
# Biotech In focus

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# What are the rules for commercially distributing genetically engineered crops in the USA?

**Since 1986, regulation of GMO plants in the U.S. has been governed by the Coordinated Framework for Regulation of Biotechnology. This agreement spreads the job of regulating genetically engineered crops across three federal agencies, each with different roles:**

In our last bulletin we explored how GMO plant varieties dominate U.S. production of three big commodities—corn, soybeans, and cotton—as well as a fruit crop familiar to many Hawaii residents, papaya. In this installment we address how new GMO crops are regulated as they leave the laboratory, are tested in the field, come to market, and finally reach dining room **tables and feedlots.**

**The U.S. Department of Agriculture (USDA)** is concerned with how the new GMO crop functions as a plant in the environment. Will it become a weed? Spread diseases or engineered genes? Hurt organisms other than pests it's been designed to target?

**The Food and Drug Administration (FDA)** decides whether the new plant is nutritious and safe to eat. Does the GMO plant contain new allergens or non-pesticide toxins? Are the nutrient levels comparable to non-transgenic plants?

**The Environmental Protection Agency (EPA)** is responsible for regulating any biological pesticides that the new GMO crop plant contains, as well as the genes for making the pesticides. As with chemical pesticides, EPA establishes how biopesticide-producing crops can be used and what levels of biopesticide residue are acceptable in food and animal feed.

In this bulletin, we focus primarily on the regulatory role of USDA; food safety and environmental safety will be discussed further in future bulletins.

For more information and past issues, please visit our website at www.ctahr.hawaii.edu/biotechinfocus

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Within USDA, the **Animal and Plant Health Inspection Service (APHIS)** asks crop developers to show that each new GMO crop plant won't become a harmful pest. APHIS also requires the developer to prevent the new GMO plant from escaping into the environment by containing the plant during shipping, keeping it separate from non-regulated plants during field testing, and eradicating it once it's been field-tested. A GMO crop that is under the authority of APHIS is said to be regulated.


Prior to interstate shipping or field testing, crop developers typically submit a notification to APHIS that details how the agency's requirements have been met. APHIS will either acknowledge the notification or deny permission to release the new GMO plant into the environment. If the notification is not accepted, the developer has the option of seeking a permit from APHIS, which involves a more extensive application and review process. (If the GMO plant produces a pesticide, the developer also requests an experimental use permit from EPA prior to field testing.)

## Non-regulated Status

The results of field tests can be used by crop developers to petition APHIS for non-regulated status. Once a crop becomes non-regulated, it can be grown without USDA oversight. Any biopesticide the plant produces must be registered with EPA, which has the authority to set conditions for its use and limits for its concentration in food or feed.

## Voluntary Consultation

Before GMO plants come to market, the FDA recommends a process of voluntary consultation to ensure that foods and animal feeds from GMO plants meet federal food safety laws. Labeling of foods produced from GMO plants is not required in the U.S.

## Who tests?

Under the U.S. system, crop developers are responsible for generating and reporting the preliminary and post-test data needed to meet regulatory requirements. Some people would rather see this testing performed by the government or a neutral party, whether because crop developers are perceived as having a conflict of interest or because the cost of testing makes it more difficult to develop and market disease-resistant genetically engineered varieties of minor crops, like GM papaya.

**Aspects of the U.S. regulatory framework are controversial, and many other nations have more restrictive policies. Whether a person feels that the U.S. approach to regulating GMOs is too permissive, too restrictive, or appropriate often reflects his or her interpretation of the risks and benefits associated with GM crops. We will look more closely at questions of risk in our next bulletin.**

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