## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 7 CFR Parts 330, 340, and 372

**[Docket No. APHIS–2018–0034]**

**RIN 0579–AE47**

## Movement of Certain Genetically Engineered Organisms

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending the regulations regarding the movement (importation, interstate movement, and environmental release) of certain genetically engineered organisms in response to advances in genetic engineering and our understanding of the plant pest risk posed by genetically engineered organisms, thereby reducing the regulatory burden for developers of organisms that are unlikely to pose plant pest risks. This final rule, which marks the first comprehensive revision of the regulations since they were established in 1987, provides a clear, predictable, and efficient regulatory pathway for innovators, facilitating the development of genetically engineered organisms that are unlikely to pose plant pest risks.

**DATES:** Effective August 17, 2020. Sections 340.4 and 340.5 are applicable beginning April 5, 2021.

**FOR FURTHER INFORMATION CONTACT:** Dr. Alan Pearson, Assistant Deputy Administrator, Biotechnology Regulatory Services, APHIS, 4700 River Road, Unit 98, Riverdale, MD 20737–1238; (301) 851–3944.

**SUPPLEMENTARY INFORMATION:**

### Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) administers the regulations in 7 CFR 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'' (referred to below as ''the regulations'').

These regulations govern the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered (GE) organisms.

Along with the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA), APHIS is responsible for the oversight and review of GE organisms. In 1986, the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework) [1] was published by the Office of Science and Technology Policy. It describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products and explains how Federal agencies use existing Federal statutes to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework explains the regulatory roles and authorities for APHIS, EPA, and the FDA. The Coordinated Framework was updated in 2017 in light of advances that had occurred since 1986 in the field of biotechnology.

APHIS first issued these regulations in 1987 under the authority of the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912, two acts that were subsumed into the Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) in 2000, along with other provisions. Since 1987, APHIS has amended the regulations six times, in 1988, 1990, 1993, 1994, 1997, and 2005, to institute exemptions from the requirement for permits to conduct activities for certain microorganisms and *Arabidopsis,* to institute the current notification process and petition procedure, and to exclude plants engineered to produce industrial compounds from the notification process.

While the regulations have been effective in ensuring the safe introduction of GE organisms during the past 30 years, they do not reflect the findings from APHIS' three decades of experience in evaluating GE organisms for plant pest risk or account for developments in genetic engineering over that period. APHIS' evaluations to date have provided evidence that genetically engineering a plant with a plant pest as a vector, vector agent, or donor does not result in a GE plant that presents a plant pest risk. Further, genetic engineering techniques have been developed that do not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents, yet may result in organisms that do pose a plant pest risk. Given these developments, as well as legal and policy issues discussed below, it has become necessary, in our view, to update our regulations accordingly.

On January 19, 2017, we published in the **Federal Register** (82 FR 7008–7039, Docket No. APHIS–2015–0057) a proposed rule [2] intended to revise our regulatory approach from ''regulate first before analyzing risks'' to ''analyze plant pest and noxious weed risks of GE organisms prior to imposing regulatory restrictions.''

Under the January 2017 proposed rule, a stakeholder could request that we conduct a risk assessment to determine whether a GE organism would pose plant pest or noxious weed risks and thus need to be regulated. Regulated GE organisms could be imported, moved interstate, or released into the environment under a flexible, risk-based permitting procedure.

APHIS received 203 comments on the proposal during the comment period. Commenters expressed concerns about many provisions of the proposed rule. Many stated that the proposed requirements would be too burdensome and had the potential to stifle innovation.

After reviewing the comments, APHIS subsequently withdrew the proposed rule. Following the withdrawal, APHIS conducted extensive outreach. Our outreach efforts took place in all regions of the United States and encompassed all sectors of the agriculture supply chain, as well as academic researchers, growers of various crops, and advocacy groups. Organizations ranged in size from small laboratories to larger scale businesses. APHIS also took proactive steps to meet with organizations both supportive and skeptical of agricultural biotechnology. In total, APHIS met with more than 80 organizations, including 17 universities, State departments of agriculture, and farmer organizations.

Much of the feedback received during this process centered on the need to focus regulatory efforts and oversight upon risk, rather than the method used to develop GE organisms. Stakeholders also expressed a desire for flexible and adaptable regulations so that future innovations do not invalidate the regulations. We also received feedback urging us to keep international trade objectives in mind when proposing new regulations and ensuring that new regulatory requirements are transparent and clearly articulated.

The feedback we received led us to update APHIS' regulatory framework, in a manner that further focuses our regulatory efforts on the properties of the GE organism itself rather than on the

[1] To view the 1986 framework, go to *https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.* To view the 2017 revision to the framework, go to *https://www.aphis.usda.gov/biotechnology/downloads/2017_coordinated_framework_update.pdf.*

[2] To view the 2017 proposed rule, the subsequent withdrawal, all supporting documents, and comments APHIS received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0057.*

method used to produce it. We believed that this regulatory approach would better reflect our current knowledge of the field of biotechnology and would therefore enable us to evaluate GE organisms for plant pest risk with greater precision than the existing framework allowed. The regulatory framework was also intended to enable APHIS to avoid conducting repetitive analyses, to utilize its staff time more efficiently than before, and to provide better stewardship of taxpayer dollars.

On June 6, 2019, we published in the **Federal Register** (84 FR 26514–26541, Docket No. APHIS–2018–0034) a proposal [3] to amend the regulations in accordance with the Secretary of Agriculture's March 28, 2018, statement on plant breeding innovations. The Secretary's statement and the accompanying explanatory details provided clarification on the USDA's oversight over plants produced through innovative, new breeding techniques, including genome editing techniques. (The statement and further details are available at: *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/2018_brs_news/plant_breeding.*)

We would note also that the June 2019 proposed rule and this final rule are consistent with the President's ''Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products'' (June 11, 2019, Executive Order 13874). Executive Order 13874 directs the Federal Government to adopt regulatory approaches for the products of agricultural biotechnology that are proportionate to the risks such products pose, and that avoid arbitrary or unjustifiable distinctions across like products developed through different technologies. Among other things, Executive Order 13874 states that regulatory decisions should be science- and evidence-based, taking economic factors into account as appropriate and consistent with applicable law; that regulatory reviews should be conducted in a timely and efficient manner; and that biotechnology regulations should be transparent, predictable, and consistent.

We solicited comments on our proposed rule and its supporting analyses until August 6, 2019. We received 6,150 comments by that date. They were from developers of GE organisms; growers of GE plants for food crops and other uses; trade associations representing both of those groups and sellers of such commodities as corn, soybeans, and grain; scientists representing academic institutions; organic farmers and trade associations representing their interests; consumer and public interest groups; and individuals. Most of the comments, while not form letters, expressed a generalized, similarly themed opposition to GE products. Of the comments that specifically addressed the provisions of the rule, approximately 25 expressed some support for the rule. The comments are discussed below by topic.

*Applicability of the Regulations*

Exemptions

The June 2019 proposed rule exempted from the regulations certain categories of plants that have been modified. Specifically, § 340.1(b)(1) through (4) proposed to exempt such plants if:

- The genetic modification is solely a deletion of any size; or
- The genetic modification is a single base pair substitution; or
- The genetic modification is solely introducing nucleic acid sequences from within the plant's natural gene pool or from editing nucleic acid sequences in a plant to correspond to a sequence known to occur in that plant's natural gene pool; or
- The plant is an offspring of a GE plant and does not retain the genetic modification in the GE plant parent.

In addition to above-listed categories, proposed § 340.1(c) stated that modified plants would not be subject to the regulations if they have plant-trait-mechanism of action (MOA) combinations that are the same as those of modified plants for which APHIS has conducted a regulatory status review (RSR) and found not to be subject to the regulations under part 340.

The above-listed exemptions elicited a broad spectrum of comments. Some commenters welcomed the regulatory relief offered by the exemptions as written, while others viewed them as too broad and still others as excessively restrictive.

Among the commenters who viewed the exemptions as excessively broad, several commenters stated that APHIS did not provide the ''necessary scientific justifications'' for the exemptions from regulation listed in proposed § 340.1(b)(1) through (3).

The exemptions in § 340.1(b)(1) through (3) are based on the principles listed below. (For reasons discussed later in this document, we are removing from this final rule the exemption contained in § 340.1(b)(4) of the proposed rule, which would have pertained to ''null segregants,'' or the offspring of a GE plant that does not retain the genetic modification in the GE plant parent; while there is still a paragraph (b)(4) in this final rule, it serves a different purpose which we discuss later in this document.)

1. Plants created through conventional breeding have a history of safe use related to plant pest risk;

2. The types of plants that qualify for these exemptions can also be created through conventional breeding; and

3. There is no evidence that use of recombinant deoxyribonucleic acid (DNA) or genome editing techniques necessarily and in and of itself introduces plant pest risk, irrespective of the technique employed.

When a plant meets one of the above-listed exemptions, therefore, it is not expected to pose plant pest risks greater than the plant pest risks posed by plants modified by conventional breeding methods and thus should rightly not be subjected to regulation under part 340. (The term ''conventional breeding'' may generally be used interchangeably with ''traditional breeding.'' In the June 2019 proposed rule, APHIS used both terms, with ''traditional breeding'' appearing more frequently in the text. Based in part on dialogue with other agencies involved in regulating biotechnology, we have elected to use the term ''conventional breeding'' throughout this final rule and its supporting documents, except when the need to quote directly indicates otherwise. For purposes of this rule and its supporting documents, ''conventional breeding'' has the meaning it is understood to have within the context of part 340, based on the examples provided immediately below. Other Federal or State regulations may use the term ''conventional breeding'' in the context of their regulations and attribute slightly different meanings.)

We noted in the preamble to the June 2019 proposed rule that conventionally bred crops have a long history of safe use with respect to plant pest risk and that the long history of conventional plant breeding gives us extensive experience in safely managing any associated plant pest risks. Conventional breeding techniques generally involve the deliberate selection of plants with desirable traits from existing population genetic variation or from new genetic variation

[3] To view the proposed rule, the comments we received, and supporting documents, go to *http://www.regulations.gov/#!docketDetail;vD=APHIS-2018-0034.* Additionally, please note that within the body of this document, that rule and this final rule are referred to at times as the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule. The SECURE rule is the nomenclature used by USDA to discuss the rule with stakeholders.

created through artificial hybridization or induced mutagenesis. As we noted in the June 2019 proposed rule, such techniques include marker-assisted breeding, tissue culture, protoplast, cell, or embryo fusion, and chemical or radiation-based mutagenesis. Products generated solely using such techniques have never been regulated under the part 340 regulations. Although conventional breeding is not risk free, the risks associated with it are, according to a 1989 National Research Council (NRC) report,[4] ''manageable by accepted standards.'' In other words, the types of traits that can be introduced through conventional breeding have not led to plant pest risk concerns.

The types of DNA modifications that occur through conventional breeding by mutagenesis are well characterized (Oladosu, *et al.,* 2016; Kharkwal, *et al.,* 2012). Among the common outcomes that result from mutagenesis are deletions, insertions, inversions, or translocations of DNA and base pair substitutions (Oladosu, *et al.,* 2016) which often result from double strand breaks in the DNA followed by natural DNA repair. Base-pair substitution also results from chemical modification of a base followed by natural DNA repair. These types of modifications occur at a low rate from naturally occurring environmental exposure to ionizing radiation, radical oxygen, chemical compounds, or biological agents such as viruses, or at an elevated rate in response to radiation and chemical-induced mutagenesis. In conventional breeding, these types of DNA modifications are introduced randomly. Individual plants possessing a mutation conferring a useful phenotype are isolated by screening, and random mutations that are introduced and do not convey a useful phenotype are addressed during backcrossing. New plant breeding technologies, such as those used in genome editing, can be used to create targeted double strand breaks in specific parts of the genome that when repaired result in deletions and small insertions, just as from natural environmental exposure or radiation mutagenesis (Chen, *et al.,* 2019). Likewise, new plant breeding technologies can also be used, in a specific, targeted manner, to create base pair substitutions that are similar to the modifications that can be created by random chemical mutagenesis. In other words, the same types of DNA modifications that occur in conventional breeding can also be constructed precisely using new plant breeding technologies (Custers, *et al.,* 2019). We are exempting plants generated using plant breeding technologies that have non-templated insertions and deletions and that have a single base pair substitution, because they could otherwise be created by conventional breeding and pose no increased plant pest risk relative to their conventionally bred counterparts.

The exemption in proposed § 340.1(b)(3) applies to the use of new plant breeding technologies to recreate the introduction of a gene, allele of a gene, or structural variation that could otherwise be introduced by crosses. APHIS notes that conventional methods of plant breeding and new plant breeding technologies often share the same goals with similar results. Human selection of plants has been used for thousands of years; and crossing has been used to introduce alleles into breeding populations since at least the early 18th century (Goulet, *et al.,* 2017). More recently, plant breeders have expanded the source of genetic material that can be used to introduce genetic changes into breeding populations through wide crosses, embryo rescue, and protoplast fusion (Bravo, *et al.,* 2011; De Filippis, 2014; Singh, 1990), as well as the rate of introduction of genetic material through marker-assisted and genomic selection; all of these approaches are considered conventional breeding methods and are used to expand and guide changes in the gene pool available within a population. Genetic engineering can be used to introduce a genetic sequence from any donor source into plants, which cannot be accomplished through conventional breeding. To limit the exemption in paragraph (b)(3) to what is possible in conventional breeding, the third exemption applies only to the introduction of a gene, allele, or structural variant known to occur from a donor source (1) in the same species as the recipient, or (2) in a species compatible via wide crosses, embryo rescue, or protoplast fusion with the recipient species.

The NRC has concluded in multiple studies[5] that there was no evidence of unique hazards inherent in the use of recombinant DNA techniques with respect to plants, and that crops modified by molecular and cellular methods should pose risks no different from those modified by conventional breeding methods for similar traits. Moreover, new molecular methods for editing genomes have been developed since the NRC studies that can be more specific and precise than those evaluated by the NRC studies, and plants modified by these new methods should also pose plant pest risks that are no different from plants that are modified for similar traits by conventional breeding methods. For all of the foregoing reasons, we consider the exemptions to be based on the best available science.

Some commenters stated that APHIS did not adequately consider risk when developing the exemptions. It was stated that the proposed exemptions do not consider potential pest risks or human, environmental, or agricultural impacts on nontarget organisms. A commenter claimed that APHIS regulates risks other than plant pest risks, such as inadvertent introduction to the food supply and economic impacts from gene flow, so there should be scientific evidence that plants exempted from regulations do not pose any of the full range of risks.

We do not agree with these comments. With regard to the commenters who stated that the exemptions failed to consider impacts on non-target organisms, APHIS considers impacts on non-target organisms that are beneficial to plants to be indirect plant pest impacts. It is not accurate to say that APHIS has previously regulated risks other than plant pest risks. Under the current regulations prior to the effective date of this final rule (referred to below as ''the current regulations''), APHIS has imposed measures to limit gene flow from GE plants that already met the definition of a *regulated article.* (Please see the ''Implementation Table'' on *Regulations.gov* regarding the dates when various provisions of this rule become applicable.) In these cases, APHIS considered the GE plants to be regulated articles because they had used a plant pest as the donor organism, recipient organism, or vector or vector agent, and therefore could pose a plant pest risk. As noted in the proposed rule, APHIS' evaluations to date have provided evidence that genetically

[4] National Research Council (NRC) 1989. Field Testing Genetically Modified Organisms: Framework for Decisions. Washington DC. National Academy Press. 185 pp. Retrieved from *http://www.nap.edu/catalog/1431.html.*

[5] National Academies of Sciences, Engineering, and Medicine (NAS) 1987. Introduction of Recombinant DNA-engineered Organisms into the Environment: Key Issues. Washington, DC National Academy Press. 24 pp. Retrieved from *https://www.nap.edu/read/18907/chapter/1.*

National Research Council (NRC) 1989. Field Testing Genetically Modified Organisms: Framework for Decisions. Washington DC. National Academy Press. 185 pp. Retrieved from *http://www.nap.edu/catalog/1431.html.*

National Academies of Sciences, Engineering, and Medicine (NAS) 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC National Academy Press. 420 pp. doi:10.17226/23395. Retrieved from *http://www.nap.edu/23395.*

engineering a plant with a plant pest does not in and of itself result in a plant that presents a plant pest risk, however. In cases where GE crops were not subject to regulation, no ''other risks'' such as inadvertent introduction to the food supply or economic impacts from gene flow have been regulated by APHIS insofar as they were outside the scope of the regulations.

A commenter opposed the exemptions listed in proposed § 340.1(b)(1) through (3) on the basis that plants produced through most methods that would be used for genome editing are regenerated from single cells in tissue culture, resulting in somaclonal variation with unpredictable consequences, and that off-target mutations caused by genome editing are more likely than chemical and radiation mutagenesis to be non-random. A second commenter asked that the exemptions be limited so that they apply only to plants produced using techniques that minimize off-target mutations. A third commenter asked whether off-target mutations are considered when determining eligibility for an exemption.

Somaclonal variation has been utilized extensively for breeding purposes, and the resultant new plant variety is not subject to the APHIS regulations in part 340 that we are replacing with this final rule (Krishna, *et al.,* 2016; Neelakandan and Wang, 2012). APHIS is not aware of a reason to mandate government oversight over new plant varieties resulting from somaclonal variation.

Background mutation occurs naturally in plants and does not raise plant pest risk concerns in conventional breeding programs. APHIS does not believe it is necessary to regulate off-target effects of genome editing in plants because (1) the off-target mutation rate from genome editing is low relative to the background mutation rate that occurs in conventional breeding, and (2) whatever changes do occur are likely to be segregated away from the target mutation during the breeding process. Comprehensive CRISPR/Cas off-target analysis on a genome-wide scale has been performed in rice, maize, tomato, and Arabidopsis (Feng, *et al.,* 2014; Feng, *et al.,* 2018; Peterson, *et al.,* 2016; Nekrasov, *et al.,* 2017; Lee, *et al.,* 2018; Tang, *et al.,* 2018). In these cases where the frequency of off-target mutation was measured in CRISPR/Cas expressing lines and their progeny, the authors concluded that the rate of off-target mutation was below the level of background mutation induced during seed amplification or tissue culture (Hahn and Nekrasov, 2019). Although there can be variation in off-target mutation rates due to the nature of the technique used and the biological system to which it is applied, the mutation rates in such conventional breeding techniques as chemical and irradiation-based mutagenesis dwarf the rate associated with such methods.

Due to the nature of plant breeding—in which populations are created and evaluated, and individual plants are selected for the intended modifications—off-target changes are likely to be lost unless they are genetically linked to the targeted modification that is introduced. APHIS wishes to clarify that, for these reasons, off-target mutations are not considered when determining eligibility for an exemption. This is also consistent with APHIS' approach regarding conventional breeding techniques. As noted above, these techniques often have a high mutation rate, but have a history of safe use with respect to plant pest risk. APHIS has modified the regulatory text in § 340.1(b) to indicate that we are considering only targeted modifications when determining eligibility for an exemption.

Some commenters stated that the scope of the exemptions listed in proposed § 340.1(b)(1) through (3) should be broadened to encompass the range of genetic modifications that are accessible to plant breeders through conventional breeding methods, and proposed alternative language that would allow an unlimited number of genetic modifications to be made and exempt from the regulations.

The commenters appear to have interpreted our references in the June 2019 proposed rule and its preamble to plants that could otherwise have been developed through ''traditional breeding methods'' to mean any type and extent of genetic change that is theoretically possible through conventional breeding methods. There are many biological and practical factors that affect a plant breeder's ability to develop a new crop variety by introducing genetic variation and intentionally selecting for desired traits. These include the number of targeted loci and type of desired genetic changes, the genetic distance between the desired changes, generation time, breeding system (sexual or asexual, self-compatibility), ploidy level and genomic complexity, resource availability (time, money, labor, and genomic resources), and other factors. These factors, and thus the extent of intentionally selected genetic variation that can be introduced, vary widely among plant species. Moreover, new plant breeding techniques can make possible more complex combinations of genetic modifications than can practically be achieved through conventional breeding methods (Custers, *et al.,* 2019; Wolter, *et al.,* 2019; Najera, *et al.,* 2019). Currently, APHIS lacks sufficient familiarity to develop a risk-based exemption for products containing complex combinations that might be produced in the future. APHIS is clarifying that the exemptions listed in § 340.1(b)(1) through (3) are based on types of modifications that are easily recognizable to the developers of the organism and on genetic changes that could be practically achieved by conventional breeding methods in any plant species. However, over time, APHIS expects to gain more familiarity with the products of these new plant breeding innovations. Accordingly, we are revising § 340.1(b) to establish a process for listing additional modifications that plants can contain while still being exempted from the regulations. This process is specified in paragraph (b)(4) of § 340.1 in this final rule.

Some commenters inquired how the exemptions in proposed § 340.1(b)(1) through (3) pertain to combinations of genetic modifications or to sequential edits. For example, would a deletion and a single base substitution made at the same time in a plant qualify for exemption? If a single change is made to a plant, when could another change be made that qualified for an exemption? Some commenters argued that there is no valid scientific reason that the exemptions should not allow multiple simultaneous genomic changes to be made. Other commenters asked us to reaffirm that the exemptions are limited to only a single genome editing change, and that a plant containing multiple changes made at the same or different times would not be exempt, or that we delete the exemptions altogether, since genome edits could be made sequentially such that each intermediate organisms would be exempt, cumulatively resulting in a final organism with many targeted changes that would also be exempt. Several commenters requested that APHIS include a process for adding new categories of exemptions and revising exemptions in order to ensure that the regulatory system stays up to date and keeps pace with advances in scientific knowledge, evidence, and experience.

APHIS seeks to clarify that exemptions listed in § 340.1(b)(1) through (3) apply to plants containing single targeted modifications. The exemptions were formulated to apply to what could otherwise be achieved through conventional plant breeding

techniques in any species. As discussed above, the plants that are eligible for exemption would have no increased plant pest risk than conventionally bred plants. APHIS realizes that in some species, a single targeted modification is often less than what could otherwise be developed through conventional breeding. However, as noted above, the extent of intentionally selected variation that could otherwise be introduced through conventional breeding varies depending on the plant species. To establish clear and unambiguous exemptions that could apply to any plant species while enabling for variation in what can be achieved through conventional breeding, APHIS has revised the regulatory text in § 340.1(b).

Initially, the exemptions will apply only to plants containing a single targeted modification in one of the categories listed. APHIS anticipates scientific information and/or experience may, over time, allow APHIS to list additional modifications that plants can contain and still be exempted from the regulations so that the regulatory system stays up to date and keeps pace with advances in scientific knowledge, evidence, and experience. This may include multiple simultaneous genomic changes. If the Administrator determines that it is appropriate to list additional modifications, APHIS will notify the public in the **Federal Register** and will take public comment. After reviewing the comments, APHIS will issue a subsequent notice announcing its determination. This process is provided in new paragraph (b)(4) in § 340.1.

One commenter requested that APHIS document examples of deletions of any size that could be made by conventional breeding.

The first exemption allows a single deletion of any size because radiation can create any size deletion. As mutations are typically detrimental to the organism, what is achievable in practice is limited by the viability and fertility of the organism. Large mutations can be maintained in a heterozygous state but do not tend to undergo homozygous inheritance (Naito, 2005). For example, in Arabidopsis, which has a genome size of 135 Mb (Arabidopsis Genome Initiative, 2000), a radiation-induced deletion of 3.1 Mb was obtained that disrupted 852 genes and was maintainable only as a heterozygote presumably because genes essential for survival are present in the deleted region (Kazama, *et al.,* 2017). Polyploid plants and those with large genomes are better able to accommodate even larger deletions (Men *et al.,* 2002). For example, in hexaploid wheat, X-ray mutagenesis was used to create a mutant, Ph1-, widely used in breeding programs, that has a 70 Mb deletion (Sears, 1977). To put the size of this deletion in perspective, it is larger than half of the entire genome of Arabidopsis.

Some commenters recommended that the exemption in § 340.1(b)(1) be broadened to allow for insertions that occur during the natural DNA repair mechanism after double-strand break of the DNA. In the proposed rule, the exemption in paragraph (b)(1) mentions only deletions.

APHIS agrees with the comment. Deletions, small insertions, and combinations of deletions and insertions are all possible outcomes resulting from the cellular mechanisms used to repair DNA breaks that occur naturally or that are induced during conventional plant breeding, and all have been used in conventional plant breeding (Manova and Gruszka, 2015; Wang, *et al.,* 2016). The exemption in § 340.1(b)(1) has been revised to reflect all of the possible outcomes of natural DNA repair mechanisms that occur in the absence of a deliberately provided repair template.

A commenter asked that APHIS eliminate the exemptions for deletions and single base pair substitutions, arguing that any type of change in a gene sequence can potentially cause phenotypic changes that have significant consequences.

APHIS disagrees with this argument. Naturally occurring single base pair substitutions and deletions are commonly induced and are widely used to generate new crop varieties in conventional mutation breeding, which includes both chemically induced and irradiation-based mutagenesis (Oladosu, *et al.,* 2016; Kharkwal, 2012; Ahloowalia and Maluszynski, 2001). The targeted single base pair substitutions or deletions covered by these exemptions are the same in kind as, and do not pose any increased plant pest risks than, the substitutions or deletions introduced through conventional breeding. Thus, they should not be subject to the regulations.

Many commenters argued that limiting the exemption in proposed § 340.1(b)(1) to a single deletion and the exemption in § 340.1(b)(2) to a single base pair substitution does not take into account that multiple base pair substitutions and/or deletions are routinely and safely introduced into plants using conventional breeding methods, including mutagenesis.

The argument that multiple substitutions or deletions can occur through conventional breeding methods, including mutagenesis, seems to be conflating the specific targeted changes that can be made via genome editing techniques with the multiple random changes that occur during conventional breeding, only one or few of which might contribute to the desired phenotype. In the case of random chemical or radiation mutagenesis, thousands of mutations are introduced into the plant but most are detrimental, or neutral at best. The fact that multiple mutations exist in the plant is a negative feature that needs to be overcome by laboriously self-fertilizing or backcrossing the mutated plant for multiple generations. Even then, a developer may not find an agronomically suitable phenotype. By applying selection, it is possible, though at a very low frequency, to get two desirable mutations in a single mutated line if the mutations are unlinked. It is improbable to get two linked mutations in a single line, particularly if the mutations are sought within the same gene. In contrast, genome editing can easily introduce multiple beneficial changes in one generation, leading to phenotypes that we have not seen by conventional breeding.

The exemptions listed in § 340.1(b) are based on measures that are easily defined, are based on familiarity, and thus are meant to be limited to genetic changes that could practically be achieved by conventional breeding methods in any plant. It is not possible to define a number of such changes greater than one which could practically be achieved by conventional breeding methods in all plant species. The number of changes that can practically be achieved through conventional breeding methods can vary widely from one species to another. For this reason, APHIS is retaining the limitation of a single modification, as this approach ensures that we can identify those plants that pose a plant pest risk. We anticipate that most plants that are not eligible for the exemption and do not pose a plant pest risk will pass through the RSR process quickly.

In addition, as noted above, we are revising § 340.1(b) by adding a new paragraph (b)(4) that establishes a process for listing additional modifications that plants can contain while being exempted from the regulations, based on what could be achieved through conventional plant breeding. Thus, while the exemptions in § 340.1(b)(1) through (3) will initially apply only to plants containing a single modification in one of the categories listed, APHIS anticipates that scientific information and/or experience will,

over time, allow multiple and sequential changes in some species after public notice and comment.

The introductory text of § 340.1(b)(4) provides that the Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be APHIS-initiated, or in response to a request.

Paragraph (b)(4)(i) sets forth the process for APHIS-initiated proposals. APHIS will publish a notice in the **Federal Register** of the proposal by the Administrator to exempt plants with additional modifications. The notice will make available any supporting documentation, and will request public comment. After reviewing the comments, APHIS will publish a subsequent notice in the **Federal Register** announcing its final determination and responding to the comments received.

Under paragraph (b)(4)(ii), any person may request that APHIS exempt plants developed with additional modifications that could be achieved through conventional breeding. The request will have to include the following supporting information, in writing:

- A description of the modification(s);
- The factual grounds demonstrating that the proposed modification(s) could be achieved through conventional plant breeding;
- Copies of scientific literature, unpublished studies, or other data that support the request; and
- Any information known to the requestor that would be unfavorable to the request.

Paragraph (b)(4)(iii) provides the timeframe for Agency review of such requests. It provides that, after APHIS receives all the information required for a request, APHIS will complete its review of the request and render a final determination within 12 months, except in circumstances that could not reasonably have been anticipated.

Under paragraph (b)(4)(iv) if, after review of the request, APHIS disagrees with the conclusions of the request or determines that there is insufficient evidence that the modification could be achieved through conventional breeding methods, APHIS will deny the request and notify the requestor in writing regarding this denial.

Paragraph (b)(4)(v) provides for Agency actions when we agree with a request. It states that, if APHIS initially determines that the modification could be achieved through conventional breeding methods, APHIS will publish a notice in the **Federal Register** in accordance with the process set forth in § 340.1(b)(4)(i).

Under paragraph (b)(4)(vi), a list specifying the additional modifications allowed will be posted on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.* This list would include both those additional modifications originally proposed by the Administrator and those that originate with a request.

Some commenters suggested a change to the exemption in proposed § 340.1(b)(2) so that it would allow a limitless number of synonymous base pair changes. Synonymous base pair changes, it was stated, do not alter the amino acid composition of the encoded protein. One commenter suggested changing the exemption to allow however many specific and known base pair changes are needed to achieve the intended MOA.

APHIS rejects the first suggestion because synonymous changes can lead, and indeed have been made, to generate significant phenotypic changes, *e.g.,* by altering mRNA splice sites, promoters, and regulatory RNAs. APHIS acknowledges that these types of phenotypic changes could, in principle, also occur through a single deletion, insertion, or base pair change in conventional breeding. However, these types of phenotypic changes are unlikely to be possible in all or perhaps even most genes through deletion or single base pair changes. Moreover, multiple targeted changes within a single gene are generally not likely to be achieved in conventional breeding. Therefore, the exemption will not be broadened to include multiple synonymous base pair changes. However, as discussed below under this same subheading of comment responses, we have revised the exemption in § 340.1(b)(3) to clarify that if multiple sequence changes are needed to generate an allele that will result in the intended phenotype and if those changes are known to occur in the plant's gene pool, the GE plant would qualify for the exemption.

One commenter stated that APHIS should eliminate the exemption in paragraph (b)(3), regarding introducing variation known to occur in the gene pool, because sequences found naturally in closely related, sexually compatible organisms do not necessarily have acceptable risks when introduced into other species. The commenter offered an example, stating that ''the introduced nucleic acids can direct the synthesis of toxins, change metabolism in harmful ways, turn on or off genes and metabolic pathways in the genetically engineered host, and make the genetically engineered organism more susceptible to pests and pathogens, or more fit in the wild and more weedy.''

APHIS disagrees with the comment. The commenter is pointing out harms that potentially could occur, and are no less likely to occur, in conventional breeding programs. However, such harms have not materialized in conventional breeding programs because they rarely occur and are intentionally eliminated during the evaluation and selection process (NRC, 1989).

One commenter wished to know whether the exemption in proposed § 340.1(b)(3) supersedes the exemption in § 340.1(b)(1) and (b)(2). Another commenter felt that the exemptions in paragraphs (b)(1) and (b)(2) were too narrow because polymorphisms, insertions, inversions, and multiple megabase deletions and translocations are abundant in nature and frequently induced in breeding programs through mutagenesis.

APHIS seeks to clarify that § 340.1(b)(3) does supersede § 340.1(b)(1) and (b)(2) in the number of changes that can be made under the exemption. APHIS also seeks to clarify that paragraphs (b)(1) and (b)(2) pertain to products of mutagenesis which have not been observed in the gene pool, whereas paragraph (b)(3) applies only to variation already known to occur in the gene pool. Therefore, the exemption in paragraph (b)(3) allows the introduction of a gene, *i.e.,* a functional unit of DNA that encodes an RNA or protein, or of an allele (a variant form of a gene or, for the purposes of this regulation, a genetic sequence) containing multiple sequence changes as long as the allele is known to occur in the gene pool of the plant. With regard to the comment that the exemptions in paragraphs (b)(1) and (b)(2) are unnecessarily restrictive because there are changes abundant in nature not covered by these exemptions, APHIS wishes to clarify that the duplications, inversions, translocations, and transpositions already known to occur in the gene pool would qualify under the exemption in paragraph (b)(3).

Some commenters suggested deleting ''natural'' from § 340.1(b)(3) because the gene pool of a plant may include variation that has been previously induced through chemical or radiation mutagenesis or that could be introduced via human-assisted wide crosses. Further comments on the exemption in paragraph (b)(3) recommended substituting the phrase ''known to occur'' with some variation of

''otherwise accessible through traditional plant breeding methods.''

APHIS agrees with the first comment and disagrees with the second. APHIS considers the known and accessible gene pool of a plant to include not only genetic sequences that can be introduced to a plant via crosses that can take place without human assistance, but also genetic sequences that can be introduced to a plant via human-assisted wide crosses between distantly related species. In systems for which breeding techniques such as bridging and embryo rescue have been developed to enable wide crosses, distantly related plants are also considered part of the gene pool. However, these categories may not be considered ''natural,'' so APHIS is in favor of deleting this term. APHIS is retaining the phrase ''known to occur,'' however. As discussed above, when we refer to GE plants that could otherwise have been developed through conventional breeding methods, we do not mean any genetic changes that are theoretically possible. Almost any genetic change is theoretically possible, given enough time. APHIS' intention in § 340.1(b)(3) is to exempt from regulation a product that could be practically expected to be pursued and achieved in a conventional breeding program. To qualify for an exemption based on occurrence in the gene pool, the genetic change must be known to occur. We do not intend the exemption to apply to limitless possibilities that are theoretically possible but not currently known to occur in the gene pool. Consequently, the exemption in paragraph (b)(3) has been slightly modified for accuracy and clarity.

Some commenters asked that the exemption in paragraph (b)(3) be expanded to include plants in which an allele has been modified to align with a similar known allele found in a close relative, or in a more distant relative beyond the family level of taxonomy, or that we exempt plants containing any sequence from a plant that is known not to be a plant pest and is routinely used for food.

APHIS considers the known and accessible gene pool of a plant to include not only genetic sequences that can be introduced to a plant via crosses that can take place without human assistance, but also human-assisted wide crosses between more distantly related species. In systems for which breeding techniques such as bridging and embryo rescue have been developed to enable wide crosses, more distantly related plants are also considered part of the known gene pool. APHIS agrees in principle that exchange of genetic information between unrelated species is likely to be safe in most cases. However, APHIS does not have the experience to definitively state that exempting all exchange of DNA between plants will not lead to increased plant pest risk. In cases where genetic material from a more distantly related plant species is introduced into the plant, developers can request an RSR.

A commenter stated that their understanding is that the exemption in § 340.1(b)(3) would include any insertion or other sequence modification of less than 20 base pairs. APHIS disagrees and seeks to clarify that even an insertion or sequence modification smaller than 20 base pairs that does not otherwise qualify for exemptions § 340.1(b)(1) or (b)(2) still has to meet the criteria of paragraph (b)(3) to qualify for exemption under paragraph (b)(3). The exemption does not apply to what is theoretically possible. The genetic variation must be known to occur in the plant's gene pool in order to qualify for the exemption.

A commenter stated that the regulation could clarify that exemption under paragraph (b)(3) covers the introduction of natural or chemically synthesized copies of nucleic acid sequences from one plant species into the same or a crossable plant species, including (a) the targeted insertion or replacement of sequences exceeding 20 base pairs in length (*e.g.,* the insertion or replacement or a promoter, terminator, exon, intron, or small open reading frame, excluding complete genes), (b) the targeted replacement of a cisgenic allele (*i.e.,* perfect allelic replacement), (c) the targeted insertion of a cisgenic sequence at the same or a different location in the genome of the recipient species, and (d) the targeted insertion of a cisgene with a new combination of genetic elements, as plants containing such changes could have occurred naturally or could result from conventional breeding since they fall under exemption under paragraph (b)(3). A second commenter stated that some genetic engineering experiments will replace promoters, altering gene expression patterns in ways that are not attainable by today's breeders.

APHIS does not intend to modify the regulation text per the commenter's suggestion. Exemption under paragraph (b)(3) will exempt from regulation plants that have been modified to introduce a gene known to occur in the plant's gene pool, or that make changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool. Some of the examples provided by the first commenter may thus not be eligible for exemption under paragraph (b)(3). For instance, (b)(3) will not exempt from regulation a plant containing an insertion of a gene that is known to occur in the gene pool if the insertion results in the creation of a gene not known to occur in the gene pool, *e.g.,* a gene that results in the production of a protein or RNA, or a loss or gain of function, that is not known to be produced by plants within the gene pool. However, if a specific modification can be demonstrated to be present in the plant's gene pool, then it can be exempted under paragraph (b)(3). If a developer has a question about whether its plant is exempt from the regulation, the developer can contact APHIS for a consultation.

Some commenters asked how the deletion exemption in § 340.1(b)(1) pertains to diploid and polyploid plants. For example, if a deletion is made to both alleles of a diploid or all four or six alleles in tetraploid and hexaploid plants, respectively, would those plants qualify for the exemption?

APHIS seeks to clarify that exemptions in § 340.1(b)(1) through (3) apply to modifications made to one pair of homologous chromosomes. It is very straightforward in conventional breeding to identify a single allele in a diploid line and then convert the heterozygote to a homozygote in the next generation. However, it is very difficult through conventional breeding to create the same allele in all homoeologous genomes in polyploid plants. Therefore, for polyploid plants, the exemptions would initially apply only to modifications made to one pair of homologous chromosomes. As an example, consider a change to a gene in common wheat (bread wheat). Common wheat has three sets (AA BB DD) of homoeologous chromosomes. A developer can qualify for the exemption if modifying the A genome through a change that qualifies for exemption (b)(1), (b)(2), or (b)(3). If the developer wanted to make the same corresponding changes to the B and D genomes, the developer would go through the RSR process (as described below). Once APHIS determines that this A/B/D plant is unlikely to pose an increased plant pest risk, it will go on the list of plant-trait-MOAs that do not require regulation (*i.e.,* the § 340.1(c) exemption list). At that point, this developer, and any others, would be able to make the same plant-trait-MOA combination and be exempt from regulation under part 340.

Some commenters noted that the exemption in proposed § 340.1(b)(4), *i.e.,* the exemption of null segregants derived from GE plants, is superfluous

because the definition of *genetic engineering* applies only to organisms whose DNA sequence has been modified.

APHIS agrees with these commenters. According to our definition of *genetic engineering,* the genome of null segregants has not been created or modified. Therefore, null segregants do not need an exemption from regulation, and APHIS is removing this exemption from the final rule.

Some commenters stated that the exemption in proposed § 340.1(c) for a GE plant with a plant-trait-MOA combination that has previously undergone an analysis in accordance with § 340.4 and has been found by the Administrator to be unlikely to pose a plant pest risk should be eliminated. One commenter stated that the impact of releasing new GE plants into the environment cannot be accurately predicted or assessed without case-by-case analysis and controlled field experiments. Another commenter stated that every transformation event is unique, and thus potentially has a novel phenotype that must be assessed to determine appropriate regulation. The commenter further stated that the National Academy of Sciences (NAS) has also advocated the use of genetic engineering [*i.e.,* transformation] as ''both a useful and scientifically justifiable regulatory trigger'' because ''there is no scientific basis'' on which to exclude GE organisms from regulatory review prior to evaluation of data on the interactions between ''trait, organism and environment.''

APHIS disagrees with these points. Based on the risk assessments we have performed in accordance with the petition process over 30 years, we have determined that, in many cases, we would have been able to evaluate the plant pest risks associated with a GE organism without field-test data. Rather, APHIS has discovered that the introduced trait of the GE organism provides the most reliable indicator of the organism's potential for deleterious effects on plants and plant products. These observations are expected and are consistent with the findings of reports of NAS (NRC, 1989; NAS, 2016). APHIS will seek additional information, potentially including data from controlled field experiments, in cases where APHIS identifies a plausible pathway to increased plant pest risk.

The same NAS study (NRC, 2002) cited by the commenter stated the following: ''Transgenic organisms have potential environmental risks, but the committee expects that most of them will not produce significant actual environmental risks. Consequently, the committee also suggests that for environmental risk regulatory oversight should be designed to winnow the potentially riskier transgenic crops from the less risky ones before a substantial regulatory burden is imposed on the less risky ones.'' APHIS has designed a system where organisms that pose a plausible plant pest risk are rapidly distinguished from those that do not, based on the RSR process described below under the subheading ''Regulatory Status Review,'' focusing regulation on the former. The exemption that we proposed in § 340.1(c) will apply only to those GE plants that have undergone a risk assessment in the RSR process. The revised regulations are proportionate to risk and are therefore consistent with the recommendation of NAS's study.

Several comments were received on the definition and application of the term MOA as it relates to the exemption in § 340.1(c). The issues raised by the commenters are discussed in detail below.

Two commenters stated that the categories of trait (defined in the June 2019 proposed rule as ''an observable (able to be seen or otherwise identified) characteristic of an organism'') and MOA (defined as ''the biochemical process(es) through which genetic material determines a trait'') could be interpreted so broadly that new GE plants that have a plant-trait-MOA combination similar to that of a nonregulated plant, yet contain unique features with unknown impacts on non-target organisms and the surrounding ecosystem, would not require review by APHIS. They stated that, for example, the ''Cry[6] protein MOA'' could include dozens of possibilities with unknown effects, and that it could even be the case that APHIS review would not be required when any gene encoding a Cry protein that targets broad orders of insect pests is inserted into a plant that had previously been engineered with any other trait and had been found by APHIS not to pose a plant pest risk.

APHIS disagrees with the suggestion that the proposed definition of MOA is too broad. The suggestion is based on a misreading of the definitions and the preamble of the June 2019 proposed rule. As described in the preamble, the MOA refers to the specific manner by which the genetic modification confers the intended trait on the plant. We noted that the same trait can be obtained by different MOAs that would thus be subject to distinct RSRs. In the example cited, the preamble was clear that non-target impacts related to Cry proteins depend on whether the non-target insect has the correct receptor in its gut to bind the Cry protein; thus, for each new Cry protein it will be important to evaluate the potential for non-target impacts. Similarly, the preamble provided an example of RNA interference-based resistance, where it would be important to consider the specific target RNA and its corresponding protein in order to determine whether there could be non-target effects. Moreover, the regulatory text and preamble were clear that it is the specific plant-trait-MOA combination that is the subject of the RSR and decision. Developers could not qualify for exemption under § 340.1(c) by inserting any *cry* gene that encodes a protein targeting a broad order or orders of insects into a plant with any other trait and MOA that was previously reviewed by APHIS.

Another commenter stated that reasonably broad MOA categories should be established that would cover broad protein functional classes, account for all normal polymorphisms found in nature at the DNA and protein levels at the genus level, and account for the normal wide variation in expression seen among transgenic events and backgrounds. An additional commenter recommended that the definition of MOA refer to the biochemical process(es) through which the gene, rather than the genetic material, determines a trait, stating that it is a gene product and not the genetic material that determines the resulting biochemical process. Finally, a commenter requested that the final rule clarify which products would qualify for the exemption in § 340.1(c), noting that APHIS alternately used the terms ''same'' and ''similar'' to describe products that could qualify based on their use of a crop-trait-MOA combination that has already been assessed by APHIS and determined unlikely to pose a plant pest risk than the appropriate comparator(s).

APHIS agrees that in most cases, the MOA could cover all normal polymorphisms of a gene found in nature, even at levels broader than the genus. For example, the outcome of an RSR would apply 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

[6] A Cry protein is a crystalline protein toxic to certain species of insects primarily produced by the bacterium *Bacillus thuringiensis* (Bt). Genes for Cry proteins have been widely used to confer resistance to insect pests in several types of crop plants.

additional biochemical reactions that differ among the source organisms. APHIS does not agree that the MOA would be so broad as to cover broad functional classes, since broad functional classes could encompass many different proteins that have multiple differences in the biochemical processes in which they participate. Typically, an RSR would be conducted at the level of the MOA of individual genes. If those genes when stacked produce a new phenotype, such as a new biochemical pathway, APHIS will consider the interaction of the gene products in the RSR. Regarding variation in expression, in most cases APHIS anticipates that variation in expression should not affect the outcome of an RSR. However, as we noted in the preamble to the June 2019 proposed rule, there may be cases where it is important to consider where, when, or at what level the genetic material is expressed in the plant. In those cases, APHIS will specify whether and in what way variation in expression limits the outcome of the review.

APHIS will not revise the definition of MOA in response to these additional comments, because some MOAs may not involve changes in gene products but rather changes in genetic material that affect the expression of gene products. As this discussion makes clear, a plant-trait-MOA combination may qualify for the exemption only if the combination is the same as a previously reviewed plant-trait-MOA combination that has been found to be unlikely to pose a plant pest risk. To be clear, a merely ''similar'' combination does not qualify as a ''same'' combination, but a ''similar'' product may qualify for the exemption if it has the same combination as a previously reviewed combination.

One commenter urged that in addition to mutated products of genome editing, the concept of exemptions due to familiarity should be broadened to include plants with transgenic traits that are familiar in type and inherently unlikely to give a significant advantage to wild plants. Examples would be sterility traits, stature reduction traits, and quality traits relevant to industrial processing (*e.g.,* modified lignin in alfalfa and trees). According to the commenter, another class of strong candidates for plant kingdom-wide exemption are the widely used marker genes, such as *nptII* for kanamycin resistance, T–DNA borders, and widely used promoters such as 35S and NOS.

APHIS appreciates these comments. The commenter did not provide any scientific evidence or explanation that would make the comments actionable at this time, however.

Several commenters asked that APHIS clarify the regulation of plants containing stacked traits. One commenter requested that APHIS codify in the regulations that plants developed through conventional breeding that are derived from products determined to not be regulated (either because of an exemption or as a result of an RSR) would themselves be unlikely to pose increased plant pest risk and therefore would not be subject to regulation. Other commenters argued that APHIS should assess the risks of stacked traits, particularly plants containing multiple herbicide resistance traits, using the noxious weed authority.

A discussion of our noxious weed authority in the context of these regulations is presented later in this document.

APHIS notes that in accordance with § 340.1(c), the regulations under part 340 do not apply to a GE plant with a plant-trait-MOA combination that has previously undergone an analysis in accordance with § 340.4 and is not subject to the regulations. APHIS notes that the word ''combination'' used in the regulation text is deliberately enumerated as singular and not plural in order to denote that the exemption applies to a single plant-trait-MOA combination and not a molecular stack of multiple plant-trait-MOA combinations. Plant-trait-MOA combinations that have undergone an analysis in accordance with § 340.4 and are not subject to the regulations may be stacked by conventional breeding methods and would still qualify for the exemption. However, this is not the case for plant-trait-MOAs stacked molecularly; today stacked traits typically have independent MOAs. In the future, we anticipate seeing more interactions between or among the products of genes in molecular stacks, potentially including new MOAs that were not evident in the review of individual traits. For this reason, APHIS anticipates that plants that are the genetically engineered product of more than one previously evaluated combination will be subject to evaluation under § 340.4. In cases where there is no interaction between trait-MOA combinations, we expect to be able to use the results of previous reviews to quickly reach a regulatory status determination.

Finally, several commenters requested clarity on the regulatory status of plant-trait-MOA combinations that were previously deregulated under part 340 or deemed to be not regulated under the ''Am I Regulated'' (AIR) process.

To provide the clarity the commenters requested, we are amending paragraph (c) to exempt from these regulations a GE plant that has a plant-trait-MOA combination contained in a GE plant determined by APHIS to be deregulated under a petition submitted prior to October 1, 2021 pursuant to § 340.6 of the current regulations in part 340. We are also adding a new paragraph (d) to § 340.1, stating that all GE plants determined not to require regulation pursuant to the AIR process will retain their nonregulated status under these regulations.

As we have noted, APHIS will publish a list (referred to earlier in this document as the § 340.1(c) exemption list) of plant-trait-MOA combinations that have been evaluated under our new RSR process and found not to require regulation under part 340. That list may be used by a developer to determine whether its novel GE plant would qualify for exemption under § 340.1(c). GE plants previously evaluated under the petition process will be included on the § 340.1(c) exemption list because such plants will have effectively been evaluated at the MOA level and determined not to pose a plant pest risk.

Plants that have been determined not to require regulation pursuant to the previous AIR process will not be included on the § 340.1(c) exemption list because they will not have been evaluated at the MOA level or by analogous criteria. Such plants will be identified at a separate list, at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.* Because the plants to be identified on this separate AIR list were not evaluated under the petition process or under the RSR process, developers will not be able to use the AIR list in determining whether new GE plants they develop should be subject to or exempt from the regulations. At the same time, we have multiple reasons for concluding that the specific plants on the AIR list should retain their nonregulated status under these regulations. Not only do we lack a basis for overturning our prior individualized determinations reached pursuant to the AIR process, we also believe that it is appropriate for us to take into account the importance of preventing potential market disruptions, including potential trade disruptions, and providing regulatory certainty for developers, third parties, and the general public.

Self Determination

Under the June 2019 proposed rule, developers would have the option to determine whether their plants belong to one of the categories listed under § 340.1(b) or (c) and are therefore

exempt from the regulations. As stated in the preamble to that proposed rule, allowing for such ''self-determinations'' would provide developers with regulatory relief and would open more efficient and predictable pathways for innovators to get new modified plants that do not require regulation to market, in turn supporting further innovation. Eliminating the need for redundant evaluations of products would allow APHIS to devote more attention to assessing and regulating GE organisms that are likely to be associated with potential plant pest risks.

While many commenters agreed with the rationale discussed above and welcomed the regulatory relief that allowing for developer ''self-determination'' would provide, others either opposed the concept entirely or expressed reservations. Many in the latter category cited what they believed to be potential risks that could result from allowing developers to determine whether their products are eligible for exemption from the regulations. Some industry commenters questioned whether allowing developers to make such determinations would actually relieve regulatory burden and incentivize innovation to the extent that we anticipated. The comments are discussed in detail in the paragraphs that follow.

Many commenters opposed ''self-determination'' on the ground that allowing developers to regulate themselves could result in conflicts of interest. It was stated that developers of GE products with a financial stake in the outcome should not be allowed to determine which products should be subject to regulatory review. According to these commenters, such an approach would fatally undermine the integrity, rigor, and credibility of what must be an independent regulatory process, weakening Agency ability to protect the public interest, and furthering mistrust in the U.S. Federal regulatory system in the public's eye and among key trading partners. By avoiding the RSR or permitting process, these commenters believed, the developer could get its new product to market without its ever having undergone an objective, third-party review. In allowing developers to determine whether their products are eligible for exemption, according to these commenters, we are effectively abdicating our regulatory authority and not carrying out our mission to protect U.S. agriculture.

We do not agree with these comments. The revised regulations in part 340 recognize that plant products that are the result of modifications that coincide with conventional plant breeding do not pose additional plant pest risk and should not be regulated under these regulations. Products that do not fall within the regulatory scope of part 340 have not been subject to compulsory regulation in the past, and developers have always been able to act accordingly to determine whether their products are subject to the regulations.

It was further argued that allowing developers to determine the regulatory status of their products will result in less transparency and greater risk of commingling with organic and other non-GE crops and will damage consumer confidence. Allowing developers to determine the regulatory status of their products, it was claimed, will result in an overall loss of transparency in that the public would not have access to the data used by developers to make their determinations. Organic farmers would have less information about modified crops grown near their fields than they do now, because the information that informed developers' determinations would remain proprietary, and their ability to take preventive measures would be hindered. Some commenters cited the recent finding in Washington of unapproved GE glyphosate-resistant wheat [7] as an example of risks posed by allowing developers to determine whether their products are eligible for exemption and by reducing our regulatory oversight over GE products more broadly.

We do not agree with these comments. With regard to transparency, we anticipate that many developers whose products fall within an exemption will request confirmation letters because the letters will help them market their products domestically and overseas. Those letters will be posted on the APHIS website and will be available to the general public, including organic and other growers of non-GE crops. Information from previous RSRs will also be available to the public. We do not agree that self-determinations will limit organic growers from learning whether their neighbors are growing GE crops. This information principally comes from conversation with neighbors and from other voluntary interactions and arrangements, and is not based on USDA decisions on regulatory status. We also do not agree that the finding of GE wheat in Washington fields is relevant to the regulatory changes made in this final rule. Under the new regulations set forth in this final rule, the GE wheat involved in the incident would not be eligible for an exemption and would need to go through the RSR process. The commenters are generally confusing a fact-specific compliance issue, which could arise under any number of regulatory schemes, with broader questions about the appropriate regulatory approach. If APHIS were to find that a plant was unlikely to pose an increased plant pest risk, APHIS would make information publicly available regarding the plant, trait, and a general description of the MOA. In cases where GE crops are not subject to regulation because they are unlikely to pose a plant pest risk, no other risks are regulated by APHIS insofar as they are outside the scope of the regulations.

In the preamble to the June 2019 proposed rule, we stated that a developer who made a determination of regulatory status that APHIS found not to be valid would be subject to remedial measures or penalties in accordance with the compliance and enforcement provisions contained in § 340.6 of the June 2019 proposed rule.

Some commenters stated that there is a need for a plan for detection and enforcement in cases where developers incorrectly determine their products to be non-regulated, or where changes in evidence may call a developer's determination into question. Without a record of what plants are being released, according to these commenters, it will be impossible to conduct any kind of periodic surveillance or audit to ensure compliance. These commenters believe that this difficulty may be partly addressed by having a compulsory reporting mechanism whereby a responsible party fills out a form to declare its modification and assert its exempt status. This would create a searchable record. According to such commenters, a database compiled from self-reported data would not offer complete protection against bad actors, but when combined with penalties that are proportional to the degree of harm done by a developer incorrectly making a determination, such a database may aid in correcting incorrect determinations by developers.

APHIS disagrees with the proposal for a mandatory process and the data base proposals associated with it and has instead included provisions in part 340 for a voluntary confirmation process for

[7] On June 7, 2019, APHIS confirmed the discovery of GE wheat plants growing in an unplanted agricultural field in Washington State. The GE wheat in question was resistant to glyphosate, commonly referred to as Round Up. On July 12, 2019, APHIS announced that the GE wheat plants in question were developed by Monsanto (now owned by Bayer CropScience (BCS)) and referred to as MON 71300 and MON 71800. APHIS also announced that there is no evidence that any GE wheat entered commerce or is in the food supply. *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-andinformation/2019_brs_news/wheat_update_jul2019.*

products exempted from the regulation. Voluntary confirmation will be public information, however, and interested parties could search for it of their own volition.

Under APHIS's long-standing regulations, APHIS regulates articles based only upon a narrow and limited plant pest mechanism. The products that commenters are concerned will be ''missed'' or ''overlooked'' in the ''future'' have no current regulatory trigger. Under this rule, APHIS' focus will be on plant pest risk associated with the product, consistent with our legal authority. Consistent with long-standing practices, we will continue to offer voluntary confirmation of regulatory status to those who seek it. APHIS agrees with comments expressing concern that a mandatory process may trigger confusion among both consumers and the international trading partners, by unnecessarily hindering global acceptance of products of biotechnology. That said, if the market demands confirmation of regulatory status, APHIS has created a mechanism for developers to request such confirmation, and for us to provide it.

APHIS also notes that a large number of commenters supported the kind of voluntary confirmation process contained in this final rule for regulatory exemptions, noting public access to the confirmation letters. Those comments noted that a voluntary process would provide domestic and international transparency, be beneficial for marketing of new products, support deregulation processes in other countries, facilitate exports, facilitate the development of new genome edited plant varieties, encourage the continued domestic and global adoption of new traits, and enhance harmonization of global trait approvals.

If a plant pest issue arises from a plant that is exempt from these regulations, APHIS has mechanisms to address such risks subsequently and has a wealth of experience in dealing with such instances. As under the current regulations, a developer could knowingly or unknowingly violate APHIS regulations by transporting, importing, or releasing into the environment a regulated plant without APHIS authorization. The PPA contains authority for the Administrator of APHIS at any point to place such articles under regulation. If a determination made by a developer should be found to be invalid, however, APHIS does have the authority to enforce sanctions. As noted in the preamble to the June 2019 proposed rule, pursuant to sections 7714 and 7731 of the PPA, APHIS may seize, quarantine, treat, destroy, or apply other remedial measures to an organism covered under the regulations that is new to or not widely prevalent or distributed in the United States to prevent dissemination of the organism. Enforcement provisions are also included in § 340.6 of this rule. APHIS has many years of experience in initiating and coordinating enforcement action as appropriate, in cases where compliance issues exist.

Even in cases where we would impose penalties for invalid determinations by developers, some commenters expressed skepticism that those penalties would be efficacious in remediating harm or preventing further harm. In the view of these commenters, if the movement or release of a GE product that had already reached the market based on a faulty determination by a developer resulted in commingling with other crops or the dissemination of plant pests, whatever penalties or remedial actions APHIS would impose would likely neither prove adequate to address injuries to innocent parties nor provide sufficient disincentives to discourage bad actors from making invalid determinations. Elaborating on the latter point, one commenter stated that penalties imposed by APHIS after the fact may not even be legally defensible if we have allowed a developer to determine whether its product is eligible for exemption. Another commenter stated that APHIS, lacking a post-commercialization monitoring program, has little capacity to recall the products of invalid determinations by developers.

We do not agree with these comments. In the event that APHIS discovers that a developer makes an invalid determination, the specific penalties and/or remedial action will be applied case by case, as appropriate. Similarly, whether the discovery of an invalid determination is too late will also be decided on a case-by-case basis. In regard to legal defensibility, the PPA provides ample flexibility and broad civil penalty authority to deter violations of the PPA. For example, the PPA provides statutory maximum penalties of $1,000,000 per violation for any person who willfully violates the PPA.

Other commenters feared that the penalties could be excessive. It was stated that any such penalty applied to a developer must be based on a demonstration of significant economic harm to another entity from the error, and not on technical or minor errors in interpretation. The commenters further stated that in such situations, the penalties must be proportional to that harm.

We agree that penalties must be proportional to the severity of violations and the harms that may result from them, and we will enforce the regulations accordingly. Furthermore, the harms must fall within the harms considered under the PPA. Congress has outlined the factors for consideration in assessing penalties under the PPA. These factors include ''the nature, circumstance, extent, and gravity of the violation or violations,'' as well as the violator's ability to pay, the effect of the penalties on the violator's ability to continue to do business, and any history of prior violations. (See 7 U.S.C. 7734.)

In the preamble to the June 2019 proposed rule, we stated that one of the benefits of ''self-determination'' is that it would enable APHIS to focus its regulatory resources and risk analyses on unfamiliar products and thereby to avoid conducting repetitive analyses on GE products that are very similar to those that we have already evaluated for regulatory status. APHIS would thus be able to utilize its staff time more efficiently, and provide better stewardship of taxpayer dollars than it could under the existing regulations.

One commenter viewed allowing developer-made determinations as evading APHIS' regulatory responsibilities rather than enabling APHIS to use its resources more efficiently. The commenter stated that if GE developers are concerned about delays in getting their products to market because, in their view, APHIS does not have sufficient resources to conduct all reviews in a timely manner, then those developers should lobby Congress to provide more funding to enable APHIS to perform its duties in a more timely manner, as opposed to having APHIS reduce its oversight role.

APHIS disagrees with this comment. The plants that qualify for exemption under part 340 fall into three categories: (1) Those that could otherwise have been developed through conventional breeding methods and have a history of safe use related to plant pest risk that does not require regulation (§ 340.1(b)(1) through (3)); (2) those that have the same plant-trait-MOA combination as other plants that have already been evaluated by APHIS and have been found to be not subject to the regulations (§ 340.1(c)); or (3) those determined to be not subject to the regulations under the AIR process. It should be noted that plants that qualify for exemption under § 340.1(c) are very similar to plants that have been evaluated previously by APHIS. APHIS can utilize its resources most efficiently

by evaluating GE plants that do not fall into these categories and therefore may pose a level of plant pest risk that requires regulation.

Many other commenters expressed skepticism from an opposing perspective about the efficacy of allowing developers to determine whether their products are eligible for exemption. These commenters doubted that such ''self-determination'' would provide the regulatory relief that we claimed in the preamble to the June 2019 proposed rule. One reason given was that most developers would seek certification or confirmation from APHIS that their determinations were valid, given the possible liabilities associated with making incorrect determinations. Such certification would therefore become a *de facto* requirement. One commenter expressed the concern that in order to receive such confirmation, developers would need to provide the information described in proposed § 340.4, which contains information requirements for RSRs. It was further suggested that while academics, startups, and small developers could see some benefit from ''self-determination,'' companies with existing portfolios of GE crops will be in a better position to benefit.

We do not agree with these comments. If innovators choose to forgo the regulatory relief provisions offered by our revision of the regulations in part 340 for any reason, they are welcome to do so. In this final rule, APHIS focuses on plant protection, while also easing regulatory burdens. Accordingly, we also aim to be responsive to repeated concerns raised by small businesses, academic-based researchers, and other innovators who have reported past difficulty successfully seeing products through to commercialization. The approach APHIS has taken is fully consistent with the priorities and direction provided by Executive Order 13874, which we have discussed earlier.

In § 340.1(d)[8] of the June 2019 proposed rule, we indicated that developers may request confirmation from APHIS that the plant is not within the scope of the regulations in part 340. A developer may find a confirmation letter useful in marketing its products domestically or overseas because the letter would serve as verification to an importing country or other party that APHIS concurs with the developer's determination. Confirmation is not required, however, and for developers not seeking confirmation letters, no submission of information to APHIS is required, nor is any response from APHIS. Guidelines for the information that would need to be submitted to enable APHIS to respond to a request for confirmation are discussed below under this same subheading of comment responses.

Some commenters expressed doubt that developers would even be able to employ the ''self-determination'' option due to what they perceived as a lack of clarity surrounding it. It was stated that decisions on a product's regulatory status would be based on APHIS' assessment of plant pest risk, but that because APHIS would define plant pest risk and because APHIS did not provide a list of traits for identification of a plant pest in the proposed rule, a developer would lack the guidance to make a determination safely.

APHIS disagrees with this comment. This rule clearly outlines the kinds of information needed to successfully navigate the APHIS regulatory system, as well as the protection goals and criteria that APHIS will consider as part of this process. Plants that meet the exemptions listed under § 340.1 will not require regulatory oversight under the regulations in part 340. The exemptions in § 340.1(b) are based not on the trait, but on whether the plant could have otherwise been produced through conventional plant breeding techniques. The exemption in § 340.1(c) is based on whether the plant-trait-MOA combination is the same as one that APHIS has previously determined to be nonregulated. APHIS will publish a list of such combinations, which developers may use in determining whether their GE plants qualify for exemption under § 340.1(c). As more GE plants undergo RSRs to determine their regulatory status, that list will grow. A list of traits for identification of a plant pest is not needed in order for developers to determine whether their products meet one of these exemptions in § 340.1(b) or (c).

Several commenters recommended that we provide more certainty about the process by issuing guidance documents to aid developers in making their determinations. Such documents, it was stated, could include, among other things, information requirements and timelines, including timelines for APHIS responses to requests for confirmation. Many commenters stated that, in general, defined timeframes for APHIS regulatory actions are important to improve predictability and to support the planning needed to conduct seasonally based field research, and therefore should be included in the regulations. Most commenters who provided specific timeframes for confirmation requests suggested that APHIS should respond to such requests within 60 days. It was further suggested that to provide developers with additional guidance for making determinations, APHIS should maintain a database of products that have undergone RSRs and been found not to be subject to the regulations.

APHIS has had a longstanding practice of providing guidance to aid the regulated community in complying with the regulations. APHIS will provide guidance to developers regarding the confirmation process. We will also maintain on our website requests for and results of RSRs. That information will aid developers in making their determinations.

Regarding timeframes, in the preamble to the proposed rule, APHIS noted that we anticipate a timely turnaround time in providing confirmation letters. APHIS agrees that providing a more specific timeframe for responses to confirmation requests would improve predictability. Based on our experience with the current AIR process, which is functionally similar to the confirmation process, APHIS has amended § 340.1(e) by adding a sentence indicating that, except in unforeseen circumstances, written responses will be provided within 120 days of receiving a confirmation request containing sufficient detail to determine whether the plant meets one of the exemptions in § 340.1.

One commenter stated that the type of information provided to APHIS by developers should be a description of the crop and the justification for meeting the exclusion, which would be similar to the information submitted for the ''Am I Regulated'' Process.

APHIS agrees with the sentiment expressed in this comment and is therefore setting out guidelines for parties requesting confirmations to submit to APHIS in support of their requests. The guidelines are listed below and will also be posted on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.* In addition, developers who have specific concerns may consult with APHIS.

In communications with APHIS requesting confirmation of exemption from the regulations, requestors will be expected to submit the following:

1. A description of the plant, trait(s), and modification(s).

2. A clear statement of which regulatory exemption the biotechnology developer is claiming for the plant and

[8] Due to the addition of a new paragraph (d) in § 340.1, as described earlier, provisions related to confirmation letters are contained in § 340.1(e) of this final rule.

why the plant qualifies for that exemption.

3. Details about the scientific method used to validate that the plant met the exemption criterion.

APHIS expects that the description of the plant will include both the scientific and common names. The trait information should include a description of the intended and any observed phenotype(s) of the plant. Details about the modification(s) must provide APHIS with a clear understanding of the genetic change in the plant. In the case of § 340.1(c) exemptions, requestors must submit the MOA.

Many commenters advocated that we establish a mandatory process for developers to notify APHIS of their determinations and for APHIS to issue confirmations. (We would note here, however, that there was considerable divergence of opinion on this issue, with 25 commenters expressing support for maintaining a voluntary confirmation process.) Some commenters requested that confirmation be mandatory for all determinations made by developers, while others stated that confirmation should be mandatory only for developer-made determinations of products that will be commercialized. Many requested that the process be streamlined and include information and self-reporting requirements and timelines. It was recommended by some commenters that developers be required to provide notice to APHIS 90 days before putting a product on the market.

We will not be making any changes to this final rule in response to these comments. The confirmation process laid out in the June 2019 proposed rule was voluntary, and switching over to a ''mandatory'' confirmation and/or notification process in this final rule would run counter to the spirit of regulatory relief underlying our new regulatory framework. A voluntary confirmation process allows the market to drive the demand for new plants, avoids codifying a process that may grow antiquated as technology develops, provides developers with a method to obtain confirmation that their products are in fact exempt from the regulations, and avoids differential treatment for genome-edited products that are otherwise equivalent to conventionally bred and/or developed products.

Commenters did not persuasively explain how developers of products that are not subject to the regulations could be compelled to comply with a requirement for mandatory participation in a confirmation process. APHIS notes that even if the commenters had provided a sufficient regulatory mechanism to impose such a requirement, a mandatory process would likely trigger the emergence of trade concerns, as products that are scientifically justified to be exempt would also appear on lists of GE organisms–essentially creating a third category of products that are required to be listed but are otherwise exempt from regulation (in addition to two other categories: (1) Organisms that were subject to RSR and determined not to be regulated by APHIS, and (2) regulated organisms). APHIS further notes that a mandatory process would likely disadvantage the very small-scale, mid-size, and university researchers and innovators that the rule was intended to aid. Lastly, APHIS notes that the proposal for a mandatory confirmation provides no added benefit in plant protection.

Some of the commenters who favored a formal or mandatory confirmation process did so because they questioned the utility of a voluntary process. It was stated that an APHIS confirmation that a determination made by a developer is valid, as provided for in the June 2019 proposed rule, will be a formulaic letter without an accompanying risk assessment. Some trading partners may not view such confirmation letters as sufficient to meet their own requirements for admission of U.S. GE products. It was stated that to keep export markets running smoothly, industry needs an official U.S. attestation that the new traits do not pose a plant pest risk.

We do not agree with these comments. The confirmation letters will state that the product in question meets a regulatory exemption or has a plant-trait-MOA combination that has already been reviewed by APHIS. APHIS currently works with, and is committed to continuing to work with, international trading partners and exporters to resolve trade concerns. International trade issues are discussed in greater detail later in this document.

Some commenters addressed the issue of whether, or how much, information pertaining to determinations made by developers and APHIS confirmations should be made public. Some commenters, citing the need for transparency and certainty, recommended that we post confirmation inquiries and confirmation letters on our website. Others, however, thought that such information should be treated as confidential business information (CBI) and therefore not be made publicly available. One commenter suggested that we use a process similar to that of the existing ''Am I Regulated'' process, under which CBI exemptions could be claimed in the request for confirmation submitted to APHIS, and a non-CBI version of the submission could be made publicly available.

In the interest of transparency, APHIS will post the confirmation letters online. APHIS notes, however, that confirmation letters are subject to claims of CBI and will proceed in implementation of such posting in accordance with all applicable laws and procedures. In accordance with USDA regulations, 7 CFR 1.8(a) through (c), a submitter of confidential commercial information must use good-faith efforts to designate, at the time of submission, any portion of its submission that it considers to be protected from disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552). When making discretionary releases of records, as is the case with the posting of the confirmation letters online, APHIS follows the FOIA, USDA, and APHIS implementing regulations (7 CFR subpart A and 7 CFR 370.5, respectively), and guidance from the U.S. Department of Justice's Office of Information Policy relating to the handling of confidential business information.

Finally, there were a few comments on proposed § 340.1 that did not fall into any of the categories discussed above.

One commenter suggested that the exemptions should focus on plant species, not variety, as well as the purpose and type of application of genome editing. The commenter stated that genome editing can be used both to produce or improve on a specific characteristic or phenotype, such as by silencing a disease sensitive gene, and to improve existing breeding processes themselves, such as by using gene editing to more efficiently induce double haploids.

The ''purpose and type of application of genome editing'' is just another way of describing the plant-trait-MOA combination. In the example given above where genome editing is used to improve an existing breeding process by more efficiently inducing double haploids, genomic modifications will be made to a specific plant, with a specific trait, having a specific MOA. Recently a widely used haploid inducer in corn was identified to be a defective allele (*matL*) of the gene named Matrilineal (Kelleher, 2017). A haploid induction trait was shown to work in rice by genome editing the *matL* allele (Yao, 2018). APHIS considers this new process to be an example of a plant (rice), trait (haploid induction), MOA (defective pollen specific phospholipase) combination. Upon

completion of an RSR for this plant trait MOA combination, the § 340.1(c) exemption would apply to all varieties of rice, not just the variety it was introduced into.

Another commenter thought that there was a possible conflict between §§ 340.1(c) and 340.2(a). The latter paragraph of the proposed rule stated that a plant with a plant-trait-MOA combination that has not been evaluated by APHIS for regulatory status in accordance with § 340.4 would have to move under permit. According to the commenter, the conflict arises because products we would allow to move without permits based on developers' determinations would not have been evaluated by APHIS.

We do not see such a conflict. When a developer determines that a GE plant falls under § 340.1(c), it is not subject to the regulations in part 340 and therefore does not require a permit for movement. We are making an editorial change to § 340.2(a), however, to clarify that a GE plant will be subject to the regulations: (1) If it has not undergone an RSR in accordance with § 340.4; or (2) if it has undergone an RSR and, as a result of the evaluation, is subject to the regulations. Such GE plants will require permits for movement.

One commenter stated that by allowing developers to determine whether their products are eligible for exemption, we would not be in compliance with the requirement of the Cartagena Protocol on Biosafety that countries list all GE organisms released into the environment in the Biosafety Clearing House.

APHIS notes this comment, and wishes to clarify that the United States is not a signatory to the Cartagena Protocol on Biosafety. APHIS also notes that Article 3 of the Cartagena Protocol on Biosafety does not reference ''GE organisms.'' Instead, Article 3 (g) states that ''living modified organism means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.'' Many international efforts are underway to align regulatory approaches and to seek compatibility for emerging technologies that were not in existence when existing policies were developed.

Two commenters requested that APHIS develop and issue guidance for developers of non-plant GE organisms to give them an opportunity to determine for themselves whether their products are subject to the regulations and to apply to APHIS for confirmation of regulatory status.

APHIS does not agree that such a new process needs to be developed. Currently, the Agency responds to the developers' questions about whether a specific GE organism, including a non-plant organism, is subject to the regulations. APHIS will continue that practice after this final rule becomes effective.

**Scope of the Regulations**

Section 340.2 of the June 2019 proposed rule delineated the scope of the regulations. We proposed to regulate, *i.e.,* require a permit for the movement of, any GE organism that:

1. Is a plant that has a plant-trait-MOA combination that has not been subject to RSR; or
2. Meets our proposed definition of a *plant pest;* or
3. Is not a plant but has received deoxyribonucleic acid (DNA) from a plant pest, and the DNA from the donor organism either is capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease; or
4. Is a microorganism used to control plant pests or an invertebrate predator or parasite (parasitoid) used to control invertebrate plant pests and could pose a plant pest risk.

As was the case with the proposed exemptions, commenters expressed a wide range of views regarding the scope of the proposed regulations. While some supported our overall approach, others expressed the view that the proposed rule would either narrow or broaden our regulatory oversight excessively.

Some commenters who favored a broader scope stated that a regulatory approach that provides for regulations of only those GE organisms that are plant pests or pose a plant pest risk is too narrow. Such an approach, it was stated, isolates the GE organism from the environment in which it is used and the process by which it is developed, thereby impeding science-based risk assessment. According to these commenters, other hazards potentially associated with GE organisms and not accounted for in the June 2019 proposed rule need to be addressed. Some concepts discussed in these submissions included the increased potential for commingling with non-GE crops; the potential for contributing to the creation of herbicide-resistant weeds; pesticide overuse; habitat destruction; reductions in insect populations; and increased herbicide use, which, according to the commenters, has been associated with GE crops and may have additional deleterious effects on the environment and on human health.

While we recognize commenters' interests in addressing these concerns, many of these comments are outside the scope of this rulemaking and APHIS's statutory authority under the PPA. Commingling between GE and non-GE crops is generally a market issue unrelated to plant pest risk. Herbicide use is regulated by EPA, not USDA, so is not within the scope of this regulation. The basis for the commenter's claim that GE crops result in habitat destruction is not clear; however, we note that APHIS does not regulate farming practices. USDA's National Resources Conservation Service does have incentive programs to promote more sustainable farming. The current rule includes an RSR process that considers, as appropriate, impacts (if any) of a GE crop on populations of beneficial insects and other non-target organisms beneficial to agriculture.

Some commenters questioned the scientific justifications for the above listed categories of GE organisms that would fall under the regulations. It was stated that APHIS needs to re-cast its entire proposal and frame it around the identification of the characteristics of the organism or phenotypes of concern for which a plausible case can be made, based not on speculation but data and experience, that they present an unreasonable risk to American agriculture. It was further argued that there is no scientific justification for regulating by plant-trait-MOA instead of phenotype associated with the trait.

In order for the regulations under part 340 to enable future innovation while simultaneously protecting American agriculture from potential risks to plant health, it is vital that the regulations be prospective rather than retrospective, while being appropriately tailored to risk. A regulation that enumerated specific phenotypes that APHIS is concerned with would not only be impractical, since a phenotype may be of concern in one plant species but not in another (including depending on whether the plant has sexually compatible relatives, an attribute important for considering the distribution of a phenotype introduced into a plant), but would become immediately obsolete upon issuance. As articulated clearly in numerous studies, including those by the National Academy of Sciences, no entity has the foresight to identify only those phenotypes that present concerns decades into the future. Moreover, the MOA utilized by the developer matters when determining if there is a plant pest risk. The same intended phenotype can result from multiple different MOAs, but each MOA may differ in other phenotypes and thus may differ in their ability to present a plant pest risk and

in the types of plant pest risk they may present.

APHIS thus does not consider the approach of regulating solely by phenotype to be feasible. Instead, APHIS has articulated a regulatory approach that is adaptable to future innovation and continues to protect against risk, even in cases where it is not possible to envision the kinds of products being developed in the future. In particular, we have developed the RSR process in order to determine, based on scientific knowledge and information, if a GE plant contains a plant-trait-MOA combination that could plausibly present an increased plant pest risk than the appropriate comparator plant(s). We will regulate a GE plant only when we identify and are unable to rule out a plausible pathway to increased plant pest risk. In this way, when sufficient data and experience are lacking to rule out a plausible risk identified by APHIS, we have a mechanism to acquire more information to test the specific plausible risk hypothesis before decision making.

The risk-based system APHIS has developed in part 340 appropriately provides entrance for genetically engineered organisms into the regulatory framework and provides appropriate off-ramps from regulation for those products that do not pose plant pest risks. Conversely, a narrowly focused characterization of an intended phenotype, regardless of the plant species or MOA by which the phenotype is conferred, would not provide a sound scientific basis for an entire regulatory program. Many commenters expressed support for our scientific and risk-based regulatory process that evaluates plants based on their plant-trait-MOA combination.

A commenter stated that the restriction in § 340.2(c) covering a non-plant GE organism that has received DNA from a plant pest is unclear and lacking in scientific justification. The commenter questioned whether receiving DNA from a plant pest would likely make the recipient into a plant pest.

The commenter misconstrues § 340.2(c), which states that non-plant GE organisms that receive DNA from a plant pest will be regulated if that DNA is capable of producing an infectious agent that causes plant disease or if the DNA encodes a compound that is capable of causing plant disease. Such non-plant GE organisms could pose a plant pest risk, justifying their regulation under part 340.

Some commenters stated that organisms and microorganisms used to control plant pests should not require regulation if they are not plant pests themselves or do not pose a plant pest risk. One commenter stated that there appears to be a conflict between § 340.2(d) and EPA's regulatory authority under the Federal Insecticide, Fungicide, and Rodenticide Act for microbial pesticides. The commenter further stated that the intent of the PPA for biological control organisms is to facilitate their development, but that APHIS is proposing to require additional regulatory requirements without indicating a need for these extra requirements in terms of protecting against plant pests.

We agree with the first comment (*i.e.,* that organisms and microorganisms used to control plant pests should not require regulation if they are not plant pests themselves or do not pose a plant pest risk), and this rulemaking does not provide for the regulation of biological control organisms if they are not plant pests themselves or do not pose a plant pest risk. As we noted in the preamble to the June 2019 proposed rule, ''GE non-plant organisms that do not pose a plant pest risk would not fall under the scope of the regulations and therefore would not require permits for movement.'' We disagree with the remaining comments. As we noted in the preamble to the proposed rule, while biological control organisms are generally not plant pests, some biological control organisms could be plant pests because their potential effects on organisms beneficial to agriculture could indirectly affect plant health. The PPA provides the authority to regulate such biological control organisms used to control plant pests to ensure that they do not pose a plant pest risk. As with non-GE biological control organisms, the types of GE biological control organisms that APHIS would regulate include organisms that could pose a plant pest risk by lacking sufficient specificity for the target pest and thereby harming beneficial non-target organisms, such as other invertebrate predators or parasites (parasitoids), pollinators, or microbes that promote plant health. Because biological control organisms are almost always intended for eventual release into the environment, it is not sufficient for us to consider only their use in controlling their target plant pest. We must also take into consideration the indirect plant pest risks that the organism may pose due to harmful impacts on non-target organisms that are beneficial to agriculture (*e.g.,* harm to natural enemies of plant pests). If the GE organism is known to have harmful impacts on beneficial non-target organisms, it is consistent with APHIS' authority under the PPA to prohibit or restrict its release. To the extent that we do not know whether a GE biological control organism is sufficiently specific to avoid harming beneficial non-target organisms, it is also prudent for us to place regulatory controls on the movement and release of the GE biological control organism until the impacts on beneficial non-target organisms and any resulting direct or indirect plant pest effects are better understood. In addition, we will exempt biological control organism-containing microbial pesticide products that are currently registered with EPA as microbial pesticide products that are not plant pests.

*Definitions*

In this final rule, we have revised the definition of *article* to provide greater clarity. The definition in the June 2019 proposed rule was drawn from that provided in the PPA. However, while the PPA indicates that an article may be an object that could harbor noxious weeds, upon review of the provisions of the proposed rule, we have determined that it is not appropriate to consider such an object an article under these revised part 340 regulations. The proposed definition could have been interpreted to suggest that APHIS intends to regulate GE organisms, and require permits for their movement, under the revised regulations based solely on their noxious weed potential. As discussed elsewhere in this document, however, this is inconsistent with APHIS' intent. The revised definition reads as follows: ''[a]ny material or tangible object that could harbor plant pests.''

A commenter stated that we need to define *environment,* because movement under permit includes release into the environment. *Environment* was defined in the proposed rule, however, and we are retaining that definition in this final rule.

In the June 2019 proposed rule, we defined environment as ''[a]ll the land, air, and water; and all living organisms in association with land, air, and water.'' We are retaining that proposed definition without modification in this final rule.

Numerous commenters stated that the proposed definition of *genetic engineering* requires greater clarity. Several commenters asked APHIS to clarify that ''synthetic'' nucleic acids, for the purposes of this regulation, are those that are non-naturally occurring. Some commenters requested that APHIS clarify what is meant by both ''recombinant'' and ''synthetic'' nucleic

acids and cited the definitions and exemptions in the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules'' (*https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf*). One commenter stated that they understood the term ''synthetic nucleic acid'' to refer to a sequence that was created ''new from scratch,'' and not to a plant's nucleic acid sequence that was modified.

APHIS does not agree that the term ''recombinant'' requires further definition in these regulations. After nearly half a century of research and development involving recombinant nucleic acids, the term ''recombinant nucleic acids'' is well understood. The definition that APHIS proposed was based on the definition of ''recombinant and synthetic nucleic acids'' contained in Section I–B of the NIH Guidelines. Accordingly, by ''synthetic'' nucleic acids we mean nucleic acids that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules. Such nucleic acids are not limited to those that are non-naturally occurring. They could also include nucleic acids with sequences identical to those that are naturally occurring, but which have been synthesized or amplified, rather than constructed by joining nucleic acid molecules (nucleic acids that have been so constructed are recombinant nucleic acids). APHIS agrees that greater clarity regarding the term ''synthetic'' would provide developers and other stakeholders with a clearer picture of the products that are included within the scope of the regulations. Therefore, we are changing the definition of ''genetic engineering'' to ''techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome.'' This change is consistent with the objectives of the Coordinated Framework, in that it aligns our usage of the term ''synthetic'' with that of the NIH.

One commenter believes that the definition for *genetic engineering* should include changes to the epigenome.

APHIS does not agree. Epigenetic changes are caused by endogenous regulatory processes, such as DNA methylation and histone modifications through naturally occurring enzymes. Epigenetic changes are also caused by small naturally occurring RNA molecules. Epigenetic changes reflect an interaction of the genome with the environment that leads to changes in gene expression without changing the sequence of DNA. Epigenetic engineering differs from genetic engineering in that the former merely adjusts the innate potential of the genome of an existing organism, whereas genetic engineering has the potential to create organisms that could not exist but for the technology.

Some commenters recommended that we add a definition of *genetically engineered organism* to provide greater clarity relating to which organisms would be regulated. The following language was a suggested definition: ''An organism developed using genetic engineering, excluding those offspring that do not retain the genetic modification of the parent. For the purposes of this part, a plant will not be considered a genetically engineered organism if it meets any of the criteria outlined in § 340.1(b)(1)(3).''

We do not agree with this comment. At the forefront, the SECURE rule establishes clear exemptions for products that are not subject to regulatory oversight under part 340, and, thereafter, sets forth definitions for *genetic engineering* and for *organism.* Although we are able to offer regulatory relief in part 340 by excluding those products of biotechnology that mimic what can be achieved though plant breeding, APHIS has not, in this rulemaking or prior rulemakings involving part 340, taken the position that genome editing does not constitute genetic engineering. Taking such a position would be inconsistent with the generally accepted scientific characterization of genome editing technology (Knott and Doudna, 2018). While some commenters have asked APHIS to revisit its proposed definition of ''genetically engineered organism'' from the 2017 proposed rule involving part 340, even in that rulemaking APHIS did not take the position that genome editing was outside the scope of genetic engineering. Instead, APHIS explained it was defining ''genetically engineered organism'' for the purpose of establishing regulatory exemptions from part 340, including exemptions for certain organisms created using techniques that fall within the scope of genetic engineering, as follows: APHIS ''would also exclude, from its definition of GE organism, certain organisms that are *created using techniques that fall within the scope of genetic engineering,* but that could otherwise have been produced using traditional breeding techniques . . . .'' (82 FR pp.7008 and 7015, January 19, 2017). As discussed above, the SECURE rule establishes regulatory exemptions at the forefront, which promotes clarity regarding the scope of part 340, and avoids adopting a confusing characterization of techniques of biotechnology.

A couple of commenters stated that the proposed rule lacked a definition of *natural gene pool* and a discussion of its relevance in terms of safety.

The term was used in the regulatory text in § 340.1(b)(3). As discussed above, we have removed ''natural'' from that paragraph. We discussed the relevance of exemption under paragraph (b)(3) to plant pest risk above. We are, however, adding a definition of the term *gene pool* to the regulations in this final rule in response to these comments. *Gene pool* is defined as germplasm within which sexual recombination is possible as a result of hybridization, including via methods such as embryo culture or bridging crosses.

One commenter viewed our proposed definition of *person* as potentially problematic in that it could open APHIS to legal challenges. The commenter expressed concern that because the definition includes not only individuals, business entities, and associations but also any other ''organized group,'' the argument could be made that APHIS falls under the definition. If so, according to the commenter, there might be the possibility of a conflict if decisions under these regulations are taken by the Administrator of APHIS. The commenter requested clarification on this issue.

The definition of *person* would apply to individuals or entities regulated by APHIS, including APHIS. Under the law, a company is an entity that is recognized as a legal person that exists independently, with rights and liabilities. APHIS has, in the past, issued itself permits in conjunction with enforcement of the regulations so that plant products could move legally across state lines. This practice is not inconsistent with the PPA or with the prior or new regulations. Therefore, regulation by APHIS under part 340 will not create conflict or otherwise be adversely impacted.

A commenter stated that the proposed definition of *plant pest* is too broad and could be construed to cover model organisms, such as *Drosophila melanogaster,* that do not have significant negative effects on agriculture. The commenter stated that an overly broad definition is of concern to biomedical researchers because some invertebrates they use could be classified as plant pests. Noting the lack of a mechanism to acknowledge that an organism that consumes plant material is not detrimental to agriculture, the commenter recommended that APHIS establish a mechanism for classifying an

organism as ''agriculturally unimportant within the plant pest category'' and that such a classification have influence on APHIS' regulatory processes.

APHIS appreciates the comment, but does not believe that it is necessary for APHIS to establish such a mechanism. The definition of *plant pest* is based directly on, and does not exceed, the definition of the term in the PPA. The proposed regulations contained an exemption from the requirement for permit for interstate movement for *Arabidopsis thaliana.* In this final rule, we are adding an exemption from some permitting requirements for GE *Drosophila melanogaster,* which we will discuss in more detail below, under the subheading ''Permits.''

Another commenter stated that by adopting a definition of *plant pest* that aligns with the definition provided in the PPA, APHIS would regulate a broad range of GE animals, including those used in medical research, thereby imposing large, new, and unwarranted regulatory burdens on researchers in medical research and other fields.

APHIS disagrees with the comment. As we stated in the preamble to the proposed rule, while the PPA gives APHIS authority to regulate any nonhuman animal as a plant pest, it is longstanding APHIS policy not to regulate vertebrate animals as plant pests. In the absence of such a policy, all herbivores and omnivores could be considered plant pests, and thus subject to regulation, an untenable position since this would require APHIS to consider livestock, such as cows, sheep, and horses, as well as many laboratory research animals, to be plant pests.

In the June 2019 proposed rule, we defined *plant pest risk* as ''[t]he possibility of harm to plants resulting from introducing or disseminating a plant pest or exacerbating the impact of a plant pest.'' Many commenters viewed the proposed definition as vague and potentially problematic due to the terminology we used.

Commenters expressed concern that the words ''possibility of'' in the proposed definition are vague and uncharacteristic of standard risk assessment terminology and methodology, which characterizes risk as either a likely or probable adverse outcome. Some commenters requested that the definition of *plant pest risk* be defined in terms of the likelihood and magnitude of harm. Commenters also expressed concern that the word ''harm'' in the proposed definition is inconsistent with the PPA, and that the regulatory end-point should be risk of causing injury to, damage to, or disease in any plant or plant product. It was stated that the inconsistency and lack of precision in the terminology used in the proposed definition could leave risk-based decisions made by APHIS open to criticism or challenge for not addressing all possibilities for harm, no matter how unlikely.

APHIS agrees with the commenters that greater clarity and consistency in the definition of *plant pest risk* would be useful. APHIS is revising the definition accordingly. We agree that the words ''possibility of'' could be construed in a manner that is inappropriate. Numerous scenarios could be put forward as the basis for events that represent the ''possibility'' of harm without any plausible basis for concluding that such scenarios have any likelihood of occurring. The glossary of the Society for Risk Analysis (SRA), which is available at *https://www.sra.org/sites/default/files/pdf/SRA_glossary_20150622.pdf,* defines *risk* as, among other things, ''the potential for realization of unwanted, negative consequences of an event.'' The SRA glossary makes clear the distinction between the qualitative definition of risk and the metrics that are used to measure or characterize risk, which are framed in terms of likelihood and magnitude of an adverse outcome. We view a qualitative definition as more appropriate for defining risk, and use likelihood and consequence to evaluate scientifically plausible risks identified in the RSR process discussed below under the subheading ''Regulatory Status Review.'' We also find the SRA terminology to be more useful than ''possibility of'' and are revising our definition of *plant pest risk* accordingly. We are also revising the definition to refer to injury to, damage to, or disease in any plant or plant product. Accordingly, this final rule defines *plant pest risk* as ''[t]he potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest.''

Importantly, while APHIS defines *plant pest risk* in this rule in reference to the potential for direct or indirect injury, damage, or disease, the RSR process itself is based on standard risk assessment practices and uses a methodology that focuses on a likelihood and magnitude assessment of *plausible* risks. Since the RSR process will require that a plausible risk be identified in order to proceed with further risk assessment, it will not be an open-ended evaluation of any conceivably ''possible'' scenario that could be imagined.

One commenter stated that the term *plant-trait-MOA is* not defined as a combination, though the individual terms are defined in the proposed rule, and that if the combination has its own meaning, APHIS should clarify that.

The term *plant-trait-MOA* refers to three individual terms/factors for analyzing whether certain GE organisms may present a plausible pathway to plant pest risk and by which we determine whether a product actually poses a plant pest risk.

Under the definition of *responsible person* in the June 2019 proposed rule, responsibility for maintaining control over a GE organism under permit during its movement and assuring compliance with all permitting conditions could be given to an individual or an institution. A commenter stated that individuals should not be included under the definition. According to the commenter, responsibility should reside only with the institution with which the signatory or any other individual bearing such responsibility is affiliated. The commenter pointed out that staff often move among jobs well before permit conditions are fulfilled.

As discussed in the preamble to the June 2019 proposed rule, attributing responsibility for a GE organism moved under permit to only an institution may be problematic for enforcement of the regulations, because such responsibility can be diffused, resulting in no individual's being held responsible for compliance with the permit conditions, the regulations in part 340, and the PPA. Our definition ensures that for each permit, there is a single individual who is responsible for ensuring an institution's compliance with permit conditions, regulatory requirements, and the PPA. If this individual moves to a different job or otherwise leaves an institution, responsibility for any permits can be officially transferred, subject to APHIS' approval, to another qualified individual, as described in § 340.5(i)(10) of this final rule (''permit conditions'').

A commenter stated that there is no justification for the requirement, contained in the proposed definitions of both *agent* and *responsible person,* that they be legal U.S. residents, and that there is no means of verifying such a requirement.

We are retaining the requirement, as it would be a stronger mechanism for ensuring accountability in the regulatory program than the existing definition. We have learned through administration of the program that the existing definition is not adequate, and has not provided the necessary framework to hold noncompliant

developers responsible (*e.g.,* academic researchers who returned to their native countries without taking steps to destroy their GE-test material prior to departure).

Finally, we have revised the definition of *State* to read as follows: ''[a]ny of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territories or possessions of the United States.'' This definition aligns with that contained in the PPA.

Regulatory Status Review

Section 340.4 of the June 2019 proposed rule set out the RSR process, under which developers may request that APHIS evaluate their novel plants and determine whether or not they fall within the scope of the regulations, *i.e.,* under one or more of the categories in § 340.2. The section contained requirements for submitting requests for reviews and re-reviews, including supporting information; listed the factors that APHIS would consider in the course of its reviews; described the review process; and provided for public notice of RSR determinations. Commenters addressed all these topics.

As noted in the preamble to the June 2019 proposed rule, the RSR process applies only to GE plants. APHIS specifically solicited comments on whether the scope of the RSR should be expanded to include non-plant GE organisms as well as GE plants, whether some equivalent process for evaluating such organisms for regulatory status should be developed instead, and, if so, what factors APHIS should consider in its analyses.

Several commenters did request that APHIS develop a process to evaluate the regulatory status of non-plant GE organisms, based on the subject organism's potential plant pest risk; however, the commenters did not provide specifics on what factors APHIS should consider in its analyses. APHIS believes that further discussion and outreach with impacted developers and other stakeholders on this issue is required before pursuing rulemaking.

We received several comments pertaining to the re-review process. Some commenters stressed the need to consider whether our requirements adequately address the risk of requests for spurious reviews. Noting that we proposed to require that any request for a re-review be supported by ''new, scientifically valid evidence bearing on plant pest risk,'' commenters urged us to clarify what we mean by ''scientifically valid evidence'' in order to ensure that trivial evidence or conjecture, or publications in non-credible online ''scientific'' journals, cannot form the basis of a request. Clarification was also requested as to whether re-reviews can be initiated for all products for which RSRs have been completed or only for those found after an initial RSR to be subject to the part 340 regulations. One commenter stated that in cases of re-reviews initiated by APHIS, APHIS needed to provide for due process by allowing developers adequate time to respond.

APHIS agrees that requests for re-review must be based on ''scientifically valid evidence'' that relates to plant pest risk. APHIS has experience dealing with such requests and will conduct an objective analysis of re-review requests to determine whether re-reviews are warranted. A valid re-review request would apply only to those GE plants or plant products that were previously found to be subject to the regulations after an initial RSR was conducted.

In the June 2019 proposed rule, § 340.4(a)(4) specified information requirements for persons submitting a request for APHIS to conduct an RSR of a GE plant and stated that additional guidance on how to meet the requirements would be found on the APHIS website. A few commenters requested that APHIS either (1) incorporate the additional guidance into the regulations; (2) commit not to change the guidance without public notice and comment procedures; or (3) make clear that the additional guidance is non-binding because any changes made to it would not otherwise be subject to formal notice and comment.

After reviewing these comments, APHIS has decided to pursue the second of the three recommended options. When APHIS seeks to make a substantive change to the information provided on our website, we will indicate the proposed change, provide an explanation for it, and take public comment on it. We will then review the comments and make a determination as to whether to implement the change. In this final rule, we are revising § 340.4 to incorporate the notice-and-comment process. The revised § 340.4 also uses the term ''detailed information'' rather than ''guidance,'' which was used in the proposed rule. We are making this change, which we have placed in a new paragraph (a)(4)(iv), to clarify that in order to satisfy the broad requirements contained in the regulations for information on the comparator plant(s), the genotype of the modified plant, and the new trait(s) of the modified plant, the developer must provide the detailed information indicated on the website. We anticipate that this change will provide more consistency and predictability regarding information requirements than would have been afforded by the June 2019 proposed rule. Such predictability is important for ensuring that developers can adequately comply with the regulations and can plan their product development activities accordingly.

A number of commenters expressed concerns about specific details of how to meet the detailed information requirements for the RSR process that will be maintained on APHIS website. Some commenters were concerned that the requirement for information on the genotype of the modified plant was unclear and could be interpreted as requiring sequence information comparing the entire genome of the modified plant with that of the unmodified plant. Commenters stated that sequence information should be limited to sequence information for the specific genetic modification(s) in the plant. One commenter noted that some gene-edited products could have had genetic material inserted during development that was subsequently segregated away, and that we could clarify that the whole genome sequence information is not required by specifying that the required sequence information pertains to the targeted modified sequence.

APHIS agrees with these comments. It was not our intent to request whole genome sequence information. Rather, we are requesting sequence information on the specific targeted genetic modification(s) in the plant. We have revised the information that will be published on the APHIS website to clarify the sequence information that must be provided.

Some commenters stated that sequence information is not needed to determine whether a GE plant poses a plant pest risk, as long as developers provide the type of modification and describe the genotype by providing information on the insertion, deletion, and/or expressed gene product, and that if sequence information is required, it should be limited only to sequences that confer the trait(s) and should exclude vector sequences that are not in the final plant.

APHIS largely disagrees with these comments. The specified sequence information is needed by APHIS in order to confirm the intended trait(s) at the molecular/genetic level; to understand the MOA for purposes of assessing the plant pest impact(s), if any, of the modification(s); and to assess similarity with previously reviewed GE

plants. For inserted genetic material, APHIS requires the sequence of the entire insert for molecular characterization. All genetic elements integrated into the plant genome need to be described; therefore, vector sequence information is not required if vector sequences are not inserted. For genome editing, the sequence of the entire edited gene or functional motif of a regulatory region (*e.g.,* a transcription factor binding site in a promoter region) is required to understand the targeted sequence modification(s). The characteristics imparted by inserted or edited regulatory sequences (such as expression levels, patterns, and timing) are necessary to verify the full extent of the engineered genetic changes as part of understanding the plant pest risk associated with the modification(s).

Commenters raised concerns about how to meet the information requirements concerning the MOA. One commenter stated that while there may be information on a specific gene product, the precise mechanism of action may not be elucidated.

APHIS recognizes that the MOA may not always be well characterized. As we indicated in the preamble to the June 2019 proposed rule, we are requiring information on the MOA to the extent that it is known. We have revised the detailed information provided on the APHIS website to clarify this point.

Other commenters stated that certain information categories appear to exceed what APHIS has historically asked for when reviewing petitions for nonregulated status under the current regulations, and that RSR information requirements should align with the information APHIS has required previously, should not increase a developer's data submission burden, and should be sufficiently flexible to accommodate the nature of the particular product being evaluated. A commenter stated that gene expression data are unnecessary in many cases and that APHIS should clarify when such data would be required, such as when the intent is to change the expression pattern of a gene. Another commenter stated that information on the production, creation, or enhancement of a reservoir for a plant pest goes beyond the type of information currently submitted by developers in support of petitions for nonregulated status.

APHIS largely disagrees with these comments but recognizes that the preamble to the June 2019 proposed rule lacked sufficient clarity regarding information requirements that apply at various stages of the RSR process. The information developers must submit, as specified in § 340.4(a) of this final rule and on the APHIS website, generally aligns with information APHIS has been seeking previously, will reduce rather than increase a developer's data submission burden, and is intended to be sufficiently flexible to accommodate the nature of the plant being evaluated. Under the petition process, developers have had to submit data and information regarding a broad range of possible harms for evaluation by APHIS, regardless of whether the plant could plausibly pose a plant pest risk. The RSR process differs from the petition process in that APHIS is requesting much less information for the initial review, with no requirement for laboratory or field-test data. If APHIS is unable to identify a plausible pathway by which the GE plant could pose an increased plant pest risk in the initial review, developers will not be required to submit any additional information to APHIS. When there is a plausible pathway to plant pest risk identified, developers will receive feedback about the type(s) of information that APHIS would need to assess the identified plausible pathway and complete a plant pest risk assessment. This information could include field-test data, gene expression data, or other data relevant to assessing whether the GE plant could have increased importance as a host for plant pests. The preamble to the proposed rule discussed some of the types of information that might be required in this situation, but incorrectly made it appear as if this information would be required for all initial reviews. We now clarify that such information could be submitted during the initial review stage, but that any such submission would be optional. To clarify that additional data would be requested on the basis of identified plausible pathways to plant pest risk, APHIS has added the following language to the existing text in § 340.4(b)(3)(i): ''APHIS may request additional information as needed to evaluate the factor(s) of concern.'' We are revising the detailed information that will be published on the APHIS website to make this distinction clear.

One commenter found it difficult to understand how plant-trait-MOA could be adequately evaluated without field trials.

Data from field trials do not provide information about the plant-trait-MOA. As we noted in the preamble to the proposed rule, APHIS' experience in preparing risk assessments in accordance with the petition process indicates that field trial data are generally not necessary unless they address an identifiable plausible pathway to plant pest risk. The introduced trait and MOA provide the most reliable indicators of the organism's potential for plant pest risk. As we also noted in the June 2019 preamble, our conclusions are consistent with findings of reports of NAS.[7] [8]

By having an understanding of the biology and any existing impacts of the plant, the genetic trait to be inserted into the plant, and the MOA, APHIS is able to conduct a review based upon a large body of scientific publications, as well as APHIS' knowledge and experience. Information from field tests would be unnecessary, in most cases, for a determination of regulatory status under these regulations. Accordingly, field test information would not be a generally applicable requirement for the initial RSR and would be requested only as needed when further analysis is required. This approach would not preclude developers from providing information from field tests that they consider pertinent to our analysis. For example, if a developer requested a reevaluation of a GE plant that APHIS had previously considered to be subject to regulation, field test information demonstrating a lack of plant pest risk could be provided in support of that request. Nor would the provisions preclude APHIS from asking for field test information if APHIS considers it necessary in order to conclude review of a particular request.

The revised detailed information requirements that will appear on the APHIS website are listed below.

1. A description of the comparator plant(s), to include common name(s), genus, species, and any relevant subspecies information that would distinguish the plant.

2. The genotype of the modified plant, including a detailed description of the differences in genotype between the modified and unmodified plant, specifically:

a. If genetic material is inserted into the genome, provide information on all inserted genetic material, including:

i. For genetic sequences, the name of the sequence, the donor organism(s) or source, the function of the sequence, the nucleotide sequence, and if applicable, the publicly available sequence identification, protein accession

[7] National Research Council (NRC) 1989. Field Testing Genetically Modified Organisms: Framework for Decisions. Washington, DC. National Academy Press. 185 pp. Retrieved from *http://www.nap.edu/catalog/1431.html.*

[8] National Academies of Sciences, Engineering, and Medicine (NAS) 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC: National Academy Press. 420 pp. doi: 10.17226/23395. Retrieved from *http://www.nap.edu/23395.*

number, and enzyme commission number. If inserted genetic sequences have been modified (*e.g.,* codon usage efficiency, gene shuffling), a statement regarding the nature and purpose of the modification, and identification of the modifications by submitting an alignment of the modified sequence with the unmodified sequence.

ii. For regulatory sequences, the function of each regulatory sequence as it relates to the gene sequence and the donor organism(s) or source of each regulatory sequence. Identify promoters as constitutive, inducible, developmental, or tissue specific. If developmental/tissue specific, describe the stage(s)/tissue(s) at/in which the promotor is intended to be active.

b. If genetic material is not inserted into, or was inserted and is no longer present in, the genome, and the genome is modified in a way that does not fall under the exemptions in § 340.1(b), provide:

i. The nature of the modification(s) and the gene(s) and function(s) being modified;

ii. For substituted based pairs, the number of substitutions;

iii. The original unmodified sequence aligned to the targeted modified sequence.

3. A detailed description of the new trait(s) of the modified plant, including:

a. The purpose and intended phenotype of the new trait and available information on the MOA by which the intended trait is conferred;

b. Any expected changes in metabolism, physiology, and development due to the trait/genetic modification, to the extent known;

c. Optional: Any additional experimental data, publications, and other science-based assessments that may be helpful for APHIS' evaluation of the potential of the plant to pose plant pest risks. Such information could include, to the extent that it is known, information about any new enzymes or other gene products produced; where, when, and at what level the introduced or modified genetic material is expressed in the plant; the biochemical action of the genetic material or its product; and how the genetic material or its product participates in or interacts with metabolic, physiological, or developmental processes in the engineered plant or in other organisms. (APHIS does not intend to require submitters to generate experimental data specifically for an RSR. However, if a submitter is aware of information or experimental data in the public domain that may support our assessment, the submitter may include the data.)

The June 2019 proposed rule specified, in § 340.4(b)(1)(i) through (iii), the factors that APHIS would consider when conducting an initial review of the plant pest risk posed by the GE plant and any sexually compatible relatives that could acquire the engineered trait, relative to that posed by their respective non-GE or other appropriate comparator(s). To provide context for the discussion that follows, we are listing those factors below, as they appeared in the proposed rule.

1. The biology of the comparator plant(s) and its sexually compatible relatives;

2. The trait and mechanism-of-action of the modification(s); and

3. The effect of the trait and mechanism-of-action on:

a. The distribution, density, or development of the plant and its sexually compatible relatives;

b. The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;

c. Harm to non-target organisms beneficial to agriculture; and

d. The weedy impacts of the plant and its sexually compatible relatives.

Commenters had concerns and questions about some of the factors. One commenter stated that APHIS should clarify that a comparator could be a GE plant, even though Codex Food Safety Guidelines do not allow a GE crop to be a comparator, because the majority of certain crops, such as corn and soybean, are already GE.

APHIS agrees that in some circumstances a GE plant could be an appropriate comparator for the purpose of evaluating plant pest risk, and notes that the Codex Guidelines address food safety and do not address plant pest risk. Typically, a comparator plant is the non-GE plant from which the GE plant is derived. In some cases it may be appropriate to use another GE variety of the plant as a comparator. This could occur if, for example, a developer is using genetic engineering to add a new trait to an existing GE plant. To date, APHIS has not generally seen the use of a GE plant as a comparator, but this could change in the future as products of genetic engineering become more complex.

One commenter requested that APHIS define how it intends to determine ''distribution, density, or development of the plant and its sexually compatible relatives and weediness across plant types.'' Another suggested that we add a definition of *weediness* because it is mentioned in the context of the RSR.

APHIS is making no changes to the rule in response to these comments. The plant pest risk assessment framework document that accompanied the proposed rule described how the distribution (including density) of the GE plant and its sexually compatible relatives can be predicted by the biological properties of the plant compared with the known distribution and properties of the comparator(s), in the context of the receiving environment. The development of the GE plant and its sexually compatible relatives can similarly be predicted. Assessment of these factors is important for determining whether the GE trait(s) could increase the prevalence or alter the distribution of the plant or its sexually compatible relative(s) in such a way that they could have increased importance as hosts for plant pests. It is also important to point out that consideration of weediness in this manner has long been a part of the plant pest risk assessments conducted in response to petitions for nonregulated status since the 1990s, under the regulations that we are replacing in this final rule. This final rule does not change this analysis, and does not expand the scope of APHIS' consideration of weediness in evaluating plant pest risks as compared with the scope of consideration that was present in APHIS' exercise of its authority under the regulations that we are replacing.

Some commenters had concerns about the factor ''harm to non-target organisms beneficial to agriculture,'' and asked us to shift our focus to adverse effect on trophic functional groups beneficial to agriculture and to articulate a scientific rationale as to how a plant, whether GE or not, could pose a plant pest risk on the basis of its potentially harming an insect predator or pollinator.

Beneficial organisms such as predators and pollinators fall squarely under APHIS' authority because predators and pollinators are essential to plant health, and harm to these organisms may result in greater injury or damage to plants. APHIS analyses are based on whether a GE trait introduced into a plant will had adverse impacts on non-target organisms beneficial to agriculture. Non-target organisms beneficial to agriculture encompass a broad range of organisms that provide ecosystem services. Focusing on certain trophic guilds is not adequate to address all aspects of plant pest risk to non-target organisms beneficial to agriculture. For example, some GE traits may have greater effects on closely related groups of insects, regardless of the trophic guild of members of that group. Focusing on trophic levels may also expand the scope to impacts

outside of agriculture. When there is a scientifically plausible link to harm to non-target organisms beneficial to agriculture, the information needed for a plant pest risk analysis would be determined on a case-by-case basis, accounting for the particular biology of the GE plant, the MOA of the GE trait, and the environment.

In addition to listing the factors discussed above, proposed § 340.4(b) set out the components of the RSR process, including making determinations and providing public notice of such determinations. Proposed paragraph (b)(1) stated that when APHIS receives a request for an RSR, APHIS will conduct an initial review of the potential plant pest risk posed by the GE plant and any sexually compatible relatives that could acquire the engineered trait, relative to the plant pest risk posed by their respective non-GE or other appropriate comparator(s), based on the factors discussed above. Proposed paragraph (b)(2) stated that if APHIS is unable to identify potential plant pest risks in the initial review, the GE plant will not be subject to the regulations. Proposed paragraph (b)(3)(i) stated that if APHIS does identify potential plant pest risks in the initial review, APHIS will conduct an evaluation of the factor(s) of concern to determine the likelihood and consequence of the potential plant pest risk posed by the GE plant. Proposed paragraph (b)(3)(iii) stated that if the GE plant is found unlikely to pose a plant pest risk and, therefore, not to require regulation under part 340, then APHIS will post the finding on its website. Proposed paragraph (b)(3)(iv) stated that if APHIS is unable to find the GE plant unlikely to pose a pest risk, then the plant will require regulation, and its movement will be allowed only under permit in accordance with § 340.5.

Commenters expressed numerous concerns about this process as we described it in the proposed rule. Some thought that we provided insufficient detail, especially concerning the distinction between the initial review and the additional evaluation that some GE plants would need to undergo. Others took issue with some of the terminology that we used, stating that it lacked clarity and could lead to confusion about our regulatory focus and decision making process. Numerous commenters proposed alternative language, in some cases arguing that their proposed alternatives were more consistent with standard risk assessment terminology and the PPA than what we had proposed. Commenters also stated that in order for regulation to be appropriately calibrated with actual risk, our decision-making criteria should incorporate the concept that the plant pest risk posed by the GE plant should be greater than that posed by the plant from which it was derived.

APHIS agrees with many of these comments. In this final rule, we have amended § 340.4(b) to provide additional detail and clarity and to incorporate the concept that in order for regulation to be appropriate, the plant pest risk posed by the GE plant or its sexually compatible relatives must pose an increased plant pest risk relative to the comparator(s).

Regarding terminology, we have revised § 340.4(b) to indicate that in the initial reviews, we will make determinations concerning whether further review is necessary based on a finding of ''plausible,'' rather than ''potential,'' plant pest risks. We view the former term as more precise and more in keeping with standard risk assessment terminology. Further, since the RSR process will require that a scientifically plausible risk be identified in order to proceed with further risk assessment, the revision will ensure that the initial review will not be an open-ended evaluation of any conceivably possible scenario that could be imagined.

As noted earlier in this document, in connection with the discussion on confirmation letters, some commenters saw a need for timeframes for APHIS regulatory processes for purposes of predictability and business planning. Commenters raised the issue in connection with the RSR as well. We agree with the commenters on the need for timeframes and are adding them to paragraphs (b)(2) and (3), as discussed below.

Revised § 340.4(b)(1) contains provisions related to the initial review. The introductory text states that when APHIS receives a request for an RSR of a GE plant, APHIS will conduct an initial review to determine whether there is any plausible pathway by which the GE plant, or any sexually compatible relatives that can acquire the engineered trait from the GE plant, would pose an increased plant pest risk relative to the plant pest risk posed by the respective non-GE or other appropriate comparator(s), based on the factors listed in paragraphs (b)(1)(i) through (iii) (also listed above), which remain the same as those in the proposed rule.

Revised § 340.4(b)(2) provides that except in unforeseen circumstances, APHIS will complete the initial review within 180 days of receiving a request that meets the requirements specified in this section. If APHIS does not identify a plausible pathway by which the GE plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, the GE plant will not be subject to the regulations. APHIS will post information on the plant and trait and a general description of the MOA on its website.

Regarding the timeframe, while the RSR process is new to APHIS, we anticipate that in many cases the initial review may be completed rapidly (that is, within 60 to 90 days). However, for plants that APHIS has infrequently authorized in the past, we anticipate that additional time may be required to compile information on the appropriate comparator(s) needed to conduct the initial review. In addition, we anticipate that additional time may be required to compile the information on less familiar or more complex MOAs needed to conduct initial reviews. Based on our experience, we anticipate that we will generally be able to complete reviews of less familiar plants and MOAs within 180 days, barring unforeseen circumstances.

Revised § 340.4(b)(3)(i) states that if APHIS does identify a plausible pathway by which the GE plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, the requestor may apply for a permit and/or request that APHIS conduct an evaluation of the factor(s) of concern to determine the likelihood and consequence of the increased plant pest risk.

Revised paragraph (b)(3)(ii) states that for those GE plants for which such an evaluation is conducted, APHIS will publish the results of the evaluation in the **Federal Register** and will solicit and review comments from the public. Soliciting public comments will allow APHIS to collect information we might have missed and receive additional comment. Except in circumstances that could not reasonably have been anticipated, APHIS will complete these steps within 15 months of receiving a request for an RSR that meets our requirements. This evaluation will be similar to the current petition process, and will include, in addition to public notice and comment, preparation of any applicable National Environmental Policy Act (NEPA) analysis; hence, the longer timeline.

Revised paragraph (b)(3)(iii) states that if APHIS finds that the GE plant and its sexually compatible relatives are unlikely to pose an increased plant pest risk relative to their comparator(s), the GE plant is not subject to part 340 and APHIS will announce the final determination in a subsequent **Federal**

**Register** notice and post the finding on its website. If APHIS does not make such a finding, the GE plant will remain regulated, and its movement will be allowed only under permit in accordance with § 340.5.

Due to the changes made in § 340.4(b)(2) and (b)(3)(iii), we are not finalizing proposed paragraph (c), as it is no longer necessary. (There is a paragraph (c) in § 340.4 of this final rule, but it discusses when the section becomes applicable, and is discussed later in this document.) APHIS does not agree with other changes to the regulatory text suggested by some commenters. Specifically, the commenters recommended that we predicate our decisionmaking on whether the GE plant poses an ''unacceptable plant pest risk'' or an ''unacceptable'' or ''unreasonable'' ''increase in plant pest risk.''

APHIS appreciates these comments and has given them full consideration. APHIS does not find these terms to be necessary for purposes of our decisionmaking, nor have we concluded that such terms would provide the necessary precision to become the foundation for regulatory analysis and decisionmaking. For example, these terms could be interpreted to take into account considerations unrelated to plant pest risk and, if used as a regulatory benchmark, could be used to attempt to place APHIS risk assessors in the position of deemphasizing scientific considerations. As such, APHIS does not make changes to the regulatory text under in part 340 as suggested by the commenters.

A commenter stated that just as the MOA for achieving a phenotypic trait in a GE organism should be taken into account, the MOA for achieving the genotype changes used to achieve those phenotypic traits should be taken into account as well. According to the commenter, the reason why APHIS regulations have historically been ''event-specific'' [9] is that genetic material is inserted into recipient plants in an essentially random manner during the genetic engineering process which can create mutations in recipients at rates of ~30–60 percent, and that uncharacterized genetic material/DNA can unintentionally become incorporated into recipients about 20 percent of the time.

We do not agree with this comment. As noted above, we have not seen evidence in the scientific literature that there are unique hazards that arise solely from the use of recombinant DNA techniques, as compared with more conventional plant breeding techniques.

One commenter stated that putting RSR results on the web would encourage copycats rather than innovators.

We do not agree with this comment. As discussed later in this document, certain sensitive RSR information will be eligible for CBI exemptions and, therefore, protected.

Permits

Paragraphs (a) and (b) of proposed § 340.5 contained, respectively, permit issuing and application requirements. Proposed § 340.5(f) contained requirements for APHIS review of permit applications.

In the June 2019 proposed rule, APHIS proposed to remove timeframes for review of permit applications so as to ensure that APHIS has the appropriate time to evaluate each permit application based upon the plant pest risk posed by the GE organism and the complexity of the application. Some commenters opposed the change and requested that we retain those requirements in the regulations or otherwise incorporate into this final rule ''reasonable'' timeframes to provide greater certainty for developers about the length of the process. Commenters had various suggestions as to the length of the timeframe(s). One commenter, for example, recommended that APHIS be allowed 10 days to review applications for permits for interstate movement and 30 days for release permit applications. It was also recommended that we establish timeframes for making determinations on permit amendments and for review and comment by State and Tribal officials on permit applications.

Although we recognize the need for certainty about the length of the process, our experience has been that some permit and notification applications take a minimal amount of time and others take longer, and we anticipate this to continue. A review of our experience over the last 2 years demonstrates that 45 days is currently sufficient to authorize import and interstate movement permits, while up to 120 days are often needed to authorize release permits. Therefore, APHIS is adding a new § 340.5(h)(5) [10] containing timeframes for review of permit applications. New paragraph (h)(5)(i) states that except in circumstances that could not reasonably have been anticipated, interstate movement and import permits will be approved or denied within 45 days of receipt of a complete permit application. New paragraph (h)(5)(ii) states that except in circumstances that could not reasonably have been anticipated, release permits will be approved or denied within 120 days of receipt of a complete permit application. New paragraph (h)(5)(iii) states that in cases where an environmental assessment or environmental impact statement is necessary to issue the permit, the 120-day period will be extended.

Paragraph (h)(3) of § 340.5 contains requirements for inspections related to permitted activities. The paragraph states that all premises associated with the permit are subject to inspection before and after permit issuance, and that all materials associated with the movement are subject to sampling after permit issuance. In addition, the responsible person and agents must provide inspectors access to premises, facilities, release locations, storage areas, waypoints, materials, equipment, means of conveyance, documents, and records related to the movement of organisms permitted under part 340.

A commenter stated that APHIS should define waypoint in a manner that accounts for the fact that applicants for permits may not be able to legally guarantee access to all waypoints, such as those that may be the sole property of a third-party shipping company.

APHIS will work cooperatively with the permit holder if there is need to gain access to a waypoint not under the permit holder's control. A permit holder will not be held responsible for providing access that is outside the permit holder's power to grant or deny.

In § 340.5(h)(3), APHIS mandates that all materials associated with activities conducted under permit would be subject to sampling. One commenter questioned the need to include this requirement in the regulations. According to the commenter, the PPA gives APHIS authority to conduct investigations, including sampling, when required. The commenter stated that sampling has never been done outside the scope of an investigation,

[9] Event-specific is used to distinguish the genome position of the same DNA insertions after transformation. As noted by the commenter, the same DNA introduced into a plant by transformation will insert randomly in the genome. To distinguish the fact that the position of the same inserted DNA varies between transformations, each transformation is referred to as an event.

[10] As explained below, we are adding new paragraphs (e), (f) and (g) to § 340.5. As a result, except where otherwise indicated by a specific reference to the proposed rule, for purposes of this discussion, paragraphs will be referred to by their designation in the regulatory text of this final rule.

and that practice should remain. The commenter said that if APHIS decides to move forward with inclusion of a sampling requirement, it should clearly describe how those samples will be handled, the level of confidentiality that they will be subject to, and the specific uses for which samples may be taken in order to protect confidential business information. The commenter further stated that such samples are of proprietary research materials and valuable enough to be targets of misappropriation if not handled appropriately.

APHIS appreciates the comment and wants to reassure the regulated community that sampling will be done only when necessary. APHIS accepts that regulated material is proprietary property of the regulated entity and will ensure the taking only of quantities of samples required for diagnostic evaluation. The language in § 340.5(h)(3) is consistent with APHIS' authority under the PPA to conduct inspections. When sampling is done, APHIS follows strict chain of custody protocols. APHIS will protect all proprietary information and CBI associated with sampling, and APHIS will share results only within USDA (marking documents containing CBI to ensure protection of such information) and with the regulated entity.

Paragraphs (c) and (d) of proposed § 340.5 contained, respectively, exemptions from permitting requirements for interstate movement for GE *Arabidopsis thaliana* and *Agrobacterium tumefaciens,* subject to certain conditions. Some commenters suggested that we consider additional exemptions. One such commenter requested that in addition to *A. thaliana,* APHIS should exempt specialty crops, in which an allele has been edited to align with a similar, known allele in a close relative. Another commenter pointed out that disarmed versions of *Agrobacterium rhizogenes* have a record for transformation that is equally useful and safe as the record for disarmed versions of *A. tumefaciens.* The commenter requested that the exemption for ''disarmed *Agrobacterium tumefaciens*'' be broadened to ''disarmed Agrobacterium strains'' or ''disarmed members of the *Rhizobiales*'', such as *Ochrobactrum haywardense.* Using the same reasons and arguments, the commenter stated that APHIS should consider exempting *Nicotiana benthamiana.* It was also suggested that because disarmed viruses are commonly used in plant molecular biology studies, any pathogen with the pathogenicity demonstrably removed could be exempted. Some commenters favored even broader exemptions, stating that most types of transgenic plants should also be exempted when shipments are small or in a form in which persistence in the environment is very unlikely. The lack of such exemptions, according to these commenters, impedes collaborative research and breeding substantially.

We agree with these comments in part. Historically, *A. thaliana* and *A. tumefaciens* have been exempted from permitting requirements for interstate movement because interstate movement of the organisms has not resulted in the dissemination of plant pests within the United States. *A. thaliana* has been a research model plant species, and the research community is very familiar with the biological and ecological characteristics of the species. We have had extensive experience assessing the plant pest risks associated with the interstate movement of both organisms. In both cases, the plant pest risks are very low, and safeguards exist that can adequately mitigate those risks. APHIS agrees that other disarmed *Agrobacterium* species can be exempted from the requirement of permits for importation or interstate movement and has revised 340.5(d) accordingly. While some strains of disarmed *Agrobacterium* species may cause mild plant disease symptoms in some cases, importing them or moving them interstate presents very low plant pest risk given their specific usage in transforming plants, their lack of persistence in the newly transformed plants, and existing practices for shipping *Agrobacterium* strains. We do not have sufficient experience with the order *Rhizobiales* to further broaden this exemption at this time. Other GE organisms, such as specialty crops, have not been exempted before, and APHIS does not have extensive experience assessing their plant pest risks. Therefore, APHIS does not think it is appropriate to exempt such GE plants at this time in the same way as *A. thaliana* and *A. tumefaciens.*

As noted earlier in the discussion of the definition of *plant pest,* we are adding to this final rule an exemption from the requirement for permits for import and interstate movement for GE *Drosophila melanogaster* in response to public comments that this organism does not have significant negative impacts on agriculture. This exemption is contained in a new paragraph (e) of § 340.5. This exemption excludes strains that have been engineered to propagate through a population by biasing the inheritance rate (*e.g.,* gene drives), because such strains could be designed to persist in the environment and we do not have sufficient experience to conclude that such strains would not pose a significant plant pest risk. We have also revised the exemption text for *Arabidopsis thaliana* and *Agrobacterium* strains in § 340.5(c) and (d), respectively, to conform with the revised definition of *genetic engineering,* which is not limited to the insertion of ''cloned'' genetic material into an organism.

In response to comments about interagency coordination, which are discussed in detail below under the subheading ''Statutory Authority, Jurisdiction, and Interagency Coordination,'' we are adding a new paragraph (f) to § 340.5, which contains an exemption from permitting requirements for any microbial pesticide that is currently registered with the EPA as a microbial pesticide, so long as the microorganism is not a plant pest as defined in § 340.3. The addition of this exemption ensures that these organisms will not be subject to duplicative regulation.

Also in the interest of interagency coordination, as well as other considerations discussed in detail later in this document in the section pertaining to plant incorporated protectants (PIPs), we are also adding a new paragraph (g) to § 340.5 that exempts from the permitting requirement for movement of any GE plant modified solely to contain a PIP that is currently registered with EPA as a pesticide product pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 *et seq.*) or that is currently exempted from FIFRA pursuant to 40 CFR 174.21.

Numerous commenters expressed concerns about our proposed permit conditions. Those issues are discussed individually in the paragraphs that follow.

One commenter viewed the permit conditions in general as excessively strict. The commenter stated that the conditions strive toward zero risk, as opposed to the Coordinated Framework criterion of unreasonable risk. It is important to maintain measures commensurate to risk, according to the commenter.

We do not agree with this commenter's suggestion that our permit conditions are too strict or are striving toward zero risk. Our permit conditions are set to ensure containment and confinement of the organism under permit. They are designed to be commensurate with the risk posed by the GE organism. The commenter did not offer specific guidance on how we should apply the ''unreasonable risk'' standard.

Some commenters requested that we clarify the distinction between standard permit conditions that apply to all GE organisms and those that apply only to GE plants or to GE microorganisms or insects.

We believe that the standard permit requirements, as listed in § 340.5(i)(1) through (10) of this final rule, make this distinction clear. As written, all the standard conditions listed in § 340.5(i) of this final rule, except for paragraph (i)(6)(ii) (which pertains specifically to GE plant volunteer monitoring), are applicable to all GE organisms. Therefore, we are not making any changes in response to these comments.

One commenter recommended that we adopt a hybrid permit system under which performance standards are primarily used as the enforcement mechanism. According to the commenter, specific permit conditions should be added only when scientifically justified.

We will not be making any changes to the final rule as a result of this comment. Some of the standard permit conditions in § 340.5(i) are, in fact, performance standards, consistent with the commenter's recommendation. For example, paragraph (i)(1) states that ''[t]he organism under permit must be maintained and disposed of in a manner so as to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment.'' Under paragraph (i)(6), records related to permit activity by the responsible person must ''be of sufficient accuracy, quality, and completeness to demonstrate compliance with all permit conditions and requirements under this part.''

Nonetheless, we do not believe that a sole or primary regulatory focus on performance standards would be desirable for the regulations in part 340. As noted in the preamble to the June 2019 proposed rule, Office of Inspector General (OIG) audits conducted in 2008 and 2015 recommended, among other things, that APHIS generally reduce its reliance on performance-based standards in the regulations in part 340. APHIS agrees with the OIG recommendations. While performance standards offer the advantages of administrative streamlining for APHIS and flexibility for regulated parties, there are also significant disadvantages to a performance-standard-based regulatory approach. The absence of specific measures that constitute compliance with the regulations in performance-based standards introduces an element of uncertainty into the process of determining whether a regulated party is in compliance with the regulations. Enforcing the regulations, and thereby protecting U.S. agriculture from plant pest risks, would thus be made more difficult than it is when compliance measures are clearly enumerated in specific permit conditions, as they always have been under the regulations in part 340 and will continue to be as a result of this rulemaking. Because permit conditions specify which actions need to be taken by the responsible person to be in compliance with the regulations and do not rely as much on subjective determinations (by both the responsible person and APHIS personnel) as do performance standards, the permitting system can provide more risk-appropriate oversight, better regulatory enforcement, and transparency.

A commenter questioned the necessity of the requirement in § 340.5(i)(6) for the submission of a report of no environmental release for all authorized locations in which an environmental release of a GE organism did not occur. It was stated that this provision is inconsistent with the policy approach of the Coordinated Framework and represents regulatory overreach that should be set aside. The commenter saw no risk mitigation value in this requirement.

APHIS appreciates the commenter's concern but disagrees with the commenter's arguments. A permit authorization often covers many sites, and planting may never occur at some sites. Similar to the need for a post-planting report (PPR) to indicate which sites are planted and when, APHIS needs to know which sites were not planted, so as to provide efficient and appropriately focused oversight. APHIS thinks that the submission of a report of no release can help APHIS track the status of all authorized test field locations in order to account for and sufficiently monitor all such locations, thereby preventing the accidental release of GE organisms into the environment. Additionally, this requirement addresses recommendations issued by USDA's OIG, following audits performed in 2015.

One commenter stated that developers may operate under multiple permits for multiple plant-trait-MOA combinations at one time. The commenter stated that plant lines within these multiple permits are planted in proximity to one another to facilitate comparative science and to utilize resources in the most efficient way possible, and that if APHIS were to issue each permit with different conditions, of which the developer may learn only weeks before planting, these materials may have to be physically separated from each other or research would need to be abandoned, inhibiting innovation and increasing the cost to develop new products.

APHIS does not consider such scenarios to be likely. The permit conditions for non-plant-made pharmaceutical and industrial (PMPI)-producing plants are based on the reproductive ecology of each species and the receiving environment. APHIS anticipates that such permit conditions will generally be consistent across multiple permits for the same species. The timeframes for the issuance of permits that have been added to the regulations will enable developers to plan adequately to meet the specified permit conditions.

One commenter stated that APHIS should specify in the regulations timeframes for the submission by the responsible person of reports of activities under permit that are required under § 340.5(i)(6).

We do not agree with this comment. The types of reports to be submitted and the timing of their submission will vary by species and, therefore, will be included in each permit in the supplemental permit conditions, rather than in the regulations.

One commenter recommended that we allow for changes in the designation of a responsible person via a notification process.

We do not agree with this comment. In § 340.3, we define *responsible person* as the person responsible for maintaining control over a GE organism under permit during its movement and for ensuring compliance with all conditions contained in any applicable permit as well as other requirements in part 340. In § 340.5(i)(10), we state that the responsible person for a permit remains responsible unless a transfer of responsibility is approved by APHIS. The requirement for APHIS approval is necessary to ensure that, in the event a transfer becomes necessary, the new responsible person is aware, prepared, and equipped to work with APHIS. That provision does not apply, however, to an agent, a term defined in the June 2019 proposed rule as someone designated by the responsible person to act on behalf of the permittee to maintain control over an organism under permit during its movement and to ensure compliance with permit conditions. A change in agent may be effected through a notification.

One commenter requested that we not require Global Positioning Satellite (GPS) coordinates in permit-related records, a requirement that, according to the commenter, is effectively a permit condition, though it is actually

contained in § 340.6, the section covering recordkeeping. The commenter stated that information on actual acreage shortly after planting would suffice.

APHIS disagrees with this comment. GPS coordinates allow APHIS to fully utilize Geographic Information System capabilities to oversee what will be released within the defined authorized area. For example, APHIS uses GPS coordinates information to determine whether a proposed release site happens to be on Federal land or critical habitat.

Paragraph (j) of § 340.5 addresses permit denials and withdrawals. One commenter stated that APHIS must make it clear that denial should occur only to prevent an unreasonable risk to U.S. agriculture. The commenter further suggested that APHIS should include assurances that a permit will be presumptively issued unless APHIS can present a plausible argument that failure to comply with the permitting conditions would result in such an unreasonable risk. Another commenter suggested that the rule should be clarified to indicate that a permit application may be withdrawn by the applicant as well as the Administrator.

We will not be making any changes to the final rule as a result of these comments. Under § 340.5(j)(1), the Administrator may deny a permit application if he or she concludes that the proposed actions under permit may not prevent the unauthorized release, spread, dispersal, and/or persistence in the environment of the GE organism; if the responsible person or agent has materially failed to comply with any provision of these regulations; or if the responsible person or agent has failed to comply with any other regulations issued pursuant to the PPA or the PPA itself. Permits will also be denied if the responsible person or agent does not agree in writing to comply with permit conditions or to allow inspection by APHIS. These conditions are necessary to protect U.S. agriculture. Regarding withdrawal, the existing regulations do not specify that a permit application may be withdrawn by the applicant. Nonetheless, under current regulations, applicants may request withdrawal of permit applications prior to the issuance of the permit. This will continue to be the case when the revised regulations become effective.

One commenter stated that developers may operate by covering multiple plant-trait-MOA combinations under a single permit. According to the commenter, permits may be requested by location, with many experiments, containing multiple plant-trait-MOA combinations, planted in the same location. The commenter submits that if a permit is terminated due to a completed RSR, the termination should not apply to the entire permit, but only to the individual plant-trait-MOA which was reviewed.

APHIS responds that in such cases, the permit would not be terminated, and that the specific plant-trait-MOA combination for which the RSR was completed (resulting in a determination that the plant-trait-MOA GE plant combination is not subject to part 340) would no longer be regulated under that permit. APHIS would continue to provide oversight for plant-trait-MOAs that are still under permit.

One commenter requested clarification on permit amendment provisions, particularly as they applied to APHIS-initiated amendments in § 340.5(l)(2). The commenter expressed a concern that APHIS may arbitrarily initiate modifications to an existing permit and stated that APHIS should have no authority to initiate such amendments without scientific evidence.

APHIS will not initiate a permit amendment process without sufficient scientific justification. Under § 340.5(l)(2), APHIS will initiate a permit amendment process upon determining that such an amendment is needed to address the plant pest risk posed by the GE organism or the activities allowed under the permit. In such cases, APHIS will provide notice to the responsible person of the amendment(s) and the reasons for it.

Another commenter questioned whether we should include provisions for amending permits in the regulations at all. It was stated that we were reducing our flexibility by including such provisions.

Contrary to the commenter's assertion, we believe that the provisions for permit amendments allow for greater regulatory flexibility by enabling a rapid response to changing circumstances. We have included these provisions to provide an opportunity for a responsible person to request an amendment to permit conditions when circumstances have changed, as opposed to our having to withdraw the permit, which would necessitate that the responsible person then reapply. Under the permit amendment provisions, APHIS would also have the flexibility to amend a permit rather than revoking it if needed to address new or previously unknown plant pest risks presented by the organism.

Another commenter recommended that APHIS specify a timeframe for review of permit amendments requested by a responsible person. The commenter stated that furthermore, APHIS should notify the requestor if the amendment request is deemed to be within or outside the scope of the existing permit.

The timeframe for the review for the permit amendment will be the same as for new permit applications and depends on the complexity of the requested change. Consistent with past practice, APHIS will continue to let requestors know if an amendment is outside the scope of an existing permit.

Finally, we are making an editorial change to paragraph (l)(1) in § 340.5 to clarify the circumstances under which (1) APHIS will approve an amendment request from a permit holder and (2) APHIS will instead require a new permit application. Specifically, we are providing examples of situations where each would apply. APHIS will allow a permit to be amended if relatively minor changes are necessary. Requests for more substantive changes will result in a denial of the amendment request and necessitate a new permit application.

Paragraph (m) of § 340.5 contains requirements for shipping under permit. Paragraph (m)(1) contains a performance standard, stating that all shipments of organisms under permit must be secure shipments. Paragraphs (m)(2) and (3) contain, respectively, documentation and labeling requirements, and paragraph (m)(4) contains provisions related to treatment and disposal of shipping containers and packing materials.

One commenter stated that if APHIS' intent in paragraph (m)(1) is to allow developers to make determinations regarding the types of containers used during transport so long as they fit the above stipulations, that represents an improvement. If this change, however, is meant to be more restrictive, especially with the removal of a variance option, then the responsible person or agent should be able to make changes to shipping container options, if needed.

Paragraph (m)(1) is performance-based. It does not prescribe specific container requirements. The change to the regulations is meant to make the performance standard more explicit while at the same time making the requirements less prescriptive. Based on the definition of *secure shipment* (''Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation''), APHIS does not anticipate that shipping variances will be needed.

One commenter requested that we revise the language in § 340.5(m)(4) to take into account reusable shipping containers. The commenter

recommended that we replace the word ''treated'' with ''cleaned to remove the organism before reuse.''

In response to this comment, we are revising the paragraph to read as follows: ''Following the completion of the shipment, all packaging material, shipping containers, and any other material accompanying the organism will be devitalized consistent with supplemental permit conditions, or disposed of to prevent unauthorized release.''

Other issues raised by commenters in relation to permits included concerns about the rigor and integrity of the process, safety of environmental releases under permit, field testing, implementation of the permitting requirements, and the formatting of permits.

One commenter, noting that the definition of *movement* in § 340.3 includes release into the environment, stated that there can be no assurances beforehand of a safe outcome of such a release. The commenter stated that all GE organisms that are to be released into the environment should be subject to strict testing requirements.

APHIS acknowledges the commenter's concerns about safely releasing GE organisms into the environment. For reasons discussed earlier in this document, it is our view that categories of organisms that fall under the exempted categories in § 340.1(b) and (c), as well as GE plants that have been subject to an RSR in accordance with § 340.4 and for which APHIS has not identified a plausible pathway by which the GE plant or its sexually compatible relatives could pose an increased plant pest risk relative to the comparator(s), can be safely released into the environment without the need for a permit. The movement, including release into the environment, of all other GE organisms will be allowed only under permit and subject to strict standards and, if appropriate, supplementary permitting conditions to effectively mitigate any risks that may be associated with such movement or release.

A commenter stated that granting developers the option to move GE plants under permit in lieu of an RSR raises concerns regarding the integrity and robustness of the regulatory process.

Providing a developer the option to move a GE plant under permit rather than requesting an RSR affords that developer the benefit of maximum flexibility in the research and development of novel GE plants. The provision does not, however, provide the developer a means of evading regulatory scrutiny of new GE plants, as the commenter appears to believe. Permits are a form of regulation, and movement of GE plants under permit regularly occurs under our current regulations. An RSR results in a determination, based on our evaluation of plant pest risk, that a GE plant either is not subject to the regulations, and can be moved with no further restriction under part 340, or is subject to the regulations and may be moved only under permit. Whether a product requires movement under permit as a result of an RSR, or because the developer has chosen the permitting option in lieu of the RSR, the GE plant will still be subject to a rigorous screening process. The developer will have to submit a permit application, along with all supporting information required under the regulations. APHIS will carefully review the application and, if warranted, approve it. Prior to issuance, the developer/responsible person will be required to agree in writing that he or she understands and will comply with all the standard and supplementary conditions listed on the permit. Compliance is monitored after a permit has been issued. Our permitting process is a longstanding and rigorous one that ensures that GE plants are moved only under conditions that provide safeguards against the risk of dissemination of plant pests.

Temporary Transition Provisions

One commenter recommended that the implementation of the new permitting provisions and elimination of notifications should be phased in so as not to disrupt seasonal field activities. Other commenters stated that given the magnitude of the changes in regulatory requirements that we proposed, we should phase in implementation so as to allow regulated parties to adjust their operations to comply with the new requirements. Some commenters recommended that we develop timelines for compliance with each component of the proposed regulation. Recommendations ranged from 30 days (30 days each for the confirmation and RSR processes) to two years (for compliance with all of the new processes). Commenters also requested that we provide guidance on the new regulatory framework to aid them in making the transition.

APHIS appreciates the commenters' concerns and supports a phased approach to implementation. This final rule identifies a date when each of the rule's sections becomes applicable. Implementation of this rule will occur as follows.

Thirty days following the publication of this rule, APHIS will discontinue receiving new AIR requests. This will allow developers sufficient time to make such requests following publication, while also ensuring that, to the best of the Agency's ability, all such requests have been acted on by the time the rule becomes effective. The exemptions identified in § 340.1, and the confirmation letter process described in that section, will become effective and will be implemented 90 days after the publication date of this rule. (Please note, however, that some of the exemptions in paragraph (c) of § 340.1 are contingent on implementation of RSR, which will not occur until April 5, 2021.) In the intervening 60-day period, developers can self-determine regulated status according to the legacy definition of *regulated article;* APHIS is available to respond to requests for assistance in such determinations. Alternatively, developers may seek permits or use the legacy notification process during that time period in order to import regulated articles, move them interstate, or release them into the environment.

The remaining provisions in this rule also will become effective (that is, will appear in the CFR) 90 days after the publication of the rule. However, they are applicable as follows: Beginning April 5, 2021, APHIS will implement the permitting provisions in § 340.5; beginning April 5, 2021, APHIS will undertake a phased implementation of the RSR process described in § 340.4 by accepting requests for reviews involving corn, soybean, cotton, potato, tomato, and alfalfa; and beginning October 1, 2021, APHIS will accept requests for RSR involving any genetically engineered plant. We have revised proposed §§ 340.4 and 340.5 to include these specific applicable dates.

Until RSR is available for a particular crop based on the schedule set forth in the previous paragraph, APHIS will continue to receive petitions for determination of nonregulated status for the crop in accordance with the current regulations in § 340.6. Accordingly, developers may submit petitions for deregulation for any GE plants through April 4, 2021; beginning April 5, 2021, APHIS will discontinue receiving petitions for corn, soybean, cotton, potato, tomato, and alfalfa, but will continue to receive petitions for all other GE plants and organisms. As is currently the case, a developer may seek a permit or use the notification process instead of, or in addition to, submitting a petition. On October 1, 2021, APHIS will discontinue receiving petitions altogether. Similarly, all currently issued notifications and permits will remain valid until the expiration dates specified in such authorizations, and

APHIS will continue to receive notifications and permit applications pursuant to the processes in the current regulations in §§ 340.3 and 340.4, as well as the operational practices associated with those regulations, through April 4, 2021. Beginning April 5, 2021, the notification process will be discontinued, and all applications for permits must be submitted in accordance with the regulations identified in this final rule.

This phased implementation mitigates potential disruption to seasonal field activities and will provide developers with the opportunity to review and adjust to the provisions in this final rule.

Commenters stated that APHIS must maintain oversight over field trials, and that such trials should be allowed only under permits that mandate stringent gene containment protocols with a management goal of full containment. According to the commenters, safeguards and monitoring must be required for the organism during field trials, and monitoring should include tracking changes associated with ecosystem harm, such as degradation of water quality, air pollution, climate impacts, or loss of biological resources. It was also stated that APHIS should publish the results of APHIS supervised field trials where they will be publicly accessible, and that permit requirements should include buffer zones for GE crop fields that adjoin organic and non-GE crop fields to reduce GE trait and chemical drift.

APHIS has established and will continue to establish appropriate oversight requirements for crops grown under permit, including isolation requirements based on the reproductive ecology of the plant species to prevent gene flow to plants not under the permit. APHIS does not believe that ecosystem impacts, such as degradation of water quality, air pollution, climate impacts, or loss of biological resources unrelated to plant pest risk, require tracking or monitoring under the part 340 regulations, and notes that growing non-GE plants may give rise to similar impacts. Under this rulemaking, there is no requirement that developers submit field-trial data to APHIS, although they may do so if they choose to support an RSR or confirmation letter request. As we noted in the preamble to the proposed rule, APHIS' experience in preparing risk assessments in accordance with the petition process indicates that field trial data are generally not necessary unless they address an identifiable plausible pathway to plant pest risk. The introduced trait and MOA provide the most reliable indicators of the organism's potential for plant pest risk. If field data are needed to address a plausible plant pest risk hypothesis, those data bearing on whether an organism posed a plant pest risk would be published in support of APHIS' decision making on the regulatory status of that plant.

A commenter stated that APHIS should further clarify the length of time after a permit expires during which access to materials and premises must be allowed. The commenter was concerned that such access could be misinterpreted to be in perpetuity, which is unnecessary.

We would require the responsible person to allow access to where the organisms regulated under part 340 are located, including field test sites after trials are harvested or terminated, throughout the volunteer monitoring period described in the permit, which may continue after permit expiration. Access to premises where regulated organisms are maintained must be allowed throughout the volunteer monitoring period even if the permit has expired, unless the product has been devitalized or APHIS has conducted an RSR and determined it to be not subject to part 340.

Two other recommendations by commenters were that we develop a publicly available database listing all permits issued by APHIS and their requirements, and that we provide for pre-approvals of containment facilities for high-risk organisms, with permits tiered to the approved facility number.

We thank the commenters for these suggestions. APHIS may explore these ideas in the future as we develop more experience with permits under the new regulations, though we do not believe that it is necessary to implement (or to decide whether to implement) these ideas immediately. For example, our ongoing experience with permits involving containment facilities may lead us at some point to consider a specific pre-approval process for certain facilities as suitable for higher-risk organisms.

Finally, one commenter stated that each permit should contain introductory text describing the unreasonable risk to U.S. agriculture that the permit is designed to prevent. The commenter further stated that if no such plausible description can be proffered, then APHIS would have no reason for exercising oversight over, or requiring a permit for, the movement of the GE organism for which APHIS intends to issue the permit.

Under the new regulations, GE organisms will be required to move under permit for one of three reasons: (1) Because APHIS has conducted an RSR and has found a likely or indeterminate plant pest risk; (2) because the developer has opted to go directly to seeking a permit rather than requesting an RSR; or (3) because the GE plant or non-plant organism fits under one of the regulated categories in § 340.2. We do not see the need for the introductory text that the commenter recommends, which is likely to be duplicative or unnecessary in many if not all cases.

In addition to the substantive changes discussed above, we are making a couple of corrections to § 340.5(b)(1) and (b)(2)(ii). In the former paragraph, which contains general information requirements for permit applications, we are adding ''the organism's genus, species and any relevant subspecies and common name information.'' Under the latter, which contains information requirements for permits for interstate movement and listed, among other things, in the June 2019 proposed rule, ''a description of the method of shipment, and means of ensuring the security of the shipment against unauthorized release of the organism,'' we are including a requirement that the quantity of the GE organism also be listed. In both cases, the requirements were in the current regulations but were inadvertently omitted from the June 2019 proposed rule.

Record Retention, Compliance, and Enforcement

Numerous commenters identified concerns about the record retention requirements described in proposed § 340.6. Issues discussed included overall clarity and scope, timeframes, and reporting requirements.

Some commenters suggested that we needed to clarify our recordkeeping and reporting requirements by adding more specific detail about what information APHIS will require and when.

The reporting and recordkeeping requirements in § 340.6 of the June 2019 proposed rule did provide specific details regarding the types of records that need to be kept and the timeframes for retention, in paragraphs (a) and (b), respectively. At the same time, the requirements that we proposed align with our historical approach, which has provided flexibility based on variations in operations performed by different entities and different subparts of a single entity. As reflected in § 340.6(a)(1), which refers the reader back to the permit-related reporting and recordkeeping requirements in § 340.5, many of the recordkeeping and reporting requirements of this

rulemaking will depend on the nature of the GE organism and the intended activity and will be included in the permit conditions.

It was suggested that some of the proposed information requirements were duplicative. One commenter stated that APHIS requires information about the location of a field release site to be included in the permit application and then requests the same information again after planting, resulting in duplicate or nearly duplicate records requests. The commenter stated that APHIS also requests the identity of the material being planted (the construct ID) on the application and then requests the same information again on the planting report. According to the commenter, during inspections this information is often requested a third time. The commenter stated that this duplication could be eliminated with no detrimental effects on compliance by having applicants provide it on the permit application and then having APHIS verify it during inspection.

These requirements are not duplicative, and it is not particularly onerous to comply with them. Information submitted in a permit application is used for specific release site analysis. Post-planting reports provide APHIS with critical information related to the activity that has been conducted under an APHIS-issued authorization. The information submitted post-planting facilitates effective compliance oversight. Planting does not occur for every genetic construct and location that is approved in an authorization. APHIS needs documentation (post-planting report) of which constructs are planted at each specific field release site in order to perform effective compliance oversight. Additionally, this requirement addresses recommendations issued by USDA's OIG following audits performed in 2015.

A commenter recommended eliminating the requirement in § 340.6(a)(2) that records be kept to identify all locations where organisms under permit were stored. The commenter noted that while APHIS regulates interstate movement, the proposed definition of *move* does not include ''store.''

We do not agree with this comment. Under § 340.5(b)(2)(i), all permit applications must include, among other things, information on the origin and destination of a GE organism moved under permit, including information on addresses of all intermediate and final destinations. Additionally, § 340.5(b) states that within the permit application, locations and destination(s) of regulated organisms shall be included. A storage facility is considered by APHIS to be a destination (premises). APHIS needs to know where the regulated GE organism has been maintained in order to perform effective compliance oversight.

We received comments that supported our proposed timeframes for record maintenance and other comments that expressed concerns about the timeframes.

One commenter raised concerns about APHIS's ability to respond to incidents effectively if APHIS retained records associated with regulatory activities for only 2 years.

The commenter may have misunderstood the recordkeeping requirement in § 340.6(b). The requirement that all records indicating that an organism that was imported or moved interstate under permit reached its intended destination be retained for 2 years applies to the responsible person(s) rather than APHIS. APHIS did not propose any changes to the duration or type of records that APHIS will retain. The proposed 2-year retention requirement did represent an increase from the one in the existing regulations, which was 1 year. APHIS believes that this 2-year record retention requirement provides sufficient time to ensure that regulated material has safely and securely reached the intended destination, without imposing an undue burden on regulated parties.

One commenter viewed the requirement to retain records of permitted activities for 5 years as burdensome for small entities and urged us to ameliorate that burden by offering small entities an option to deposit such records electronically with APHIS for retention.

We do not agree with this comment. APHIS does retain the records of permitted activities that are submitted to APHIS, such as required reports and other information needed to determine compliance. Large and small regulated entities also generate and retain records that they may not be required to submit to APHIS but are kept to demonstrate compliance with permit conditions and for the entities' own stewardship purposes. Should those types of records be submitted to APHIS for retention, they would then be considered Federal records subject to the Freedom of Information Act (FOIA), which, among other things, would give rise to considerable administrative burdens for APHIS, which would be obliged (for instance) to protect submitters' confidential business information in maintaining such records and responding to FOIA requests. Furthermore, adopting the commenter's recommendation could raise concerns about disparate treatment. The comment did not include size criteria or definitions or a description of a process that would enable APHIS to make a fair determination of who could or could not submit documents for APHIS to retain.

Finally, one commenter recommended that APHIS utilize the APHIS-initiated amendment procedure for site-specific enforcement in instances of noncompliance and amend § 340.6(c)(i) to explicitly allow the Administrator to deny an application or withdraw a permit ''in whole or part.'' The commenter contended that this would provide APHIS the flexibility to apply site-specific, measured enforcement.

APHIS agrees with the intent of the comment but disagrees with the suggestion that a regulatory text change is necessary, because the permit-amendment provisions in § 340.5(j)(2) already allow us sufficient flexibility to respond to compliance issues in the manner recommended by the commenter.

Confidential Business Information (CBI)

Commenters took divergent views on the issue of the proposed Confidential Business Information (CBI) exemptions in the proposed rule. Some thought the exemptions, as explained in the preamble to the proposed rule, did not provide enough protection for submitters, while others thought that the exemptions were too broad.

Several commenters stated that CBI protections should extend to information pertaining to MOA and other information required to be submitted for an RSR or needed by APHIS to confirm a determination by a developer that its product is exempt from these regulations. Some commenters also suggested that submitters may forgo seeking confirmation or an RSR, and may opt to go under permits, if the MOA will be made public after a product has come through the confirmation or RSR process, because submitters want to protect that information.

As noted in the preamble to the proposed rule, APHIS intends to release a general description of the plant, the trait, and the MOA of GE plants that go through an RSR, but APHIS would do so without revealing CBI. APHIS would similarly release a general description of the plant, trait, and, as applicable, the MOA associated with confirmation requests, again without revealing CBI. APHIS wants to clarify that we are not requiring submitters to waive their

applicable CBI claims. Further, as we noted in the preamble, certain technical information, such as data that could be used to re-create an organism and that were not otherwise made publicly available by the submitters, may be eligible for CBI designation. To the extent that CBI claims exist, APHIS will review them, consistent with applicable laws and statutory authorities, on a case-by-case basis. Submitters will be given the opportunity to review and comment on a proposed general description prior to public disclosure. Regardless of CBI determination, developers will have the flexibility to select the regulatory options, whether RSR or permit, that they deem best for their business needs.

Other commenters expressed concern that extensive granting of CBI designations could impede the ability of developers to determine whether their products are eligible for exemption, and could impede peer-reviewable risk assessment. These commenters favored posting confirmation requests and responses and RSR determinations online. It was suggested that if such data are not available, developers will lack the necessary information to make reliable determinations for their GE plants and may choose permitting instead. According to these commenters, this would attenuate the regulatory relief that is one of the objectives of this rulemaking.

APHIS will post confirmation requests and responses, as well as determinations of nonregulated status pursuant to the outcomes of initial RSRs, on the APHIS website, with CBI redacted. When additional review is requested, as discussed earlier in this document, the analysis, outcome, and supporting documents will be published in the **Federal Register** and on the website, also with CBI redacted. We recognize that, in some cases, information necessary for researchers and developers to make determinations pursuant to § 340.1(c) may not be made public, due to CBI claims.

Commenters also expressed the view that mandatory field trial data should not be eligible for CBI exemption.

Under this rulemaking, there is no requirement that developers submit field-trial data to APHIS, though they may do so if they choose to support an RSR or confirmation letter request. As noted above, APHIS would allow only CBI exemptions that are consistent with applicable case law and statutory authorities.

A commenter requested that we clarify how the process for submitting CBI exemption requests and justifications for exemptions differs from the process that occurs under the current regulations.

The process for submitting and justifying CBI claims will not change under this rulemaking. Persons submitting any document to APHIS in accordance with the regulations must identify those portions of the document deemed to be CBI. Each page containing such information must be marked ''CBI Copy.'' A second copy of the document must be submitted with all such CBI deleted, and each page where the CBI was deleted must be marked ''CBI Deleted.'' In addition, any person submitting a CBI exemption request must justify the request by demonstrating how each piece of information to which the request applies is a trade secret or is commercial or financial information and is thereby privileged or confidential.

Economic Analysis

Some comments directly addressed the economic analysis that accompanied the June 2019 proposed rule. It was claimed that the analysis was light on data characterizing the potential economic and social impacts of the proposal. It was also stated that we did not offer sufficient analysis of the challenges of assuring other countries that imports of GE products from the United States are safe and meet the importers' requirements.

In the analysis accompanying the June 2019 proposed rule, we did request comments from the public on the potential economic impacts of the rule on affected entities. Most of the commenters who addressed potential economic impacts did so as part of a broader discussion of other issues, such as the potential economic effects of commingling, rather than addressing the economic analysis directly. Commenters did not supply actual data that would have aided us in characterizing potential social and economic impacts of the proposed rule. We do discuss potential international trade issues at some length later in this document.

Regulation of Plants That Produce Plant-Made Pharmaceuticals and Industrials (PMPIs)

We stated in the June 2019 proposed rule that the likelihood existed that most, if not all, GE PMPI-producing plants that are currently under APHIS permits could be determined to be not regulated if an RSR found them to be unlikely to pose a plant pest risk. We also noted that our proposed rule envisioned that were this to occur, such plants could be grown outdoors without the need for APHIS permits and without APHIS oversight.

We received many comments on this issue. Some commenters expressed concern that the proposed change to our regulatory approach to PMPI-producing plants would weaken or eliminate APHIS' oversight of them. Others favored less regulatory oversight of PMPI-producing plants than that provided in the existing regulations. Still others requested that we provide greater clarification of our regulatory approach to PMPI-producing plants under this rulemaking and emphasized the need for cooperation among regulatory agencies. These varying viewpoints are discussed in greater detail below.

Some commenters stated that as a result of this rulemaking, APHIS would abdicate its oversight role, leaving the planting of PMPI-producing plants essentially unregulated. As a result, according to these commenters, our agricultural food systems could be made vulnerable to introduction of experimental GE crops, and environmental quality and human health could be negatively affected based on the end use of those crops for pharmaceutical or industrial purposes. One commenter expressed concern that PMPI-producing plant developers would be able to determine for themselves whether their products are eligible for exemption. All of these commenters urged us to maintain our existing level of regulatory oversight of PMPI-producing plants.

Some commenters favored still more stringent requirements. They argued in favor of more restrictive oversight of PMPI-producing plants than was provided for in either the proposed rule or the existing regulations. They asserted that allowing PMPI-producing plants to be grown outdoors without APHIS oversight does not comport with the OIG's recommendations on regulating PMPI-producing plants to prevent inadvertent release.

Finally, a few commenters stated that they did not consider PMPI-producing plants to present inherent risks and argued that developers of PMPI-producing plants should be able to sufficiently self-regulate the planting of such plants. Some of these commenters took the view that APHIS' regulatory oversight over PMPI-producing plants was, if anything, already excessive and would remain excessive or become still more so under the proposed rule. One commenter stated that developers should be given the option to be regulated by the agency most relevant to their GE products. Other commenters stressed the need for APHIS and FDA to have a memorandum of understanding

(MOU) for the regulation of PMPI-producing plants.

After considering the comments received, we have decided to continue to maintain regulatory oversight of PMPI-producing plants by continuing to require permits for their movement. We are adding this requirement to § 340.2 of this final rule as paragraph (e), which states that a permit is required for the movement of a plant that encodes a product intended for pharmaceutical or industrial use. Accordingly, PMPI-producing plants will not be eligible for the RSR process. We also have determined that APHIS can continue to exercise oversight of PMPIs pursuant to our existing statutory authority under the PPA. We discuss how we arrived at this determination below.

The commenters who favored more stringent oversight of PMPI-producing plants than under the current regulations often considered them to present a significant inherent risk by virtue of being PMPI-producing plants and/or considered our existing regulations in part 340 to contain inadequate safeguards.

We do not agree that more regulatory oversight of PMPI-producing plants than under the current regulations is warranted, and we do not consider our current regulatory framework to provide inadequate safeguards. Since 1994 (58 FR 17047), we have required permits for the movement of plants that produce pharmaceutical compounds. In 2003, APHIS published an interim rule in the **Federal Register** (68 FR 46434–46436, Docket No. 03–038–1) that extended this permitting requirement to plants that produce industrial compounds; that same year, we implemented additional safeguards for PMPI-producing plant field trials that exceeded those previously in effect. These added safeguards, which were implemented as permitting conditions, included requiring location coordinates, authorizing release only in low-production geographies for the particular crop at issue, requiring dedicated equipment, and providing for frequent inspections of each trial site.

Since 2003, permits for field trials of PMPI-producing plants have made up a small percentage of the overall permits that APHIS has issued pursuant to the regulations in part 340. In the intervening 17 years, we have not encountered any issues with field trials of PMPI-producing plants that call into question the overall adequacy of our permitting conditions for PMPI-producing plants. Furthermore, over time, APHIS has regulated a large number of field trials of non-PMPI producing plants under permit conditions for diverse plants, traits, MOAs, geographic locations, and agroecological conditions. Regardless of whether the plant is a PMPI-producing plant or not, these permit conditions have been successful in ensuring that genetically engineered plants are confined to the field trial location. Based on our experience in permitting field trials of genetically engineered plants, we are confident in our ability to devise appropriate permit conditions to ensure confinement of all regulated plants, including PMPI-producing plants as we have done for the past 17 years.

For this same reason, we do not consider it necessary to regulate PMPI-producing plants as Federal noxious weeds in accordance with our regulations in 7 CFR part 360, one of the options which we mentioned in the proposed rule. We believe that doing so could suggest that APHIS has identified unique risks associated with PMPI-producing plants based on our data since 2003; this is not the case. Instead, we agree with those commenters who have asked us to maintain our current level of regulatory oversight based on the framework first elucidated in 2003.

The commenters who urged us to continue to exercise a similar or greater level of regulatory oversight of PMPI-producing plants do raise a salient point: PMPI-producing plants are not developed for food or feed use and can encode compounds that are intended to have a physiological effect in humans or animals. This is important for several reasons.

First, in the 2003 interim rule that required permits for plants that encode for industrials, we stated that APHIS' regulatory experience and scientific familiarity lay primarily at the time with GE plants produced for food or feed. This remains the case; while the Agency certainly has more familiarity with PMPI-producing plants than we possessed in 2003, PMPI-producing plants account for less than one percent of the total number of GE plants for which we have issued permits, and none have been designated nonregulated. Accordingly, the Agency still has significantly more experience with GE plants that produce food or feed than with those that produce PMPIs.

Second, as we set forth in the proposed rule, the intended use of PMPIs makes them differently situated than other GE plants regulated by APHIS, such that additional evaluation beyond RSR may be needed. We therefore consider it appropriate to maintain the status quo and continue to require permits for PMPI-producing plants.

In such instances when the risks associated with a plant or organism are not fully understood, APHIS has interpreted its authority under sections 7711 and 7712 of the Plant Protection Act and its predecessor statutes to provide a basis for regulating the plant or organism based on our best understanding of the risks presented (see 58 FR 17047; 68 FR 46434–46436).

Accordingly, APHIS will continue to exercise its authority under the Plant Protection Act to maintain regulatory oversight of PMPI-producing plants. FDA has authority under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 301 *et seq.*) to take action to have foods withdrawn from the market if they contain PMPIs not approved for use in food. FDA also regulates drugs and human biological products under the FFDCA and therefore would have oversight over such products from PMPI-producing plants. FDA has not traditionally overseen field trials of PMPI-producing plants. APHIS will maintain the status quo by continuing to require permits for movement and environmental release of all PMPI-producing plants. It is not clear to us how an MOU between FDA and APHIS would be beneficial in providing oversight.

One commenter recommended that we list categories of the types of PMPI-producing plants that could generate food adulteration, should they find their way into the food supply, and regulate only those types of PMPI-producing plants.

Another commenter stated that we needed to clarify and possibly refine our overall regulatory approach to PMPI-producing plants. The commenter expressed a concern that a lack of clarity may result in unnecessary costs and time delays in bringing new products to market, thereby disproportionately impacting smaller developers and limiting the availability of new opportunities for farmers. As an example of a possible refinement to our regulatory approach, the same commenter suggested that in regulating PMPI-producing plants, APHIS should consider the likelihood that PMPI-producing plants will be produced in niche crops, which can be readily segregated from commodity crops, thus reducing the potential for their entering the food chain.

APHIS does not plan to develop a list of food adulterants or of categories of the types of PMPI-producing plants that could generate food adulteration. As noted above, the primary oversight authority in matters concerning food

safety involving plants, such as whether the presence of a particular substance in a food would make it adulterated, rests with FDA rather than APHIS. With regard to the latter comment, in establishing permitting requirements for PMPI-producing plant field trials, APHIS does take into consideration the specific crop in which the PMPI is produced.

Regulation of Plant-Incorporated Protectants (PIPs)

As noted in the preamble to the June 2019 proposed rule, certain plants are genetically engineered to produce PIPs, meaning that they produce pesticides. PIPs fall under the regulatory oversight of EPA. However, because EPA generally only requires Experimental Use Permits for field tests on 10 acres or more of land, only APHIS has historically exercised regulatory oversight over plantings of PIP-producing plants on 10 acres or less of land.

Under the provisions of the June 2019 proposed rule, there would be a likelihood that many PIP-producing plants that are currently regulated under APHIS permits or notifications could be determined not to be covered by the regulations after RSRs, because such plants are unlikely to pose greater plant pest risks by comparison with their comparators. Such plants could therefore be grown outdoors without the need for an APHIS permit and without undergoing APHIS oversight. Thus, Federal oversight over small-scale (10 acres or less) outdoor field test plantings of some PIPs would rest solely with EPA.

Commenters expressed a broad range of views regarding the scope of our regulatory oversight over PIP-producing plants. Some commenters expressed the view that APHIS should leave the regulation of PIPs entirely to EPA. Others stated that APHIS should continue its oversight over PIP-producing plants in coordination with EPA to ensure that PIPs are regulated at all scales. Concerns were expressed by some commenters about what they perceived as potentially a broadened regulatory scope. It was stated that small releases of PIP-producing plants that are not currently subject to APHIS regulations could be regulated under the proposed rule.

After reviewing these comments, we have decided that the approach presented in our June 2019 proposed rule remains appropriate. All PIPs, as noted in that rule, are properly under the regulatory oversight of EPA; to date, EPA has not seen a need to exercise oversight over PIP-producing plants planted on 10 acres or less because APHIS has exercised such oversight.

Accordingly, APHIS will continue to conduct oversight over PIP-producing plants at all scales unless the PIP-producing plant were to meet the conditions for an exemption from regulation in our revised regulations, or were determined following RSR not to be covered by the regulations. If APHIS determines that a PIP-producing plant is not regulated under these regulations; EPA would still retain regulatory authority and may decide to require an Experimental Use Permit and provide oversight of field trials under 10 acres. APHIS has avenues for cooperation with EPA, such as an agreement to provide oversight assistance to EPA under the Economy Act, should EPA decide that oversight of small PIP field trials is appropriate.

We have, however, decided to modify this final rule slightly to clarify the nature of this interaction between APHIS and EPA regarding PIPs. As noted above, we are adding a new § 340.5(g) stating that a permit is not required for the movement of any GE plant modified solely to contain a PIP that is currently registered with EPA as a pesticide product pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 *et seq.*), or that is currently exempted from FIFRA pursuant to 40 CFR 174.21.

Under FIFRA, EPA is authorized to regulate pesticides. Pursuant to FIFRA, EPA regulates certain PIPs as ''substances,'' and has established a registration process for their use as pesticides. In determining whether to grant a registration for a PIP with pesticidal properties, EPA conducts ecological risk assessments to determine what risks are posed by the PIP and whether changes to the use or proposed use are necessary to protect the environment. The product is registered under FIFRA and thereby eligible for sale on the market if the results of the risk assessment indicate that the pesticide will not pose any unreasonable risks to wildlife and the environment. Environmental effects considered include effects on nontarget organisms. A PIP that is currently registered will have undergone such a risk assessment and will therefore have been determined not to pose unreasonable risks to other plants. For that reason, we can exempt, and have decided to exempt, such PIP-producing plants from our regulations.

We can also exempt, and have decided to exempt, modified PIP-producing plants that EPA has exempted from FIFRA pursuant to 40 CFR part 174.21. Section 25(b) of FIFRA allows EPA to promulgate regulations to exempt from the requirements of FIFRA any pesticide which the Administrator determines is ''of a character which is unnecessary to be subject to [FIFRA] in order to carry out the purposes of [FIFRA].'' Pursuant to this statutory authority, EPA's regulations in 40 CFR part 174.21 set forth criteria used by EPA for exempting PIPs from FIFRA requirements, including that the genetic material encoding the PIP or leading to the production of the PIP is from a plant that is sexually compatible with the recipient plant. These criteria currently do not pertain to GE plants containing PIPs.

However, if EPA were to establish criteria for exemption from FIFRA for certain additional plants containing PIPs, plants meeting those criteria would, by statute, have been determined by EPA to be of a character unnecessary to be subject to FIFRA in order to carry out the purposes of FIFRA. Because EPA could not make such a broad determination without consideration of the effects of such plants on the environment, including risks to other plants, we are exempting such plants from APHIS permitting requirements, as well.

Other commenters expressed concern that small releases of PIP-producing plants that are not currently subject to APHIS regulations could be regulated under this rule.

It is true 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, was previously exempt from APHIS regulations under part 340 but could fall within the scope of these revised regulations if it does not qualify for an exemption under § 340.1 or under new § 340.5(g). This is, in fact, true of all GE plants that are created without the use of a plant pest donor organism, recipient organism, or vector or vector agent. However, as we discuss at greater length in the economic analysis that accompanies this final rule, we believe the number of producers and products that may be newly regulated as a result of this rule is extremely small. Moreover, we are not aware of any GE

PIP-producing plant that has been produced to date without the use of a plant pest as the donor organism, recipient organism, or vector or vector agent.

Finally, one commenter stated that regulating PIPs more strictly than regulating chemicals is not scientifically justifiable. The commenter noted that EPA considers biological pesticides, including PIPs, to ''generally pose less risk than most conventional pesticides.''

This comment pertains to EPA's regulatory structure for PIPs. As such, it is outside the scope of the current rulemaking.

International Trade Implications

A number of commenters expressed the concern that the regulatory approach that underpins this rulemaking is out of step with that of key international markets and governments. It was suggested that the rule could result in greater asymmetry in regulatory approach between APHIS and U.S. trading partners, thereby endangering U.S. export markets, and that obtaining international acceptance of our new regulatory approach should be a precondition for finalization. A commenter further stated that we need to balance our regulation of GE organisms with the need for industry to comply with international markets that are sensitive to the unintended presence of GE organisms in non-GE products.

The fundamental APHIS protection goal under our regulations in part 340, which stem from and are delimited by our statutory authority to regulate plant pests under the PPA, is to protect agriculture against increased plant pest risks resulting from GE organisms. This regulatory approach has always been different from that of other national systems, which may not necessarily focus on plant pest risk and instead may be technique-based. Nevertheless, our trading partners have historically judged our approach to be acceptable, as it is transparent and science- and risk-based. Trading partners that have understood and accepted our regulatory system will not find our updated approach to meeting the same objectives confusing. Thus, we do not see this revised system as less compatible with those of our trading partners than in the past. As we have in the past, we will continue to provide technical expertise, information, and explanation to our trading partners regarding our regulatory system and determinations of regulatory status.

It was further stated by commenters that a possible consequence of the unwillingness of trading partners to accept our new regulatory approach could be the undermining of the progress being made in the Global Low-Level Presence Initiative (GLI), in which countries (including the United States) are striving to achieve a science-based and risk-based approach that would allow for a commercially achievable tolerance for the presence of a biotechnology-enhanced trait that (1) has been approved as safe by an exporting country based upon scientific analysis and CODEX-adopted risk assessment principles, but (2) has not yet been approved by an importing country. Additionally, the commenter interpreted the U.S.-Mexico-Canada Agreement (USMCA) to expressly commit all three countries to develop a low-level presence policy for imports.

To maintain global acceptance for its regulatory approach, APHIS needs to continue to maintain and enhance its credibility and its leadership role in the field of biotechnology regulation. It was with that goal in mind that we proposed these new regulations, which reflect both the knowledge we have gained, over the more than 30 years since we first promulgated our biotechnology regulations, and new developments in the field.

While it is gratifying that the APHIS system of regulation is perceived to provide protection against commingling or low level presence of plant products that are unwanted or are unauthorized in foreign (or even domestic) markets, the PPA, under which these regulations are promulgated, does not authorize APHIS to use the potential for low level presence as a basis for determining regulatory status or for monitoring what has been commercialized. USDA recognizes the focus of the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants (2003) and the associated annex addressing low level presence, an international standard. However, we note that the subject of this guidance and its agreed-upon annex is for food safety alone. USDA–APHIS reviews GE plants for the potential for plant pest risk, not food safety.

Finally, we disagree with the commenter's interpretation of the USMCA. We note that it instead stipulates that each Party shall adopt or maintain policies or approaches designed to facilitate the management of any LLP Occurrence. It does not mandate development of an overarching policy.

Elaborating on the concerns discussed above, some commenters emphasized the need for APHIS to develop and execute an international engagement strategy with our trading partners that explains the rationale for APHIS' pre-market regulatory approaches.

For 30 years, APHIS has consistently engaged and led in many international contexts to provide knowledge of its regulatory policy, science, and systems to encourage the safe development and trade of the products of agricultural biotechnology. Most recently, APHIS has worked to implement the Presidential Executive Order *Modernizing the Regulatory Framework for Agricultural Biotechnology Products* (June 11, 2019, E.O. 13874) to ''provide leadership in international fora to promote scientific competency, understanding of the U.S. regulatory approach, and regulatory compatibility worldwide for biotechnology products.'' [11] For the past several years, APHIS has shared rationales, experience, and information on potential regulatory changes with U.S. trade agencies (*e.g.,* the United States Trade Representative, the Department of State, the USDA Foreign Agricultural Service), U.S. trading partners, like-minded countries, and other countries in order to garner understanding and support for this updated regulatory approach. APHIS intends to continue such engagement.

Statutory Authority, Jurisdiction, and Interagency Coordination

We received many comments regarding our statutory authority, or lack thereof, to implement our proposed regulations. Some commenters claimed that we did not have such authority, while others expressed the view that we were abdicating the authority we do possess and, in some cases, failing to meet our statutory obligations. Some of these issues have already been discussed elsewhere in this document in relation to topics such as allowing developers to determine whether their products are eligible for exemption.

As noted above, we base our determinations of regulatory status on whether a GE plant or its sexually compatible relatives could pose an increased plant pest risk relative to the comparator(s). One commenter asserted that the PPA gives the Secretary the authority to develop regulations for the movement of plant pests only, and not the authority to develop regulations for the movement of organisms that pose a plant pest risk.

We do not agree with this comment. In addition to the authority to regulate the movement of plant pests under § 7711 of the PPA, including ''[a]ny article similar to or allied with any of the'' specific plant pests listed in § 7702(14), as cited by the commenter, we note that § 7712 of the PPA specifically provides the Secretary with broad authority to protect plants by regulating the movement of, among other items, plants and articles in order to *prevent* the introduction or dissemination of a plant pest within the United States.

[11] National Strategy for Modernizing the Regulatory System for Biotechnology Products. September, 2016.

As noted many times in this document, for GE organisms that fall under the regulations, permits are required for three activities: Importation, interstate movement, and environmental release. One commenter asserted that regulation of environmental releases done within a State or territory is unconstitutional.

We do not agree with this comment. The impact of an unauthorized environmental release may extend beyond the borders of the State in which the GE organism was released. *See Atay* v. *County of Maui,* 842 F.3d at 701–02 (''Under the PPA, 'movement' is defined broadly and expressly includes a plant's 'release into the environment,' [7 U.S.C.] § 7702(9)(E), such as open-air field testing of GE plants. Experimental GE plants grown on test fields in Maui are without doubt involved in interstate commerce. Setting aside the global market for GE seed crops, seeds and other organisms carried afield by wind or other vectors ''do not acknowledge State lines.'' 52 FR 22892, 22894 (June 16, 1987).'') (citation omitted); *id.* at 702 (''While the phrase 'movement in interstate commerce' within the meaning of the PPA's preemption clause may be narrower than the full scope of Congress's Commerce Clause power, we find that the phrase encompasses federally regulated GE crops grown in Hawaii. [The plaintiff's] narrower interpretation, which would limit the scope of the preemption clause to local laws addressing plants that are in the act of traveling to or through at least one other State, is less consistent with the statute's larger context and purpose, which clearly envisions the dissemination of plants and seeds from fields as implicating movement in interstate commerce. See, *e.g.,* 7 U.S.C. 7711(a). Indeed, Congress expressly recognized in the PPA that 'all plant pests, noxious weeds, plants, plant products, articles capable of harboring plant pests or noxious weeds regulated under this chapter are in or affect interstate commerce.' *Id.* § 7701(9).'') (citation omitted).

In contrast to the comments discussed above, which questioned the reach of our authority to regulate, other comments faulted us for not using our authority to regulate noxious weeds under the PPA. It was stated that by not considering noxious weed potential as a criterion for determining regulatory status of GE organisms, we restrict our authority under the PPA. One commenter argued that APHIS is statutorily obligated to integrate and apply the noxious weed authority to GE crops.

APHIS recognizes that genetic engineering may be used to introduce a trait that increases the distribution, density, or development of a plant or the weedy impacts of the plant, factors that are considered aspects of a plant's weediness. Accordingly, we would continue our current practice of considering the weediness of the unmodified plant and whether the new trait could in any way change the weediness. We would also consider potential effects on the weediness of other plants with which the engineered plant can interbreed, because it is relevant to the assessment of the plant's plant pest risk. Plants and their sexually compatible relatives could have increased importance as reservoirs for plant pests if they are distributed differently, are more prevalent, or are altered with respect to the time period during which they serve as a host for plant pests due to the introduced trait. As part of the RSR, APHIS would continue to consider whether the trait might change plant pest interactions, establishment, and persistence for both the plant engineered and any other plants with which it can interbreed. If the plant had the potential to be a truly troublesome and impactful weed, we would need to consider whether the plant with the specific trait being evaluated should be considered for regulation pursuant to our separate statutory authority to regulate noxious weeds and the regulations issued under that authority. The proposed regulation does not change this analysis.

APHIS disagrees with the proposition that APHIS is statutorily obligated to integrate noxious weed authority into a revised part 340. In the PPA, Congress identified plant pests and noxious weeds as separate concerns, and delegated authority to the Secretary to determine how to best use this authority. See, *e.g.,* 7 U.S.C. 7711, 7712, 7754, 7758(c); *see also Center for Food Safety* v. *Vilsack,* 718 F.3d 829, 843 (9th Cir. 2013) (''Plant pests and noxious weeds are regulated under separate regulatory frameworks. Regulations for plant pests are contained in 7 CFR parts 330 and 340 while the regulations governing noxious weeds are contained in 7 CFR part 360. The separate regulatory frameworks for plant pests and noxious weeds are consistent with standards of the statute treating plant pests and noxious weeds separately. Indeed, the PPA kept in place the separate regulatory frameworks for plant pests and noxious weeds that were originally promulgated under the Federal Plant Pest Act and the Federal Noxious Weed Act.'') (Citing 7 U.S.C. 7758(c)). We also do not perceive a basis at this time for overhauling part 360 noxious weed regulations, which we believe have functioned well over the years, or establishing alternate regulations in title 7 governing noxious weeds.

Other commenters expressed the concern that by asserting our statutory authority narrowly and emphasizing deregulation in this rulemaking, we could be creating a regulatory vacuum. It was suggested that States or localities may take advantage of that vacuum and assert their own authorities, possibly intervening to disrupt necessary field trials.

With regard to overall scope, the regulations proposed under part 340 are functionally equivalent to the rules under which APHIS has been operating for essentially three decades. Under the existing regulations, APHIS communicates with and cooperates with State and local governments as appropriate and as circumstances warrant, including for coordination of enforcement and permitting activities. APHIS does not anticipate that the working relationship with State and local governments will be changed in any significant way based upon issuance of this rule. Federal courts have already considered the applicability of preemption principles in this area, including by applying the Plant Protection Act's express preemption provision, 7 U.S.C. 7756. *See generally Atay* v. *County of Maui,* 842 F.3d at 698–705.

Some commenters addressed issues of interagency and intra-agency coordination in the regulation of GE products. A commenter suggested that we needed to coordinate with EPA to improve the commercial availability of herbicide resistant crops, concomitant with the registration of herbicides for use on those crops. The commenter stated that the asynchronous timing of USDA's deregulation of an herbicide-resistant crop cultivar and of EPA's associated herbicide registration has led to some scenarios in which growers are tempted to illegally apply unregistered herbicide formulations. Another commenter stated that duplicative regulations from oversight agencies, including FDA, EPA, and APHIS, should be streamlined into a common regulatory oversight regime depending on the product and its intended use.

The interagency working group which drafted the Coordinated Framework sought to ensure regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding beneficial innovation. The former commenter

believes that a delay in USDA regulatory decisions to better coordinate with EPA registration decisions will curtail growers and applicators from illegally applying unregistered herbicide formulations. However, USDA needs to consider whether additional regulatory burden is warranted or legally appropriate, given that the pesticide activity noted is already considered to be illegal by existing regulation. We note that one of the purposes of the Coordinated Framework is to ensure that there is a standard mechanism for communication and, to the extent possible, coordination among FDA, EPA, and APHIS as they perform their respective regulatory functions. USDA and EPA are in communication over the overarching purpose of coordination as it pertains to the pesticide regulatory issues identified by the commenter. At the same time, this rule does not impose delays on USDA decision making based on factors within the regulatory jurisdiction of other agencies, nor do we think that such delays would be appropriate.

With regard to the latter commenter, while FDA, EPA, and APHIS have distinct areas of regulatory oversight relative to GE organisms, the Agencies are committed to implementing Executive Order 13874, including its requirements that EPA and USDA streamline regulations and guidance documents within their purview and that these agencies ''use existing statutory authority, as appropriate, to exempt low-risk products of agricultural biotechnology from undue regulation.'' Where areas of overlapping jurisdiction exist, the Agencies are seeking to avoid redundant regulation. For example, FDA has jurisdiction over animals, including insects, but does not regulate when another agency is regulating, as APHIS is with GE moths and bollworm. With this rule, APHIS is avoiding redundant regulation with regard to microbial pesticides and plant incorporated protectants. As noted above, new § 340.5(f) states that a permit is not required for any GE microorganism product that is currently registered with the EPA as a microbial pesticide, so long as the microorganism is not a plant pest as defined in § 340.3. Similarly, § 340.5(g) states that a permit is not required for the movement of any plant modified solely to contain a plant incorporated protectant that is currently registered with the EPA or exempt from EPA regulations.

Finally, multiple commenters recommended that we provide greater clarity regarding the regulatory jurisdiction of two agencies within APHIS—Biotechnology Research Services (BRS) and Plant Protection and Quarantine (PPQ)—that regulate, among other things, GE and non-GE plants, respectively. The commenters expressed concern that some of the revisions we proposed, in particular those in § 340.2, may create opportunities for duplicative regulation of products under part 340 by BRS and under 7 CFR part 330 by PPQ.

The regulations in part 330 govern the movement of plant pests, biological control organisms, and associated articles, such as soil. Prior to a final rule [12] published in the **Federal Register** on June 25, 2019 (84 FR 29938–29967, Docket No. APHIS–2008–0076), the regulations in part 330 had specifically exempted from regulation under that part any plant pests that had been genetically engineered, as that term was defined in § 340.1. In the June 25, 2019 final rule, that specific exemption was removed from part 330. In its place, a requirement, currently found in § 330.200(a), was added. This new requirement provided that plant pests, biological control organisms, and associated articles that are not authorized for importation, interstate movement, or environmental release in accordance with part 330, and are not explicitly exempted from regulation under part 330, must be authorized for importation, interstate movement, or environmental release under other regulations in title 7 of the Code of Federal Regulations in order for that movement to be lawful.

The intent of this revision was to signal that there are multiple parts in title 7 of the Code of Federal Regulations, not just part 330, that contain requirements regarding the importation, interstate movement, or environmental release of plant pests, biological control organisms, or associated articles. However, we agree with the commenter that one of the unintended effects was to cause confusion within this rulemaking concerning the clear delineation between the requirements for the movement of GE plant pests, which are found in part 340, and the requirements for plant pests that had not been genetically engineered, which are found in part 330.

Accordingly, we are revising § 330.200 to indicate that GE plant pests and biological organisms are exempted from regulation under part 330, and are regulated under part 340.

A commenter expressed the concern that this rulemaking does not further the Coordinated Framework established in the 1980s among USDA, FDA, and EPA regarding federal biotechnology regulation. The commenter states that the proposed rule amended part of this Coordinated Framework without fully engaging EPA and FDA and did not reflect a truly holistic approach, in the spirit of the Framework, to updating the regulatory landscape for certain GE plants. The commenter strongly believes that APHIS should follow the intent of the Coordinated Framework.

APHIS has continued to coordinate with our Coordinated Framework partners at FDA and EPA on an ongoing basis, and we are committed to continuing this coordination with the implementation and operationalization of this rule. In 2017, the three agencies collaborated on an update to the Coordinated Framework. This update was intended to:

- Clarify which biotechnology product areas are within the authority and responsibility of each agency;
- Clarify the roles each agency plays in regulating different product areas, particularly for those products that fall within the scope of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment;
- Provide a standard mechanism for communication and, as appropriate, coordination among agencies while they perform their respective regulatory functions, and identify agency designees responsible for this coordination function; and
- Specify the mechanisms and timelines for regularly reviewing, and updating as appropriate, the Coordinated Framework to minimize delays, support innovation, protect health and the environment and promote public trust in the regulatory systems for biotechnology products.

The updated Coordinated Framework is available at: *https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf.*

Additionally, as part of the rulemaking process, EPA and FDA have had the opportunity to comment on this proposal and to provide meaningful insight that informed this process.

Another commenter stated that language in the section of the proposed rule describing regulation of PMPI-producing plants suggests that the Coordinated Framework for regulating GE crops in the United States is not nearly as ''coordinated'' as is necessary to ensure the safety of our food supply. According to this commenter, a statute should be enacted to create a new Federal agency that would have explicit authority to provide oversight over all GE organisms (plants, animals, and GE

[12] To view the rule, its supporting documents, or the comments that we received, go to *https://www.regulations.gov/docket?D=APHIS-2008-0076.*

microorganisms) for all possible risks, including plant pest and noxious weed risks, environmental risks to beneficial organisms as well as to ''neutral'' organisms like monarch butterflies, and human health risks such as those associated with animal carcinogens and probable human carcinogens like glyphosate.

Regulation of PMPI-producing GE plants is discussed above. The remainder of this comment is outside the scope of the current rulemaking and of APHIS' regulatory authority. We note, moreover, that scientific evidence does not support the conclusion that GE organisms, as a class, present risks that are different in degree or kind from the risks that are presented by comparable non-GE organisms (NRC, 2010; NAS, 2016b)

NEPA Implementing Regulations

As noted earlier, the June 2019 proposed rule proposed that the notification and petition processes be removed from the regulations. Concurrently, we proposed to remove language pertaining to notifications and petitions from the NEPA implementing regulations in 7 CFR part 372. Specifically, we proposed to remove language pertaining to notifications from § 372.5(c)(3)(iii), and to remove language pertaining to petitions from paragraphs (b)(7) and (c)(4) of § 372.5. These changes were proposed to make the NEPA regulations consistent with the proposed revised part 340.

Several commenters recommended that APHIS revise its NEPA implementing regulations to ensure that individual actions taken under the proposed rule are appropriately addressed and to describe the type of environmental analysis and documentation that will generally be developed. One commenter stated that APHIS should revise § 372.5(b) to include the proposed RSR as a type of action that normally requires an environmental assessment but not necessarily an Environmental Impact Statement. Another commenter recommended that APHIS clarify that certain actions are not expected to have an impact on the environment and therefore qualify for a categorical exclusion from the requirements of NEPA.

APHIS disagrees with the suggestion that part 372 needs to be further revised to more specifically describe the type of environmental analysis that is necessary for individual actions under the final rule. Actions will be accompanied by appropriate environmental analysis based on the degree of environmental impact, consistent with the final programmatic environmental impact statement (PEIS). In regard to the new proposed RSR, APHIS stated in the final PEIS that RSRs will be accompanied by an appropriate environmental analysis depending on the degree of environmental impact.

APHIS seeks to further clarify APHIS' NEPA obligations under various circumstances. When a modified plant qualifies for one of the exemptions in § 340.1(b), (c), or (d), the plant is not subject to part 340 at all and APHIS renders no determination regarding its plant pest risk. Therefore, APHIS will not complete a NEPA analysis for the plant.

In the case of RSRs, whether conducted before or after a person requests a permit, only some outcomes will require analysis pursuant to NEPA. If, after initial review, APHIS finds a plausible pathway to increased plant pest risk, APHIS will conduct a Plant Pest Risk Assessment (PPRA) to evaluate the factor(s) of concern. In this situation, APHIS will complete a NEPA analysis, as appropriate, for an unconfined environmental release. Finally, when permits are issued for confined environmental release, NEPA will apply as appropriate. Under most circumstances, confined environmental releases are categorically excluded in part 372 from the need to prepare an Environmental Assessment or an Environmental Impact Statement.

List of Taxa

In the preamble to the June 2019 proposed rule, we noted that we were proposing to remove the list of taxa containing plant pests from the regulations. Instead, APHIS proposed to maintain a list of taxa that contain plant pests on its website. We explained that the list on the website would be more useful and reliable than a static list of taxa, which becomes outdated. We solicited public comment on the proposed change.

Commenters supported this change. One commenter, however, suggested that it would be useful to maintain a version history on the website, so that developers can be aware of the latest updates. The commenter also recommended that whenever the website is updated, APHIS should send an email notification to stakeholders. Another commenter requested clarification on how the list would be maintained and modified.

APHIS agrees with the comment. Since taxonomic designations sometimes change and new plant pests are continually being discovered, APHIS will maintain a version history for the list of taxa that contain plant pests and will provide an email notification to stakeholders when the list is changed.

Oversight and Transparency

Some commenters expressed the concern that the regulatory framework set forth in the June 2019 proposed rule would result in an overall weakening of APHIS' regulatory oversight over GE products. Commenters discussed a number of potential consequences of what they regarded as diminishing APHIS' oversight role. As noted earlier in the discussion pertaining to allowing developers to determine whether their products are eligible for exemption, commenters were concerned that there could be an increased risk of commingling of non-GE crops with GE crops. It was also stated that because GE crops are already associated with greater herbicide and pesticide use than non-GE crops, the rule could result in the development of more herbicide- and pesticide-resistant pests and weeds, leading to increased environmental and human health risks. Some commenters stated that we needed to strengthen, rather than loosen, our regulatory oversight.

We have addressed many of these issues earlier in this document and the PEIS (§§ 4.3.5 Agricultural Weeds and HR management; 4.6.2 Domestic Socioeconomic Environment; and 4.6.3 International Trade). Additional discussion is presented below, under the heading ''General Opposition to GE Products.'' As we have noted, however, these issues are mostly outside the scope of the current regulations and of our statutory authority under the PPA.

It was also suggested that the proposed new regulatory framework could lead to a loss of transparency. Growers of non-GE crops, as noted above, could lose access to information about neighboring GE crops. According to some commenters, the public would also lose access to important data. In particular, field-test data would no longer be available to the public because the submission and publication of such data would not always be required under the proposed rule.

One commenter recommended that in addition to providing the information currently set forth in the proposed rule, APHIS should establish on its website a single list of all GE organisms that are being released into the environment. According to the commenter, that list should include all plant-trait-MOA combinations, all RSRs, all permitting, and all confirmations of developers' determinations of an exemption. The commenter believes that with a complete and accurate list of all GE organisms that have been released into

the environment, food industry stakeholders and the public will be able to determine which GE plants have entered the food supply. Further, according to the commenter, a transparent and comprehensive list will provide helpful information if any food safety and environmental threats materialize. In the commenter's view, this information will also be important for international trade because it may prevent unnecessary trade barriers from being constructed based on inaccurate information about which GE plants may be entering a country without the proper regulatory approval. Also, according to the commenter, it will improve consumer confidence about GE plants because consumers will realize that their existence is not being hidden from them. The commenter recommended that to be as useful and as transparent as possible, the list should include information about the plant, the type of modifications or edits performed, the changed traits, a summary of data about the benefits of the traits, and any testing for safety concerns.

We do not agree with these comments. Under this rule, APHIS will continue to make information available that is related to permits issued under § 340.5. APHIS will also make information available concerning responses to confirmation requests under § 340.1 and RSR requests and results under § 340.4. The information will be available at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.* As to organisms that are not regulated by APHIS, APHIS is not in the best position to provide accurate and up-to-date information about such organisms. In this regard, APHIS notes that pursuant to Executive Order 13874, USDA, EPA, and FDA recently released a unified website that provides a one-stop-shop for information about the actions that the Federal Government is taking to oversee the development of agricultural biotechnology products. See *https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home.* The website provides links to relevant USDA, EPA, and FDA websites. See *https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/resources.*

General Opposition to GE Products

Many individuals who commented opposed the rule because of their concerns about GE products generally. An issue of particular concern, raised by a large number of commenters, was the possibility of unsafe GE products' getting into the food supply without consumers' knowledge. Many of the commenters favored labeling of foods derived from GE products. Commenters expressed the view that genetic engineering techniques are not as safe as conventional breeding methods and that all products developed using genetic engineering should be regulated, with no exemptions allowed. Others stated that we should require long-term testing of GE products prior to allowing commercialization. It was further stated that in light of these considerations, our proposed regulatory approach, with its focus on unfamiliar products developed using genetic engineering, does not adequately evaluate products of genetic engineering for potential long-term risk. Many commenters argued that all GE organisms should be subject to assessments of their long-term effects on the environment and human health and also evaluated for indirect economic effects. Commenters also claimed that the proposed rule, with its deregulatory emphasis, favored certain economic interests at the expense of public health and safety and the environment.

One commenter further stated that APHIS or a new GE organism-specific agency should provide oversight over all GE organisms for all possible risks, including any associated with the MOA used for gene insertion, *e.g.* extra antibiotic-resistance genes, insertional mutations, and unintended changes in the inserted genetic material. According to this commenter, APHIS should require developers of GE organisms to utilize the precision of the technology available to identify the off-target effects of genetic engineering and to ensure that associated risks are minimal.

The comments discussed above appear to be based on the premise that the genetic engineering process itself is inherently risky. As we noted in the preamble to the June 2019 proposed rule, and in this document, available evidence, including reports from the National Academies of Sciences, Engineering, and Medicine cited earlier in this document, does not support this view. Moreover, the comments discussed above do not reflect an accurate understanding of the limits of APHIS' statutory authority, as explained elsewhere in this preamble.

In the reports we cited, issued in 1987 and 1989, respectively, by the NRC,[13] [14] it was stated that there was no evidence for unique hazards inherent in the use of recombinant DNA techniques and that with respect to plants, crops modified by molecular and cellular methods should pose risks no different from those modified by conventional breeding methods for similar traits. A key conclusion from these reports, taken together, is that it is not the process of genetic engineering *per se* that imparts the risk, but the trait or traits that it is used to introduce. A more recent NAS report, issued in 2016, reaffirmed this conclusion.[15]

Several commenters took a position diametrically opposed to the comments discussed above. The commenters stated that there is no scientific rationale for the continued regulation of plant products developed using genetic engineering techniques and legacy methods.

We do not agree with this comment. As discussed above, responsibility for regulating GE and non-GE plants for plant pest risk is divided between APHIS BRS and APHIS PPQ. In both cases, plants and plant products are regulated or not regulated based on the risk of introducing or disseminating plant pests that may be posed by their movement or release into the environment. Because some (but not all) GE and non-GE plants are associated with increased risk, it is necessary for APHIS to regulate such plants in order to carry out its mission of protecting U.S. agriculture.

Concerns were expressed by the organic farm industry regarding the economic impact that the regulatory relief offered to developers in this rulemaking would have on organic farmers, particularly as it relates to the issue of GE crops commingling with organic crops. The commenters stated that APHIS must consider how it will address the needs of USDA-certified organic operations to prevent commingling with GE organisms. Such considerations, it was stated, were not addressed in the proposed rule. The commenters asserted that the USDA National Organic Program regulations prohibit the use of genetic engineering in the production of agricultural products marketed as organic in the United States. According to these commenters, even inadvertent presence of GE organisms can jeopardize the organic status of an otherwise compliant organic product, and can lead to loss of markets and significant industry disruption. Organic farms that reported crop loss from the presence of GE organisms between 2011 and 2014

[13] Introduction of Recombinant DNA-Engineered Organisms Into the Environment: Key Issues. 1987. NRC. Washington, DC. National Academies Press (US).

[14] Field Testing Genetically Modified Organisms: Framework for Decisions. 1989. NRC (US) Washington (DC). National Academies Press (US).

[15] NAS. 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC: The National Academies Press. doi: 10.17226/23395.

reported an average loss of $70,000 per farm (2014 USDA Organic Survey).

APHIS has fully considered these factors from an economic perspective and would refer the commenter to the economic analysis accompanying this final rule. APHIS in that analysis expanded the discussion of the various costs, including the costs associated with buffer strips, spatial and temporal isolation, and the loss of premiums associated with the risk to organic and non-GE growers from cross-pollination or commingling. We note that organic crops and non-GE products that are kept separate from their GE equivalents are treated as value-added crops commanding premiums that vary according to prevailing supply and demand conditions. Organic and other identity-preserved crops generally receive a price premium, a premium adversely impacted by the unintended presence of GE traits. The premiums compensate farmers and traders for incremental costs they incur, including those borne to maintain the segregation of non-GE and other IP production from GE crops throughout the supply chain (through buffer zones, spatial and temporal isolation, etc.). In the United States, the coexistence of GE and non-GE production systems has been left to market forces. Non-GE growers bear costs of coexistence and, in turn, pass those costs on to purchasers of non-GE crops (Kalaitzandonakes and Magnier, 2016).

One commenter stated that in addition to the threat of economic harm from unintended presence of GE plant material, farmers who unintentionally grow patented GE seeds or who harvest crops that are cross-pollinated with GE traits could face costly lawsuits by biotechnology companies for ''seed piracy.''

The issue raised by the commenter is outside the scope of the plant pest authority delegated to APHIS under the PPA.

Some commenters argued that APHIS should conduct ongoing monitoring and assessment of GE product impacts both in pre-market field trials and following commercialization in order to protect the integrity of conventional and organic seed and crops from prohibited substances and excluded methods, including the methods of genetic engineering. According to these commenters, safeguards and monitoring must be required for the organism post-commercialization, and the FDA GRAS (Generally Recognized as Safe) notification process is not enough for such safeguards. In these commenters' view, monitoring should include tracking changes associated with ecosystem harm, such as degradation of water quality, air pollution, climate impacts, or loss of biological resources. The commenters believe that this process must be rigorous, transparent, and inclusive of APHIS's plant pest and noxious weed authority under the PPA.

APHIS does not agree with these comments. Once APHIS determines that a plant product does not pose a plant pest risk, APHIS has no further authority to regulate it as such and to mandate requirements for the submission of data unless there are new facts, such as a compliance incident, that warrant such action. The FDA regulates human and animal food from GE plants as FDA regulates all food within its regulatory jurisdiction. The existing FDA safety requirements impose a clear legal duty on everyone in the farm to table continuum to market safe foods to consumers, regardless of the process by which such foods are created. It is unlawful to produce, process, store, ship or sell to consumers unsafe foods. Comments concerning FDA's process and requirements should be directed to FDA.

One commenter discussed the need for compensating organic and other growers of non-GE crops who could suffer harm as a result of this rulemaking. It was argued that we need to establish a compensation mechanism for those harmed by commingling, and that liability in cases of commingling caused by GE crops should rest with the developers or patent holders. One commenter also recommended that we establish a fair compensation mechanism for losses caused by herbicides drifting from fields planted with herbicide-resistant GE plants.

We thank the commenters for these recommendations; however, they fall outside the scope of the regulations in part 340, which establish the oversight and regulation of certain GE organisms. Regarding the final comment, application protocols/practices for pesticides are established and enumerated through EPA's labeling requirements. Once APHIS determines that a plant product does not pose a plant pest risk, it is not subject to our regulations in part 340 unless there are new facts, such as a compliance incident, that warrant such action.

Additional Comments

Commenters offered a number of additional recommendations that are beyond the scope of the current rulemaking. Some commenters recommended that we invest in research to develop lower-cost rapid testing technology. It was further suggested that we commit resources to researching, tracking and analyzing incidences of unintended GE presence and associated economic losses at all levels of the supply chain. One commenter recommended that we coordinate with the USDA Agricultural Marketing Service to establish contract protections for organic and identity preservation grain growers to ensure that they have fair access to testing data and recourse.

We thank the commenters for these recommendations. As noted above, however, all of these recommended activities would fall outside the scope of the regulations in part 340, which establish the oversight and regulation of certain GE organisms.

One commenter stated that APHIS should consider protection goals that align with making U.S. agriculture more sustainable, more environmentally friendly, and less in need of future ''solutions'' to genetic-engineering-produced noxious weed problems that involve developing additional GE crops engineered to be tolerant of different, more noxious herbicides.

This comment is outside the scope of these regulations. The PPA provides for detection, control, eradication, suppression, prevention or retardation of plant pests or noxious weeds.

Another commenter expressed concern over biodiversity and food security in the context of accelerating climate change. The commenter stated that genetic uniformity leads to disease susceptibility and that biodiversity management systems need to be improved in terms of equity. According to the commenter, we need systems that support keeping diverse seeds in use, but genetic engineering has gone hand in hand with large monoculture production.

This comment is outside the scope of these regulations. We note, however, that the concerns identified by the commenter do not seem specific to genetic engineering.

Other commenters expressed concerns about corporate concentration and what they viewed as related feedback loops of seeds and chemical use. Particular concern was expressed over the possible consolidation of the seed industry that commenters thought could result from this rulemaking. It was stated that legal and government systems favor the largest companies, and that efforts to check the power of the largest seed companies have been overridden or have fizzled out.

APHIS acknowledges the concern that the commenters have raised on this topic. The regulations proposed under part 340 are intended to streamline and offer additional regulatory relief to developers of all sizes. We anticipate

that since smaller-scale business and academics have limited resources and capacity to navigate regulatory systems, this rule will provide especially acute benefits to smaller researchers and businesses. APHIS has outlined and provided detailed descriptions of this dynamic in the economic analysis accompanying this regulation.

Some commenters opposed the elimination of the notification and petition procedures contained in the existing regulations. It was stated that APHIS should not eliminate the petition process without more clearly defining a streamlined, predictable path through which responsible individuals can establish that their innovation no longer needs to be reviewed by APHIS prior to release and commercialization. Commenters opposed eliminating the notification procedure because they were concerned that doing so would require many developers to go to permitting, potentially disrupting business practices. Alternatives suggested by these commenters included adding provisions for streamlined permitting with standardized conditions for low-risk organisms and returning to requiring individuals to provide information on how they intend to meet performance standards.

In many ways, the APHIS evaluations for notifications under current regulations are very similar to those done for permit applications, but the notification procedure relies on applicants' agreeing to meet the performance-based standards described in the regulations rather than submitting an application for APHIS review describing the specific measures that they will employ for the activity (as is the case for permits). With permits, but not with notifications, APHIS can accept the proposed measures or add to them, and the result is a set of binding customized permit conditions.

We will not be making any changes in response to these comments. As we noted in the preamble to the June 2019 proposed rule, the notification procedure in the current regulations relies upon performance-based standards. Since the specific measures that constitute compliance with the regulations are not enumerated in the performance standards, it can be difficult for APHIS inspectors to determine whether a notification holder is in compliance. This uncertainty can make enforcing the regulations, and thereby protecting U.S. agriculture from plant pest risks, more difficult than it would be if compliance measures were clearly enumerated as they are in specific conditions under a permit. For this reason and to comply with OIG recommendations with which we agreed, we proposed to eliminate the notification procedure. We do not agree with the recommendation to provide streamlined permit conditions for low-risk organisms. The standard permitting conditions in § 340.5(i) are needed to ensure that activities conducted under permit for all GE organisms can be performed with adequate mitigations for plant pest risk. Differences in the level of risk associated with different organisms will be reflected in the supplemental permitting conditions.

The current petition process for GE plants stems from the manner in which *regulated article* is defined. As noted above, the current regulations consider a GE organism to pose a plant pest risk and therefore be a regulated article if the donor organism, recipient organism, vector, or vector agent is a plant pest. Under the proposed regulations, however, we would evaluate whether an organism would require a permit for movement based on the characteristics of the organism itself rather than on the method by which the organism is genetically engineered. Based on the proposed change in approach, APHIS believes that the petition process is no longer necessary and is removing the petition process from the regulations. (As discussed previously in this document, however, until RSR is available for a particular crop, we will continue to receive petitions under the process for that crop.)

Some commenters advocated that we retain the existing regulatory framework rather than adopting the one we proposed. In the view of one commenter, the proposed rule constituted a shift from a streamlined, performance-based regulatory approach to a more prescriptive one. The commenter saw that shift as a step backwards. Another commenter expressed a preference for the process-based approach of the existing regulations rather than the product-based one that we proposed. The commenter stated that APHIS should regulate biotechnology products based on the process by which they are created, using genetic engineering as the trigger for regulatory review, to ensure that none evade oversight entirely.

For reasons discussed at length in this document and in the June 2019 proposed rule, we do not agree with these comments.

One commenter viewed our overall regulatory approach as not sufficiently flexible to take into account the relative risk levels associated with different crops. The commenter recommended that we consider such differences when making determinations about the appropriate levels of regulation for different crops. We do not agree with this comment. Our assessment of the risks associated with specific GE crops will be reflected in our RSR determinations and in the permit conditions we assign.

One commenter stated that our policy on low-level presence of Regulated Genetically Engineered Plant Materials, discussed in the 2008 proposal, is absent from this one.

APHIS intends to continue its support of U.S. trade agencies to address low level presence issues, as is further discussed above. This approach is consistent with APHIS' statutory authority to regulate plant pests, as further explained above.

One commenter stated that the June 2019 proposed rule lacked the summary of commenters that is common to proposed rules from other agencies. The commenter stated that APHIS should publish such a summary in the final rule and should hold at least one public consultation with stakeholders that do not have a direct or indirect financial interest in the proposed regulations.

We do not agree with this comment. As we noted in the preamble to the June 2019 proposed rule: ''Following the withdrawal of the January 2017 proposed rule, APHIS conducted extensive outreach to Land Grant and public university researchers, as well as small-scale biotechnology developers, agriculture innovators, and other interested stakeholders. In total, APHIS met with more than 80 organizations, including 17 universities, State Departments of Agriculture, and farmer organizations.'' In this final rule, we have further delineated the nature of these discussions.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the processes in this final rule, we have prepared a final environmental impact statement (EIS). The final EIS is based on a draft EIS, which we drafted after soliciting public comment through a notice in the **Federal Register** to help us delineate the scope of the issues and alternatives to be analyzed. The final EIS responds to public comments, analyzes each alternative and its environmental consequences, if any, and provides APHIS' preferred alternative. The EIS was prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions

of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Copies of the final EIS are available on the *Regulations.gov* website (see footnote 3 in this document for a link to *Regulations.gov*) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Executive Orders 12866, 13563, 13771 and Regulatory Flexibility Act

This final rule is an Executive Order 13771 deregulatory action. Details on the estimated costs of this final rule can be found in the rule's economic analysis.

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, and equity considerations). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides a final regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available on the *Regulations.gov* website (see footnote 1 in this document for a link to *Regulations.gov*) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

The revisions to part 340 in this final rule create the framework for more focused, risk-based regulation of the GE organisms that pose plant pest risk. Under this rule, certain categories of plants are exempted from the regulations in part 340. Developers are able to determine, when appropriate, whether their products fit into one of the exempted categories and are therefore not subject to APHIS' regulations.

The rule also provides for a process to determine the regulatory status of a plant under part 340. GE plants having the same plant-trait-MOA combination as those previously found by APHIS to be not subject to the regulations will not be regulated, nor will they be required to undergo an RSR. GE plants found likely to pose a plant pest risk and GE plants that are not eligible for an RSR will be allowed to move only under permit. For plants that do not fall into any of the exempted categories and are eligible for an RSR, developers have the option of either requesting a review or requesting a permit for the movement (including importation, interstate movement, or environmental release) of their organism in lieu of an RSR. Developers of GE organisms that are plant pests will continue to need permits to import, move interstate, or environmentally release those organisms.

Shipping standards under this rule are less prescriptive and more generally applicable, and the rule provides for the issuance of multi-year permits. The provisions for record retention, compliance, and enforcement have been altered to ensure that APHIS has sufficient information to monitor compliance with its regulations and maintain effective oversight of regulated GE organisms, in accordance with provisions of the 2008 Farm Bill and recommendations of the 2015 USDA OIG report on GE organisms. These changes improve the efficiency and clarity of the regulations.

The amendments in this rule will benefit developers, producers, and consumers of certain GE organisms; public and private research entities; and APHIS. There will be no decrease in the level of protection provided against plant pest risks. The regulatory framework, including the RSR process used to determine regulatory status established under this rule, will provide cost savings to some plant developers and will allow for reallocation of APHIS resources to Biotechnology Regulatory Services (BRS) priorities.

Under this rule, APHIS regulatory oversight (through permitting) will not be required for plants that fall into one of the exempted categories or have been assessed by means of an RSR and have been found unlikely to pose an increased plant pest risk relative to its comparator. Direct regulatory costs to some plant developers will be reduced for the development of GE plants for which APHIS permits are no longer necessary. Savings to the regulated community will result from a reduced need to collect field data, fewer reporting requirements, and lower management costs. Costs now associated with petitions for non-regulated status will be reduced or eliminated where APHIS permits are no longer necessary.

Cost savings for these entities are expected to more than offset the new costs. APHIS estimated the cost savings for two regulatory oversight scenarios where USDA either has sole regulatory authority or shares oversight with EPA and/or FDA, based on a study of the costs encountered by private biotechnology developers as they pursue regulatory authorization of their innovations. When only APHIS has regulatory oversight, compliance cost savings under the rule could range from $1.6 million to $5.6 million ($3.6 million on average) for the development of a given GE plant. If EPA and/or FDA also have an oversight role in the development of a given GE plant, compliance cost savings could range from $551,000 to $937,000 ($744,000 on average; see Table A below and Table 5 of the RIA). From 1992 through September 2019, an average of just under 5 petitions were processed (granted non-regulated status or the petition withdrawn) in a given year, with a high of 14 in 1995. As the rule is expected to spur innovation, we expect the number of new GE plants developed annually to increase over time. In particular, the rule may provide impetus to the development of new horticultural varieties, where the costs of acquiring non-regulated status in the past may have been prohibitively high relative to the potential market.

In the following estimate of impacts, we use the average cost savings reported above per GE plant developed and assume the annual number of new GE plants developed under the rule without APHIS permits ranges from 5 (the current annual average number of processed petitions) to 10 (twice this average). We further assume that about 20 percent of those new GE plants are solely within the purview of APHIS oversight, and that the remaining 80 percent will also be under the purview of FDA and/or EPA oversight. If five new GE plants are developed annually without APHIS permits (all with no APHIS permit, but four still with EPA and/or FDA evaluation), the annual savings would be $6.5 million.[16] If 10 new GE plants are developed annually without APHIS permits (all with no APHIS permit, but 8 still with EPA and/or FDA evaluation), the annual savings will be $13.1 million.[17]

New costs borne by regulated entities under the rule will include rule familiarization and recordkeeping. Annual recordkeeping costs are based

[16] 1 × $3,573,500 = $3,573,500. 4 × $744,000 = $2,976,000. $3,573,000 + $2,976,000 = $6,549,500.

[17] 2 × $3,573,500 = $7,147,000. 8 × $744,000 = $5,952,000. $7,147,000 + $5,952,000 = $13,099,000.

on information collection categories that were described in the Paperwork Reduction Act section of the proposed rule, and are estimated to total about $1,070,000. New maintenance and record retention requirements in this rule should not significantly affect permit holders. While some of the specific records required under this rule were not explicitly included in the current regulations, they have been required as part of the supplemental permit conditions that accompany an issued permit. These records are integral to the activities under the permit and should already be maintained by the permit holder as a normal part of business operations and therefore readily be accessible. About 1,250 distinct entities have applied for permits or notifications under part 340. APHIS estimates that each of those entities will spend a total of about 24 hours becoming familiar with the provisions of this rule, at a total one-time cost of about $1.5 million.

Some plants that would not have been regulated under previous regulations in part 340, because a plant pest was not used in their development, would now be under the purview of APHIS oversight. APHIS expects the number of plants in this category will be very small, likely less than 1 per year based on historical activity. For those few instances where an APHIS permit is required, developers could incur new costs associated with permitting ranging from about $13,000 to $671,000, depending on recordkeeping, reporting, stewardship, and testing requirements.[18]

In accordance with guidance on complying with Executive Order 13771, the primary estimate of the annual net private sector cost savings for this rule is $8.3 million. This value is the mid-point estimate of the net private cost savings annualized in perpetuity using a 7 percent discount rate.

Current annual APHIS personnel costs for conducting genetic engineering related activities that will be affected by this rule total about $3.4 million. These include compliance activities, inspection activities, 'Am I Regulated' (AIR) process activities, notification activities, permit activities, and petition activities. Under this rule, APHIS' overall annual personnel costs of regulating GE plants are not expected to change. While the volume of specific activities will change, the overall volume of regulatory activities, the general nature of those activities, and the level of skills necessary to perform those activities will not change.

Costs to APHIS of implementing this rule include outreach activities, developing guidance documents, training, and adjusting the permit system. APHIS estimates that public outreach, guidance and training will cost about $77,000. Requests for RSRs and response letters under the rule will be handled in a manner similar to the current AIR process, outside the electronic permitting system and without incurring new costs.

Certain plants are genetically engineered in order to produce PMPIs. To date, PMPI-producing GE plants regulated by APHIS have been genetically engineered using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current regulations in part 340. In this rule, APHIS will maintain its oversight of PMPI-producing plants. In this final rule, we are adding this requirement to § 340.2, as paragraph (e), which states that a permit is required for the movement of a plant that encodes a product intended for pharmaceutical or industrial use.

Certain plants are genetically engineered to produce PIPs, meaning that they produce pesticides. APHIS has regulated those PIP-producing plants that are captured by current regulations, *i.e.,* when plant pests or plant pest sequences are used. The PIPs also fall under the regulatory oversight of EPA. However, because EPA generally requires Experimental Use Permits (EUP) only for field tests on 10 acres or more of land, APHIS has exercised regulatory oversight of PIP plantings on fewer than 10 acres. Under this rule, GE PIP-producing plants that are unlikely to pose an increased plant pest risk relative to their comparators will not be regulated by APHIS following an RSR. Therefore, under this rule Federal oversight of GE PIPs will rest solely with EPA. EPA may decide to require EUPs for all, some, or none of the PIPs for test plantings on fewer than 10 acres of land, and may conduct inspections of all, some, or none of the PIPs that are under permit. EPA may also exempt certain PIPs from requirements under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Current inspection costs incurred by APHIS average roughly $800 per inspection.

A quicker APHIS evaluation process will mean a shorter period of regulatory uncertainty that may facilitate developers' ability to raise venture capital. Reduced regulatory requirements may also lead to greater participation by public and private academic institutions in genetic engineering research and product development. These indirect benefits of the rule may spur genetic engineering innovations, particularly in small acreage crops where genetic engineering has not been widely utilized due to the expense of regulation.

In general, new plant varieties, including GE crop varieties, are not required to be reviewed or approved for food safety by the FDA before going to market. However, the developer is responsible for ensuring product safety and developers of GE plant varieties have routinely consulted with FDA prior to marketing new varieties to resolve food safety or other questions about food within FDA's jurisdiction.

APHIS expects that stewardship practices currently used to conduct field trials of GE plant varieties will be maintained under the new rule. It will be in a plant developer's best interest to supervise and control the development process as at present, to prevent undesired cross-pollination or commingling with non-GE crops. Developers have various legal, quality control, and marketing motivations to maintain rigorous voluntary stewardship measures. APHIS therefore believes that developers will continue to utilize strict control measures for field testing even in cases where APHIS does not require a permit.

Farmers who adopt GE crops may benefit from the rule. GE crop adoption varies by crop and technology and can affect yields, net returns, and pesticide use. Fernandez-Cornejo, *et al.* (2014) showed that planting insect-resistant cotton and corn seed is associated with higher net returns when pest pressure is high. The extent to which adoption of herbicide tolerant (HT) traits affects net returns is mixed and depends primarily on how much weed control costs are reduced and seed costs are increased. HT soybean adoption is associated with an increase in total household income because HT soybeans require less management and enable farmers to generate income via off-farm activities or by expanding their operations. Farmers may benefit by having access to a wider variety of traits as well as a greater number of new GE crop species,

[18] Additional recordkeeping and reporting costs could be about $13,000 annually for a field trial that requires 25 reports per year. Because few plants tested in the field are likely to demonstrate commercial viability, we expect they would be tested on a limited number of sites. Additional stewardship costs could range from about $20,000 to $120,000. In the rare case in which a plant demonstrates commercial viability and warrants further data collection under the RSR process, the developer could incur additional testing costs, which under current regulations are estimated to range between about $152,000 and $538,000. Because the data required under the RSR process will be more targeted than under the current process, testing costs would likely be closer to the lower bound.

affording them a broader selection of crops to suit their particular management objectives. Among the types of innovations expected are crops with greater resistance to disease and insect pests; greater tolerance of stress conditions such as drought, high temperature, low temperature, and salt; and more efficient use of fertilizer. These types of traits can lower farmer input costs (water, fertilizer, pesticide) and increase yields during times of adverse growing conditions.

As mentioned, regulatory costs are expected to be lower under this rule, thereby potentially spurring developer innovation, especially among small companies and universities. Consumers will benefit from a wider variety of available products, including ones with improved taste, storage longevity, or nutritional content. In terms of the potential benefits of GE crop plants, an emerging area of interest is the nutritional modification of crop plants through the use of biotechnology to provide human health benefits. Some of these types of modifications are discussed in the EIS in section 4.4.1.4. They include rice varieties developed to provide vitamin A and to address iron and folate deficiency; wheat varieties with reduced levels of celiac-disease-triggering gliadins and with increased levels of lysine and zinc; and cyanide-free cassava. Innovations may also benefit consumers through lower prices for existing products.

In addition to the compliance costs associated with regulation, there are opportunity costs of delayed innovation if the approval process for a plant is longer than necessary to ensure safety with reasonable scientific certainty. Regulatory delays mean that the benefits of innovation occur later than they would otherwise and most likely at lower levels. The forgone benefits due to delayed innovation can be substantial and developers, producers and consumers all lose from regulatory delays. The forgone benefits stemming from even a relatively brief delay in product release can overshadow both research and regulatory costs.

It should be noted that while the rule will alter APHIS' evaluation process for GE plants, it is not expected to affect the evaluation of such plants by FDA or EPA or foreign regulatory agencies, the actions of whom may affect the opportunity costs of regulatory delay. When FDA and/or EPA also have a regulatory role, substantial time savings due to the rule are most likely to be realized in those instances in which the APHIS process takes the longest time. When APHIS is the only agency with oversight (as with many new horticultural varieties such as petunias or carnations modified to produce different flower color, morphology, or longevity), there could be significant time savings over the current petition process.

Some farmers (*e.g.,* growers of identity-preserved crops, including organic, other non-GE and other agricultural commodities segregated for specific purity and quality tolerances) could be indirectly negatively impacted by increased GE innovations. Identity preservation (IP) refers to a process or system of maintaining the segregation and documenting the identity of a product. Crops with unique product quality traits such as low linolenic canola require IP to capture the added value. Similarly, organic commodities must be produced according to specific criteria and segregated in the marketplace in order to receive premium prices. Some consumers choose not to purchase products derived from GE crops and instead purchase commodities such as those labeled ''non-GMO.'' In addition, the USDA organic standard does not allow for the intentional use of GE seeds. In cases where crops intended for the non-GE or other identity-preserved marketplaces contain unintended GE products, their profitability may be diminished. Unintended GE presence and diminished profitability may also occur for identity-preserved GE crops with special attributes. Such crops are more likely to be developed under the new rule.

Effects of this rule on the variety of GE crop species grown in the United States and their wider adoption may increase the possibility of cross-pollination or commingling. As commercial acreage of any given GE crop increases and as a greater variety of crops are modified using genetic engineering, the potential for more instances of unintended presence of a GE organism increases. Costs incurred by growers of organic and other identity-preserved varieties who seek to prevent such unintended presence may increase.

Entities potentially affected by the rule fall under various categories of the North American Industry Classification System. Economic data are not available on business size for some entities. Nonetheless, based on industry data obtained from the Economic Census and the Census of Agriculture, we can assume that the majority of the businesses affected by the rule will be small.

Table A provides a summary statement of the expected direct costs and cost savings of the rule:

TABLE A—EXPECTED COSTS AND COSTS SAVINGS OF THE RULE FOR THE BIOTECHNOLOGY INDUSTRY AND FOR APHIS

[2016 dollars]

| | | |
|---|---|---|
| Biotechnology Industry<br>One-time industry-wide costs of rule familiarization | $1,468,000. | |
| Annual industry-wide recordkeeping costs | $1,070,000. | |
| Annual cost of permits for plants not previously regulated [1] | $13,000 to $671,000. | |
| Developer Savings per Trait [2] | Lower Bound Estimate | Upper Bound Estimate. |
| APHIS sole regulatory oversight | $1,559,000 | $5,588,000. |
| APHIS oversight together with FDA and/or EPA oversight | $551,000 | $937,000. |
| APHIS Biotechnology Regulatory Services<br>Annual costs for public outreach, training, and e-permitting [3] | $77,000. | |

[1] The number of plants in this category is expected to be very small, likely less than 1 per year based on historical activity. The range in cost shown is for one permit. The actual cost will depend on additional recordkeeping, reporting, stewardship, and testing requirements.

[2] These savings are shown on a per trait basis. On average, if five new GE plants are developed annually without APHIS permits (all with no APHIS permit, but four still with EPA and/or FDA evaluation), the annual savings will be $6.5 million. If 10 new GE plants are developed annually without APHIS permits (all with no APHIS permit, but 8 still with EPA and/or FDA evaluation), the annual savings will be $13.1 million.

[3] Requests for regulatory status and response letters under the rule will be handled in a manner similar to the current 'Am I Regulated' process, outside the electronic permitting system and without incurring new costs.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 13175

The USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian Tribes and determined that this rule has Tribal implications; however, OTR has determined that Tribal consultation under Executive Order 13175 is not required at this time.

If a Tribe requests consultation, APHIS will work with the OTR to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), some of the information collection requirements included in this final rule have been approved under Office of Management and Budget (OMB) control number 0579–0085 and some of the information collection requirements were filed under OMB comment-filed number 0579–0471, which has been submitted to OMB for approval. When OMB notifies us of its decision, if approval is denied, we will publish a document in the **Federal Register** providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851–2483.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs has designated this action as a rule that is not a major rule, as defined by 5 U.S.C. 804(2).

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**List of Subjects**

*7 CFR Part 330*

Customs duties and inspection, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

*7 CFR Part 340*

Administrative practice and procedure, Packaging and containers, Plant diseases and pests, Reporting and recordkeeping requirements, Transportation.

*7 CFR Part 372*

Environmental impact statements.

Accordingly, we are amending 7 CFR parts 330, 340, and 372 as follows:

## PART 330—FEDERAL PLANT PEST REGULATIONS; GENERAL; PLANT PESTS, BIOLOGICAL CONTROL ORGANISMS, AND ASSOCIATED ARTICLES; GARBAGE

■ 1. The authority citation for part 330 continues to read as follows:

**Authority:** 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

■ 2. In § 330.200, paragraphs (b) and (d) are revised to read as follows:

### § 330.200 Scope and general restrictions.

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(b) *Plant pests regulated by this subpart.* For the purposes of this subpart, and except for an organism that has undergone genetic engineering as defined in § 340.3 of this chapter, APHIS will consider an organism to be a plant pest if the organism directly or indirectly injures, causes damage to, or causes disease in a plant or plant product, or if the organism is an unknown risk to plants or plant products, but is similar to an organism known to directly or indirectly injure, cause damage to, or cause disease in a plant or plant product. Plant pests that have undergone genetic engineering, as defined in § 340.3 of this chapter, are subject to the regulations of part 340 of this chapter.

* * * * *

(d) *Biological control organisms not regulated by this subpart.* Paragraph (c) of this section notwithstanding, biological control organisms that have undergone genetic engineering, as defined in § 340.3 of this chapter, as well as products that are currently under an EPA experimental use permit, a Federal Insecticide Fungicide and Rodenticide Act (FIFRA) section 18 emergency exemption, or products that are currently registered with EPA as a microbial pesticide product, are not regulated under this subpart. Additionally, biological control organisms that are pesticides that are not registered with EPA, but are being transferred, sold, or distributed in accordance with EPA's regulations in 40 CFR 152.30, are not regulated under this subpart for their interstate movement or importation. However, an importer desiring to import a shipment of biological control organisms subject to FIFRA must submit to the EPA Administrator a Notice of Arrival of Pesticides and Devices as required by CBP regulations at 19 CFR 12.112. The Administrator will provide notification to the importer indicating the disposition to be made of shipment upon its entry into the customs territory of the United States.

■ 3. Part 340 is revised to read as follows:

## PART 340—MOVEMENT OF ORGANISMS MODIFIED OR PRODUCED THROUGH GENETIC ENGINEERING

Sec.



**Authority:** 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

### § 340.1 Applicability of this part.

(a) The regulations in this part apply to those organisms described in § 340.2, but not to any organism that is exempt from this part under paragraph (b), (c), or (d) of this section.

(b) The regulations in this part do not apply to plants that have been modified such that they contain either a single modification of a type listed in paragraphs (b)(1) through (3) of this section, or additional modifications as determined by the Administrator, and described in paragraph (b)(4) of this section.

(1) The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or

(2) The genetic modification is a targeted single base pair substitution; or

(3) The genetic modification introduces a gene known to occur in the plant's gene pool, or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a

known structural variation present in the gene pool.

(4) The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be Agency-initiated, and follow the process in paragraph (b)(4)(i) of this section, or in response to a request made in accordance with paragraph (b)(4)(ii) of this section.

(i) *APHIS-initiated proposals for exemptions.* APHIS will publish a notice in the **Federal Register** of the proposal by the Administrator to exempt plants with additional modifications. The notice will make available any supporting documentation, and will request public comment. After reviewing the comments, APHIS will publish a subsequent notice in the **Federal Register** announcing its final determination.

(ii) *Other parties' requests for exemptions.* Any person may request that the Administrator exempt plants developed with additional modifications that could be achieved through conventional breeding. To submit a request, the person must provide, in writing, information supporting the modification(s). Supporting information must include the following:

(A) A description of the modification(s);

(B) The factual grounds demonstrating that the proposed modification(s) could be achieved through conventional plant breeding;

(C) Copies of scientific literature, unpublished studies, or other data that support the request; and

(D) Any information known to the requestor that would be unfavorable to the request.

(iii) *Timeframe for Agency review of requests for additional exemptions.* After APHIS receives all information required under paragraph (b)(4)(ii) of this section, APHIS will complete its review of the request and render a determination within 12 months, except in circumstances that could not reasonably have been anticipated.

(iv) *Denial of requests.* If APHIS disagrees with the conclusions of the request or determines that there is insufficient evidence that the modification could be achieved through conventional breeding methods, APHIS will deny the request and notify the requestor in writing regarding this denial.

(v) *Agreement with requests.* If APHIS initially determines that the modification could be achieved through conventional breeding methods, APHIS will publish a notice in the **Federal Register** and request public comments in accordance with the process set forth in paragraph (b)(4)(i) of this section. After reviewing the comments, APHIS will publish a subsequent notice in the **Federal Register** announcing its final determination.

(vi) *website posting.* A list specifying the additional modifications will be posted on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.*

(c) The regulations in this part do not apply to a plant with:

(1) A plant-trait-mechanism of action combination that has previously undergone an analysis by APHIS in accordance with § 340.4 and has been determined by APHIS not to be regulated under this part, or

(2) A plant-trait-mechanism of action combination found in a plant that APHIS determined to be deregulated in response to a petition submitted prior to October 1, 2021, pursuant to § 340.6 as that section was set forth prior to August 17, 2020. All plants determined by APHIS to be deregulated pursuant to § 340.6 as that section was set forth prior to August 17, 2020 will retain their nonregulated status under these regulations.

(d) The regulations in this part do not apply to plants determined by APHIS not to require regulation under this part pursuant to the ''Am I Regulated'' process. All plants determined by APHIS not to require regulation under this part pursuant to the ''Am I Regulated'' process will retain their nonregulated status under these regulations.

(e) Developers may request confirmation from APHIS that a plant is not within the scope of this part. APHIS will provide a written response (confirmation letter) within 120 days of receiving a sufficiently detailed confirmation request, except in circumstances that could not reasonably have been anticipated.

(Approved by the Office of Management and Budget under control number 0579–0471)

### § 340.2 Scope of this part.

Except under a permit issued by the Administrator in accordance with § 340.5, no person shall move any GE organism that:

(a) Is a plant that has a plant-trait-mechanism of action combination that has not been evaluated by APHIS in accordance with § 340.4 or that, as a result of such evaluation, is subject to the regulations; or

(b) Meets the definition of a *plant pest* in § 340.3; or

(c) Is not a plant but has received deoxyribonucleic acid (DNA) from a plant pest, as defined in § 340.3, and the DNA from the donor organism either is capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease; or

(d) Is a microorganism used to control plant pests, or an invertebrate predator or parasite (parasitoid) used to control invertebrate plant pests, and could pose a plant pest risk; or

(e) Is a plant that encodes a product intended for pharmaceutical or industrial use.

### § 340.3 Definitions.

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

*Access.* The ability during regular business hours to enter, or pass to and from, a location, inspect, and/or obtain or make use or copies of any records, data, or samples necessary to evaluate compliance with this part and all conditions of a permit issued in accordance with § 340.5.

*Administrator.* The Administrator of the Animal and Plant Health Inspection Service (APHIS) or any other employee of APHIS to whom authority has been or may be delegated to act in the Administrator's stead.

*Agent.* A person who is designated by the responsible person to act in whole or in part on behalf of the permittee to maintain control over an organism under permit during its movement and to ensure compliance with all applicable permit conditions and the requirements in this part. Multiple agents may be associated with a single responsible person or permit. Agents may be, but are not limited to, brokers, farmers, researchers, or site cooperators. An agent must be at least 18 years of age and be a legal resident of the United States.

*Animal and Plant Health Inspection Service (APHIS).* An agency of the United States Department of Agriculture (USDA).

*Article.* Any material or tangible object that could harbor plant pests.

*Contained facility.* A structure for the storage and/or propagation of living organisms designed with physical barriers capable of preventing the escape of the organisms. Examples include but are not limited to laboratories, growth chambers,

fermenters, and containment greenhouses.

*Donor organism.* The organism from which genetic material is obtained for transfer to the recipient organism.

*Environment.* All the land, air, and water; and all living organisms in association with land, air, and water.

*Gene pool.* Germplasm within which sexual recombination is possible as a result of hybridization, including via methods such as embryo culture or bridging crosses.

*Genetic engineering.* Techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome.

*Import (importation).* To move into, or the act of movement into, the territorial limits of the United States.

*Inspector.* Any individual authorized by the Administrator or by the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

*Interstate.* From one State into or through any other State or within the District of Columbia, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

*Mechanism of action (MOA).* The biochemical process(es) through which genetic material determines a trait.

*Move (moving, movement).* To carry, enter, import, mail, ship, or transport; aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment; or to allow any of the above activities to occur.

*Organism.* Any active, infective, or dormant stage of life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

*Permit.* A written authorization, including by electronic methods, by the Administrator to move organisms regulated under this part and associated articles under conditions prescribed by the Administrator.

*Person.* Any individual, partnership, corporation, company, society, association, or other organized group.

*Plant.* Any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, or a seed.

*Plant pest.* Any living stage of a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing, that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.

*Plant pest risk.* The potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest.

*Plant product.* (1) Any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of plant; or

(2) Any manufactured or processed plant or plant part.

*Recipient organism.* The organism whose nucleic acid sequence will be modified through the use of genetic engineering.

*Release into the environment (environmental release).* The use of an organism outside the physical constraints of a contained facility.

*Responsible person.* The individual responsible for maintaining control over a GE organism under permit during its movement and for ensuring compliance with all conditions contained in any applicable permit as well as with other requirements in this part and in the Plant Protection Act (7 U.S.C. 7701 *et seq.*). This individual must sign the permit application, and must be at least 18 years of age, and must be a legal resident of the United States.

*Secure shipment.* Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

*State.* Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territories or possessions of the United States.

*State or Tribal regulatory official.* State or Tribal official with responsibilities for plant health, or any other duly designated State or Tribal official, in the State or on the Tribal lands where the movement is to take place.

*Trait.* An observable (able to be seen or otherwise identified) characteristic of an organism.

*Unauthorized release.* The intentional or accidental movement of an organism under a permit issued pursuant to this part in a manner not authorized by the permit; or the intentional or accidental movement without a permit of an organism that is subject to the regulations in this part.

### § 340.4 Regulatory status review.

(a)(1) Any person may submit a request to APHIS for a regulatory status review, pursuant to paragraph (b)(3) of this section.

(2) Any person may request re-review of a GE plant previously found to be subject to this part after an initial review was conducted, provided that the request is supported by new, scientifically valid evidence bearing on the plant pest risk associated with movement of the plant.

(3) APHIS may also initiate a regulatory status review or re-review of a GE plant to identify whether it is subject to regulation under this part.

(4) Information submitted in support of a request for a regulatory status review or re-review must meet the requirements listed in paragraphs (a)(4)(i) through (iii) of this section.

(i) A description of the comparator plant(s), to include genus, species, and any relevant subspecies information;

(ii) The genotype of the modified plant, including a detailed description of the differences in genotype between the modified and unmodified plant; and

(iii) A detailed description of the new trait(s) of the modified plant.

(iv) Detailed information on how to meet the above-listed requirements can be found on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.* If APHIS proposes revisions to the detailed information on the APHIS website, APHIS will make the proposed revisions available for notice and public comment prior to implementation.

(b)(1) When APHIS receives a request for a regulatory status review of a GE plant, APHIS will conduct an initial review to determine whether there is a plausible pathway by which the GE plant, or any sexually compatible relatives that can acquire the engineered trait from the GE plant, would pose an increased plant pest risk relative to the plant pest risk posed by the respective non-GE or other appropriate comparator(s), based on the following factors:

(i) The biology of the comparator plant(s) and its sexually compatible relatives;

(ii) The trait and mechanism-of-action of the modification(s); and

(iii) The effect of the trait and mechanism-of-action on:

(A) The distribution, density, or development of the plant and its sexually compatible relatives;

(B) The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;

(C) Harm to non-target organisms beneficial to agriculture; and

(D) The weedy impacts of the plant and its sexually compatible relatives.

(2) APHIS will complete the initial review within 180 days of receiving a request for a regulatory status review that meets the requirements specified in paragraph (a)(4) of this section, except in circumstances that could not reasonably have been anticipated. If APHIS does not identify a plausible pathway by which the GE plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, the GE plant is not subject to the regulations in this part. APHIS will post the plant, trait, and general description of the MOA on its website.

(b)(3)(i) If APHIS does identify a plausible pathway by which the GE plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, the requestor may apply for a permit and/or request that APHIS conduct an evaluation of the factor(s) of concern identified in the initial review to determine the likelihood and consequence of the plausible increased plant pest risk. APHIS may request additional information as needed to evaluate the factor(s) of concern.

(ii) For those GE plants for which such an evaluation is conducted, APHIS will publish the results of the evaluation in the **Federal Register** and will solicit and review comments from the public. Except in circumstances that could not reasonably have been anticipated, APHIS will complete these steps within 15 months of receiving a request for a regulatory status review that meets the requirements specified in paragraph (a)(4) of this section.

(iii) If APHIS finds that the GE plant and its sexually compatible relatives are unlikely to pose an increased plant pest risk relative to their comparator(s), the GE plant is not subject to this part. APHIS will publish its evaluation of the plant-trait-MOA combination in a subsequent **Federal Register** document and will also post it on the APHIS website. If APHIS does not make such a finding, the GE plant will remain regulated under this part, and its movement will be allowed only under permit in accordance with § 340.5.

(c) This section is applicable beginning April 5, 2021 for GE corn, soybean, cotton, potato, tomato, and alfalfa, and on October 1, 2021 for all GE plants.

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**§ 340.5 Permits.**

(a) *Permit requirement.* A permit from APHIS is required for the movement of all GE organisms subject to the regulations under this part.

(b) *Permit application requirements.* All applications for permits must be submitted in accordance with the requirements of this section. The responsible person must apply for and obtain a permit through APHIS' website. The application must also include the following information:

(1) *General information requirements for all permit applications.* All permit applications must include the name, title, and contact information of the responsible person and agent (if any); the country (or countries) and locality (or localities) where the organism was collected, developed, manufactured, reared, cultivated, and cultured (as applicable); the organism's genus, species and any relevant subspecies and common name information; the intended activity (*i.e.,* importation, interstate movement, or release into the environment of the GE organism); and information on the intended trait and the genotype of the intended trait. All permit applications must be signed by the responsible person.

(2) *Information requirements for permit applications for interstate movement or importation.* Applications for permits for interstate movement or importation of GE organisms must include the following additional information:

(i) The origin and destination of the GE organism, including information on the addresses and contact details of the sender and recipient, if different from the responsible person;

(ii) The quantity of the GE organism, the method of shipment, and means of ensuring the security of the shipment against unauthorized release of the organism; and

(iii) The manner in which packaging material, shipping containers, and any other material accompanying the organism will be disposed of to prevent unauthorized release.

(3) *Information requirements for permit applications for release into the environment.* Applications for permits for release of GE organisms into the environment must include information on all proposed environmental release sites, including land area (size), Global Positioning System coordinates, addresses, and land use history of the site and adjacent areas; and the name and contact information of a person at each environmental release site, if different from the responsible person. In the event that additional release sites are requested after the issuance of a permit, APHIS will evaluate and amend permits as appropriate, in accordance with paragraph (l) of this section.

(c) *Exemption for GE Arabidopsis thaliana.* A permit for interstate movement is not required for GE *Arabidopsis thaliana,* provided that it is moved as a secure shipment, the modified genetic material is stably integrated into the plant genome, and the modified material does not include the complete infectious genome of a plant pest.

(d) *Exemption for GE disarmed Agrobacterium* species. A permit for importation or interstate movement is not required for any GE disarmed *Agrobacterium* species, provided that it is moved as a secure shipment, the modified genetic material is stably integrated into the genome, and the modified material does not include the complete infectious genome of a plant pest.

(e) *Exemption for Drosophila melanogaster.* A permit for importation or interstate movement is not required for GE *Drosophila melanogaster,* provided that it is moved as a secure shipment and that any introduced genetic material is not designed to propagate through a population by biasing the inheritance rate.

(f) *Exemption for certain microbial pesticides.* A permit is not required for the movement of any GE microorganism product that is currently registered with the Environmental Protection Agency (EPA) as a microbial pesticide, so long as the microorganism is not a plant pest as defined in § 340.3.

(g) *Exemption of certain plant-incorporated protectants.* A permit is not required for the movement of any GE plant modified solely to contain a plant-incorporated protectant that is currently registered with EPA as a pesticide product pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.,* FIFRA) or that is currently exempted from FIFRA pursuant to 40 CFR 174.21.

(h) *Administrative actions*—(1) *Review of permit applications.* APHIS will review the permit application to determine whether it is complete. APHIS will notify the applicant orally or in writing if the application is incomplete, and the applicant will be

provided the opportunity to revise the application. Once an application is complete, APHIS will review it to determine whether to approve or deny the application.

(2) *APHIS assignment of permit conditions.* If a permit application is approved, the Administrator will issue a permit with conditions as described in paragraph (i) of this section. Prior to issuance of a permit, the responsible person must agree in writing, in a manner prescribed by the Administrator, that the responsible person and all agents of the responsible person are aware of, understand, and will comply with the permit conditions. Failure to comply with this provision will be grounds for the denial of a permit.

(3) *Inspections.* All premises associated with the permit are subject to inspection before and after permit issuance, and all materials associated with the movement are subject to sampling after permit issuance. The responsible person and agents must provide inspectors access to premises, facilities, release locations, storage areas, waypoints, materials, equipment, means of conveyance, documents, and records related to the movement of organisms permitted under this part. Failure to provide access for inspection prior to the issuance of a permit will be grounds for the denial of a permit. Failure to provide access for inspection following permit issuance will be grounds for withdrawal of the permit.

(4) *State or Tribal review and comment.* The Administrator will submit for notification and review a copy of the permit application, without confidential business information (CBI), and any permit conditions to the appropriate State or Tribal regulatory official. Timely comments received from the State or Tribal regulatory official will be considered by the Administrator prior to permit issuance.

(5) *Approval or denial of a permit.* Except in circumstances that could not reasonably have been anticipated, APHIS will approve or deny the permit within:

(i) 45 days of receipt of a complete application for a permit for interstate movement or for importation; or

(ii) 120 days of receipt of a complete application for a permit for release into the environment.

(iii) The 120-day period may be extended if preparation of an environmental assessment or environmental impact statement is necessary.

(i) *Permit conditions.* The standard conditions listed in this paragraph (i) will be assigned to all permits issued under this section. The Administrator may assign supplemental permit conditions as deemed necessary to ensure confinement of the GE organism. Prior to issuance of a permit or an amended permit, the responsible person will be required to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the permit, as described in this paragraph (i). If the responsible person does not agree to the conditions, the amendment will be denied.

(1) The organism under permit must be maintained and disposed of in a manner so as to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment.

(2) The organism under permit must be kept separate from other organisms, except as specifically allowed in the permit.

(3) The organism under permit must be maintained only in areas and premises specified in the permit.

(4) The identity of the organism under permit must be maintained and verifiable at all times.

(5) Authorized activities may be engaged in only while the permit is valid; the duration for which the permit is valid will be listed on the permit itself.

(6) Records related to activities carried out under the permit must be maintained by the responsible person and must be of sufficient accuracy, quality, and completeness to demonstrate compliance with all permit conditions and requirements under this part. APHIS must be allowed access to all records, to include visual inspection and reproduction (*e.g.,* photocopying, digital reproduction). The responsible person must submit reports and notices to APHIS, containing the information specified within the permit, at the times specified in the permit. At a minimum:

(i) Following an environmental release, environmental release reports must be submitted for all authorized release locations where the release occurred. Environmental release reports must contain details of sufficient accuracy, quality, and completeness to identify the location, shape, and size of the release and the organism(s) released into the environment. In the event no release occurs at an authorized location, an environmental release report of no environmental release must be submitted for all authorized locations where an environmental release did not occur. Unauthorized releases must be reported in accordance with paragraph (i)(9) of this section.

(ii) When the environmental release is of a plant, reports of volunteer monitoring activities and findings must be submitted for all authorized release locations where an environmental release occurred. If no monitoring activities are conducted, a volunteer monitoring report of no monitoring must be submitted indicating why no volunteer monitoring was done.

(7) Inspectors must be allowed access, during regular business hours, to all locations related to the permitted activities.

(8) The organism under permit must undergo the application of measures determined by the Administrator to be necessary to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment.

(9) In the event of a possible or actual unauthorized release, the responsible person must contact APHIS as described in the permit within 24 hours of discovery and must subsequently supply a statement of facts in writing no later than 5 business days after discovery.

(10) The responsible person for a permit remains the responsible person for the permit unless a transfer of responsibility is approved by APHIS. The responsible person must contact APHIS to initiate any transfer. The new responsible person assumes all responsibilities for ensuring compliance with the existing permit and permit conditions and for meeting the requirements of this part.

(j) *Denial or withdrawal of a permit.* Permit applications may be denied, or permits withdrawn, in accordance with this paragraph.

(1) *Denial of permits.* The Administrator may deny, either orally or in writing, any application for a permit. If the denial is oral, the Administrator will then communicate, as promptly as circumstances allow, the denial, and the reasons for it, in writing. The Administrator may deny a permit application if:

(i) The Administrator concludes that the proposed actions, *e.g.,* movements under permit, may not prevent the unauthorized release, spread, dispersal, and/or persistence in the environment of the organism; or

(ii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply with any material provision of this part, any other regulations issued pursuant to the Plant Protection Act (7 U.S.C. 7701 *et seq.*) or the Plant Protection Act itself;

(iii) In addition, no permit will be issued if the responsible person and his or her agents do not agree in writing, in accordance with paragraph (h)(2) of this section, to comply with the permit conditions or, in accordance with

paragraph (h)(3) of this section, to allow inspection by APHIS.

(2) *Withdrawal of permits.* The Administrator may withdraw, either orally or in writing, any permit that has been issued. If the withdrawal is oral, the Administrator will communicate, as promptly as circumstances allow, the withdrawal, and the reasons for it, in writing. The Administrator may withdraw a permit if:

(i) Following issuance of the permit, the Administrator receives information that would have provided grounds for APHIS to deny the original permit application;

(ii) The Administrator determines that actions taken under the permit have resulted in the unauthorized release, spread, dispersal, and/or persistence in the environment of the organism under permit; or

(iii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any material provision of this part or with any other regulations issued pursuant to the Plant Protection Act (7 U.S.C. 7701 *et seq.*). This includes failure to comply with the conditions of any permit issued.

(k) *Appeal of denial or withdrawal of permit.* Any person whose permit application has been denied or whose permit has been withdrawn may appeal the decision in writing to the Administrator.[1] The applicant must submit in writing an acknowledgment of the denial or withdrawal, and a statement of intent to appeal, within 10 days after receiving written notification of the denial or withdrawal. The applicant may request additional time to prepare the appeal. The appeal must state all of the facts and reasons upon which the person relies to assert that the permit was wrongfully denied or withdrawn. The Administrator will grant or deny the appeal in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict.

(l) *Amendment of permits*—(1) *Amendment at responsible person's request.* If the responsible person determines that circumstances have changed since the permit was initially issued and wishes the permit to be amended accordingly, the responsible person must request the amendment by contacting APHIS directly. The responsible person will have to provide supporting information justifying the amendment. APHIS will review the amendment request, and will amend the permit if APHIS determines that relatively minor changes are necessary. Requests for more substantive changes will require a new permit application. Prior to issuance of an amended permit, the responsible person will be required to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the amended permit. If the responsible person does not agree to the conditions, the amendment will be denied.

(2) *Amendment initiated by APHIS.* APHIS may amend any permit and its conditions at any time, upon determining that the amendment is needed to address plant pest risks presented by the organism or the activities allowed under the permit. APHIS will notify the responsible person of the amendment to the permit and, as soon as circumstances allow, the reason(s) for it. The responsible person may have to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the amended permit before APHIS will issue it. If APHIS requests such an agreement, and the responsible person does not accept it, the existing permit will be withdrawn.

(m) *Shipping under a permit.* (1) All shipments of organisms under permit must be secure shipments. Organisms under permit must be shipped in accordance with the regulations in 49 CFR part 178.

(2) The container must be accompanied by a document that includes the names and contact details for the sender and recipient.

(3) For any organism to be imported into the United States, the outmost container must bear information regarding the nature and quantity of the contents; the country (or countries) and locality (localities) where collected, developed, manufactured, reared, cultivated, and cultured (as applicable); the name and address of the shipper, owner, or person shipping or forwarding the organism; the name, address, and telephone number of the consignee; the identifying shipper's mark and number; and the permit number authorizing the importation. For organisms imported under permits by mail, the container must also be addressed to a plant inspection station listed in the USDA Plants for Planting Manual, which can be accessed at: *https://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/plants_for_planting.pdf.* All imported containers of organisms under permits must be accompanied by an invoice or packing list indicating the contents of the shipment.

(4) Following the completion of the shipment, all packaging material, shipping containers, and any other material accompanying the organism will be devitalized consistent with supplemental permit conditions, or disposed of to prevent unauthorized release.

(n) *Applicability date:* This section is applicable beginning April 5, 2021.

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**§ 340.6 Record retention, compliance, and enforcement.**

(a) *Recordkeeping.* Responsible persons and their agents are required to establish, keep, and make available to APHIS the following records:

(1) Records and reports required under § 340.5(i);

(2) Addresses and any other information (*e.g.,* GPS coordinates, maps) needed to identify all locations where the organism under permit was stored or used, including all contained facilities and environmental release locations;

(3) A copy of the APHIS permit authorizing the permitted activity; and

(4) Legible copies of contracts (including amendments to contracts) between the responsible person and agents that conduct activities subject to this part for the responsible person, and copies of documents relating to agreements made without a written contract.

(b) *Record retention.* Records indicating that an organism under permit that was imported or moved interstate reached its intended destination must be retained for at least 2 years. All other records related to a permit must be retained for 5 years following the expiration of the permit, unless a longer retention period is determined to be needed by the Administrator and is documented in the supplemental permit conditions.

(c) *Compliance and enforcement.* (1) Responsible persons and their agents must comply with all of the requirements of this part. Failure to comply with any of the requirements of this part may result in any or all of the following:

(i) Denial of a permit application or withdrawal of a permit in accordance with § 340.5(j);

(ii) Application of remedial measures in accordance with the Plant Protection Act (7 U.S.C. 7701 *et seq.*); and

[1] The Office of the Administrator, as established in § 371.2 of this chapter, will review appeals involving the denial or withdrawal of a permit. Appeals may be sent to Office of the Administrator, United States Department of Agriculture, Jamie L. Whitten Building, Room 312–E, 1400 Independence Ave. SW, Washington, DC 20250.

(iii) Criminal and/or civil penalties in accordance with the Plant Protection Act (7 U.S.C. 7701 *et seq.*).

(2) Prior to the issuance of a complaint seeking a civil penalty, the Administrator may enter into a stipulation, in accordance with § 380.10 of this chapter.

(d) *Liability for acts of an agent.* For purposes of enforcing this part, the act, omission, or failure of any agent for a responsible person may be deemed also to be the act, omission, or failure of the responsible person.

(Approved by the Office of Management and Budget under control number 0579–0471)

**§ 340.7 Confidential business information.**

Persons including confidential business information (CBI) in any document submitted to APHIS under this part should do so in the following manner. If there are portions of a document deemed to contain confidential business information, those portions must be identified, and each page containing such information must be marked ''CBI Copy.'' A second copy of the document must be submitted with all such CBI deleted, and each page where the CBI was deleted must be marked ''CBI Deleted.'' In addition, any person submitting CBI must justify how each piece of information requested to be treated as CBI is a trade secret or, if not a trade secret, is either commercial or financial information that is privileged or confidential.

**§ 340.8 Costs and charges.**

The services of the inspector related to carrying out this part and provided during regularly assigned hours of duty and at the usual places of duty will be furnished by APHIS without cost to the responsible person.[1] The U.S. Department of Agriculture will not be responsible for any costs or charges incidental to inspections or compliance with the provisions of this part, other than for the services of the inspector.

[1] The Department's provisions relating to overtime charges for an inspector's services are set forth in part 354 of this chapter.

## PART 372—NATIONAL ENVIRONMENTAL POLICY ACT IMPLEMENTING PROCEDURES

■ 4. The authority citation for part 372 continues to read as follows:

**Authority:** 42 U.S.C. 4321 *et seq.;* 40 CFR parts 1500–1508; 7 CFR parts 1b, 2.22, 2.80, and 371.9.

**§ 372.5 [Amended]**

■ 5. Section 372.5 is amended as follows:

■ a. By removing paragraph (b)(7);

■ b. In paragraph (c)(3)(iii), by removing the words '', or acknowledgment of notifications for,'' and adding the word ''for'' in their place; and

■ c. By removing and reserving paragraph (c)(4).

Done in Washington, DC, this 13th day of May 2020.

**Lorren Walker,**

*Acting Under Secretary for Marketing and Regulatory Programs.*

[FR Doc. 2020–10638 Filed 5–15–20; 8:45 am]

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