, that the agency has no further questions regarding the product's safety. All commercially produced biotechnology-derived foods in the U.S. have undergone this process and received such a letter.

FDA has broad enforcement powers under the FFDCA, authorizing it to seize adulterated food, enjoin its distribution, and prosecute those individuals responsible for distribution. Under FDA's 1992 policy, any substance that occurs unexpectedly in biotechnology-derived food at a level that may be injurious to health may be considered an adulterant, subjecting the food to appropriate enforcement action.

This brief overview demonstrates the authority the relevant federal agencies may exercise over plant products of biotechnology. The U.S. regulatory process is science-based and data driven, and has been successfully applied to a growing array of products since 1986. Looking to the future, the process is flexible enough to address new plant varieties, including trees, that are being developed. The application of biotechnology to trees presents a vast potential for environmental and social benefit, but present no revolutionary differences that would justify changes to the basic regulatory framework that has been working successfully for almost 20 years. BIO and its member companies look forward to working with the regulatory agencies and other stakeholders to develop science-based policies that will be protective of human health, agriculture and the environment, while allowing the research and development necessary to allow biotechnology to achieve its enormous potential in the fields of forest and fruit trees.