

Fact Sheet

7 CFR part 340 Regulations for Biotech Plant Products

BIO has always supported a rigorous, science-based, transparent regulatory system for agricultural biotechnology. Such regulations ensure that biotech-derived products can be safely developed and brought to the marketplace with the full confidence of growers, consumers, and global trading partners.

Regulatory oversight of agricultural biotechnology should keep pace with the latest scientific findings and accommodate the full range of crop/trait combinations, while at the same time recognize the many years of safe use and benefits of these products so that oversight is appropriate.

USDA's rules (7 CFR part 340) have functioned well for almost twenty years to enable the interstate movement, importation, and field testing of biotech-derived crops under a system of permits and notifications. This system also allows for the removal of biotech-derived plants from regulatory oversight once the government determines that these products pose no greater risks to agriculture than conventionally bred varieties.

Background

The original (7 CFR part 340) regulations for plant biotechnology were promulgated by USDA-APHIS in 1987. The rules underwent minor revisions in 1993 and 1997 to allow greater public participation in permitting and deregulation decisions. Efficiency has also been greatly increased through the development of an integrated, electronic permitting system.

In late 2003, the White House Office of Science and Technology Policy directed USDA-APHIS to undertake a major revision of its rules governing biotechnology, and the department announced its intent to revise the regulations after completion of a programmatic environmental impact statement (EIS). It is anticipated that the final EIS will be published together with the final rule.

Updating the Current Rules

To address the latest science, increase flexibility, and address changes in the global marketplace, APHIS announced several proposed revisions to its rules on October 2, 2008. These proposals, and other alternatives not selected by APHIS, were thoroughly discussed and analyzed in a draft programmatic Environmental Impact Statement, published in 2007. Briefly, APHIS proposes to make the following changes in the regulations:

- Expand the scope of organisms and non-living genetically engineered material that APHIS regulates;
- Increase the flexibility and transparency of both the permitting and deregulation processes;
- Address low-level presence of regulated material in commodity crops; and
- Address the importation of genetically engineered commodity crops from other countries.

In its comments on the draft programmatic EIS, BIO expressed its support of the proposed changes, recognizing that the agency's thinking on the changes might continue to develop over

the course of preparing the Notice of Proposed Rulemaking. Generally, BIO supports broad regulatory oversight of biotech-derived products.

Comment Period

The public will have opportunity to provide input during the 45-day comment period. This assures transparency which BIO believes is essential within the regulatory process.

BIO and its member companies are reviewing the agency's proposed revisions and will submit comments. Science-based regulations, implemented in a timely and transparent manner with adequate input from industry stakeholders, will help farmers use agriculture biotechnology to produce high quality crops to feed and fuel the world's growing population.