FOOD SAFETY:
REGULATING PLANT AGRICULTURAL BIOTECHNOLOGY IN THE UNITED STATES

Consumers worldwide are rightly concerned about the safety of the foods they eat. This concern has intensified with advancements in bioengineered foods. Under a policy developed in 1986, three lead federal agencies — the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS), the Department of Health and Human Services' Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) — have the responsibility for implementing the nation's biotechnology regulatory framework. Within this framework, the U.S. regulatory process is constantly being reassessed and refined for all foods, both bioengineered and traditional.

The United States has more than a decade of experience in regulating bioengineered foods. About 50 varieties of bioengineered food crops have gone through the U.S. government regulatory procedures, and thousands of foods containing ingredients from these bioengineered crops are currently on the U.S. market. This fact sheet outlines the five regulatory procedures that occur from the time a scientist has an idea for a potentially marketable bioengineered plant product to when the product finally ends up in the local food market.

PRE-SUBMISSION DISCUSSIONS

Biotech regulation at the federal level starts as the product nears the first field test after development in the laboratory. Early in the process, the developer of a new plant line discusses the product with the three regulatory agencies to determine the kinds of data and information that will be necessary to support the regulatory review. While not required, these pre-submission consultations are strongly encouraged so as to avoid problems and delays later.

FIELD TRIALS APPROVALS

USDA-APHIS regulates the development and field testing of genetically engineered plants. Plant breeders normally do several years of field testing to evaluate virtually every element involved in growing a new variety that has been developed in the laboratory or greenhouse — from its ability to resist disease to a variety of individual characteristics about the plant. USDA-APHIS regulations cover this field testing, since they provide procedures for obtaining a permit or for providing notification prior to importation, interstate movement, or release of a "regulated" article into the United States. Regulated articles are living organisms, primarily plants and microorganisms, and products altered or produced through genetic engineering that could be considered plant pests, or that could pose some risk to plants. For a developer to even ship genetically engineered seed interstate, USDA-APHIS must be notified.

To satisfy USDA-APHIS regulatory requirements, a field test must be conducted in such a way that neither the genetically engineered plant nor its offspring establishes or survives beyond the field trial in either the agricultural or nonagricultural environment. Specific precautions must be taken to prevent the escape of pollen, plants, or plant parts from the field-test site. The field-test plot must be monitored the following year to assure that no "volunteer" plants survive and grow on the plot. In addition, once USDA-APHIS approves a new biotechnology-derived plant for field testing, agency officials and their state counterparts may inspect the field-test site before, during, and after a test to ensure that the test is conducted and managed safely.

PETITIONING USDA-APHIS FOR "NON-REGULATED STATUS"

After several years of laboratory and field testing, a developer may decide to commercialize the genetically engineered plant variety and petition USDA-APHIS to be released from regulatory oversight. Following review of all materials — from field-test reports to the scientific literature and disease lists — USDA-APHIS will make a determination that the product is no longer a "regulated article" if the new plant variety poses no significant risk to other plants in the environment and is as safe to use as more traditional varieties. This determination enables the new plant to be cultivated, tested, or used for crop breeding without any additional USDA-APHIS action. Both the

petition and the accompanying environmental assessment developed by USDA-APHIS are published and made available for public comment. This process normally takes about 10 months once the agency receives all the information it needs. Civil and criminal penalties can be levied for failure to comply with USDA-APHIS regulations. In making its determination, USDA-APHIS examines potential environmental consequences such as:

Possible plant pest consequences. USDA-APHIS examines the biology of the plant (i.e., is the plant an annual or perennial, where does it grow naturally, what is its life cycle), the genetics of the plant, and the nature and origin of the genetic material used. It also examines the genetically engineered plant's possible effects on other organisms in the environment and on agricultural products, assessing its potential for creating plant pest risk such as new virus diseases, altered disease and pest susceptibilities of the new plant, and the potential for gene transfer to a wild plant relative that might create a weed problem.

Possible consequences to other organisms. USDA-APHIS must consider whether the biotech crop can affect wildlife, including birds and mammals that could feed on crops. The effects on beneficial organisms such as bees, endangered species, and other nontarget organisms are also evaluated. This analysis includes looking at the consequences of adding the new gene, such as the production of new enzymes or changes to plant metabolism.

Possible weed consequences. USDA-APHIS considers whether the modified crop has the potential to become a weed. It examines the unmodified crop plant for weediness characteristics like ease of seed dispersal, whether seeds survive over winter, and the viability of the seeds. Then the new traits that have been introduced are evaluated for their potential to enhance the weediness of the plant.

EPA REGULATION OF CROPS WITH PEST CONTROL PROPERTIES

If a plant is genetically engineered to express a protein with pest control properties, the Environmental Protection Agency has oversight responsibilities throughout the development, commercialization, and post-commercialization phases. An example would be corn expressing a protein to control corn borer, often referred to as Bt corn. In the case of herbicide-tolerant crops, the plant itself does not have pest control properties but is made to resist a chemical that would normally kill it. For these plants, EPA not only looks at the environmental safety of a herbicide but also determines whether applying the herbicide poses risks to food or feed safety that would require specific labeling and determines the maximum residue levels ("tolerances") that would be safe for the public to consume. In those cases, detailed herbicide residue data must be submitted for the herbicide-tolerant crop.

Development Phase: When a developer of a pesticidal plant variety seeks to conduct nonfood and nonfeed trials on greater than 10 acres of terrestrial or one acre of aquatic use, the developer consults with EPA staff regarding data necessary to obtain a testing permit (termed an "Experimental Use Permit," or EUP) and data that should be generated during EUP testing for the next step, which is a review to determine whether a product can be registered for use as a pesticide in the United States. EUPs are required at the development phase for all crops that may enter the food supply. EUP applications must provide "sufficient" information to allow for a determination that the proposed uses will not result in "unreasonable adverse effects," as defined in the U.S. pesticide law. Field tests during an EUP are usually required to be carried out with strict containment measures to reduce environmental and human health concerns (e.g., crop destruction after field testing). The law allows EPA 120 days to make a determination on issuance of an EUP. The public is invited through published notices to comment on the EUP request.

Commercialization Phase: Unless specifically exempted, all pesticides, including those contained within living plants, must be reviewed by and registered with EPA before they can be sold or distributed. For registration of pesticides, EPA must consider data on all potential human and environmental risks, and find that the pesticide "will not generally cause unreasonable adverse effects." It generally takes a year for EPA to review a "complete" information package for the product and reach a decision. A complete package typically includes information on product characterization, health effects (toxicology), nontarget organism effects, and the fate of the pesticide in the environment. Insect resistance management — the likelihood of insects to develop a resistance to the bioengineered plant — also is evaluated. Public comment is invited again.

Product characterization. For example, EPA considers the source of the gene, how the gene is expressed, the biology of the recipient plant, and the nature of the pesticide produced.

Health effects. Dietary intake is presumed to be a major route of exposure for food and feed plants bioengineered to produce pest control substances. For all food or feed plants producing pesticidal substances, EPA examines data on acute oral studies obtained through laboratory experiments using mice. EPA also assesses potential allergenicity and digestibility of the new pesticidal protein.

Environmental fate. EPA reviews data on the rate of degradation of the pesticidal protein in plant tissue in the soil. EPA considers any potential for gene transfer to weedy or wild relatives by cross-pollination as well as the geographic proximity of the cultivation area to related cultivars or weedy relatives that can cross-pollinate.

Effects on nontarget organisms. For bioengineered plants, pesticidal substances (usually a protein) are contained within the plant. Thus, exposure of nontarget organisms to the pesticidal substance occurs mainly when nontargets feed on the pesticidal plants. EPA considers whether the introduced pesticidal substance is toxic

to wildlife, beneficial insects, fish, or other organisms and, if so, whether those organisms will be exposed to the protein. For example, Bt proteins have been tested at doses typically 10 to 100 times the expected exposure from the pesticidal plant. The tests are carried out with a range of nontarget insects such as honeybees, green lacewing, ladybird beetles, and parasitic wasps, and with other organisms such as earthworms, fish, birds, and rodents.

In addition to data requirements for pesticide registration, EPA must review all animal and human dietary risks of the pest control protein to determine whether a tolerance limit should be set on the amount of protein in food derived from the improved plant. Public comment is invited. If there is already substantial data on the safety of the protein and a history of safe use, the developer may request an exemption from the tolerance requirement. Such exemptions are not automatically granted.

Post-Commercialization Phase: The U.S. pesticide law gives EPA authority to amend or revoke existing registrations in the event "unreasonable adverse effects" have been observed. In addition, EPA can impose new measures as new information becomes available. For example, for purposes of insect resistance management, beginning in the 2000 crop year, growers must plant an area of non-Bt corn equal to 20 percent of their acreage, along with their Bt corn seeds. For Bt corn grown in cotton areas, farmers must plant at least 50 percent non-Bt corn. This provides what is called a "refuge" and is used to manage the genetics of pest insect populations to prevent the development of resistance to Bt in insects feeding on the corn.

FDA REVIEW OF FOOD AND FEED SAFETY

The Department of Health and Human Services' Food and Drug Administration has the responsibility for the safety of foods and feeds. FDA meets with the developer of a product and provides guidance as to what studies FDA considers appropriate to ensure food and feed safety. This process may begin before, during, or after the developer has initiated field studies or discussions with the other agencies, depending on the kinds of questions the developer or FDA may have about the product.

Developers send FDA documents summarizing the information and data they have generated to demonstrate that a bioengineered food is as safe as its conventional counterpart. The documents describe the genes they use; whether they are from a plant whose food is known to produce allergic reactions in some people; and the characteristics of the proteins made by the genes, including their biological function, their relative safety in humans and animals, and how much of them will be found in the food. Developers tell FDA whether the new food contains the expected levels of nutrients or toxins and any other information about the safety and use of the product.

The type of studies a developer will perform will vary depending on the characteristics of the food product and the kinds of modifications introduced into the food crop. The studies generally examine whether the introduction of the genetic material into the plant caused any unexpected effects by analyzing the composition of the food, paying particular attention to levels of known toxicants and significant nutrients. In the case of a new protein, they check to determine whether:

- It is substantially the same as other proteins commonly present in food, and whether it is present in comparable levels.

- It comes from a commonly allergenic food, such as milk, eggs, wheat, fish, tree nuts, and legumes. If so, it would be presumed to be an allergen unless the sponsor could demonstrate otherwise to FDA's satisfaction. If the developer could not demonstrate that the protein was not an allergen, the agency either would require that the food be labeled to indicate the presence of the allergen or, in situations in which labeling would not be considered adequate to ensure safety, the agency would not allow marketing of the food.

- It is rapidly digested to minimize the likelihood that it will become allergenic.

The current FDA consultation process described above is voluntary, although, to date, all companies have made use of it prior to commercializing any bioengineered food in the United States. FDA is planning to publish a proposed regulation that will, when finalized, make it mandatory for a developer wishing to market a bioengineered food product to notify and provide information about the food to FDA at least 120 days before marketing. At the end of this process, if FDA is satisfied with the information it has received and has found no safety or other regulatory concerns pertaining to the food, the FDA will provide a letter to the developer confirming that it has no more questions related to the food and feed safety of the product.

To make sure that consumers also have access to product information, FDA will post information and the agency's conclusions on the FDA Web site, consistent with applicable disclosure laws.

However, should concerns arise after a product is on the market, FDA has the authority to remove immediately any food from the market that it deems unsafe.

This pamphlet on the regulation of plant agricultural biotechnology in the United States has been issued

by the U.S. Department of State. It was prepared with the cooperation of the Department of Agriculture's Animal and Plant Health Inspection Service, the Environmental Protection Agency, the Food and Drug Administration, the U.S. Agency for International Development, the Department of Commerce, and the Office of the U.S. Trade Representative.

BACK TO TOP