U.S. REGULATION OF AGRICULTURAL BIOTECHNOLOGY

Three U.S. government agencies—the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA)—are responsible for oversight of genetically engineered plants and products. Their responsibilities are complementary, and in some cases overlapping. USDA's Animal and Plant Health Inspection Service has jurisdiction over the planting of genetically engineered plants. EPA has jurisdiction over the testing, distribution, and use of pesticides engineered into plants, and FDA has jurisdiction over the food and feed uses of all foods from plants. The following excerpt is a brief overview of the role these agencies play in regulating genetically modified organisms.

U.S. Department of Agriculture
Animal and Plant Health Inspection Service

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agriculture from pests and diseases. Under the Plant Protection Act, USDA-APHIS has regulatory oversight of products of modern biotechnology that could pose such a risk. Accordingly, USDA-APHIS regulates organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic engineering. These are called "regulated articles." USDA-APHIS regulates the import, handling, interstate movement, and release into the environment of regulated organisms that are products of biotechnology, including organisms undergoing confined experimental use or field trials. Regulated articles are reviewed to ensure that, under the proposed conditions of use, they do not present a plant pest risk through ensuring appropriate handling, confinement, and disposal.

USDA-APHIS regulations provide a petition process for the determination of nonregulated status. If a petition is granted, that organism will no longer be considered a regulated article and will no longer be subject to oversight by USDA-APHIS. The petitioner must supply information such as the biology of the recipient plant, experimental data and publications, genotypic and phenotypic descriptions of the genetically engineered organism, and field test reports. The agency evaluates a variety of issues, including the potential for plant pest risk; disease and pest susceptibilities; the expression of gene products, new enzymes, or changes to plant metabolism; weediness and impact on sexually compatible plants; agricultural or cultivation practices; effects on non-target organisms; and the potential for gene transfer to other types of organisms. A notice is filed in the [government-published] *Federal Register*, and public comments are considered on the environmental assessment and determination written for the decision on granting the petition. Copies of the USDA-APHIS documents are available to the public.

For further information, visit
http://www.aphis.usda.gov/brs/.

Under the Virus, Serum, Toxin Act, USDA-APHIS Veterinary Services inspects biologics production establishments and licenses veterinary biological substances, including animal vaccines that are products of biotechnology.

For further information, visit
http://www.aphis.usda.gov/vs/.

U.S. Environmental Protection Agency

The EPA, through a registration process, regulates the sale, distribution, and use of pesticides in order to protect health and the environment, regardless of how the pesticide was made or its mode of action. This includes regulation of those pesticides that are produced by an organism through techniques of modern biotechnology. The Biopesticides and Pollution Prevention Division of the Office of Pesticide Programs, under the Federal Insecticide, Fungicide, and Rodenticide Act, regulates the distribution, sale, use, and testing of pesticidal substances produced in plants and microbes. Generally, experimental use permits are issued for field testing. Applicants must register pesticidal products prior to their sale and distribution, and the EPA may establish conditions for use as part of the registration. The EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or

establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act.

For further information, visit
http://www.epa.gov/pesticides/biopesticides.

The EPA's Toxic Substance Control Act Biotechnology Program of the Office of Prevention and Toxic Substances currently regulates microorganisms intended for general industrial uses. The program conducts a pre-market review of "new" microorganisms, that is those microorganisms formed by deliberate combinations of genetic material from organisms classified in different taxonomic genera.

For further information, visit
http://www.epa.gov/oppt/biotech/.

U.S. Food and Drug Administration

The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those developed through bioengineering. All foods and feeds, whether imported or domestic and whether derived from crops modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards. Under the Federal Food, Drug, and Cosmetic Act, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. In addition, any food additive, including one introduced into food or feed by way of plant breeding, must receive FDA approval before marketing. (The term "food additive" refers to substances introduced into food that are not pesticides and are not generally recognized as safe by qualified scientific experts.)

The FDA ensures that food and feed manufacturers meet their obligations through its enforcement authority under the Federal Food, Drug, and Cosmetic Act. To help sponsors of foods and feeds derived from genetically engineered crops comply with their obligations, the FDA encourages them to participate in its voluntary consultation process. All foods and feeds from genetically engineered crops currently on the market in the United States have gone through this consultation process. With one exception, none of these foods and feeds was considered to contain a food additive, and so did not require approval prior to marketing.

For further information, visit
http://www.cfsan.fda.gov/~lrd/biotechm.html

Source: United States Regulatory Agencies Unified Biotechnology Web Site: http://usbiotechreg.nbii.gov/roles.asp