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# USDA Declares "Do-Over" on Overhaul of Biotechnology Regulations

The U.S. Department of Agriculture's ("USDA") Animal and Plant Health Information Service ("APHIS") is renewing efforts to amend or replace its existing rules governing plant-based biotechnology, while highlighting possible changes to its regulations that may significantly expand the scope of biotechnology products and processes subject to APHIS jurisdiction. Akin to an advance notice of proposed rulemaking, APHIS's Notice of Intent seeks public input on scoping for a Programmatic Environmental Impact Statement ("PEIS") under the National Environmental Policy Act ("NEPA"). APHIS's non-exclusive proposals range from status quo to transformative, and its notice provides a rare opportunity for agriculture and biotechnology stakeholders to help shape what may become a wholly new regulatory program to replace APHIS's three-decades-old regulations at 7 C.F.R. Part 340. **Comments are due by April 21, 2016.**

### Background

Consistent with its authority to regulate "plant pests" under the Plant Protection Act ("PPA"), APHIS regulates the introduction of certain genetically engineered ("GE") organisms that may cause injury or harm to plants. When originally issued in 1987, APHIS's implementing regulations at 7 C.F.R. Part 340 addressed nearly all GE plants, since most of the then-existing plant-based GE technologies involved the use of modified plant pests such as *Agrobacterium* to transfer new genes to plants.

In 2008, however, APHIS first proposed to prescribe new regulatory standards and processes by which companies could develop, test, and commercially market new genetic traits. As APHIS explained at the time, technological advances over the last two decades had "led to the possibility of developing GE organisms that do not fit within the plant pest definition, but may cause environmental or other types of physical harm or damage covered by the definition of noxious weed in the PPA." A "noxious weed" is defined by the PPA to include any plant that can injure or cause damage to crops, public health, or the environment.

Accordingly, APHIS proposed to expand the scope of its regulatory program beyond plant pests, consistent with its additional PPA authority over noxious weeds. APHIS's 2008 proposal did not suggest any changes to the definition of

the term "genetic engineering" itself, which is defined under Part 340 to mean "the genetic modification of organisms by recombinant DNA techniques." Seven years and thousands of comments later, APHIS in 2015 formally withdrew its proposed rule, and instead initiated a series of public webinars and outreach to more broadly evaluate alternative approaches to the regulation of biotechnology under the PPA. [Click here for our previous article on APHIS's withdrawal.]

**The New APHIS Notice**

APHIS now is once again raising the possibility of revising or replacing its biotechnology regulatory program by, among other things, aligning the range of potential risks that may be considered under APHIS's regulations with its PPA jurisdiction over both plant pests and noxious weeds. Fundamentally, APHIS may introduce a new defined term, "biotechnology," which would include all "laboratory-based techniques to create or modify a genome that result in a viable organism with intended altered phenotypes," such as gene deletion, gene addition, directed gene alteration, direct injection, and cell fusion techniques. Some of these techniques do not meet the narrower, rDNA-focused definition of "genetic engineering" currently used in APHIS's regulations. In turn, a "product of biotechnology" subject to regulation under Part 340 would mean any organism "developed using biotechnology." At the same time, APHIS is interested in more "efficiency and precision" in its regulations, and proposes replacing its defined term "regulated article" with a narrower "regulated organism" term encompassing an "organism developed using biotechnology" that APHIS has definitively found to pose a plant pest or noxious weed risk warranting APHIS regulation.

The newly published Notice of Intent seeks feedback from stakeholders and members of the public on these possible definitions and their incorporation into alternative regulatory frameworks, along with their associated environmental impacts. All ideas are currently on the table. The Notice of Intent identifies four alternatives in particular:

- No action. As required in any NEPA analysis, APHIS must consider doing nothing, which here would leave its current Part 340 rules in place. Companies would continue to file permit applications or notifications in connection with the movement and field testing of GE organisms, and petitions to deregulate their products for widespread environmental release, according to existing APHIS definitions and rules now in place.
- Analyze first; regulate as needed. This alternative would introduce a two-step evaluation process for new biotechnology products. First, the agency would determine whether a plant pest or noxious weed risk exists for a particular product of biotechnology. According to APHIS, certain products that lack any "realistic potential" to pose such risks (for example, nucleotide deletions, single base pair substitutions, or other modifications that could reasonably be expected to be obtained through mutagenic techniques) would be exempt from regulation. For other products that do not meet these criteria, APHIS would employ a plant pest or noxious weed risk analysis and issue permits with "risk-appropriate" conditions to mitigate risks.
- Regulate all products of biotechnology that pose plant pest or noxious weed risks. Under this alternative, all products of biotechnology that are developed using a plant pest or that pose a noxious weed risk would be subject to permit requirements, without exception. Here, APHIS anticipates retaining jurisdiction over many more products as regulated articles, fundamentally expanding the reach of APHIS' program and multiplying its responsibilities. It is unclear from the Notice of Intent whether or how APHIS would revisit existing approvals of non-regulated status. How the "mitigation" required for APHIS permits under this alternative would differ from the conditions APHIS contemplates under the second alternative above also is uncertain.
- Withdraw APHIS's Part 340 regulations. In contrast, APHIS also is weighing whether to regulate GE plant pests and noxious weeds no differently than conventional (non-GE) ones, under its existing regulations at 7 C.F.R. Parts 330 and 360. Under this alternative, APHIS envisions still providing consultative services to developers, upon request, to help analyze plant pest and noxious weed risks and facilitate the movement and release of biotechnology products that do not pose risks regulated by the PPA.

The alternatives highlighted in APHIS's Notice provide key insight into some of the core changes to Part 340 now under consideration by APHIS. For example, as in its 2008 proposal, APHIS continues to seek public comment on the prospect of expanding its jurisdiction over biotechnology products by incorporating its noxious weed authority within its biotechnology rules for the first time. APHIS's newly introduced definition of "biotechnology" suggests that APHIS may also seek to significantly expand the types of genetic modification processes covered under its regulatory program. Moreover, under most of its anticipated scenarios, APHIS would no longer entertain deregulation petitions and notifications that are now familiar practice within the industry and APHIS; instead, a particular product of biotechnology would either be cleared upfront, always remain regulated, or not be specially regulated in the first instance. Other common considerations among the potential alternatives include to what extent different APHIS decisions will trigger NEPA reviews, and whether APHIS will exert greater oversight for biotechnology products intended for industrial and pharmaceutical uses.

**The Programmatic EIS and Opportunity for Comment**

APHIS's current scoping process will dictate the topics covered by any draft PEIS. APHIS states that its PEIS will consider environmental factors like herbicide resistance and gene flow although the agency traditionally has deemed review of such factors to be beyond its jurisdiction, and the courts have agreed. The spectrum of scoping comments that APHIS will receive is likely to mirror comments submitted in response to its previous proposal in 2008. Commenters are likely to advocate for everything from full non-regulation of biotechnology under the PPA to total bans on all genetically modified organisms, as well as many intermediate options. Coordinating this PEIS process with other potential forthcoming changes to "modernize" the Federal Coordinated Framework for the Regulation of Biotechnology among APHIS, the U.S. Environmental Protection Agency, and the U.S. Food and Drug Administration, will also be a challenge.

In any event, the comment process provides stakeholders, together with all members of the public, a rare and important opportunity to influence APHIS's evolving regulatory framework and help the agency craft a program with significantly improved efficacy and efficiency over the current process. While there will be additional opportunities for public comment both throughout the NEPA process and when a new rule is formally proposed, upfront participation by stakeholders is critical to ensure the NEPA and rulemaking processes proceed along a constructive path, reflect the best available science, and avoid unnecessary diversions. The contents and quality of the administrative record will also be critical in any future litigation over the final rule, whenever it may be issued.

*Beveridge & Diamond will continue to closely follow APHIS's NEPA and rulemaking efforts in this area and provide regular updates to clients on key developments as they are announced. We are available to address questions regarding potential changes to APHIS's policy or about APHIS's regulation of GE organisms more generally. For more information, please contact the authors.*