Revised Biotechnology Regulations (Previously SECURE Rule)

Last Modified:

On May 18, 2020, APHIS published the first comprehensive revision of APHIS' biotechnology regulations since they were established in 1987, with a phased implementation through 2021.

The revised rule differs from the previous regulatory framework by focusing on an organism's properties and not on the method used to produce it, enabling APHIS to regulate modified organisms with greater precision and reducing regulatory burden for developers.

Biotechnology Regulations 7 CFR part 340
Expand All

Key Changes

Exemptions and Confirmations

Under the revised regulations, certain categories of modified plants are exempt from the regulations because they could otherwise have been developed through

conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants. Developers can request a confirmation from APHIS that a modified plant qualifies for an exemption and is not subject to the regulations in 7 CFR part 340.

View Exemptions and Confirmations

Regulatory Status Reviews

Under the revised regulations, developers have the option of requesting a regulatory status review of a plant developed using genetic engineering that has not been previously evaluated and determined to be nonregulated. This process replaces the petition process in the preexisting regulations.

Learn More About Regulatory Status Reviews

Notification Process Retired

As part of the revised regulations, the former notification process was discontinued on April 5, 2021. All applications to move organisms subject to the regulations must now be submitted through the permitting process.

View Legacy Notification Process

Final Rule

- Final Rule
- View May 18, 2020, Federal Register Notice
- Final Environmental Impact Statement
- Record of Decision
- Questions and Answers (1.5 MB)

Proposed Rule

As part of revising the biotechnology regulations, APHIS published a Proposed Rule and a draft Programmatic Environmental Impact Statement (pEIS) for public comment. The draft Programmatic EIS evaluated the environmental impacts of updating its regulations, as required by National Environmental Policy Act. Programmatic EISs are often prepared for actions that typically involve the agency, an entire program or a substantial program component. They are preceded by a Notice of Intent (NOI) to prepare an EIS.

- Proposed Rule
- DRAFT Environmental Impact Statement
- EPA EIS Federal Register Notice
- Notice of Intent
- Public Comments

Previously, APHIS published proposed rules in 2008 and 2017 for potential changes to the regulations. APHIS withdrew both rules in response to public comments and to reengage in a fresh dialogue with stakeholders on the regulation of biotechnology.

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