BRS Factsheet
Biotechnology Regulatory Services

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service

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Questions and Answers: Biotechnology and the USDA

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Biotechnology

Q. What is agricultural biotechnology?
A. Agricultural biotechnology is a range of tools—including both genetic engineering and traditional breeding techniques—that alter living organisms or parts of organisms to make or modify products, improve plants or animals, or develop micro-organisms for specific agricultural uses.

Q. What is genetic engineering?
A. Genetic engineering 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 organism(s) into a second organism. In its regulations for genetically engineered (GE) organisms, the U.S. Department of Agriculture (USDA) defines genetic engineering as the genetic modification of organisms by recombinant DNA (rDNA) techniques.

Q. What are GE crops designed to do?
A. GE crops have a wide variety of traits that can benefit farmers, consumers, and the environment. For example, GE crops can tolerate drought conditions and herbicides, resist insects and viruses, and provide enhanced quality and nutrition for consumers.

Regulating Biotechnology

Q. Who is responsible for regulating GE crops?
A. The three main Federal agencies responsible for regulating the safe use of organisms derived from modern biotechnology are the USDA's Animal and Plant Health Inspection Service (APHIS), the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA). These agencies work together in what is commonly referred to as the Coordinated Framework for the Regulation of Biotechnology. The White House Office of Science and Technology Policy established this Federal framework as a formal policy in 1986.

APHIS regulates the introduction (meaning the importation, interstate movement, and environmental release/field testing) of certain GE organisms that may pose a risk to plant health. EPA regulates pesticides, including plants with plant-incorporated protectants (pesticides intended to be produced and used in a living plant), to ensure public safety. EPA also sets limits on pesticide residues on food and animal feed. FDA has primary responsibility for ensuring the safety of human food and animal feed, as well as proper labeling and safety of all plant-derived foods and feeds.

Q. How do I know what is regulated by APHIS?
A. The Federal regulations for biotechnology explain what items and processes APHIS regulates and how they may be regulated (e.g., timeframes, permitting procedures, penalties for regulatory violations). These regulations are published in title 7, part 340 of the *Code of Federal Regulations* (CFR). You can download a copy of the regulations online at www.gpo.gov/fdsys/pkg/CFR-2008-title7-vol1/content-detail.html. More information is also available on APHIS' Web site at www.aphis.usda.gov/biotechnology/regulations.shtml.

Compliance

Q. What is the regulatory process for GE organisms?
A. Developers seeking to field-test, move interstate, or import a GE organism must first submit detailed information to APHIS' Biotechnology Regulatory Services (BRS) for review and receive regulatory approval. During its review, BRS assesses the information for potential plant health risks before the introduction can be approved. Depending on the characteristics of the GE organism, a developer either files a *notification letter* or applies for a *permit.*

Q. When would a developer be eligible to use the notification process?
A. GE plants that meet the six specific criteria listed below (per 7 CFR 340.3) are eligible for an administratively streamlined alternative to the permit process, known as "notification." Upon approval, notifications are valid for 1 year from the date of issue. The eligibility criteria are:

1. The GE plant is not listed as a Federal noxious weed and is not considered a weed in the area of introduction.

2. The genetic material must be "stably integrated" into the plant genome.

3. The newly introduced gene's function must be known and not result in plant disease.

4. The newly introduced gene's function must not cause production of a plant pest, cause the plant to produce substances that are toxic to nontarget organisms, or be genetically engineered for the purpose of producing compounds intended for pharmaceutical or industrial use.

5. The newly introduced gene must not cause the creation of a new plant virus.

6. The plant must not have been modified to contain genes from animal or human pathogens.

Q. When is the permit process applicable?
A. The permit process applies to GE plants that do not meet all six criteria for notification and to GE organisms other than plants (e.g., insects, microbes) that fall under APHIS regulation. This process involves a more comprehensive review than notification. Applicants must provide the same data required for notification plus a detailed description of how they will perform a field test, including specific measures to reduce the risk of harm to other plants. Depending on the characteristics of the GE organism, APHIS may impose additional measures and supplemental permit conditions. Permits are valid for up to 3 years from the date of issue.

Q. What system does APHIS have in place to ensure compliance with biotechnology regulations and permit conditions?
A. APHIS has a comprehensive program of proactive measures in place to ensure that biotechnology organizations maintain compliance with all relevant provisions of the agency's regulations, including authorizations under the permitting and notification processes. APHIS officials perform inspections tailored to the specific requirements of the notification or permit. In addition, APHIS provides continuous education and outreach to the regulated community, including the Biotechnology Quality Management System (BQMS) Program. This program, in particular, provides participants with specific tools and guidance to develop a BQMS tailored to their own needs, which helps them to better maintain compliance with APHIS regulations.

Q. How does APHIS address regulatory violations?
A. BRS compliance specialists and APHIS inspectors perform targeted inspections and audits to thoroughly evaluate suspected or reported compliance infractions. The Plant Protection Act of 2000 allows substantial penalties for serious infractions, including fines of up to $500,000, the possibility of criminal prosecution, and other corrective measures. APHIS also works closely with State departments of agriculture and other Federal agencies, including the FDA and the EPA, to ensure compliance with regulations.

Q. Are all release authorizations (i.e., field tests) inspected?
A. Releases under notification are randomly selected for inspection by APHIS. All releases under permit are inspected once in each State each year.

Q. What are common compliance infractions?
A. Compliance infractions can range from administrative issues, such as the wrong name on a permit, to more serious infractions, such as failure to observe separation distances. Unforeseen events such as the accidental release of a regulated article or the destruction of a field test by livestock, wild animals, or strong winds can also be considered infractions when they result in violations of permit conditions. Even though developers have no control over these events, it is important to notify APHIS immediately so that mitigation measures can be implement-

ed quickly. Developers must notify APHIS of all possible compliance infractions, and failure to do so immediately is itself a compliance infraction.

Q. What role does APHIS play to ensure commercial food and feed is free of field-test materials?
A. When APHIS issues a permit for the movement, importation, or field testing of a GE organism, the developer must adhere to certain conditions to ensure that the regulated GE organism does not enter the food or feed supply. These conditions include confinement measures, such as separation distances, to prevent pollen flow; regularly cleaning all equipment and containers and keeping them in good working order; and labeling all regulated articles to prevent accidental use or incorporation with other crops. If a regulated GE organism becomes intermingled with unregulated GE food or feed, government agencies have the authority to seize the food or feed and require its destruction to prevent it from entering the food supply. At the end of all field tests, developers must destroy or properly dispose of any viable plant material and ensure that no regulated articles persist in the environment beyond the duration of the trial.

Determining Nonregulated Status

Q. How is nonregulated status determined?
A. Under the Plant Protection Act of 2000 and 7 CFR 340.6, if developers (applicants) can demonstrate that a GE organism is not a plant pest, they can submit a petition (request) to APHIS for a determination of nonregulated status; this status means that the GE organism is no longer subject to regulatory oversight under 7 CFR part 340. The petitioner must provide data, often gathered through confined field tests regulated by APHIS, to help inform APHIS' decision. APHIS analyzes data from the petitioner, researches current scientific findings, and prepares a plant pest risk assessment (PPRA) in accordance with the Act.

APHIS also prepares documentation required by the National Environmental Policy Act of 1969 (NEPA). Under NEPA, all Federal agencies must take a close look at the potential environmental impacts of their proposed actions prior to making decisions and provide opportunities for public comment during that process. Therefore, at the same time as it develops a PPRA, APHIS prepares either an environmental assessment (EA) or an environmental impact statement (EIS) to analyze potential environmental impacts the GE plant may have. Once complete, APHIS makes the document available to the public for comment. Overall, the petition process allows for two, and in some cases three, opportunities for public input. After receiving and considering all comments, APHIS determines nonregulated status if it concludes that the GE organism does not pose a plant pest risk.

Q. What is an environmental assessment (EA)?
A. An EA is a concise public document that provides sufficient evidence and analysis for determining whether a proposed Federal action will have a significant impact on the environment. If the agency finds no significant impact during the assessment process, it issues a finding of no significant impact (FONSI), a public document explaining the agency's reasons for this conclusion.

Q. What is an environmental impact statement (EIS)?
A. An EIS is a more detailed document required by NEPA if the agency is proposing a major Federal action that significantly affects the quality of the environment. Specifically, this document informs the decision maker and the public of potential environmental impacts, if any, and what steps may be taken to minimize those impacts. It describes the positive and negative environmental effects of a proposed action and lists at least two alternative actions.

Q. When can a GE crop be safely commercialized?
A. Once APHIS has made a determination of nonregulated status, the GE organism is no longer subject to APHIS regulations and may be freely moved and planted without permits or other regulatory oversight. Most developers will seek to obtain nonregulated status for their organism, along with completing applicable reviews at other agencies, as a practical step toward commercialization.

Q. Where can I find a list of GE crops that have nonregulated status?
A. The United States Regulatory Agencies Unified Biotechnology Web site (www1.usgs.gov/usbiotechreg) contains a searchable database of biotechnology products that have completed reviews for use in the United States. The APHIS biotechnology Web site also provides access to permits, decisions, and information on the biotechnology regulatory process, including deregulation. A list of petitions for determination of nonregulated status is available on APHIS' Web site at www.aphis.usda.gov/biotechnology/not_reg.html.

Q. Does APHIS involve the public in important policy decisions?
A. APHIS makes it a priority to be transparent in all of its procedures, decisions, and activities. On its Web site, APHIS publishes all relevant environmental and regulatory documents for the GE crops it regulates, and it announces regulatory actions and the availability of related documents in the *Federal Register.* APHIS also provides opportunities for public comment on proposed actions through an online system, conventional mail, and at various public meetings.

Q. Where can I go for more information?
A. The APHIS biotechnology Web site (www.aphis.usda.gov/biotechnology/brs_main.shtml) offers access to a wide range of information, including official documents, guidance for GE developers, application status, news, and upcoming events. APHIS also encourages people who are interested in program initiatives and current activities to join its biotechnology stakeholder registry. To receive automatic updates and other useful information, register at https://web01.aphis.usda.gov/BRS/BRSWeb.nsf.

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