

# How Biotech Crops are Evaluated for Environmental Safety in the United States

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First generation biotech crops (herbicide and insect resistant plants) have been in commercial use since 1995 in the United States. Farmers are adopting this technology readily because of two primary reasons: (1) it simplifies weed or insect management in their agricultural production systems, and (2) the economic benefits outweigh the costs.

A common concern with the release of any biotechnology derived product is the effects it could have on the environment. In the previous chapter titled, "Is this Stuff Safe to Eat?," the regulatory agency we focused on was the FDA (United States Food and Drug Administration). When deciding whether or not a genetically engineered product is safe for the environment, the primary regulating agencies involved are the United States Department of Agriculture (USDA) and the United States Environmental Protection Agency (EPA). All three agencies (USDA, FDA, and EPA) overlap in their responsibilities, but each also has unique duties.

## **The Roles of the USDA and the EPA**

In the United States, when determining if a food crop is safe enough to be grown in the environment the USDA and EPA are the most involved agencies.

## **United States Department of Agriculture (USDA)**

The USDA is a regulatory agency that monitors and regulates the use of biotechnology for agricultural purposes. They have the responsibility of reviewing data generated from field trials to determine whether a product or crop would have the potential to become a plant pest or cause any detrimental effects on the environment. Genetically engineered herbicide-tolerant crops are included in this because they do not actually produce a pesticide, which would be the responsibility of the EPA (discussed below). Instead, herbicide-tolerant crops are engineered to produce a protein which are resistant to a specific herbicide sprayed on them. An example of this is glyphosate-tolerant soybean, corn, and canola.

The USDA is comprised of several agencies that are all designed to advise different groups to meet their specific needs. An example is the Animal and Plant Health Inspection Agency (APHIS). The Animal and Plant Health Inspection Agency regulates

the movement, importation, and field testing of genetically engineered organisms through permitting and notification procedures. APHIS also is responsible for inspecting veterinary biologics production. A few other agencies included within the USDA are the Forest Service, Risk Management Agency, and Agricultural Research Service.

## **Environmental Protection Agency (EPA)**

The EPA's mission is to protect the quality and health of the environment. In terms of protecting the environment from biotechnology products, their main focus is on the regulation of pest management products. There are three categories of pesticides the EPA reviews for registration. The three pesticide categories are antimicrobials, biopesticides, and conventional pesticides. Before a pesticide can be used, it has to be approved by the EPA to ensure that it is not harmful to humans or the environment. For this article, we will focus on the EPA's role in regulating biopesticides, specifically Plant-Incorporated Protectants (PIPs). Biopesticides consist of biochemical pesticides, microbial pesticides, and PIPs. Plant-Incorporated Protectants are pesticidal substances produced by plants containing added genetic material. When regulating PIPs, the EPA regulates the new protein and its genetic material, not the plant itself.

## **Regulation**

Biotech crops go through rigorous testing for several years before they are ever put on a farmer's field. In the U.S., there are nine steps in the regulatory process that usually take seven to ten years to complete, which is far more rigorous of a process than any conventionally derived food ever goes through. The USDA/APHIS is responsible for ensuring that any released organisms are safe and will not pose any negative effects on the environment, whereas the EPA evaluates the safety of transgenic plants containing PIPs. They consider where and how the protein is produced in the plant and its potential to be toxic to humans and other organisms.

Before pesticides can be marketed, the EPA considers factors regarding PIPs such as:

- Risks to humans
- Risks to non-target organisms and the environment
- Gene flow potential
- Insect resistance management plans

The EPA also requires certain tests to be conducted to identify any risks to humans and the environment. These tests are listed below.

- Identification of new genetic material and all new proteins
- Mammalian toxicity testing of all new proteins

- Comparison of new proteins to known toxins and allergens
- Toxicity testing on birds, fish, earthworms, insects such as bees, ladybird beetles, and lacewings
- Toxicity testing on insects related to target insect pests
- Length of time required for the new proteins to degrade in the environment

The development of a transgenic plant requires researchers to meet with one or more regulatory agency (EPA, USDA/APHIS, or FDA) to discuss the outline of the projects and decide which studies will be necessary to ensure safety of the end product. Throughout the study the developer sends the data of the ongoing research to the appropriate agency. For many biotech crops, the product then goes through a deregulation process in which the USDA/APHIS reviews the data received from the developer and decides whether or not the transgenic plant causes a negative outcome in the environment by genetically crossing with native species or out-competing them. They also try to ensure that the transgenic plant does not have any negative effects on wildlife, and does not become a “super-weed.” The overall goal of the regulatory agencies is to ensure that biotech crops are as safe as their non-genetically modified counterparts.

### **Preventing a “Super-weed” and Insect Resistance**

A “super-weed” can occur in two ways: (1) when pollen from a genetically modified crop pollinates a weedy relative and that weedy relative then becomes resistant to the herbicide that was originally produced to kill it, and (2) when an herbicide-tolerant crop escapes cultivation and becomes a weed. For this reason, the EPA developed a regulatory framework to ensure that the appropriate tests are done to maintain that biotech crops are safe for the environment. They have not approved a genetically engineered crop that is known to have a weedy relative on the continent in which it grows. Many of our major crops, such as cotton and corn, are not native species to North America and their weedy relatives do not grow near them. For the crops that do have weedy relatives, the concern of a super-weed is not a new problem. For years plant breeders have bred plants to be superior agriculturally to any wild plant, and when grown near their weedy relatives they can already cross-pollinate and transfer their genes. An example of this is sunflowers grown for agricultural purposes can, and do, cross pollinate with wild sunflowers.

A concern with insect resistant crops, such as Bt corn, is that insects feeding upon the corn will eventually become resistant to the transgenic plant, defeating the purpose of

growing the insect-resistant plant. The EPA has taken precautions to help prevent this scenario by requiring farmers who grow genetically engineered crops to also grow conventional crops nearby as “refuges” where insects aren’t exposed to the genetically modified crop that contain insect resistance. In theory this allows non-resistant insects to continue breeding and remain present in the environment, and mate with any resistant survivor of the genetically modified crop. A non-resistant insect that mates with a resistant insect helps to ensure that the dominant gene of non-resistance evolves from one generation to the next, which maintains a population of insects that will still be susceptible to the insect-resistant crops. There are also issues surrounding the topic of harming beneficial insects with genetically engineered plants. To date, there have been no observed effects on beneficial insects. It is important to keep in mind that conventional methods of spraying crops for insect pests kill many beneficial insects and are not as specific on insect targets as transgenic crops resistant to a certain species of insect.

### **Helping the Environment**

Over the years, as biotech crops have been grown, the notion that transgenic crops are actually improving the environment and may be safer to use has been a topic of debate. The “healthy environment” idea has arisen because the amount of herbicides put on herbicide-resistant crops is usually less than conventional crops and the herbicides used (mainly glyphosate) are often less toxic than other chemicals used on agricultural crops. A study conducted by Gianessi et al. (2002), confirmed that soybeans, corn, cotton, papaya, squash and canola, all crops using genetic engineering that are currently on the market, helped to reduce the pesticide volume by approximately 46 million pounds during 2001.

Genetically engineered crops have an awesome potential to benefit people from all parts of the world. For this technology to be successful, regulatory processes are important to establish and implement. As biotechnology evolves, the regulatory agencies will surely have to re-structure their process to best ensure that products are safe and to be mindful so as not to inhibit the technology from moving forward. For the years that these biotech crops have been on the market, it is uncertain even to the people who have performed all the safety checks, what the long term results these plants will have on the environment, and humans. All new ideas or technologies will have risks associated with them, but the technologies that last are those whose benefits outweigh the risks. To date there have been no confirmed adverse health

effects from biotech products. The regulatory agencies involved are doing what they believe is best at the moment to ensure that each product is safe.

**Notes:**

1 - [EPA] Environmental Protection Agency. 2005.

<http://www.epa.gov/pesticides/biopesticides/pips/index.htm>

2 – Federoff, N. V. 2001. What is the future of GMO's? In Teich, A.H., Nelson, S.D., McEnaney C., Lita, S.J. (eds.) AAAS Science and Technology Policy Yearbook. NW, Washington DC. <http://www.aaas.org/spp/rd/ch13.pdf>  
<http://www.aaas.org/spp/rd/yr01pref.pdf>

3 – Gianessi, L.P., Silvers, C.S., Sankula, S., Carpenter, J.E. 2002. Plant Biotechnology: current and potential impact for improving pest management in U.S. agriculture. National Center for Food and Agriculture Policy. <http://www.ncfap.org>

4 – Gregory, J., and Miller, S. 1998. Science in the Public: Communication, Culture, and Credibility. Plenum Press. New York. Ch. 7 pg. 166.

5 – Oliver, G.R., Gibson, J.E., Wolt, J.D., Shanahan, D.M. 2000. Biotech foods: a closed and reopened case. Chemical Innovations. 30(7): 12-19.

6 - [USDA] U. S. Department of Agriculture. 2005. Agencies and Offices

[http://www.usda.gov/wps/portal/!ut/p/\\_s.7\\_0\\_A/7\\_0\\_1OB?navid=AGENCIES\\_OFFICE\\_S\\_C&parentnav=AGENCIES\\_OFFICES&navtype=RT](http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?navid=AGENCIES_OFFICE_S_C&parentnav=AGENCIES_OFFICES&navtype=RT)

7 – Vines, R. 2002. The regulation of biotechnology. Virginia Cooperative Extension. <http://www.ext.vt.edu/pubs/biotech/443-006/443-006.html>

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