THE
NATIONAL LAW REVIEW

Update: Industry Urges USDA to Start Over on Proposed Rule to Revamp APHIS Biotech Regs

Friday, July 7, 2017

For decades, the U.S. government has regulated genetically modified organisms (GMOs) under a regulatory framework called the "Coordinated Framework for the Regulation of Biotechnology" (Coordinated Framework). The Coordinated Framework explains the different roles played by the three major agencies involved in the regulation of GMOs:

- The Food and Drug Administration (FDA) regulates GMOs under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and ensures the safety and proper labeling of GMO-derived foods and feed.
- The Environmental Protection Agency (EPA) regulates plant-incorporated protectants (PIPs) — a type of pesticide that is bioengineered into crops — under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and sets tolerance limits or exemptions from tolerance for pesticide residues on or in food and animal feed. EPA also regulates certain biological control organisms under the Toxic Control Substances Act (TSCA).
- The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) regulates GMOs under the Plant Pest Act. APHIS reviews GM crops to determine whether they meet the definition of a "plant pest" and may pose risks to domestic agriculture.

KELLER AND HECKMAN LLP

Article By
Food and Drug Law at Keller and Heckman
Keller and Heckman LLPThe Daily Intake

Biotech, Food, Drug
All Federal

On January 19, 2017, APHIS published a proposed rule to revise the Agency's biotechnology regulations (82 Fed. Reg. 7008). The proposed rule seeks to update the regulations in a number of areas, all within the Agency's current statutory authority under the Plant Protection Act.

More specifically, APHIS is proposing a regulatory program in which it first assesses GE organisms to determine if they pose plant pest or noxious weed risks. If APHIS concludes that a GE organism does not pose a plant pest or noxious weed risk, then APHIS would not require a permit for the importation, interstate movement, and environmental release (outdoor use) of the GE organism. If, on the other hand, the Agency determines – based on a risk analysis – that controls on movement are needed, APHIS would require a permit and work with the regulated entity to establish appropriate permit conditions to manage identified risks to allow safe movement (i.e., import, interstate movement, or environmental release (regulated controlled outdoor use such as in field trials)).

In recent comments submitted to USDA, industry stakeholders have applauded the Agency's proposed rule as underscoring the need to promote innovation in biotechnology and for proposing to ease regulation of gene-edited products. But at the same time, industry has called out a number of proposed revisions as improperly expanding USDA's review process in certain respects which could effectively hamstring developers before they can even begin testing products.

For example, one key provision would leverage USDA's authority under the Plant Protection Act (PPA) to begin assessing genetically engineered plants for their potential to become a "noxious weed," which would potentially expand the Agency's review process. The existing regulatory review process is focused on assessing whether a biotech plant would be a "plant pest." The Agency's proposed new approach would thus add a new layer of regulatory review. The Biotechnology Innovation Organization, contends in its comments that APHIS already assesses plants for weediness under its existing regulatory review process and argues that the proposed rule "would create two parallel regulatory systems to evaluate the same risk, under the same statutory authority, in

potentially inconsistent ways."

In another set of comments, the National Grain and Feed Association and other organizations that represent companies that process and export grain and oilseeds urged USDA to withdraw the proposed rule on the basis that USDA did not consult with foreign markets and international regulators in preparing the proposed rule to ensure they would approve U.S. crop traits that would be commercialized under the proposed new system.

In light of industry's feedback on the proposed rule, and with a new administration taking office since the issuance of the proposed rule, it is possible that USDA will go back to the drawing board on its plan to revamp its biotechnology regulations. We will be sure to monitor developments on this issue as they unfold and report them to you here.

Source URL: https://www.natlawreview.com/article/update-industry-urges-usda-to-start-over-proposed-rule-to-revamp-aphis-biotech-regs