BRS Qs&As

Biotechnology Regulatory Services

U.S. Department of Agriculture
Animal and Plant Health Inspection Service

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Questions and Answers About Biotechnology and the USDA

Q. What is the difference between biotechnology and genetic engineering?

A. Though the terms "biotechnology" and "genetic engineering" are sometimes used synonymously, it is more accurate to regard genetic engineering as a modern advancement in biotechnology. Biotechnology began centuries ago when people began using yeasts and bacteria to leaven bread and ferment cheeses. In 1917, the word biotechnology was given to traditional techniques, such as selective breeding, used by farmers to improve the quality of their plants and animals.

Genetic engineering is a recent, 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 organisms, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), defines genetic engineering as the genetic modification of organisms by recombinant DNA techniques.

Q. What are genetically engineered (GE) crops designed to do?

A. GE crops are being produced that have a wide variety of traits that can benefit farmers and consumers. For example, GE crops that can tolerate drought conditions and herbicides, resist insects and viruses, and provide enhanced quality and nutrition for consumers are being tested and grown under controlled conditions by private companies, universities, and other researchers. Genetic engineering can also be used to create plants that produce pharmaceutical and industrial compounds. To ensure safety, plants engineered to produce pharmaceutical and industrial compounds are handled differently from those being developed for use as food or feed.

Q. Who is responsible for regulating GE crops?

A. In 1986, the Federal Government published a policy document known as the Coordinated Framework for the Regulation of Biotechnology, which described the Government's plan to regulate biotechnology. According to this document, USDA's APHIS, the U.S Department of Health and Human Services' Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) share responsibility for regulating biotechnology in the United States based on various laws for protecting human health, agriculture, and the environment. Products are regulated according to their intended use, and some products are regulated by more than one agency. Together, these agencies ensure that the products of modern biotechnology are safe to grow, safe to eat, and safe for the environment.

Q. How do USDA, EPA, and FDA ensure the safety of agriculture, the environment, and the food supply?

A. USDA and EPA are responsible for ensuring the safety of agriculture and the environment. Through APHIS' Biotechnology Regulatory Service (BRS), USDA ensures the safe introduction (confined field testing, interstate movement, and importation) of new GE plants with significant safeguards to prevent the accidental release of any GE material. EPA is responsible for ensuring that pesticides engineered and used in living plants can be safely consumed and safely used in the environment. FDA has primary responsibility for ensuring the safety of the food supply and any food ingredients derived from genetic engineering.

Following the principles of the coordinated framework, USDA, EPA, and FDA focus on safety based on the biological characteristics of the product, not the process employed to create the product. USDA imposes stringent safeguards throughout the development phase to ensure that GE products remain confined until they are deemed as safe as their conventional counterparts.

Q. How are developers of GE organisms regulated by APHIS?

A. Companies and organizations that wish to introduce a GE organism must obtain APHIS' permission. Depending on the nature of the GE organism, an applicant files either a notification or a permit application. With either application, the developer must adhere to APHIS regulations and, in some cases, to conditions imposed specifically for that permit to ensure adequate confinement of the organism. Under the authority of the Plant Protection Act, BRS further ensures the safety of field tests and the strict adherence to regulations and permit conditions through targeted inspections and audits.

Q. What is a notification?

A. Most GE plants are regulated under the notification process. The notification process is streamlined and may be used only for familiar plants and traits that meet certain safety-based criteria. For example, the gene used must not create plant diseases, viruses, or unintended toxic substances; the plant must not contain genes from animal or human pathogens; and the plant must not produce pharmaceutical or industrial compounds. To ensure confinement, the developer must perform the test in a way that meets performance standards that are specified in APHIS' regulations. If a plant does not meet the criteria for notification, the applicant must follow the full permitting process.

Q. What is a permit?

A. Permits are required for any GE introductions that are not covered under notifications. Permits are generally more restrictive than notifications and are used for any GE organism that is not a plant, as well as for GE plants that could pose an elevated plant pest risk, such as plants engineered to produce pharmaceutical or industrial compounds.

A list of standard permit conditions is available in the Code of Federal Regulations, at Title 7, Part 340.4(f), and can be accessed through the BRS Web site at <http://www.aphis.usda.gov/brs/usergd.html>. Supplemental conditions that are tailored to fit the specific circumstances of each field test may also be imposed before a permit is granted.

Applicants must provide the same detailed data for permits as required in the notification process, including the size, duration, and location of field tests; plant information; and descriptions of any genes used and the genetic modifications. In addition, the developer must provide detailed descriptions of how field tests will be performed, including specific measures for reducing the risk of harm to other organisms. If portions of the application contain trade secrets or confidential business information (CBI), applicants must submit two versions of the application: one with CBI marked and included and one with CBI marked and redacted. The CBI-redacted version is the edited version that is circulated for review by officials outside APHIS, such as State departments of agriculture.

Field-test permits are issued on a case-by-case basis after scientific experts complete an extensive environmental assessment (EA), which analyzes possible impacts on the environment.

Q. What are crops that produce pharmaceutical and industrial compounds, and how are they regulated?

A. Crops that produce pharmaceutical compounds are specifically engineered to produce compounds for medicinal drugs, such as vaccines, for humans or animals. Crops that produce industrial compounds are specifically engineered to produce chemicals for industrial purposes, such as enzymes used in detergent manufacturing. Crops engineered to produce pharmaceutical and industrial compounds fall into a distinct category and are handled differently from those plants being developed for use as

food or feed. BRS issues permits for field tests for crops that produce pharmaceutical and industrial compounds on a case-by-case basis and addresses any new issues raised by such crops in EAs.

Developers must apply for a permit rather than a notification to field test crops that produce pharmaceutical and industrial compounds. When applying for a permit, applicants must include specific measures to reduce the risk of harm to other organisms. APHIS also imposes more-stringent confinement measures on these field tests. This includes increased isolation distances and fallow zones (areas that are not in production), restrictions on growing crops that produce pharmaceutical and industrial compounds on the same land used to produce food or feed crops, and dedicated equipment and storage facilities for those crops. BRS inspects these test sites seven times, with inspections corresponding to critical times in production.

Q. What is an EA?

A. An EA is a public document that analyzes possible impacts of certain Government actions on the environment as required under the National Environmental Policy Act (NEPA). It is prepared by BRS before granting petitions for deregulation and before approving permits when the plant species, the trait, or both are considered new or novel. If a proposed action does not have the potential to significantly impact the environment, BRS will prepare a finding of no significant impact. If BRS determines that the proposed action has the potential to significantly impact the environment, then it will prepare an environmental impact statement (EIS), which involves a more comprehensive environmental analysis of the proposal and reasonable alternatives.

Q. What is an EIS?

A. An EIS is a detailed and comprehensive environmental analysis that must be prepared when proposed Government actions are broad in scope or have the potential to significantly impact the environment. As with an EA, the EIS is required for certain Government actions in order to comply with NEPA. An EIS evaluates the environmental impacts of GE organisms, and as part of this document, BRS must present and assess alternative courses of action for these potential impacts. BRS may also specify actions that would mitigate any impacts of the biotechnology product.

Q. What is CBI, and how does deleted CBI affect BRS' and the States' ability to judge permit applications?

A. Certain qualifying financial or commercial information that the developer does not want disclosed for competitive reasons can be claimed as CBI. BRS sees and reviews all confidential and nonconfidential information and is able to make sound, science-based decisions when reviewing all notifications applications, permit applications, and petitions for deregulation. Although BRS cannot provide CBI data to the States or any other outside parties, State agricultural officials may contact the companies directly to request any CBI-deleted information that may be needed to make decisions about the environmental safety of a GE organism. BRS posts CBI-deleted versions of petitions online, and all nonconfidential data submitted in support of a petition are available for public inspection.

Q. How does BRS ensure compliance with regulations and permit conditions?

A. BRS maintains a rigorous regulatory process that includes strict compliance and inspection practices. When it issues a permit for movement, importation, or field testing of a GE organism, BRS imposes certain conditions to which the developer must adhere. To ensure that the conditions set forth by APHIS are carefully followed, compliance specialists and inspectors from APHIS' Plant Protection and Quarantine (PPQ) program perform targeted inspections and audits of field tests. Depending on the GE crop being tested, a site may be inspected for compliance seven times. BRS also works closely with other Federal agencies, including FDA and EPA, to monitor compliance with regulations. These agencies, along with State departments of agriculture, can submit

external incident reports of any potential compliance infractions to BRS. As a result of these rigorous standards, overall compliance rates with BRS regulations are very high.

Additionally, APHIS regulations require permit holders to notify BRS immediately upon discovery of potential compliance issues and follow up with a written report within 24 hours of the incident. Developers who do not follow these guidelines face the potential for fines and other penalties.

Q. Are all field tests inspected, and how often?

A. All permitted field tests are inspected, with the number of inspections based on the relative risk of each trial. Field-test sites for crops that produce pharmaceutical and industrial compounds, for example, are inspected seven times before, during, and after the growing season.

Notification field tests have been extensively regulated in the past and have a low plant pest potential. These field tests are given a computer-generated score based on several parameters, including the regulated article's traits and characteristics, acreage planted, and the length of time an applicant has been in business. Field tests are selected for inspection based on this score, as well as by random sample.

BRS maintains a comprehensive database that captures and tracks inspection-related information to ensure that all required inspections are accomplished.

Q. What are compliance infractions, and how does BRS resolve incidents of noncompliance?

A. Compliance infractions can include a wide range of incidents from administrative issues, such as the wrong name on a permit, to more serious infractions, such as failure to observe isolation 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 compliance infractions when they cause the developer to be in noncompliance with permit conditions. While developers have no control over these events, immediate notification of BRS is important in order to implement any necessary mitigation measures quickly. Developers are required to notify BRS of all possible compliance infractions, and failure to do so immediately is itself a compliance infraction.

When a developer fails to adhere to BRS' regulations and permit conditions, employees in the compliance and inspection branch ensure that corrective measures are taken. In these cases, the developer must immediately take remedial measures to protect agriculture, the food supply, and the environment. These measures include, but are not limited to, safeguarding the field-test site and regulated articles, returning to compliance with permit conditions or notification performance standards, and supplying all necessary information to BRS and the State. In some cases, the field test may need to be terminated and the crop destroyed.

Intentional violation of any biotechnology regulations can bring high monetary fines and other punitive criminal actions to the offender(s) by any or all of the three biotechnology regulating agencies.

Q. What role does BRS play in ensuring commercial food and feed is free of field-test materials?

A. Under the Coordinated Framework for the Regulation of Biotechnology, USDA, EPA, and FDA work together to regulate biotechnology. FDA has primary responsibility for ensuring the safety of the food supply and any food ingredients derived from genetic engineering. When BRS issues a permit for movement, importation, or field testing of a GE organism, the developer must adhere to certain conditions that ensure that the regulated GE organism does not persist in the environment or enter the food or feed supply. These conditions include stringent confinement measures, such as isolation distances, to prevent pollen flow; clean equipment and containers, in good working order, to prevent cross-contamination; and labeling of all regulated articles to prevent

accidental use or incorporation with other crops. In the event that a regulated GE organism does become intermingled with unregulated GE food or feed, Government agencies have the authority to seize the food or feed and require its destruction, thereby preventing 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.

Q. What process does a GE crop go through before USDA determines that it can be safely commercialized?

A. In a practical sense, being granted nonregulated status is usually necessary before a GE crop is sold and produced commercially. Nonregulated status allows the product to be moved and planted freely without the need for notifications or permits. A developer may file a petition for deregulation or nonregulatory status only after a GE crop has been field tested extensively and the developer can show that the product does not pose a plant pest risk.

After an intensive review of the data, BRS prepares an EA to analyze the potential impacts the crop may have on the environment and seeks public comment on the findings. BRS approves a petition for deregulation only after determining that the organism does not pose a plant pest risk.

Before being made commercially available, the crop may also be subject to regulatory review by other agencies. For example, crops to be used as food or feed are reviewed by FDA and are declared equal to conventional food crops only when deemed as safe as their conventional counterparts.

Once BRS has granted a product nonregulatory status, the product may be freely moved and planted without the need of permits or other regulatory oversight by BRS. Since 1987, APHIS has deregulated more than 60 GE products. BRS has the authority to bring any of the deregulated items back under regulation if new information demonstrates that they are plant pests. This authority, however, has never been used, and deregulated products have an established history of safe use in U.S. agriculture.

Q. What GE crops are available commercially, and are these products labeled?

A. Deregulated GE crops, such as corn, soybean, cotton, rapeseed (canola), flax, alfalfa, sugar beet, squash, and papaya, have been made commercially available. Soybeans, corn, cotton, and canola that are herbicide tolerant or insect resistant are the most popular items. GE products that are commercially available today are not required to be labeled just because genetic engineering was used in producing the plants. These products have been reviewed for safety by the relevant agencies and have been found to be as safe as traditional varieties.

Q. How do APHIS regulations keep pace with the science of biotechnology?

A. APHIS revised its regulations in 1993 and 1997 to increase agency regulatory efficiency and keep pace with new technologies. In 2003, BRS published two *Federal Register* notices announcing more-stringent permit conditions for field tests of plants engineered to produce pharmaceutical and industrial compounds. These regulatory policy changes resulted in stricter confinement measures and greater oversight.

Driven by recent technological trends, such as the increased interest in GE organisms as a means to produce pharmaceutical compounds, BRS is planning to revise its current regulations. The first step in this process is the development of a programmatic EIS to provide a detailed environmental analysis of the proposed revisions and allow for public input and comment. This EIS will identify the range of actions, alternatives, and impacts that need to be considered when evaluating APHIS' biotechnology regulations and possible regulation changes, such as multitiered, risk-based permitting to replace the current permit/notification system. Using the information and alternatives contained in the

EIS, BRS will be able to make informed decisions on policy changes and clearly lay out the rationale for these recommended changes.

BRS established an Office of Science to ensure that APHIS' biotechnology-related regulations are grounded in the latest science. The Office of Science helps BRS remain informed about the latest scientific knowledge useful for the development of regulatory policies and decisions and allows BRS to pass on this knowledge to the research, regulatory, and stakeholder communities. One of the primary responsibilities of the Office of Science is to oversee the peer-review process for the scientific information used as the basis of APHIS' regulatory policies and decisions. Peer review can be used when BRS produces an EIS, including BRS' programmatic EIS.

Q. How does BRS involve the public and stakeholders in important policy discussions and decisions?

A. BRS makes it a priority to ensure that our processes, decisions, and activities are transparent to the public and our stakeholders. The United States Regulatory Agencies Unified Biotechnology Web site <http://usbiotechreg.nbii.gov> contains a searchable database of biotechnology products that have completed reviews for use in the United States. BRS' Web site provides accessibility to permits, decisions, and information on the regulatory process, including the deregulation process. EAs for field tests of crops engineered to produce pharmaceutical and industrial compounds are posted for viewing and for a 30-day comment period, allowing stakeholders and the public to be part of the decisionmaking process. An online stakeholder registry system lets stakeholders sign up to receive information based on selected topics of interest. Interested individuals can sign up for the registry by visiting the BRS Web site at http://www.aphis.usda.gov/brs and clicking on Stakeholder Registration. In addition to its Web site, BRS regularly provides briefings and information to the media and Congress and holds open public meetings to gain feedback directly from the public on issues of importance.