



## U.S. REGULATION OF AGRICULTURAL BIOTECHNOLOGY

The regulation of agricultural biotechnology products in the United States is comprehensive, rigorous, and above all, science based — and often misunderstood. Biotech crops undergo intense regulatory scrutiny from the research lab, to field trials, to commercial plantings by farmers, so they are safe for food and the environment.

Three federal U.S. agencies share primary responsibilities for regulatory oversight of agricultural biotechnology products:

1. U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA APHIS)
2. U.S. Environmental Protection Agency (EPA)
3. U.S. Food and Drug Administration (FDA)

Their responsibilities are coordinated under a policy known as the "Coordinated Framework," which was adopted in 1986 by the White House Office of Science and Technology Policy (OSTP).

**USDA's Biotechnology Regulatory Services (BRS)** oversees the safety of field trials and the commercial growth of biotech crops to safeguard U.S. agriculture from pests and diseases. To obtain a field trial permit, applicants must submit comprehensive scientific data that extensively characterizes the novel crop in terms of its genetics, patterns of growth and flowering, relationship to relevant diseases and their vectors, impacts on other organisms likely to be found in the vicinity, potential for gene flow to neighboring plants, and other data sets. These data are reviewed by a specialist on staff who prepares a site-specific environmental assessment, in compliance with the National Environmental Policy Act (NEPA), to support granting or denying the requested permit and document the relevant analysis and reasoning.

The USDA APHIS regulations have been amended numerous times to take into account researchers' and regulators' increased familiarity with different products based on experience. This means that the 500<sup>th</sup> request for permission to field test a new variety of pest-resistant biotech cotton is not required to undergo the same level of scrutiny as did the first application, since a strong database of experience to answer most of the relevant questions exists. USDA APHIS also has the ability to ease the scrutiny of biotech crops ready for commercialization and large scale cultivation, though review requirements can be reinstated at any time based on any new or emerging data for which reporting is required. This agency also identifies some classes for which field trials will always require the high level of scrutiny associated with a full permit, as with the use of crop plants to produce medicines (plant-made pharmaceuticals).

**EPA** is responsible for crops improved to resist insect pests through the incorporation of a “plant incorporated protectant” (PIP), such as the protein from *Bacillus thuringiensis* (Bt), a bacterium that occurs naturally in soil that can produce proteins that are lethal to certain insects.

EPA also requires that biotech-based pesticides be managed in order to postpone the evolution of resistance by target pests, keeping valuable new pest control techniques viable for much longer than might otherwise be the case. The agricultural biotechnology industry has raised the standards for product stewardship with this approach.

**FDA** is responsible for the safety and proper labeling of all plant-derived foods and feeds in the U.S. food supply. Biotech foods and feeds undergo FDA review through consultations with the developer. While this consultation process is not required by law, biotech companies consider it to be *de facto* mandatory and have long supported FDA’s proposal to make it so. All biotech-derived foods currently in the U.S. marketplace have undergone this consultation process so there are no inadvertent changes to the composition of the foods that could impact safety. The consensus among the scientific community is that foods derived through biotechnology are at least as safe, if not safer than other foods because of the heightened scrutiny they receive.