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News Alert

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APHIS Announces Proposal to Revise Regulation of Genetically Engineered Organisms

On January 19, 2017, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) proposed major changes to its existing rules governing plant-based biotechnology. The proposal would represent the first comprehensive revision of APHIS's biotechnology regulations since they were first established in 1987. Comments must be submitted by May 19, 2017. On the same date, APHIS also proposed revisions of its separate regulations governing plant pests, biological control organisms, and noxious weeds.

As outlined by the new proposal, APHIS will no longer consider GE organisms to be regulated organisms solely because of the plant pest status of the donor, vector, or vector agent used in the process, thereby focusing APHIS resources on those GE organisms that may present a plant pest and/or noxious weed risk.

Instead, a GE organism will be considered a "regulated organism" under the proposal only if it has been specifically evaluated by APHIS and determined to pose a plant pest or noxious weed risk, or:

- prior to the genetic engineering, it belonged to a listed "plant pest" taxon and was capable of causing injury, damage, or disease to a plant;
- it has not yet been evaluated by APHIS for plant pest risk but it received DNA from a "plant pest" taxon donor organism that is sufficient to produce an infectious entity capable of causing plant disease or encoding a pathogenesis-related compound; or
- it is a plant that has a plant and trait combination that has not been evaluated by APHIS.

Under the proposed rules, if the GE organism is not a regulated organism, it may be imported, moved interstate, or released into the environment without further restriction. APHIS acknowledges that this new framework would likely have significant impacts on several specific product categories:

- **Plant-Made Pharmaceuticals.** According to APHIS, "most, if not all" GE plants that produce plant-made pharmaceuticals and industrials (PMPI) that are currently under APHIS permits could be determined not regulated under the provisions of the proposed regulations because

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they do not represent risk as a plant pest or noxious weed. Accordingly, such plants could be grown outdoors without the need for permits and without APHIS oversight. APHIS recognizes this may result in a gap in Federal oversight of PMPI-producing plants and lead to intentional or inadvertent introduction of unevaluated PMPI products into the human or animal food supply. To address this, APHIS suggests that a new statue could be enacted, or an existing statute could be amended, to grant one or more Federal agencies authority to provide oversight of outdoor plantings of all GE PMPI-producing plants and evaluate all possible risks. Alternatively, APHIS suggests that EPA or other appropriate agencies might exercise oversight to the extent that existing authorities allow.

- **Plant-Incorporated Protectants.** APHIS states that "many" GE plant-incorporated protectant (PIP)-producing plants currently regulated under APHIS permits or notifications could be determined not regulated under the provisions of the proposed regulations because they do not represent risks as a plant pest or noxious weed. As anticipated by APHIS, federal oversight of small-scale outdoor plantings of PIPs would shift to EPA, which APHIS suggests may decide to require experimental use products (EUPs) for all or some such PIPs under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).
- **GE Herbicide-Resistant Plants.** APHIS explains that "many" GE herbicide-resistant plants that are currently regulated under APHIS permits or notifications could be determined not regulated under the proposed regulations because they do not represent risks as a plant pest or noxious weeds. Consider ways to address illegal use of pesticides by farmers on seed that is not regulated by APHIS and commercially available before the commercial availability of the herbicide designed for those crops. New statute to make it illegal to sell seeds for herbicide-resistant crops before registration approval.

A request to have a GE organism's regulatory status evaluated would be made available for public review, together with the APHIS-conducted risk analysis. Once evaluated by APHIS and determined to have a plant pest or noxious weed risk, a regulated organism may only be imported, moved interstate, or released into the environment consistent with an APHIS-issued permit. APHIS will assign permit conditions to each permit commensurate with the risk of the regulated organism and activity. The existing procedures for "notification" and petitions for nonregulated status would be eliminated under the proposed framework.

Among other key changes, APHIS is proposing to broadly define the term "genetic engineering" to mean "techniques that use recombinant DNA or synthetic nucleic acids with the intent to create or alter a genome." While this term would excludes traditional breeding techniques or chemical/radiation-based mutagenesis, APHIS notes its intention to include genome-editing within this definition.

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