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USDA's New Rule Modernizing the Regulation of Biotechnology: A Practical Legal Summary

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Continuing its efforts to update and modernize its regulations applicable to certain genetically engineered (GE) organisms, the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) on May 18, 2020, published a final rule revising the 7 C.F.R. Part 340 regulations (85 Fed. Reg. 29790). The rule implements APHIS's statutory authority under the Plant Protection Act (PPA) to regulate the importation, interstate movement, and environmental release of genetically engineered organisms that are or may be plant pests. Publication of this final Part 340 final rule completes an extended rulemaking process that began during the George W. Bush administration and involved three separate proposed rules, the last published on June 6, 2019.

Among the highlights of USDA's so-called SECURE (Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient) Rule, new exemptions are codified in USDA's regulations for certain, straightforward genetic engineering modifications in plants. The final rule also includes provisions that will provide biotech plant developers the opportunity and a process to apply for additional exemptions in the future. Also, the regulation of plants used to manufacture pharmaceuticals and industrial products is now incorporated into Part 340. USDA's current procedures for companies to ask for nonregulated status/deregulation decisions are being discontinued and replaced. The effective date of this rule is August 17, 2020, although certain key aspects (Regulatory Status Reviews for plants and the new permit provisions of § 340.5 discussed below) do not take effect until April 5, 2021 at the earliest.

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In its June 6, 2019 proposal, APHIS stated that this rule would better able it to "focus its resources on regulating genetically engineered (GE) organisms that may pose plant pest or noxious weed risks, and will enhance regulatory flexibilities that foster innovation." This is ideally what federal biotech regulations should do – (1) focus on products that may pose actual risks, and (2) not impose unnecessary burdens that inhibit or hinder innovation. As promulgated, the final Part 340 rule may accomplish those goals for U.S. agricultural biotechnology.

The Basic Framework

APHIS regulates the importation, interstate movement, and environmental release of genetically engineered organisms that are, or may be, plant pests or biological control organisms under the Plant Protection Act (7 U.S.C. 7701 – 7786). The focus of these regulations is USDA's determinations concerning whether the GE organisms are plant pests or non-exempt biological control organisms such that activities involving their use are subject to federal permit requirements. The regulations implementing this authority are at 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*. The Part 340 regulations were promulgated in 1987 and the new rule is the first comprehensive revision of these rules.

Since the publication of the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework) by the Office of Science and Technology Policy (OSTP) in 1986, the stated policy of the U.S. Government has been that the products of agricultural biotechnology should be regulated on the basis of an assessment of risk of a product, not on the method by which the product was developed. Notwithstanding this policy, affirmed in an update to the Coordinated Framework in 1992, the three Coordinated Framework agencies have, as a matter of course, imposed heightened regulatory burden on products of biotechnology. APHIS's revised Part 340 regulations are a well overdue effort to bring the risk-regulatory burden equation in the context of products under its jurisdiction into some semblance of balance.

As APHIS notes in this final rule, it now has over three decades of experience regulating such products. During that time, the scientific advances in biotechnology have been astronomical. Moreover, in part due to the regulatory burden imposed by Federal agency oversight, agricultural biotechnology products developers have developed techniques of beneficially altering genomes that do not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents. As a result of such developments, it became imperative for APHIS to revise and update its regulations.

What's Covered in Revised Part 340

The potential scope of the revised Part 340 regulations remains largely the same with more options for exemption determinations for GE plants and useful jurisdictional clarifications concerning EPA-regulated products under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Specifically, product developers are required to obtain a permit to move a GE organism if they fall into one of the following covered categories:

1. A plant and trait mechanism of action combination has not been previously evaluated by APHIS;
2. A GE organism that meets the definition of plant pest;
3. A plant that is intended to produce a product intended for pharmaceutical or industrial use;
4. A non-plant organism that has received DNA from a plant pest that can produce a plant infectious agent or can cause plant disease; or
5. A microorganism that can control plant pests or is a parasite that can control invertebrate plant pests, and could be a plant pest risk.

Confirmation determinations can be obtained from APHIS for any GE organism to ascertain if it is subject to Part 340. These determinations will replace the current Am I Regulated under 7 C.F.R. Part 340? (AIR) request process. APHIS will no longer be accepting AIR requests as of June 17, 2020, although the confirmation determination process does not become effective until August 17, 2020. This schedule leaves a 60 day gap that companies in need of these determinations should plan for - placing an AIR request prior to the June deadline could avoid commercial delay. Confirmation determinations will be posted on a public website.

For GE plants only, the regulations include a **Regulatory Status Review (RSR)** process for product developers to request evaluation and confirmation by APHIS that a plant is not subject to regulation. This process does not go into effect until April 5, 2021, at which time it will replace the current deregulation request process. APHIS has up to 180 days to reach an initial RSR determination per § 340.4 of the rules. If the RSR review results in an initial determination of an increased plant pest risk, submitters can either seek to obtain a permit or ask for a further evaluation of the significance of the risk. APHIS will post RSR determinations on a website and include a general description of the plant, the trait, and the mode of action (MOA) of GE plants that go through an RSR.

A useful scope clarification for companies is provided in the final rule, where APHIS confirms that the outcome of an RSR would apply, for example, to genetic material encoding an enzyme that catalyzes a specific biochemical reaction regardless of whether the genetic material is sourced from a plant or a microbe, as long as the enzyme catalyzes the same biochemical reaction regardless of the organism from which the genetic material encoding the enzyme is obtained, and does not catalyze any other side reactions.

Under the new rule, records of permitted shipments need to be retained for 2 years while all other permit records have to be kept for 5 years after the permit expires. Determination decisions from USDA that the GE organism is not a plant pest should be retained throughout the commercial lifespan of the product.

New Exemptions for GE Plants

The regulation exempts the following plants from the requirement of a permit in advance of importation or movement:

1. GE plants that have a single modification that resulted from a cell's own repair of a targeted DNA break, or

2. A targeted single base pair substitution; or
3. GE plants that have been modified to incorporate a gene from the plant's natural gene pool; and
4. Other modifications that APHIS may propose that could have been achieved through conventional breeding.

Importantly, the rule permits product developers and plant breeders expanded opportunities to self-determine whether their product qualifies for one of these exemptions. Companies can propose additional exemptions using the procedures specified in § 340.1(b)(4); APHIS may also initiate new exemptions.

In addition, specifically exempted from the requirement of an APHIS permit are plants that:

1. Have a plant trait-mechanism of action combination previously exempted by APHIS;
2. Have a plant trait-mechanism of action combination found in a plant previously deregulated by APHIS; and
3. Were previously determined by APHIS to be deregulated under the AIR process.

We note that APHIS has committed to implementing the RSR process in a manner that provides necessary transparency regarding plant trait-MOA combinations reviewed by APHIS, but that also protects product developer's confidential business information. Therefore, future product developers will have sufficient information to know which plant trait-MOA combinations are exempt from further review, while the confidential information of the product developer that went through the RSR process will be protected.

APHIS states that these exemptions for plants are intended to bring the regulation of the specified categories of potentially regulated GE products more in line with the regulation of conventionally bred crops, which while not "risk free" have been determined to have risks that are "manageable by accepted standards." Therefore, for example, revised Part 340 exempts plants that have a single base pair substitution, because such an effect could also be created by conventional breeding. A number of comments on the proposed rule urged APHIS to expand the scope of exempted products consistent with the actual risks posed by products other than those included in the rule. While the exemptions in the rule are somewhat narrowly circumscribed, the rule includes a procedure to ask APHIS to consider amending the rules to expand the scope of the exemptions in the future.

Historically USDA has exempted from the need for a permit GE *Arabidopsis thaliana* (*A. thaliana*) and *Agrobacterium tumefaciens* (*A. tumefaciens*). The permit exemption for secure shipments of GE Arabidopsis thaliana is retained, providing stable integration of the modified genetic material and the complete infectious genome of a plate pest is not included. If these same conditions are met, no permit is required for importation or interstate movement of GE disarmed *Agrobacterium* species. This exemption is no longer limited to *A. tumefaciens*. A new permit exemption is established for importation or interstate shipment is needed for the common fruit fly *Drosophila melanogaster* as long as shipments are secure and the introduced genetic material is not designed to propagate through a population by biasing the inheritance rate.

Coordination with Pesticide Registration Requirements

To avoid duplicative regulation, § 340.5(f) specifically exempts the movement or release of microbial pesticide products registered with EPA from needing an APHIS permit, unless they are plant pests. An EPA-registered GE microbial pesticide that is a plant pest remains subject to USDA review.

Similarly, plants modified to contain a plant incorporated protectant (PIP) do not need an APHIS permit for their movement so long as the PIP is an EPA-registered pesticide product or exempt from FIFRA. In this regard, APHIS acknowledges that a GE PIP-producing plant that is not created using a plant pest as a donor organism, recipient organism, or vector or vector agent, which was previously exempt from APHIS regulations under Part 340, could fall within the scope of the revised regulations if it does not qualify for the new exemption. APHIS concluded that most PIP-producing plants will not fall in this narrow category and be brought back into the scope of the rule, and finalized the exemption as proposed.

For plants that are genetically engineered to produce PIPs, meaning that they produce pesticides, EPA generally requires Experimental Use Permits for field tests on 10 acres or more of land. On the other hand, APHIS has historically exercised regulatory oversight over plantings of PIP- producing plants on 10 acres or less of land. While the proposed rule considered the need to continue this practice, APHIS oversight of small PIP trials is discontinued under the new rules. It remains to be seen whether EPA now will require an EUP for small-scale experimental releases, given APHIS's abdication of this oversight role.

The SECURE Rule also clarifies that GE plant pests, GE biological control agents, and products regulated by EPA under FIFRA are not subject to duplicative regulation under Part 330 which implements the Plant Protection and Quarantine (PPQ) program for the movement of non-GE containing organisms and associated articles such as soil which may be or contain plant pests or biological control organisms.

Protecting CBI

CBI information submitted to APHIS under this rule must be clearly marked, and a copy of the submission must be included that has all information claimed as CBI deleted. Substantiation for all CBI, trade secret, and privileged information claims must be provided at the time of submission.

Parting Observations

The risk-based system of Part 340 presumes regulatory oversight over GE organisms designed for agricultural biotechnology as well as other uses. For example, the importation and interstate movement of GE microorganisms for a non-agricultural purpose, including research and development needs to be evaluated for compliance with these rules. Such products may be designed for release in open environments such as, for example, for bioremediation use at contaminated sites. There are a number of plants being explored as feedstocks for cellulosic ethanol and biodiesel including switchgrass, sorghum, miscanthus, short rotation woody crops, and algae. The PPA does not specifically grant APHIS authority over GE bioenergy plants or other organisms used for fuel production, but APHIS could be involved in regulation of these types of GE organisms where they present plant pest risks. In the case of GE insects for vector control, these products fall

under the jurisdiction of EPA; however, it is not clear where jurisdiction lies currently for GE insects for agricultural pest control.

The Part 340 regulations have always had an "off-ramp" from regulation if products do not pose a plant pest risk. USDA's modernized approach establishes more off-ramps, earlier in the process, for GE plants. While the actual benefits of USDA's modernized approach to regulating agricultural biotechnology GE plants under Part 340 will become apparent as APHIS implements the new regulations, as promulgated, they are clearly an improvement over the old Part 340.