

Low-Level Presence

Agricultural Genetic Engineering

Genetic engineering (GE) is a precise and predictable method used to introduce new traits into plants and animals by moving genes and other genetic elements from one or more organisms into another organism.

- GE crops are being produced that have a wide variety of traits that benefit farmers and consumers. For example, GE crops can tolerate drought conditions and herbicides, resist insects and viruses, and provide enhanced quality and nutrition for consumers. GE crops are being developed by private companies, universities, and other researchers.
- GE crops that are currently consumed for food, fiber or feed include corn, soybeans, cotton, canola, and squash.
- USDA's National Agricultural Statistics Service estimates that in 2006, 61 percent of the corn, 83 percent of the cotton and 89 percent of the soybeans planted in the United States were biotech varieties.

Biotechnology Regulatory Authority

Under a coordinated regulatory framework, USDA's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA) share responsibility for regulating biotechnology products to ensure that approved biotechnology products developed in the U.S. pose no risk to human health or the environment.

APHIS, through its Biotechnology Regulatory Services (BRS) program, oversees the development and introduction (importation, interstate movement and environmental release) of GE organisms. The Agency is committed to ensuring that this technology moves forward safely through our rigorous regulatory system. Developers must adhere to certain performance standards or conditions that ensure that the regulated GE organisms do not persist in the environment or enter the food or feed supply. Depending on the field test, these conditions could include stringent confinement measures, such as isolation distances, to prevent pollen flow; clean equipment and containers to prevent cross-contamination; and labeling of all regulated articles to prevent accidental use or incorporation with other crops. At the end of all field tests, developers must destroy or properly handle or contain any viable

plant material in the field and ensure that no regulated materials persist in the environment beyond the duration of the trial.

APHIS Policy On Responding To The Low-Level Presence Of Regulated Genetically Engineered Plant Materials

APHIS is clarifying the Agency's existing approach for handling detections of regulated GE plant material in commercial seeds and grain.

- APHIS' policy is to respond to these occurrences with actions appropriate to the level of risk and warranted by the facts in each case.
- APHIS will always initiate an inquiry whenever regulated materials are detected in commercial seeds and grain to evaluate any risk, to determine the circumstances surrounding the release and to determine what remedial and/or enforcement actions may be required.
- If APHIS determines that an occurrence involving regulated GE plant material could pose a risk to plant health or the environment, APHIS will take appropriate steps to mitigate that risk using its authority under the Plant Protection Act (PPA).
- In cases in which APHIS determines that action may not be necessary to mitigate the low-level presence of the regulated GE plant material to protect plant health and the environment, APHIS is not precluded from taking enforcement action against a company or individual for violations of APHIS regulations.
- APHIS considers six safety-related criteria when determining a GE plant material's potential to pose a risk to plant health or the environment. The criteria are:
 1. The plant is not a Federal noxious weed or considered a weed in the area of introduction.
 2. The introduced genetic material must remain inside the living cell and replicate only with the plant DNA.
 3. The introduced genetic material's function is known and does not create a plant disease.
 4. The introduced genetic material does not create an infectious entity or unintended toxins, or produce products intended for pharmaceutical or industrial use.
 5. The introduced genetic material does not cause the creation of a new plant virus.
 6. The plant does not contain genes from animal or human pathogens, or contain coding sequences whose products are known agents of diseases in humans or nontarget animals.

Glossary Of Terminology

Agricultural Biotechnology: A range of tools, including traditional breeding techniques, that alter living organisms, or parts of organisms, to make or modify products; improve plants or animals; or develop microorganisms for specific agricultural uses. Modern biotechnology today includes the tools of genetic engineering.

Deregulated: If a GE crop has gone through the regulatory process for USDA to determine that it can be safely commercialized, it is commonly referred to as being a deregulated crop. This is necessary before it is sold and produced commercially. It allows the product to be moved and planted freely without the need for notification or permits. A developer may file a petition for deregulation only after a GE crop has been tested extensively and the developer can show that the product does not pose a plant pest risk.

Gene: The fundamental physical and functional unit of heredity. A gene is typically a specific segment of a chromosome and encodes a specific functional product (such as a protein or RNA molecule).

Genetic engineering: Manipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques.

Herbicide-tolerant crops: Crops that have been developed to survive application(s) of particular herbicides by the incorporation of certain gene(s) either through genetic engineering or traditional breeding methods. The genes allow the herbicides to be applied to the crop to provide effective weed control without damaging the crop itself.

Low-level presence: The low-level mixing of genes and gene products from unintended plant sources. This can occur with both conventionally bred plants as well as biotechnology-derived plants. These occurrences can result from natural processes such as the movement of seeds or pollen, or human-mediated processes associated with field testing, plant breeding, or seed production.

Protein: A molecule composed of one or more chains of amino acids in a specific order. Proteins are required for the structure, function, and regulation of the body's cells, tissues, and organs, and each protein has a unique function.

Regulated: If a GE crop has not gone through the regulatory process for USDA to determine if it can be safely commercialized, it is commonly referred to as being in regulated status or a regulated crop.

Remedial measures: APHIS has authority under the PPA to take or order remedial measures which include the authority to hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of regulated materials if it is determined that such measures are necessary to prevent the dissemination of a plant pest within or throughout the United States.

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