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Office of Science and Technology Policy

Proposed Federal Actions To Update Field Test Requirements for Biotechnology Derived Plants and To Establish Early Food Safety Assessments for New Proteins Produced by Such Plants; Notice

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Proposed Federal Actions To Update Field Test Requirements for Biotechnology Derived Plants and To Establish Early Food Safety Assessments for New Proteins Produced by Such Plants

AGENCY: Office of Science and Technology Policy.

ACTION: Request public comments on proposed federal actions.

SUMMARY: These proposed federal actions are put forward to address regulatory issues associated with the expanding development and use of biotechnology-derived crops. Rapid developments in genomics are resulting in dramatic changes in the way new plant varieties are developed and commercialized. Scientific advances are expected to accelerate significantly over the next decade, leading to the development and commercialization of a greater number and diversity of biotechnology-derived crops. Consistent with the Coordinated Framework for the Regulation of Biotechnology Products (51 FR 23302, June 26,1986), the Office of Science and Technology Policy (OSTP), working with Departments of Agriculture (USDA) and Health and Human Services (HHS) and the Environmental Protection Agency (EPA), is proposing these coordinated actions to update field testing requirements of biotechnology-derived food and feed crop plants and to establish early food safety assessments for new proteins produced by such plants.

DATES: The Office of Science and Technology Policy welcomes comments on the proposed federal actions. To be assured consideration by USDA, HHS, and EPA, comments must be postmarked no later than September 30, 2002.

ADDRESSES: Comments on this notice should be sent to OSTP by e-mail at *comments@ostp.eop.gov* or by FAX at 202–456–6027.

Background

The use of biotechnology-derived crops in the United States has increased markedly over the past decade. In 1994, approximately 7,000 acres were planted under 593 USDA field-test authorizations, compared to 57,000 acres under 1,117 authorizations in 2001. The first biotechnology-derived crops were commercialized in 1996 and, in 2001, approximately 88 million acres were planted in the United States and 130 million acres were planted worldwide (ISAAA). While the increases are most dramatic in the United States, other nations (*e.g.,* Canada, Argentina, China) are also experiencing significant growth in the development and use of biotechnology-derived crops.

Rapid developments in genomics (plant, animal, and microbial) are making this expansion possible. The genomes of the model plant Arabidopsis and rice have been sequenced. Such scientific advances are expected to accelerate significantly over the next decade, leading to the development and commercialization of a greater number and diversity of biotechnology-derived crops. In addition to developing plants expressing traits for improved agronomic properties (*e.g.,* disease and pest resistance and drought and herbicide tolerance), scientists are adding traits for the benefit of the consumer (*e.g.,* enhanced nutrition, other health benefits, and prolonged shelf-life), and traits that produce substances not intended for consumption through food or feed (*e.g.,* industrial enzymes and pharmaceuticals).

While the expansion of biotechnology-derived crops is expected to result in net benefits to producers, consumers, and the environment, the federal government must maintain appropriate regulatory oversight, adjusting its requirements based on scientific developments and industry trends. For example, the National Research Council's reports ''Environmental Effects of Transgenic Plants'' (NRC, 2002) and ''Genetically Modified Pest-Protected Plants: Science and Regulation'' (NRC, 2000) make several recommendations to strengthen various aspects of federal oversight of agricultural biotechnology.

The overall federal regulatory structure for biotechnology products (Coordinated Framework) was adopted by federal agencies in 1986 (51 FR 23302, June 26, 1986). The Coordinated Framework provides a regulatory approach that is intended to ensure the safety of biotechnology research and products, using existing statutory authority and building upon agency experience with agricultural, pharmaceutical, industrial, and other products developed through traditional genetic modification techniques. The oversight of biotechnology-derived plants rests with the USDA's Animal and Plant Health Inspection Service (APHIS), the HHS' Food and Drug Administration (FDA), and the EPA. The Coordinated Framework anticipated that agencies might need to develop specific regulations or guidelines under existing statutory authority. The Framework also anticipated further elaboration of federal biotechnology policy consistent with scientific advances and product development.

Federal regulatory agencies recognized that the expansion in agricultural biotechnology increasingly will put pressure on seed production and commodity handling systems to ensure applicable seed, commodity, and food and feed safety standards are met. Those plants that have already been reviewed by federal regulatory agencies and found safe are not of concern. While existing field-testing requirements have been appropriate for current agricultural biotechnology development and commercialization activities, federal regulations must anticipate future activities. As the number and diversity of field tests increase, the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced under field tests with commercial seeds or grain may also increase. This could result in intermittent, low-levels of biotechnology-derived genes, and gene products occurring in commerce that have not gone through all applicable regulatory reviews.

Therefore, in anticipation of the expansion of the development and commercialization of agricultural biotechnology, these proposed federal actions would establish a coordinated regulatory approach to update field testing requirements of biotechnology-derived plants and to establish early food safety assessments for new proteins produced by such plants that are intended for food or feed use. The measures proposed in this Notice address only those biotechnology-derived crop plants intended for food and feed use. These measures are aimed at preventing low levels of biotechnology-derived genes and gene products from being found in commercial seed, commodities, and processed food and feed until appropriate safety standards can be met. Actions addressing other regulatory aspects of biotechnology-derived crop plants may be proposed in the future.

Proposed Federal Actions

These proposals are aimed at further reducing in commercial seed lots, bulk commodities, and processed food and feed the likelihood of the occurrence of intermittent, low levels of biotechnology-derived genes and gene products from crops under development for food or feed use until all appropriate safety standards have been met. These actions are part of the government's continuing protection of public health

and the environment and efforts to enhance public confidence in the regulatory oversight of biotechnology-derived food crops and foods/feeds derived from such crops.

These proposals would be implemented through the coordinated actions of FDA, USDA, and EPA. In developing these proposals, the U.S. government has relied on the following three principles:

- The level of confinement under which a field test of a biotechnology-derived plant is conducted should be consistent with the level of environmental, human, and animal health risk associated with the introduced protein and trait.
- If a trait or protein presents an unacceptable risk or the risks cannot be determined adequately, field test confinement requirements would be rigorous to restrict out-crossing and commingling of seed and the occurrence at any level of biotechnology-derived genes and gene products from these field tests would be prohibited in commercial seed, commodities, and processed food and feed.
- Even if a trait or protein does not present an unacceptable risk to the environment or public health, field test requirements should still minimize the occurrence of out-crossing and commingling of seed from these field tests, but intermittent, low levels of biotechnology-derived genes and gene products from such field tests could be found acceptable based on data and information indicating the newly introduced traits and proteins meet the applicable regulatory standards.

FDA

FDA would publish for comment draft guidance on procedures to address the possible intermittent, low level presence in food and feed of new non-pesticidal proteins from biotechnology-derived crops under development for food or feed use, but that have not gone through FDA's premarket consultation process. The guidance would focus on proteins new to such plants, because FDA believes that at the low levels expected from such material, any food or feed safety concerns would be limited to the potential that a new protein could cause an allergic reaction in some people or could be a toxin. Through this guidance, FDA would encourage sponsors (domestic and foreign) to submit protein safety information once field testing was about to reach a stage of development such that there could be concerns that new non-pesticidal proteins produced in the field-tested plants might be found in commercial seed, commodities, or food/feed.

For this kind of low-level intermittent exposure, FDA does not believe there is a need to evaluate potential unintended compositional changes in food that might be associated with separate transformation events. Consequently, the agency would propose to establish procedures under which developers could provide FDA with food/feed safety information on any non-pesticidal protein engineered into a food/feed crop when that protein has not previously been evaluated by FDA and is new to the food crop into which it was engineered. FDA would principally be interested in looking at data and other information addressing potential toxicity and allergenicity. For developers who have intentionally altered the composition of the food or feed, FDA would encourage them to consult with the agency about whether the presence in food/feed of such material at low and intermittent levels would raise any potential safety issues.

Since this guidance would be focusing only on the new protein and its potential allergenicity and toxicity, FDA would not expect multiple submissions for the same protein from the same source gene. FDA also would not expect submissions for proteins moved within the same species, as such movement would not raise new toxicity or allergenicity issues for the food.

Consistent with procedures the agency has implemented or has proposed to implement for its voluntary premarket consultation process and proposed mandatory premarket notification process for foods/feeds from bioengineered plants, the agency would propose in the draft guidance to provide developers with a written response at the conclusion of its evaluation, and to make the submission and FDA's response available through its web site. FDA would propose to maintain a list on its website, consistent with confidentiality requirements, of all proteins it had evaluated and considered acceptable (or unacceptable) through this procedure. FDA would still expect developers to conduct a complete consultation with FDA prior to marketing food or feed from the plant, consistent with current practices.

EPA

EPA would rely on its existing processes to address residues of pesticidal proteins in food, and would publish for comment guidance for individuals and organizations conducting field-testing on plant-incorporated protectants (PIPs). PIPs are pesticidal substances and the genetic material necessary to produce the substance, when produced and used in living plants, and are regulated as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). This guidance would address broadly two issues: (1) The process for obtaining EPA review of the safety of the presence of low-level intermittent residues of PIPs in food and (2) guidance on containment controls that a person should employ when conducting experimental field trials, in order to minimize the potential occurrence of unapproved PIPs in food.

EPA would encourage developers to seek approval for residues of PIPs in food very early in the research and development process, if there is a likelihood for the pesticide to be in food through gene flow. EPA decisions about the safety in food of low levels of PIPs would be made under the provisions of section 408 of the FFDCA, which requires that EPA determine whether there is a reasonable certainty of no harm from aggregate exposure to the pesticide. EPA would discuss its legal authority and would explain that, like all safety determinations for PIPs, EPA would need to issue a rule under FFDCA permitting the residues of the PIP to be present in food, even if the PIP is only found at low levels. Such rules typically would last only as long as necessary to allow any food that might contain residues to pass through the food distribution chain. A person seeking an approval under the FFDCA to allow the PIP residue to be present in food would need to submit PIP-specific information sufficient to establish the PIP's safety. In general, EPA would expect the same types and amount of information as FDA, with the focus on product identity and potential allergenicity and toxicity. In a few areas, however, EPA would likely need some additional data because the products regulated by EPA have a different character—they are intended to display pesticidal properties—from the products that FDA reviews.

In addition, EPA would discuss the regulation of PIPs under FIFRA, focusing on the provisions which require a person to obtain an experimental use permit (EUP) prior to conducting field research with a pesticide. EPA would provide guidance on the circumstances under which the Agency would ''reasonably anticipate'' that PIP residues would be present in food, and thus would presumptively require an EUP. EPA would also describe the containment controls that would be appropriate for experimental field trials to minimize the potential for gene-flow to commercial seed production fields or commercial

commodity production fields, either through pollen drift or other avenues of transfer of genetic material, such that those responsible for the field trials would not anticipate residues. EPA would coordinate its approach to containment controls for field testing with other federal agencies.

USDA

USDA has strengthened field-testing controls for permits on those bioengineered traits that are not intended for commodity uses, such as pharmaceuticals, veterinary biologics, or certain industrial products. This has been accomplished by requiring specific additional safeguards as a condition of permits for confined release into the environment of such products. The potential for exposure would be mitigated through additional appropriate safeguards. These safeguards may include overall confinement procedures, performance standards, and monitoring/auditing practices for ensuring that out-crossing or commingling of non-commodity appropriate traits with seeds and commodities are prevented.

USDA would also propose, under its biotechnology regulations in 7 CFR part 340, to amend its regulations to provide criteria under which regulated articles may be allowable in commercial seed and commodities, if they pose no unacceptable environmental risk. Criteria would be announced as part of an overall updating of 7 CFR part 340, incorporating APHIS' new authorities under the Plant Protection Act and in consideration of recommendations given to USDA in the National Research Council (February 2002) report ''Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation.''

USDA will also continue and expand a critical emphasis on transparency of the regulatory process and on the use of broad internal and external scientific expertise and review as the foundation for decision-making.

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