

# **Federal Oversight and Regulation of GM Crops**

## **Biotechnology**

Biotechnology or genetic modification is the practice of extracting a gene carrying a desired trait and inserting it into the DNA of another organism (from the same or different species). This process allows plants and animals to exhibit the traits of organisms that could not crossbreed in nature or that would take much longer to develop.

Traditional breeding can take decades to produce breeds in which desired traits are apparent. Genetic engineering speeds up this process by destroying natural boundaries and limits that exist between and within species.

For example, strawberry DNA can be modified with a gene that keeps fish from freezing, making the strawberry resistant to frost.

## **History of Biotechnology Regulation**

In 1986, after deciding that no new laws were necessary in order to regulate biotechnology, the federal government adopted the Coordinated Framework for Regulation of Biotechnology. This policy operates under two assumptions: 1) biotechnology poses no distinct risk to human health, agriculture or the environment and 2) a commercial product should be regulated according to its intended use and makeup, regardless of how it is developed.<sup>1</sup>

Under these guidelines, plants and foods produced with biotechnology do not require any distinctive or additional testing than foods produced conventionally, although they still must comply with any state or federal safety regulations before release into the environment and/or commercial markets.

## **Regulation at the Federal Level**

There is no one statute or federal agency devoted to the regulation of biotechnology. All products created with biotechnology must comply with state and federal safety regulations before release into the environment and/or commercial markets. The regulation of genetically modified plants and organisms falls under the jurisdiction of three federal agencies: U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA), and Environmental Protection Agency (EPA).

Each agency has specific roles in regards to determining the safety of genetically modified products. There are at least 11 laws that give the agencies authority, and some products are regulated by more than one agency. These laws were developed before the widespread use of biotechnology. The approval process for a genetically modified plant can take 10 years or more.

## **USDA/APHIS**

Protection from pests and diseases falls under the jurisdiction of the Animal and Plant Health Inspection Service (APHIS) within USDA. APHIS determines whether a new product is safe to grow, and is responsible for assuring that the introduced plant cannot harm native plants and organisms.<sup>2</sup> With the authority of the Federal Plant Pest Act and the Plant Quarantine Act, APHIS also regulates environmental safety of the field testing of genetically modified plants.

Products that fall under USDA's jurisdiction include plants, plant pests, and veterinary biologics. USDA also determines that the research facilities are adequate for continued research and development.

The company developing the plant or product must also apply to USDA for approval to conduct field trials. When approval is granted, USDA-APHIS officials may inspect the test plots at any time to ensure the research is being done safely.

All new agricultural products that could potentially be introduced into the U.S must go through the APHIS application process. Introducing a product includes any import into or any interstate movement within the United States, as well as a release into the environment outside of a physically confined area.

For example, biotechnology companies such as Monsanto must apply to APHIS for deregulation of a new variety of plant before they can sell it in commercial markets. According to the APHIS website, the application must include “a full statement explaining the factual grounds why the organism should not be regulated...copies of scientific literature and copies of any unpublished studies” as well as data from any testing.<sup>3</sup> The application also requires that any “unfavorable” information concerning the plant must be included in the application; if no such information known to the petitioner, the petitioner must only note that in the application.

More than 1,000 field trials are authorized by APHIS each year. APHIS annual budget for post-market oversight of field trials is \$4 million.<sup>4</sup>

USDA also supervises any movement of seeds from research facilities to field test plots until a “determination of non-regulated status” is granted. For this to happen, APHIS must review all field trial studies and determine that the plant will pose no significant risks to the environment or to wildlife. This process can take nearly a year and requires the developer to provide specific scientific data, including:

**Environmental Effects:** if the plant could crossbreed with other plants

**Wildlife Effects:** if the plant could have adverse effects on wildlife

**Weediness:** if the plant has the potential to become a “superweed”

Current regulations do not require APHIS to conduct tests or studies on their own; they may rely on the information submitted to them by the developing company.

Plant developers must also submit copies of this application to the state agriculture departments for review. At this time, the plant’s safety is determined, and APHIS has the authority to halt any further development or approve restricted use.

## EPA

The EPA must determine if the product is safe for the environment and assess the pesticidal properties of plants that were designed to protect themselves against insects and viruses. However, herbicide-resistant plants are treated the same as conventional plants; the EPA can only regulate the amount of pesticides that can be applied to the plant.

Products under EPA’s jurisdiction include microbial/plant pesticides, new uses of existing pesticides and novel microorganisms. The BioPesticides and Pollution Prevention Division of the Office of Pesticide Programs regulates the distribution, sale, use and testing of plants and microbes that produce plant incorporated protectants (PIPs) and ensures the safety of pesticides, both chemical and those that are produced biologically.

If the plant variety being developed is resistant to any pesticides, the EPA must also grant approval. An Experimental Use Permit must be granted for test plots of 10 or more acres.

The EPA also establishes tolerance levels for plants containing pesticide resistant genes. To do this, the EPA considers the following questions:

**Product Characterization:** Where in the plant are the new traits expressed? Do the traits act the same way in the new plant as they did in nature? What is the exact action or pesticidal substance produced in the plant?

**Toxicology:** Is the introduced gene or trait toxic? How long does it take this protein to break down in the digestive system?

**Allergenicity:** Does this protein break down like other proteins? (This helps the EPA determine if the plant may cause an allergic reaction, in which case the plant and all products derived from it would require special labeling.)

**Non-target Organisms:** Is the protein toxic to wildlife or insects? Will wildlife be exposed to toxic proteins? If so, how?

**Environmental Fate:** How fast does the protein break down in the soil?

**Potential Pest Resistance:** What other steps must be followed to ensure pest resistance<sup>5</sup>?

Finally, before granting approval, EPA examines all relevant environmental and toxicological information. This process can take 18 months. EPA has the authority to halt development and sale of the plant at any time if findings reveal that the plant is unsafe, or it can issue planting restrictions as a condition of approval.

## **FDA**

The FDA is the primary agency for regulating and establishing safety requirements for all food intended for human consumption, with the exception of meat and poultry but including dairy products.<sup>6</sup> The FDA also regulates animal feed, food additives, and veterinary and human drugs.

The Federal Food, Drug and Cosmetic Act (FFDCA) was established to promote fairness with regulations that specify quality standards for food intended for human or animal consumption. Examples falling under FFDCA include the genetic modification of food-producing animals to produce a human vaccine, to enhance the nutritional value of food products derived from that animal, or to increase the animal's growth rate, reproduction, or disease resistance.

As part of the Department of Health and Human Services, FDA regulates foods and feed produced from new plant varieties, and determines if they are safe for human consumption. FDA's policy, adopted in 1992, is based on existing food law, only requires that genetically modified foods meet the same safety and nutritional standards required of conventionally produced foods. Under this policy genetically modified (GM) food is considered to be "generally recognized as safe" (GRAS) and does not require safety testing unless there is reason for concern *in the judgment of the manufacturer*.<sup>7</sup>

FDA's guidelines consider the following when evaluating GM food:

**Introduced material:** Is the new gene already present in other food? Is this gene comparable to genes already present in food? Is the gene allergenic?

**Biological and Agronomic Properties:** How are the biologic and agronomic properties of the GM plant different from its conventional counterpart?

**Nutritional Composition:** Will nutrients, vitamins, and minerals occur at the same level as conventionally grown plants?

The CFRB only applies to substances intentionally added to food through genetic modification if they are significantly different in structure, function, or amount than traditional substances found in food products. However, according to the FDA, many of the food crops currently being developed using biotechnology do not contain substances that are *significantly different* from those already in the diet and thus do not require pre-market approval.<sup>8</sup>

FDA requires that all developers of GM products notify the agency and submit all research at least four months in advance of releasing them into the market. FDA does not do any

safety testing of its own; relying instead on the results of studies completed by the company applying for deregulation.

In the early 1990's FDA scientists warned the agency that genetic modification could create instable genes that may increase levels of toxins in food. The scientists recommended that long-term testing be done on genetically modified foods before they are released into the market.<sup>9</sup>

**SIDE BAR** – In the mid 1990's Calgene Flavr Savr™ tomatoes were designed to ripen on the vine and have a longer shelf life. Despite the fact that these tomatoes caused stomach lesions when given to lab rats, the FDA and Canadian government still allowed the tomatoes into commercial markets. Due to poor quality, insufficient disease resistance and poor consumer response, the Flavr Savr™ tomatoes failed in commercial markets. Calgene, close to bankruptcy, was then bought by Monsanto.

### **Post-Market Regulation**

Post-market regulation of biotech crops must be handled differently than conventional crops because GM crops can cross-breed with conventional crops and/or enter a food supply they were not approved for. Additionally, GM crops approved in the U.S. are commonly not approved for use in Europe and Asia; contamination of the conventional supply may disrupt or end U.S. exports to many countries.

### **Gaps in Regulatory Oversight**

According to the Pew Initiative on Food and Biotechnology, regulatory oversight of biotechnology is focused almost solely on pre-market approval. Post-market oversight, which includes guidelines such as requiring buffer zones between conventional and GM crops, seems to be less of a priority, and because of this resources are limited for this phase of regulation, resulting in gaps in federal oversight.

The U.S. government considers the identity preservation (IP) of GM foods in regards to potential contamination of non-GM foods a commercial issue, which must be dealt with by sellers ensuring customer satisfaction<sup>10</sup>

The USDA, EPA, and FDA neither have the authority or resources to conduct any post-market testing on GM products. The “substantial equivalent” and GRAS policies may be the result of reliance on biotech companies for data concerning the safety of new products.

### **USDA**

**Biotech Oversight Role:** To regulate and inspect field trials

#### **Gaps:**

- USDA/APHIS does not have the authority under the CFRB to monitor the use of GM crops once they have been deregulated, nor can they require biotech developers to monitor those crops' impact on the environment after the crops have been released.
- Although recommended by a National Academy of Sciences committee, current regulations do not require APHIS to conduct independent tests or studies; they rely instead on information submitted to them by the plant developer<sup>11</sup>.

### **EPA**

**Biotech Oversight Role:** To regulate the environmental safety of PIPs and to ensure their safety in food products

### **Gaps:**

- Farmers are not legally accountable to EPA for meeting standards set for pesticide use; there are no federal guidelines or audits that monitor farmers' pesticide use.
- EPA guidelines hold the biotech company accountable for assuring that farmers are in compliance with pesticide use restrictions. The companies are expected, through the use of grower agreements, to monitor the use of their pesticides in the fields based on information given by farmers.
- EPA has no budget for ensuring compliance or guidelines that determine a level of compliance; it relies on reports by the biotech companies.

### **FDA**

**Biotech Oversight Role:** To regulate the safety of foods made from biotech crops and to enforce EPA's limitations of PIPs in food

### **Gaps:**

- Because of its GRAS policy, FDA has no post-market inspection or compliance guidelines for biotech foods, although it does have guidelines for other food and drug products under its jurisdiction.
- There are also questions about whether FDA has adequate resources and authority to do testing and inspections on a large scale should concerns arise over a biotech crop<sup>12</sup>.

### **Regulatory Neglect**

In 1998, a lawsuit was filed against FDA by a group of consumer advocates, scientists, claiming that FDA failed to carry out its regulatory obligations. During the proceedings, FDA had to release internal documents stating that FDA scientists opposed the GRAS policy, and had recommended that extensive testing be done on each new GM product.

### **SIDE BAR - Brazil Nuts, Soybeans and Starlink Corn**

Soybeans are an important source of protein in livestock diets, although they are naturally deficient in the essential amino acid methionine. Animals with a diet consisting mainly on soybeans also require methionine as a dietary supplement.

In the early 1990's researchers at Pioneer Hi-Bred International developed a variety of soybean that contained a gene from a Brazil nut, which has a naturally high content of methionine, and is also a known food allergen.

Although these soybeans were developed for animal and not human consumption, Pioneer could not be certain these they could be kept from the human food supply. The company funded a study at the University of Nebraska to determine the health effects of the soybeans on humans. The study found that humans with an allergy to Brazil nuts were also had adverse effects to the soybeans, and Pioneer abandoned the project.

Less than 10 years later, in 2000, a variety of GM corn called Starlink™ was discovered Taco Bell taco shells, by Friends of the Earth, an environmental group. Starlink corn was genetically modified to contain a bacterium called *Bacillus thuringiensis* (Bt), which allows the plant to produce its own pesticide.

Starlink™ corn was approved in 1998 by the EPA for animal feed only and given a zero tolerance level for human food, as there was concern that it could cause allergies and because the Bt protein is not easily digestible by humans. Aventis, the company that developed Starlink™,

was required to inform farmers about the planting and sale restrictions of the corn to help ensure the corn did not enter the food supply.

In September 2000, Taco Bell brand taco shells tested positive for Starlink corn. 300 corn products in the U.S. were recalled including taco shells, taco chips, tortillas, and tostadas. Starlink was also found to have contaminated corn meant for export to Canada, Korea, and Japan, although it is only approved for use in the U.S. It is not known exactly how much Starlink entered the food supply, but experts believe that over 1 billion bushels of corn may have been contaminated in Iowa alone.

Evidence shows that Aventis and the federal government might have known at least six months before it was discovered that Starlink™ was entering the human food supply. A survey conducted by Aventis in December 1999 found that 2 of the 230 farmers who were growing Starlink had sold the corn for food use or export. The study also found that almost 13% of the farmers said they did not know what had happened to the corn after it was sold. Aventis sent the results of this survey to the EPA on January 27<sup>th</sup>, 2000, nine months before Starlink™ was discovered in taco shells.

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1 For more information, see Pew Initiative on Food and Biotechnology's Guide to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products

2 A list of products approved for deregulation is available at the APHIS web site:  
[http://www.aphis.usda.gov/biotech/not\\_reg.html](http://www.aphis.usda.gov/biotech/not_reg.html)

3 APHIS Biotechnology Permits -- 7 Code of Federal Regulations part 340  
<http://www.aphis.usda.gov/brs/7cfr340.html#340.6>

4 Post-Market Study of Biotech Foods. Pew Initiative on Food and Biotechnology.  
<http://pewagbiotech.org/research/postmarket> April 2003.

5 Plant Biotechnology Regulation. CropLife America. <http://www.croplifeamerica.org>

6 The safety and accurate labeling of meat and poultry is regulated by the USDA Food Safety and Inspection Service (FSIS).

7 <http://www.mercola.com/2001/jul/14/biotech4.htm>

8 Department of Health and Human Services, FDA. Docket No. 92N-0139 Statement of Policy: Foods Derived from New Plant Varieties; <http://vm.cfsan.fda.gov/~lrd/bio1992.html>

9 CFS Lawsuit Reveals U.S. FDA Genetically Engineered Foods Policy Issued Over the Objections of Agency Scientists. <http://www.centerforfoodsafety.org/li/GEexec.html>

10 Post-Market Study of Biotech Foods. Pew Initiative on Food and Biotechnology.  
<http://pewagbiotech.org/research/postmarket> April 2003.

11 Post-Market Study of Biotech Foods. Pew Initiative on Food and B88iotechnology.  
<http://pewagbiotech.org/research/postmarket> April 2003.

12 Post-Market Study of Biotech Foods. Pew Initiative on Food and Biotechnology.  
<http://pewagbiotech.org/research/postmarket> April 2003.