



Biotechnology Facts

Office of the United States Trade Representative
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Agricultural Biotechnology: The U.S. Biotechnology Regulatory System

- The United States government has a coordinated, risk-based system to ensure new biotechnology products are safe for the environment and human and animal health.
- The U.S. regulatory process ensures that all biotech products that are commercially grown, processed, sold, and consumed are as safe for the environment and for human and animal health as their conventional counterparts. Biotechnology in the United States is rigorously regulated under a risk-based system and was initially established in 1986 under the Coordinated Framework. The U.S. government's regulatory system is transparent, predictable, open to public comment, and based on sound science. It is continuously reviewed and evaluated to ensure that it meets the challenges of this evolving technology. The agencies responsible for its regulation are the USDA's Animal and Plant Health Inspection Service, the Environmental Protection Agency, and the Food and Drug Administration.
- USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for protecting American agriculture against pests and diseases and ensures that biotech products are safe for agricultural and the environment. APHIS is the U.S. government's lead agency regulating the safe field-testing of biotechnology-derived, new plant varieties and certain microorganisms. APHIS also approves and licenses veterinary biological substances, including animal vaccines, which may be products of biotechnology.
- The Environmental Protection Agency (EPA) is responsible for regulating herbicidal and pesticidal substances, including those that are the product of biotechnology, to ensure that such products can be safely used. This includes oversight of field testing and commercial-scale use of herbicides and biotechnology-derived plants containing pesticidal substances. In reviewing a pesticide, EPA evaluates human safety, including whether consumption of the pesticide residues in food is safe, the fate of the substance in the environment, its effectiveness on the target pest, and any effects on other, "non-target" species.
- The Food and Drug Administration (FDA) is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those developed through bioengineering. All foods and feeds, whether imported or domestic and whether derived from crops modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards. In addition, any food additive, including one introduced into food or feed by way of plant breeding, must receive FDA approval before marketing.
- Every biotech plant variety commercially grown in the United States has gone through the necessary regulatory process at APHIS, EPA, and FDA.

Please consult the links below for further information on the U.S. regulatory system:

- <http://usbiotechreg.nhii.gov/>
- <http://www.aphis.usda.gov/publications/biotechnology/index.shtml>