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NEWSLETTER

USDA Publishes Proposed Rule on Environmental Releases of Genetically Engineered Organisms

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Product Stewardship and Sustainability Report

On January 19, 2017, the USDA's Animal and Plant Health Inspection Service (APHIS) published a proposal to revise the 7 C.F.R. Part 340 regulations that implement APHIS's statutory authority under the Plant Protection Act (PPA)[1] to regulate the importation, interstate movement, and environmental release of genetically engineered (GE) organisms that may be plant pests.[2] This proposal represents APHIS's second attempt to overhaul these 30-year old regulations in the last decade. Given the significant deficiencies in the new proposal, it is not clear that the likelihood of this proposal going forward is much greater than the previous proposal. In any event, because the new proposal, rather than provide regulatory relief to innovative agricultural technology developers, likely will increase the unnecessary regulatory burdens that they face, interested parties should take the opportunity to comment on this proposed rule.

The APHIS regulations implementing its authority under the PPA were originally promulgated in 1987, and they have not been comprehensively revised since then.[3] APHIS states that its proposed rule would better enable APHIS to "focus its resources on regulating genetically GE organisms that may pose plant pest or noxious weed risks, and will enhance regulatory flexibilities that foster innovation." The new proposal, however, does not go far enough in providing the kind of meaningful regulatory relief that is needed by agtech developers – and, indeed, may actually unnecessarily increase regulatory burden.

Practice Areas

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APHIS first proposed comprehensive revisions to the Part 340 rules in 2008. In response, APHIS received over 5,500 submissions containing 88,000 comments over a 9-month period. In 2015, in significant part based on the critical comments received, APHIS withdrew the proposed rule, pointing to substantive issues raised by some of the comments, "experience we have gained over the past 28 years," and "continuing advances in biotechnology."

In its January 19, 2017 proposal, APHIS notes that "advances in genetic engineering have occurred" since the regulations were promulgated in 1987 and, importantly, that the evaluations associated with over 43,000 regulatory decisions under the 1987 regulations "have provided evidence that most genetic engineering techniques, even those that use a plant pest as a vector, vector agent, or donor, do not result in a GE organism that presents a plant pest risk." Notwithstanding this conclusion, the regulatory scheme proposed by APHIS still requires almost all new GE organisms potentially subject to regulation under the PPA to come to APHIS for a comprehensive assessment of whether the organism constitutes a potential plant pest risk. APHIS describes the proposed approach as follows: "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 movement of the GE organism. On the other hand, if APHIS determines, based upon the risk analysis that controls on movement are needed, APHIS will work with the requestor to establish appropriate permit conditions to manage identified risks to allow safe movement." APHIS touts this as a change from its current "regulate first/analyze later" approach, but it is not at all clear that moving to a "analyze first/regulate (or not) later" approach will have meaningful burden reduction impact for developers who, in the context of the current system, face a "regulate first/analyze second/deregulate third" approach.

Significant provisions of the proposal include: (1) a new regulatory risk analysis to evaluate GE organisms for noxious weed potential; (2) elimination of the notification process for certain GE organisms in favor of an affirmative permitting scheme; (3) a process for regulating GE organisms intended for use as biological control agents; (4) new criteria for regulation of plants genetically engineered to produce industrial chemicals and pharmaceuticals; (5) new criteria for regulation of small-scale field testing of new plant-incorporated-protectants (PIPs); and (6) a commitment to work with EPA to try to better coordinate regulatory decisions for herbicide-resistant plants and approvals of new uses for the associated herbicides.

That the proposal may not represent a meaningful burden reduction is demonstrated by the types of GE organisms that APHIS proposes to exclude from regulation, and by the fact that no products of gene editing would be presumptively excluded from regulation. First, APHIS proposes to exclude from the definition of organisms subject to regulation: (1) organisms in which the genetic modification consists solely of a deletion of genetic material, or a single base pair substitution that could otherwise be obtained by either chemical or radiation mutagenesis; (2) cisgenic transformations; and (3) organisms that are "the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, but the donor nucleic acid is not passed to the recipient organism's progeny and the donor nucleic acid has not altered the DNA sequence of the progeny." In effect, the description of (3) confirms that "organisms that are not genetically altered will not be considered genetically engineered organisms."

Moreover, the preamble to the proposed rule explains that APHIS will continue to exclude from Part 340 regulation organisms created through chemical or radiation based mutagenesis (82 Fed. Reg. at 7015.2). This highlights a basic flaw in the APHIS regulatory scheme – that it is not risk-based, but instead is process-based. Indeed, in that same section of the preamble, APHIS describes mutagenetic modification and does not address at all the potential for risks that is entailed in the creation of "thousands of mutations in a single organism" (82 Fed. Reg. at 7015.3). Nor does APHIS contrast the comparative lack of risk entailed in the relatively precise genetic transformations now possible. Thus, the proposed rule represents a significant missed opportunity for APHIS to begin the transformation of its regulatory system to a risk-based system that is reflective of the near-universal consensus among scientists that agricultural products produced using the techniques of biotechnology do not entail any greater risk than conventionally developed foods. Similarly, the proposal does not meaningfully address gene editing techniques. APHIS thus also misses an opportunity to meaningfully address these significant advances in biotechnological techniques, and to propose what might constitute a rational regulatory approach to biotechnology techniques that entail a further diminution of risk in agricultural product development. It is critical that significant and substantive comments be submitted on the APHIS proposal highlighting these deficiencies.

The APHIS proposal, if promulgated as proposed, would at the very least constitute a missed opportunity for meaningful regulatory relief, and, at worse, could in fact increase regulatory burden. APHIS states that "[t]he rule is likely to result in a broader range of GE organisms being required to come in for review, but fewer would be subject to regulatory controls." APHIS does not expound on the wisdom of requiring "a broader range" of presumptively less risky products to undergo review, when it has already concluded that fewer of those presumptively less risky products will actually be subject to regulatory controls. This begs the question of whether this approach can conceivably be considered a rational regulatory choice.

Individuals and companies that intend to release, move interstate, or import any genetically engineered organism not intended for pesticidal use should carefully review the APHIS proposed rule and consider submitting comments on relevant provisions. It is important to provide APHIS with substantive input, both to possibly influence the final rule, and to preserve important issues for possible judicial challenge.

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[1] 7 U.S.C. §§ 7701 – 7786.

[2] On February 10, 2017, APHIS published a notice extending the comment period for the January 19, 2017, proposed rule to June 19, 2017.

[3] 7 C.F.R Part 340, Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests.