BRS Factsheet

Biotechnology Regulatory Services

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

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National Environmental Policy Act and Its Role in USDA's Regulation of Biotechnology

NEPA establishes a national policy for the protection of the environment through an informed decision-making process for implementing projects and programs that have potential impacts on the environment.

Through its Biotechnology Regulatory Services (BRS) program, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for regulating the importation, movement, and field release of genetically engineered (GE) plants, insects, and micro-organisms that may pose a plant pest risk.

As the complexity and scope of biotechnology in the United States grow and new GE organisms continue to be developed, the Federal Government must continue to ensure that biotechnology products are developed and field-tested safely. Consistent with the Coordinated Framework (51 FR 233302, June 26, 1986), USDA works with the Environmental Protection Agency and the Food and Drug Administration to ensure the safe development of GE products.

USDA first implemented regulations for biotechnology (Title 7 Code of Federal Regulations, Part 340) in 1987 under the authorities of the Federal Plant Pest Act and the Plant Quarantine Act. Under these regulations, transgenic plants, micro-organisms, insects, and mollusks were subject to regulation if they had the potential to pose a plant pest risk. These regulations provided broad authority over the introduction of such organisms and used a permitting system to authorize importation, interstate movements, and field releases of GE organisms. The major actions of all Federal agencies that significantly affect the human environment are subject to the National Environmental Policy Act (NEPA), and APHIS considers impacts on the human environment in its decisionmaking, not just the potential for plant pest risk.

NEPA—the environmental charter for the U.S. Government—mandates a process for evaluating environmental impacts resulting from agency actions. NEPA establishes a national policy for the protection of the environment through an informed decisionmaking process for implementing projects and programs that have potential impacts on the environment. NEPA applies to almost all Federal agencies, which means that BRS must weigh environmental impacts prior to undertaking any major Federal action with the potential to significantly affect the environment, including rulemaking. Section 102 (2) of NEPA declares that this policy is to be implemented through the regulations established by the President's Council on Environmental Quality.

Unless an agency action is categorically excluded from a NEPA-mandated environmental analysis, the agency must analyze the action through the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS).

Categorical Exclusions

An action that would result in less-than-significant or no environmental impacts may be categorically excluded from the requirement to prepare an EA or EIS. For example, a categorical exclusion would apply to the permitting of the confined release of a GE organism involving a well-known species that does not raise any new issues. A categorical exclusion is not an exemption from NEPA but a determination that an EA or EIS is not necessary.

Environmental Assessment

An EA is prepared by BRS to determine whether a proposed action may have significant impacts on the quality of the human environment. The EA discusses the need for the proposed action, possible alternatives including the no-action alternative, the potential impacts of the proposed action and alternatives, and information regarding any consultation or agency coordi-

nation. The EA, which is a public document, briefly provides sufficient evidence and analysis for determining whether to prepare an EIS. If the proposed action does not have a significant impact on the environment, APHIS will issue a Finding of No Significant Impact (FONSI). If BRS determines that any aspect of the quality of the human environment may be significantly affected by the proposed action, then it will prepare an EIS, which involves a more in-depth inquiry into the proposal and any reasonable alternatives to it.

BRS writes an EA before granting permits for introductions of GE organisms that are considered new or novel (either the crop species, the trait, or both), and it is BRS's current practice to give the public the opportunity to comment on an EA before the permit is granted. APHIS also prepares an EA when it decides that a GE plant or micro-organism will no longer be regulated.

The environmental assessment preparation process includes:

- Consultation and coordination with other Federal, Tribal, State, or local agencies;
- Public scoping;
- *Federal Register* Notices;
- Public comments on a draft EA;
- Public meetings on a draft EA;
- Publication of final EA and FONSI; and
- Supplements to a previous EA.

Environmental Impact Statement

An EIS is the most detailed and comprehensive environmental analysis specified under NEPA and must be prepared if the preceding EA is not resolved with a FONSI. The EIS evaluates the environmental impacts of broad agency actions, such as rulemaking, adopting strategic or long-range plans, and developing major programs with extensive commitments of resources. APHIS may also decide to use the NEPA process to better inform the decisionmaking behind projects of a more narrow scope, such as the deregulation of a specific GE crop. The evaluation includes a discussion of direct, indirect, and cumulative impacts resulting from the adoption of one of several reasonable alternatives, including the no-action alternative. Additionally, BRS may also specify and discuss actions that would mitigate any impact of the biotechnology product. An EIS is developed by a multidisciplinary team and can take between 1 and 6 years to complete.

The environmental impact statement preparation process includes:

- Consultation and coordination with other Federal, Tribal, State, or local agencies when appropriate;
- Scoping;
- *Federal Register* notices;
- Public comment on draft EIS;
- Public meetings on draft EIS when appropriate;
- Publication of a final EIS; and
- Supplements to an inadequate EIS when necessary.

BRS is committed to the use of NEPA to strengthen its approach to regulating the field-testing of GE crops to ensure that these tests neither pose plant pest risks nor pose significant impacts to the human environment.

Additional Information

For more information about the NEPA process as it relates to the introduction of GE organisms, contact
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or visit the APHIS Web site at

<http://www.aphis.usda.gov/brs/index.html>.

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