



Questions & Answers

BIOTECHNOLOGY: FINAL PLANT- PESTICIDE/PLANT INCORPORATED PROTECTANTS (PIPs) RULES

BACKGROUND

The Environmental Protection Agency (EPA) is the federal agency responsible for regulating pesticides in the United States. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA must regulate pesticides to ensure that they meet federal safety standards. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that EPA determine safe levels of pesticide residues in food. Plant-incorporated protectants (PIPs), the pesticidal substance and the genetic material necessary to produce the substance, pesticides regulated under FIFRA and FFDCA.

In 1986, the federal government produced a document called the "Coordinated Framework for Biotechnology," in which it was made clear that the regulation of pesticidal substances produced through biotechnology would be regulated by EPA under the pesticide laws. In 1994, EPA published proposed regulations describing EPA's policies for plant-incorporated protectants (then called "plant-pesticides") under FIFRA and FFDCA. Since EPA published the proposed plant-pesticide rules in 1994, we have consulted with independent panels of scientists and solicited public comments through supplemental notices on a variety of issues related to the rule. EPA recently issued the final versions of these rules, which will formalize EPA's policies for regulating plant-incorporated protectants. This document answers common questions regarding this recent action.

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1. What is a plant-incorporated protectant?

Plant-incorporated protectants are pesticidal substances produced and used by the living plant, typically to protect the plant from pests, such as insects, viruses, and fungi. Plant-incorporated protectants can occur naturally in plants, or can be introduced into plants through either the conventional breeding of sexually compatible plants or through the techniques of modern biology (e.g. genetic engineering). For example, the Cry proteins from *Bacillus thuringiensis* (Bt) bacteria can be introduced into plants, which then produce the pesticidal protein and provide the plant with resistance to Lepidopteran insects (e.g. the European corn borer larvae). Plant-incorporated protectants have also been referred to as plant-pesticides.

2. What action is EPA taking on plant-incorporated protectants?

EPA has issued three final rules clarifying and formalizing EPA's framework for federal oversight of plant-incorporated protectants. Under the final rules, most components of plant-incorporated protectants derived from genetic engineering will be subject to FIFRA and FFDCA requirements. This requires EPA to ensure that genetically engineered plant-incorporated protectants meet federal safety standards by subjecting them to a rigorous registration process. EPA must also set a food tolerance for residues of the plant-incorporated protectant (or determine on a case-by-case basis to exempt it from the food tolerance requirement) before it can be marketed.

In our thorough scientific review of plant-incorporated protectants, the Agency has determined that plant-incorporated protectants developed through conventional breeding pose little or no health or environmental risks. Thus, plant-incorporated protectants derived from conventional breeding of sexually compatible plants will be exempt from most FIFRA and FFDCA requirements with the exception of requirements for manufacturers to report adverse effects. Certain components of the genetic material necessary for the production of plant-incorporated protectants will also be exempt from the requirement for a tolerance under FFDCA.

3. Which actions proposed in 1994 were not finalized in the recently issued plant-incorporated protectants rules ?

EPA has indicated in a supplemental notice, which is part of the final rule package, that it intends to consider further public comment before making final determinations on three additional exemptions from the 1994 proposal not finalized in these rules.

- PIPs derived through genetic engineering from sexually compatible plants;
- PIPs that act primarily by affecting the plant (e.g., thicker wax cuticles); and
- PIPs based on viral coat proteins (substances that encapsulate and protect the genetic material of certain plant viruses).

EPA has also solicited public comment on the National Academy of Sciences report, published in April 2000, entitled “Genetically Modified Pest-Protected Plants: Science and Regulation,” as it relates to plant-incorporated protectants derived through genetic engineering.

4. What is the difference between plant-incorporated protectants produced through genetic engineering and those produced through conventional breeding?

Conventional breeding is a method in which genes for pesticidal traits are introduced into a plant through natural methods, such as cross-pollination. For a plant-incorporated pesticide, one would breed a plant that produces a pesticide with a sexually compatible plant that does not possess this property but possesses other properties of interest to the breeder, e.g., sweeter fruit. Then, out of the offspring, the breeder would choose the offspring plant that produces the pesticide, and therefore expresses the desired pesticidal trait, as well as producing sweeter fruit.

Genetically engineered plant-incorporated protectants are created through a process that utilizes several different modern scientific techniques to introduce a specific pesticide-producing gene into a plant’s DNA genetic material. For example, a desired gene that produces a desired pesticides (e.g., the insecticidal protein Bt from the bacterium, *Bacillus thuringiensis*) can be isolated from another organism, such as a bacterium, and then inserted into a plant. The desired gene becomes part of the plant’s DNA. The plant then expresses the incorporated gene and produces the pesticidal protein as it would one of its own components.

5. How does the federal government regulate plant-incorporated protectants and ensure their safe use in foods?

EPA regulates the manufacture, sale and use of pesticides, including plant-incorporated protectants, in the United States. In addition to ensuring that registered pesticides will not pose unreasonable adverse effects to human health and the environment when used in accordance with the label, the Agency also assures that pesticide residues in food are safe by setting limits on the amount of a pesticide residue that can be present on foods (called a food tolerance).

Under these rules, unless a plant-incorporated protectant falls under a legal exemption, EPA must register it and set a food tolerance for residues of the plant-incorporated protectant (or determine on a case-by-case basis to exempt it from the food tolerance requirement) before it can be marketed.

FDA scientists test food commodity samples to see if any substances, such as plant-incorporated protectant residues, are present in unacceptable amounts. If contaminants are identified, FDA takes

corrective action. FDA also examines food labeling standards to ensure that such labels are not misleading and to help consumers know what is in the foods they buy.

The plant itself is regulated by the United States Department of Agriculture (USDA). USDA also regulates crops genetically engineered to be resistant to herbicides, but not the herbicide produced by the plant. (EPA regulates any pesticide used on herbicide resistant plants).

6. How will the plant-incorporated protectants rules change EPA's current registration process?

The rules clarify which plant-incorporated protectants are required to be evaluated under FIFRA and FFDCA and which plant-incorporated protectants are exempt. EPA has been reviewing and registering plant-incorporated protectants since publication of the proposed rules and policies in 1994. As a result, the final rules largely formalize EPA's existing process for regulating plant-incorporated protectants and do not change significantly EPA's current system for scientifically evaluating a plant-incorporated protectant.

7. What are the benefits of plant-incorporated protectants?

Plant-incorporated protectants can be a promising pest management alternative where traditional pesticides may not be as effective and/or where other options may be more expensive. In some cases, the use of plant-incorporated protectants could increase crop yield and/or reduce farmers' costs; provide additional tools for integrated pest management programs, and provide other environmental benefits. Plant-incorporated protectants can be used as a part of Integrated Pest Management and have the potential to reduce the use of conventional pesticides, which may pose higher risk to human health and the environment.

8. Who did EPA consult with outside of the Agency in making this rule?

EPA consulted with many agencies, organizations, and individuals in the process of finalizing the plant-incorporated protectant rules, including FDA, USDA, the Department of Commerce, and the United States Trade Representative. Since 1994, EPA has held workshops, requested advice from two scientific advisory committees, the Scientific Advisory Panel (SAP) and the Biotechnology Science Advisory Committee, testified to Congressional committees, and met with numerous groups and individuals. The meetings of the scientific advisory committees also provided the public with additional opportunity to comment. Many public comments were collected through the docket and carefully considered in the process of finalizing the rules.

9. Will the plant-incorporated protectants rules affect the Bt reassessment?

No. To ensure that our biotechnology assessments reflect the latest data on health and ecological effects, EPA is in the process of reviewing currently registered genetically modified plants expressing *Bacillus thuringiensis* (Bt) products. Such Bt products are categorized as plant-incorporated protectants and are registered under FIFRA. All Bt plant-incorporated protectants have already been assessed on a case-by-case basis; therefore, the plant-incorporated protectant rules will not affect current registration of Bt products.

10. Will there be an opportunity to comment?

In a supplemental notice accompanying the final rule package, EPA is soliciting additional information and public comment on issues from the 1994 proposal not finalized in these rules. In addition, we are opening a public comment period on the NAS report, published in April 2000, entitled “Genetically Modified Pest-Protected Plants: Science and Regulation,” as it relates to plant-incorporated protectants derived through genetic engineering. EPA plans to make final determinations regarding additional rulemakings within nine to twelve months after the close of the comment period. Currently, the comment period is set at 30 days. Please send your comments to the public docket at

US EPA
OPP Public Regulatory Docket (7502C)
Docket No. OPP-300369B
Ariel Rios Building
1200 Pennsylvania Ave. NW
Washington, DC 20460.

For more information on EPA’s biotechnology program, you may visit our web site at www.epa.gov/pesticides/biopesticides.