ITIF | INFORMATION TECHNOLOGY & INNOVATION FOUNDATION

August 6, 2019

Regulatory Analysis and Development
APHIS Station 3A-03.8
U.S. Department of Agriculture
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Re: Comments for proposed rulemaking on "Movement of Certain Genetically Engineered Organisms," Docket APHIS-2018-0034, http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0034.

Thank you for the opportunity to provide comments on the proposed rule that would revise the U.S. Department of Agriculture's regulations regarding the movement of certain genetically engineered organisms in response to advances in genetic engineering and our understanding of the plant pest risk posed by them. The Information Technology and Innovation Foundation (ITIF) is an independent, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized as the world's leading science and technology think tank, ITIF's mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress. ITIF's interest in issues related to genetic engineering stems from its focus on how advances in plant and animal biotechnology increase agricultural productivity and sustainably boost production of food, feed, and fiber.

The subject matter of this docket previously has been the focus of several proposed updates to APHIS' regulations in recent years, including Docket No. APHIS-2015-0057, to which ITIF also has provided comments. Many of those remain relevant to the present proposal, and so we incorporate them into this comment letter by reference.[1] We also attach to this comment letter a copy of the PDF file of the Federal Register notice containing the proposed regulatory changes, within which we have inserted comments and suggestions that go beyond what are included in this letter, and which we also incorporate here by reference.

There is much in this proposal that is logical and worthy, indeed overdue. But it is framed in a way that tends to obscure the valid portions of the proposal while accentuating the bureaucratic aspects which, in fact, work against the overall thrust and objective of the proposed revisions.

[1] L. Val Giddings, "Letter to USDA/APHIS commenting on Docket No. APHIS-2015-0057," June 14, 2017, http://www2.itif.org/2017-usda-aphis.pdf?_ga=2.137899440.1208512437.1564311591-1394096080.1536250378.

APHIS introduces this proposed revision to its regulations by stating “APHIS has now accumulated three decades of experience in evaluating GE organisms for plant pest risk. The Agency’s evaluations to date have provided evidence that genetically engineering a plant with a plant pest as a vector, vector agent, or donor does not in and of itself result in a GE plant that presents a plant pest risk.” This empirical observation needs to be fully incorporated into the regulations proposed in this draft. It is not. Instead, APHIS is proposing to apply a "guilty until proven innocent" standard that is inconsistent with longstanding U.S. policy since 1986 under the Coordinated Framework. This is neither scientifically nor administratively defensible.
It is worth recalling first principles: APHIS’ regulations under 7CFR340 were promulgated in 1987 to implement the Coordinated Framework. APHIS’ mandate under the CF was and remains to “prevent unreasonable risks to US agriculture.” It is not to achieve or approach compliance of zero risk and/or “precautionary” avoidance.

In implementing the regulations APHIS has increasingly strayed from this fundamental *raison d'être* in the direction of increased stringency, even while steadily accumulating evidence that the regulated articles captured for oversight under the regulations are conspicuously safe, and do not, as a class, present anything close to the potential for unreasonable risk sufficient to justify the severity of regulation to which they are subject.

APHIS asserts that “oversight will be exercised only where the risk posed by the introduction is unreasonable’’ and that it will “focus on the properties of the GE organism itself rather than on the method used to produce it.” This is the appropriate standard. But while the proposed new approach is commendably flexible, and would eliminate indefensible regulatory scrutiny of many items APHIS has found to be safe and undeserving of regulatory scrutiny, the mechanism APHIS proposes herein is not, in fact, "risk-based." It does not identify hazards that can lead to unacceptable risks so as to apply regulatory scrutiny to such items and not others. By exempting only items APHIS has already considered and cleared, APHIS’ proposal inescapably discourages novel products, and thus specifically disincentivizes exactly the sort of innovative breakthroughs it claims to want to facilitate. A more effective approach would be for APHIS to identify phenotypes of concern to capture for oversight and exempt all innovations that fall outside such categories.

APHIS proposes to use a regulatory trigger that “would define plant pest risk in this proposed rule as ‘‘[t]he possibility of harm resulting from introducing, disseminating, or exacerbating the impact of a plant pest.’’ But this can too easily be construed to apply to innovations that would not pose unreasonable risks, as the

Coordinated Framework requires. It would be more aligned with longstanding U.S. policy, the scientific recommendations of a dozen US National Academy of Sciences studies from 1986-2016, and APHIS' own vast body of experience to use language along the lines of "a significant probability of imposing an unreasonable risk to agriculture." Once again, the focus here could be usefully sharpened if APHIS were to identify phenotypes of concern on which regulatory attention should be focused, and exempt innovations falling outside such a scope.

APHIS also states that "GE non-plant organisms that do not pose a plant pest risk would not fall under the scope of the regulations," again, apparently without realizing it, applying a process-specific regulatory trigger that APHIS has already conceded cannot be justified on the basis of science, data, or experience.
APHIS states that "certain categories of modified plants would be exempted from the regulations in part 340 because they could be produced through traditional breeding techniques and thus are unlikely to pose a greater plant pest risk than traditionally bred crops…" APHIS also writes that:

> Under § 340.1(b) of the proposed rule, certain categories of modified plants would be exempted from the regulations in part 340 because they could be produced through traditional breeding techniques and thus are unlikely to pose a greater plant pest risk than traditionally bred crops, which APHIS has historically not regulated. These products of biotechnology are likely to pose no greater plant pest risk than their traditionally bred comparators.

Again, this is appropriate, but if APHIS were to apply this criterion consistently they would never again capture for regulatory scrutiny any bioengineered herbicide tolerant crop plant. Even herbicide tolerant crop plants developed with a mechanism of action APHIS has not before examined, which would still be captured under the proposed revisions, arguably present no novel hazards likely to present unreasonable risks to U.S. agriculture. (The hazards associated with the use of herbicide tolerant plants generally derive from the application of the associated herbicides, which is under EPA's jurisdiction, and not from the existence of the plants themselves, which are not intrinsically hazardous.) Such misapplications of regulatory energies could be reduced if APHIS were instead to identify phenotypes of concern to capture for regulatory scrutiny, instead of using "novelty" as the *de facto* regulatory trigger.

APHIS also proposes to allow innovators to "self-determine" whether or not their product is subject to regulatory review: "Allowing for self-determinations would provide developers with regulatory relief and open more efficient and predictable pathways for innovators." But for this commendable proposal to bear the

intended fruit, APHIS still needs to draw a brighter line between those items that will be subject to regulatory review, and those that will not. Once again, this would be far easier if APHIS were to define phenotypes of concern that may present "unreasonable risk."

APHIS requested "comments from the public… on whether the scope of the regulatory status review 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 the Agency should consider in its analyses." APHIS has already shown and conceded that the "GE" status of an organism is no predictor of hazard or risk, and therefore cannot be defended as a basis for regulatory capture. This means APHIS must set it aside. There is no easier nor more efficient way to pick up any slack here than by defining phenotypes of concern that should be captured for regulatory scrutiny. APHIS has the largest database in the world of actual experience on which to base such an approach, and the time to undertake it is now. If that is done, the same principles for identifying non plant organisms that might present unreasonable risks would and arguably should apply.

APHIS notes that "Information pertaining to the results of all completed regulatory status reviews would be publicly accessible on the APHIS website. This information would include a comprehensive list of GE plant-trait-MOA combinations that we have evaluated for plant pest risk via the regulatory status review process under proposed § 340.4. The list would also include GE plants for which we have made determinations of nonregulated status under the petition process." Laudable as this proposal is, it really doesn't help innovators as much as it does copy cats. What APHIS needs to do, per comments submitted in response to previous proposals, is identify phenotypes of concern that should presumptively be subject to regulatory scrutiny based on plausible findings of hazard and likelihood of harm from exposure. Articles falling outside this scope should not be regulated. This would deliver a regulatory regime that might, in fact, actually encourage innovation.

APHIS notes correctly that "Federal oversight of outdoor plantings of PMPI-producing plants could be necessary to prevent the unlawful introduction into the human or animal food supply of pharmaceutical or industrial PMPI products, even when the principal purpose of the plants is not for human or animal food use." So why not lay out categories of the types of PMPI producing plants (i.e., the types of pharmaceutical or industrial compounds they might produce) that would generate undesirable food adulteration should they find their way into the food supply? Then regulate those and leave the rest alone?

With respect to "GE PIP-producing plants that are currently regulated… APHIS understands that this proposal [to stop regulating some] would shift Federal oversight of small scale (10 acres or less) outdoor plantings of some PIPs to EPA. EPA may decide to require experimental use permits for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under permit." Perhaps the most compelling reason for APHIS to exercise oversight in this area would be to pre-empt EPA, which has a history of unscientific, innovation-hostile posture in this space. But whatever APHIS does here, the emphasis must be on identifying categories of PMP phenotypes that may pose unreasonable threats to American agriculture. Given EPA's track record in this space, ceding any authority to EPA would serve to undermine APHIS' stated objectives in undertaking these revisions to 7CFR 340.

APHIS proposes to exempt from regulatory oversight several categories of "GE" 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.

All these are good and legitimate categories for exclusion. But APHIS continues to approach this with a pinched and narrow view that inverts the principles laid down in the Coordinated Framework. The permissible objective under the Coordinated Framework is to prevent or manage unreasonable risks, not prevent any risk. For decades, now, APHIS (and EPA, and FDA) has been applying its regulations as if it was required to achieve zero risk. This has been a major impediment to innovation and discouraged the development of countless new products before they could reach field trial stage, much less commercialization. The sterling safety record and documented enormous environmental and economic benefits derived from crops improved through biotechnology confirm that this approach represents bad public policy that works against improving the safety, sustainability, and productivity of agriculture. Instead, APHIS should, as has been suggested repeatedly, define phenotypes of concern for which preemptive screening should be applied, and otherwise avoid actions that would disincentive innovation while delivering no compensatory benefit.

If APHIS cannot articulate in advance a credible hazard and risk scenario that would likely produce unreasonable risk, then APHIS has no authority under the Coordinated Framework to exercise regulatory

oversight. "Because something might go wrong via a mechanism we cannot now imagine" is not a defensible cause of action under the Coordinated Framework.

APHIS states that it "does not plan to regulate plants that could otherwise have been developed through traditional breeding techniques. But products of biotechnology are likely to pose no greater plant pest risk than their traditionally bred comparators, which APHIS does not regulate. All four categories of plants listed in the exemptions above could otherwise have been produced by traditional breeding methods." This is good, but far too timid. Here APHIS explicitly acknowledges the obvious - that the issue of concern is driven by phenotypic characteristics and not the means through which they are brought about. APHIS needs to apply this insight consistently. This is best done, as APHIS has seen through decades of experience, with positive lists of categories/items of concern, not by broad categories lacking any basis in science or experience. And given what we have learned since 1986 about the nature and ubiquity of horizontal gene flow in nature, APHIS is taking here far too archaic an approach to this issue. The criteria stipulated bear no resemblance to any risk based system of classification. They are at best a poor surrogate for familiarity. Instead of engaging in philosophical gymnastics to try and retain as expansive an oversight portfolio as possible, APHIS should honor the objectives it says it is trying to serve and invest energy in defining categories of hazard and pathways of exposure sufficiently likely to produce unreasonable risks so as to justify regulatory oversight.

APHIS acknowledges, again, that the National Academies of Science have repeatedly, over three decades, found there is "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 classical genetic 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 which are introduced. A recent National Academies of Sciences, Engineering, and Medicine report, issued in 2016, reaffirmed this conclusion." It is time for APHIS to put forward regulations that actually take this finding, corroborated by its own vast experience, seriously, and are framed in a manner that suggests they actually believe and understand this. It requires APHIS to take a different approach.

"APHIS requests comment from the public regarding the categories of plants listed under proposed § 340.1 as not subject to the regulations, including their breadth, whether we need to provide greater specificity in the exemptions, and whether additional categories should also be considered for exemption from the requirements of part 340." The categories APHIS lists as candidates for exemption from regulatory scrutiny are good as far as they go. But in light of the experience APHIS has accumulated over the last 33 years, and as

the National Academies of Science have repeatedly noted, and APHIS has cited above, they do not go nearly far enough. It is no longer possible to claim any shred of scientific legitimacy or credibility for any regulatory review process triggered by "genetic modification" or any of its synonyms or surrogate terms. Yet thinking organized around this point of view continues to be implicit throughout the present proposal, and in so doing stigmatizes and disincentives the use of the most precise, predictable, powerful and safe technologies humans have ever had to improve plants and animals for our use. APHIS needs to re-cast its entire proposal and frame it around the identification of 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. Despite many positive facets, the present proposal does not accomplish this and cannot be rendered defensible under science or longstanding U.S. policy until it does.

"…If as a result of the modification, the plant became a reservoir for pests or diseases in such a way that plant pest issues were exacerbated not just for those who used the new variety, but for others in the surrounding area, APHIS might find it appropriate to take regulatory action." Here APHIS takes the first steps towards defining a truly risk-based approach to regulating the products of new technologies. APHIS should continue on this path and invite comments to help define which categories of innovations, under what circumstances, present an unreasonable level of hazard that would require regulation and management, including pre-marketing reviews. Anything falling outside these categories should not be captured for regulation. The Coordinated Framework makes it clear that regulation should be driven by data and experience, not unfounded fears of hypotheticals that have not materialized despite four decades of diligent searching.

APHIS writes "the mere presence of plant pest sequences has not been shown in APHIS' evaluation of data to cause a GE organism, particularly if it is a plant, to become a plant pest. Indeed, experience has shown that the use of genes from donor organisms which are plant pests, as well as the use of vectors which are from plant pests, has not to date resulted in plant pest risks of any sort in recipient organisms that are not already plant pests." This is an accurate distillation of APHIS' vast experience since first promulgating regulations at 7CFR340 in 1987. It require APHIS to set aside entirely the regulatory triggers it has relied on since then. The present proposal takes tentative, initial steps in that direction, but data, experience, and the bedrock principles of the Coordinated Framework require much more. Experience suggests there is no more direct path to a defensible, risk-based regulatory process than by identifying phenotypes of concern.

APHIS writes that "…advances in our knowledge of biotechnology notwithstanding, under § 340.2(b), we would continue to regulate GE organisms in those cases where the organism which is engineered is itself a

plant pest as defined in the PPA." This is at once both entirely logical, and indefensible. The "GE organisms" APHIS would continue to regulate under this provision are being captured not because they are "GE" – a factor APHIS has already admitted is irrelevant to whether or not the organism poses an unreasonable risk. They are captured because they are on a positive list of identified "plant pests" per the PPA, where they have been placed because of aspects of their phenotype. So here again, APHIS flirts with the solution to the challenge it faces. Seize it.

"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, the Agency believes the petition process is no longer necessary and is proposing to remove the petition process from the regulations." There is great potential here for this regulatory change to be administered so as to effect a giant step backwards. 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/commercialization. The present proposal does not clear this threshold, though with some judicious changes, as suggested, it should be able to.

APHIS proposes that "If [responsible individuals] choose to request a regulatory status review, and the Agency finds that the plant-trait-MOA combination is not likely to pose a plant pest risk and therefore is not subject to the regulations, the developer could proceed with product development and marketing activities free from regulation under part 340." This is a praiseworthy proposal but to reduce angst in the regulated community of innovators, and prevent backsliding/slipping in application/administration of the new rules APHIS should re-cast this as a refinement of the Petition process, and make clear it will be administered in a more streamlined, efficient, hazard mitigating manner than the present Petition process has become.

APHIS requests "…public comment on whether the regulatory status review process or some equivalent process should apply to non-plant GE organisms and, if so, what factors should be analyzed." This is the substantive core of the entire proposal - to recast the entire approach APHIS takes to regulating innovations in this space by identifying phenotypes of concern and defining ways to apply principles of hazard identification, risk analysis, risk management and mitigation to avoid unreasonable risk, per the CF. It should be presented early in the draft and used to frame all that follows, not buried in the middle of 28 pages of soporific bureaucratic prose.

"With regard to the genotype of the GE organism, APHIS would add specific information requirements for gene sequences, regulatory sequences, and genome modifications. The current regulations in § 340.6 require the petitioner to supply a detailed description of the genotype of the GE organism, but do not specify that a description of the gene sequences, regulatory sequences, or genome editing of the organism is required. Operationally, however, APHIS considers this information to be necessary." The attitude manifest in this proposal is problematic. It is inarguably appropriate for APHIS to request information characterizing the genotype of the regulated article, including the kinds of information listed. But this lends itself too easily to becoming a de facto requirement for primary genome sequence data that, themselves, provide no clue to the regulator as to what signifies a hazard and what does not. Regulators, for the vast majority of cases, will lack the ability to infer from such DNA sequence data any actions they could/should take to mitigate the potential for an unreasonable risk. Given this reality, no matter how nice it might be for a regulator to have such data, inasmuch as they confer on the regulator no improvement in his/her ability to ensure they can mitigate potentially unreasonable risks they are objectively useless. Yet the cost of generating such data, though much lower than it was a decade ago, remains non trivial and a potential deterrent to innovation. APHIS must take measures to ensure that asking for useless data does not disincentivize innovation from entities lacking the deep pockets of large multinational corporations.

"To date, APHIS has authorized more than 100,000 field trials—a single permit or notification may authorize multiple trials—and APHIS has not received a report of unintended deleterious effects on plants, non-target organisms, or the environment. 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, the Agency 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."

Why, then, is APHIS not proposing wholesale exemptions from further regulatory scrutiny for wide categories of DNA modified innovations in agriculture? How much more data are needed to liberate APHIS to act on what they have acknowledged the data already show - that "genetic modification" technology is not intrinsically hazardous and its products do not, in general, present unreasonable risks? The CF authorizes APHIS to protect against unreasonable risks, not implausible hypotheticals unsupported by data and falsified by experience. The present proposal is thus, by its own admission, far too timid where it should be bold, and falls far short of what the facts justify in terms of regulatory rationalization and relief.

"In cases where no potential plant pest risks are identified, APHIS will conclude that the plant-trait-MOA combination is not likely to pose a plant pest risk, and, therefore, the agency will have no discretion to regulate. As such, and consistent with our current process for AIR inquiries, there will be no comment period or need for publication in the Federal Register." This is entirely appropriate given the data and experience APHIS has cited, and if done right this would be a de facto designation of categories exempt from regulatory oversight. APHIS should expect and be prepared to address legal challenges from opposition groups.

The section titled "Permits" - Each permit should contain an opening chapeaux describing the unreasonable risk to US agriculture the permit is designed and being issued to prevent. If no such plausible description can be proffered, then APHIS would have, under the CF, no reason for exercising oversight over the activity or requiring a permit for it. APHIS' biotechnologists have drifted over the years into requiring various data simply because that requirement has become canonized by practice and entrenched in the culture, even as evidence has mounted, as APHIS has now documented and conceded, such data and associated constraints on innovation do nothing to prevent unreasonable risks to U.S. agriculture as stipulated under the Coordinated Framework. Until APHIS can develop and apply a superior means of keeping the team focused on APHIS' *raison d'être* this should be done.

"APHIS is proposing to remove current notification provisions from the regulations and require that movement of all GE organisms subject to part 340 be conducted under permit." To move away from performance-based criteria for streamlined approvals and back to a more prescription approach is wrong on every level. APHIS has documented that this entire subject matter area is marked by conspicuously low levels of hazard/risk. Increasing the stringency of regulatory oversight would therefore require a demonstration of failures to the notification process, IOW damage to U.S. agriculture, they have not provided... because it doesn't exist. APHIS' authority to regulate certain articles under the CF is focused on preventing or managing unreasonable risk. This proposal does not do that, but in fact holds significant potential for unjustifiably increasing regulatory burdens. It should be set aside.

"In both the OIG audits and the 2008 Farm Bill, concern was expressed regarding the use of performance-based standards to regulate field tests of regulated articles. It was recommended that APHIS amend the regulations to exercise greater oversight and enforcement of such field tests and to require more extensive reporting and record retention regarding such tests." APHIS' proposal here is too deferential to the "2005 and 2015" OIG audits. These are largely out of date and were not, in the first place, drafted with due recognition of APHIS mandate under the 1986 CF to "prevent unreasonable risk." The OIG audits are, in fact, driven

more by a bureaucratic perception of bookkeeping aesthetics than a scientifically informed and data based approach to hazard identification and risk management. APHIS has documented a substantial basis in data and experience for setting the OIG recommendations aside, which they should offer up with confidence in the event of any challenge.

APHIS is proposing to "continue to exempt *Arabidopsis thaliana* from permitting requirements for interstate movement, provided that it is moved in a secure shipment and the cloned genetic material is stably integrated into the plant genome and does not include the complete infectious genome of a plant pest. This exemption is based on that organism's historically exempt status, which exists because interstate movement of the organism has not resulted in the dissemination of plant pests within the United States." This is a sound proposal, but as APHIS has shown, many other organisms have equally robust records of safety in interstate movement, field trials, and commercial use, and no plausible hypotheses for hazard. APHIS should extend the same exemption to those organisms – indeed, APHIS should turn this provision on its head, and instead of crafting a narrow exemption it should identify organisms and phenotypes of concern which present too high a probability of unreasonable risks, and therefore require regulatory approval for those and those alone, per the Coordinated Framework.

The proposal for exempting "disarmed *Agrobacterium tumefaciens* from permitting requirements" is also sound and should be adopted.

APHIS writes that "the 2005 and 2015 OIG audits suggested that APHIS exercise greater and more coordinated oversight over field tests of GE organisms. APHIS identified regular reporting regarding actual release site coordinates and details of the release as a key means of exercising such oversight. Adding this reporting requirement as a general permitting condition will ensure that it is communicated to all responsible persons. Similarly, to respond to the recommendations of the 2015 OIG audit, APHIS would add a requirement as a general permitting condition that the responsible person must notify the Agency in writing if any activity associated with environmental release under permit will not be conducted. OIG recommended that APHIS implement improvements to track the status of all authorized test field locations in order to account for and sufficiently monitor all such locations and thereby prevent the inadvertent release of GE organisms into the environment. Thus, APHIS is proposing to require the submission of reports so APHIS knows the status and location of authorized field trials."

APHIS proposes here a series of measures to comply with OIG recommendations that would advance comprehensive, if irrelevant record keeping while doing nothing at all to serve APHIS' primary mission of preventing unreasonable risks. Where is there any possible risk mitigation value in APHIS demanding permit holders tell APHIS about something they were approved to do that they did not, in fact, do? Indeed, by compelling APHIS to devote resources and staff time to irrelevant record keeping APHIS' ability to focus on the prevention of unreasonable risks would be impaired. APHIS can easily marshal substantive reasons on the basis of both biology and sound management for setting aside most of these OIG recommendations, and should do so.

"APHIS is proposing to require the submission of a report of no release to account for all approved test fields under an authorization." The Coordinated Framework was not established to mandate or enable agencies comprehensively to track research and development of ag biotech innovations. It was established to empower agencies to prevent unacceptable risks to U.S. agriculture. This provision, aesthetically attractive though it may be, is outside the bounds of the policy laid down in the Coordinated Framework. It represents regulatory overreach that cannot be defended and should be set aside.

APHIS describes conditions under which a permit may be denied, writing "A denial may occur when the Administrator concludes that, based on the application or additional information, the proposed actions, i.e., movements under permit, may result in the unauthorized release, spread, dispersal, and/or persistence of a GE organism in the environment. Such a situation would arise if we determined that the possibility of the unauthorized release would exist regardless of any permit conditions we could assign." APHIS must make it clear that these justifications are valid only when the release would likely result in an unreasonable risk to U.S. agriculture. Otherwise this will be nothing but more bureaucracy inconsistent with the policy laid out in the Coordinated Framework.

APHIS writes that "Finally, if all other application requirements are met, we would still decline to issue the permit if the applicant does not agree in writing to comply with the permit conditions we assign for movement of the organism or does not allow inspection, in accordance with the regulations, of the premises associated with the permit." This seems reasonable, but it presumes a degree of good faith and sound judgement from APHIS that has not always characterized the decisions taken by bureaucracies. This proposal will be more palatable to the regulated community if APHIS were to include assurances that permits will be presumptively issued unless they can present a plausible argument, rooted in data and experience, that to do so would result in an unreasonable threat to U.Ss agriculture. Absent such a provision the exercise of APHIS'

authority here could easily be seen as arbitrary and capricious, outside the scope of actions allowable under the Coordinated Framework, and untethered by any accountability.

APHIS writes that "In the current regulations, the administrative practices that APHIS uses to amend permits are not stated explicitly. Adding them to the regulations would provide increased transparency and efficiency." But enshrining this provision in formal regulations would seem to reduce APHIS flexibility, and constitute little more than an exercise in bureaucratic atherosclerosis. Can APHIS provide examples where the lack of this bureaucratic arterial plaque resulted in undesirable consequences or unreasonable threats to US agriculture? If not, there is neither need nor justification for this proposal and it should be withdrawn.

In re APHIS NEPA PEIS… better to establish also categorical exclusions lest predictable and expected harassment litigation tie APHIS up in knots for years.

APHIS proposes a number of changes to record keeping requirements, and "…recognizes that, in practice, our proposed requirements would require most records associated with activities conducted under permit to be retained for 5 years (or longer), and that this is a significant duration to retain a potentially substantial number of records pertaining to permit activities, especially for a researcher or small company." Perhaps APHIS could ameliorate this burden by offering small entities an option to deposit such records electronically with APHIS for retention.

APHIS notes that "…the foregone benefits due to delayed innovation can be substantial and developers, producers, and consumers all lose from regulatory delays. The foregone benefits stemming from even a relatively brief delay in product release overshadow both research and regulatory costs." This language should appear at the beginning of the proposal, not as an afterthought at the end.

APHIS notes that "Unauthorized releases of regulated GE crop plants and the entry of regulated plant material in the commercial food and feed supply can have impacts on domestic or international markets. While such releases have occurred and may occur again, such incidents are expected to be rare." It should be noted, however, that the markets most likely to be disrupted by the adventitious presence of unapproved "GMO" materials are generally those in countries that are not abiding by their obligations under the SPS. Their quickest and most robust means of avoiding such trade disruptions is to bring their own regulations into compliance with the SPS, and until they have done so they neither merit nor deserve any consideration from U.S. regulators or trade authorities. APHIS should be working closely with USTR to encourage such

countries to bring their own regulations into compliance with their treaty obligations under the SPS in order to reduce the potential for trade disruptions as described.

Thank you for the opportunity to provide comments on this proposal.

Sincerely,

/s/
L. Val Giddings, Ph.D.
Senior Fellow, The Information Technology and Innovation Foundation

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 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: Proposed rule.

SUMMARY: We are proposing to revise our 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 them, thereby reducing regulatory burden for developers of organisms that are unlikely to pose plant pest risks. This proposed rule, which would mark the first comprehensive revision of the regulations since they were established in 1987, would provide a clear, predictable, and efficient regulatory pathway for innovators, facilitating the development of new and novel genetically engineered organisms that are unlikely to pose plant pest risks.

DATES: We will consider all comments that we receive on or before August 5, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0034*.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2018–0034, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0034* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

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.

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. Under APHIS' current regulations, a GE organism is considered to be a regulated article if the donor organism, recipient organism, vector, or vector agent [2] is a plant pest or if the Administrator has reason to believe the GE organism is a plant pest. A *plant pest* is defined in current § 340.1 as ''Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.'' For a GE organism that is a regulated article to be introduced, a permit authorizing the introduction must be issued by APHIS, or the introduction must occur under a notification acknowledged by APHIS, a procedure that is discussed in detail below. If the introduction entails movement of the organism, it must be moved in a container that meets the requirements of current § 340.8, and the container must be marked in accordance with the requirements listed under § 340.7.

A permit may authorize the introduction of regulated articles if developers follow the permit conditions specified by the Administrator to be necessary for each activity to prevent the dissemination and establishment of the GE organism. Such conditions include, but are not limited to, maintenance of the regulated article's identity through labeling, retention of records related to the article's specified use, segregation of the regulated article from other organisms, inspection of a site or facility where regulated articles are to undergo environmental release or will be contained after their interstate movement or importation, and the maintenance and disposal of the regulated article and all packing material, shipping containers, and any other material accompanying the regulated article to prevent the dissemination and establishment of plant pests. If a permit holder does not comply with any of the permit conditions, the permit may be canceled, and if so, further movement or environmental release of GE organisms under that permit will be prohibited.

For authorizations under the notification process, the regulations contain performance-based standards applicable to shipping, environmental release, and field trials of GE organisms. These standards are aimed at preventing

[1] To view the framework, go to *https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.*

[2] These terms are defined in the current § 340.1 of the regulations.

the unwanted dissemination of such organisms during transit or as a result of an environmental release and the persistence of the organisms in the environment. APHIS conducts inspections of authorized facilities or environmental release sites to evaluate compliance with the regulations.

In addition to issuing permits and acknowledging notifications, APHIS responds to petitions requesting nonregulated status under these regulations. Under the petition procedure, which is currently described in § 340.6, any person may submit a petition to APHIS seeking a determination as to whether or not an article is regulated under part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the detailed information and scientific data supporting the petition. As of December 2018, of 162 petitions submitted for APHIS review since July 1992, APHIS has granted 130 determinations of nonregulated status. Thirty-two petitions have been withdrawn. All of these determinations have been for GE plants. More information about these determinations is posted at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status*. Many of these plants are grown for agricultural production in the United States. APHIS' determinations of nonregulated status apply to the GE plants as well as their progeny, meaning the nonregulated GE plant can be used in plant breeding programs and in agriculture without further oversight from APHIS.

Although, as discussed above, the current regulations have various functions, their primary function to date has been as a means for APHIS to regulate the introduction of certain GE organisms via the permit and notification procedures referred to above. Permits and notifications are collectively known as ''authorizations.'' As of July 2018, APHIS has issued more than 19,500 authorizations for the environmental release of GE organisms in multiple sites, primarily for research and development of crop varieties for agriculture. Additionally, APHIS has issued nearly 14,000 authorizations for the importation of GE organisms, and more than 12,000 authorizations for the interstate movement of GE organisms. APHIS has denied slightly more than 1,600 requests for authorizations, many of which were denied because APHIS ultimately decided the requests lacked sufficient information on which to base an Agency decision. Some of these were resubmitted with the additional necessary information.

While the current regulations have been effective in ensuring the safe introduction of GE organisms during the past 30 years, advances in genetic engineering have occurred since they were promulgated. APHIS has now accumulated three decades of experience in evaluating GE organisms for plant pest risk. The Agency's evaluations to date have provided evidence that genetically engineering a plant with a plant pest as a vector, vector agent, or donor does not in and of itself result in a GE plant that presents a plant pest risk. Additionally, GE techniques have been developed that do not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents yet may result in GE organisms that 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.

OIG Audits and 2008 Farm Bill

Audits conducted by USDA's Office of Inspector General (OIG) have provided another impetus for updating our regulations. In 2005, OIG conducted an audit of APHIS' regulatory program for GE organisms. OIG found that the use of performance-based standards in APHIS' notification process allowed for a broad spectrum of methods to meet the standards, particularly regarding how the release would be confined to its test field, but Agency practices did not require responsible persons to provide written protocols detailing the exact methods that would be used to meet the standards. OIG suggested that APHIS revise the regulations to ''minimize the risk of inadvertent release'' of regulated articles ''into the environment.'' Among other things, OIG recommended that we include in the regulations a provision that would ''require developers to provide written protocols prior to approval of the field trial.'' Other recommendations regarding reporting have been met by the issuance of policies, procedures, and guidelines, but OIG indicated that these recommendations should ultimately be made permanent in regulation.

In 2015, OIG issued another audit, urging APHIS to implement the recommendations from the 2005 audit that APHIS had not yet implemented, including that APHIS ''revise its regulations to consolidate all requirements for conducting field tests of regulated materials.''

In addition, in 2008, The Food, Conservation, and Energy Act of 2008 (Farm Bill) was enacted. Section 10204 of the Farm Bill requires the Secretary of Agriculture to take action on each issue identified in the APHIS document entitled ''Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework,'' [3] and, where appropriate, promulgate regulations. Like the 2005 and 2015 OIG audits, the lessons learned document suggested revising the regulations to provide for greater regulatory oversight of field tests of regulated articles.

On October 9, 2008, APHIS published a proposal [4] in the **Federal Register** (73 FR 60007–60048, Docket No. APHIS–2008–0023) to amend the regulations to address advances in genetic engineering, to make explicit our criteria for evaluation of GE organisms for noxious weed potential, and to respond to the remaining recommendations of the 2005 OIG audit and the provisions of the Farm Bill.

APHIS sought public comment on the proposal from October 9, 2008, to June 29, 2009. APHIS received more than 88,300 comments during the comment period. Many commenters expressed concerns regarding the lack of details surrounding a proposed risk-based system that would determine which organisms would fall under APHIS oversight, as well as concerns about a proposed multi-tiered permit system. Commenters also expressed concern about what they perceived to be a significant expansion of Agency regulatory authority.

Based on the breadth and nature of the comments received, we subsequently withdrew that proposed rule and began a fresh stakeholder engagement process aimed at exploring a variety of regulatory approaches.

On January 19, 2017, we published in the **Federal Register** (82 FR 7008–7039, Docket No. APHIS–2015–0057) a second proposed rule.[5] In that document, we proposed 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

[3] *https://www.aphis.usda.gov/biotechnology/downloads/supportingdocs/LessonsLearned10-2007.pdf.*

[4] To view the 2008 proposed rule, the subsequent withdrawal, all supporting documents, and comments APHIS received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0023.*

[5] 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.*

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. Over time, APHIS would build up a library of such assessments and their results and post the information on its website. For a GE organism with the same organism-trait combination (traits are discussed in detail below) as another GE organism that we had already concluded did not require regulation, neither the request nor the risk assessment would be necessary. Additionally, APHIS proposed to exclude from regulation some GE organisms that could have been produced using traditional breeding methods. These provisions were intended to provide regulatory relief to developers.

APHIS sought public comment on the proposal from January 19, 2017, until June 19, 2017. APHIS received 203 comments during the comment period.

Commenters expressed concerns about many provisions of the proposed rule. Many thought that the proposed requirements would be too burdensome and had the potential to stifle innovation.

After reviewing the comments, APHIS published a document in the **Federal Register** on November 7, 2017 (82 FR 51582–51583, Docket No. APHIS–2015–0057), withdrawing the proposal to allow APHIS to reengage with stakeholders and deliberate further on how best to revise the regulations in part 340.

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. 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.

Overview of the New APHIS Regulatory Framework

Based on the feedback we received from stakeholders and on our internal Agency deliberations, we are proposing to revise the regulations in accordance with a new regulatory framework. The new framework will provide a clear, predictable, and efficient regulatory pathway for innovators while facilitating the development of new and novel GE plants that are unlikely to pose a plant pest risk. It will protect the health and value of America's agriculture and natural resources and help foster safe and predictable agricultural trade worldwide. We anticipate that adopting the new framework will result in significant savings for developers of GE organisms.

The revised regulatory framework would reflect the Secretary of Agriculture's March 28, 2018, statement that provided clarification on the USDA's oversight of plants produced through plant breeding innovations. 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.*

The proposed framework is also consistent with the OIG recommendations, the 2008 Farm Bill requirements, as outlined above, and with the guiding principle of the Coordinated Framework that, ''[i]n order to ensure that limited Federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable.''

APHIS' new regulatory approach is intended to prepare the Agency for future advances in the genetic modification of plants. (APHIS' approach to the regulation of non-plant GE organisms is discussed below.) For convenience, in this document we sometimes refer to plant varieties produced with innovative techniques that could otherwise have been achieved using methods of traditional plant breeding as plant breeding innovations. Where genetic modifications are similar in kind to those modifications made through traditional breeding, the plant pest risks should also be similar. These types of plants are equivalent to those that have a history of safe use and would be exempted from our proposed regulation. On the other hand, genetic modifications made in the future may result in increasingly complex products which, in turn, may pose new types of risks with which the Agency has less familiarity. This latter category of engineered plants would be subject to review under our new regulations. Once products are reviewed by the Agency and found unlikely to pose a plant pest risk, similar products would be exempt from further review.

Our approach for GE organisms is consistent with the 2017 National Academy of Sciences Future Products of Biotechnology report, which stated that regulation should take into account familiarity. The report, which is available at *https://www.nap.edu/catalog/24605/preparing-for-future-products-of-biotechnology,* noted that unfamiliar products, and those that may be developed in the future, may have few or no comparators with existing products within the regulatory system. Such products, therefore, would require more regulatory oversight than familiar products until enough is known about the new products to enable us to assess accurately the plant pest risks associated with them. By focusing regulatory resources and risk analyses on unfamiliar products, APHIS will be able to avoid conducting repetitive analyses, utilize its staff time more efficiently, and provide better stewardship of taxpayer dollars.

Key Features of the Proposed Rule

The approach we are proposing would differ from the current regulatory framework in that regulatory efforts would focus on the properties of the GE organism itself rather than on the method used to produce it. We believe that this new approach, which reflects our current knowledge of the field of biotechnology, would enable us to evaluate GE organisms for plant pest risk with greater precision than the current approach allows. GE organisms that pose a plant pest risk would fall within the scope of the proposed regulations and require permits for movement. As discussed in more detail later in this document, we would define plant pest risk in this proposed rule as ''[t]he possibility of harm resulting from introducing, disseminating, or exacerbating the impact of a plant pest.''

APHIS will continue to regulate GE organisms that are, in and of themselves, plant pests, as well as other GE non-plant organisms that pose plant pest risks. Such organisms would require permits for movement. Other 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.

Under the current system, when making decisions regarding regulatory oversight of GE plants, APHIS assesses each transformation event (also sometimes referred to as the individual transformed line, transgenic line, or GE line) separately, even though the inserted genetic material may be identical or very similar to transformation events already assessed. This has sometimes been referred to as an ''event-by-event'' approach.

Under the proposed rule, developers would have the option of requesting a permit or a regulatory status review of a GE plant that has not been previously reviewed and determined to be nonregulated. Decisions on regulatory status would be based on our assessment of plant pest risk. If movement of a GE plant, by which we mean its importation, interstate movement, or environmental release (throughout the discussion that follows, the terms *move* and *movement* are used to refer to all of those activities, except where otherwise indicated) is found to be unlikely to pose a plant pest risk, APHIS would not have authority under the PPA to regulate the plant in accordance with part 340. If we were unable to reach such a finding, APHIS would regulate the subject plant, which would be allowed to move only under permit.

Under § 340.1(b) of the proposed rule, certain categories of modified plants would be exempted from the regulations in part 340 because they could be produced through traditional breeding techniques and thus are unlikely to pose a greater plant pest risk than traditionally bred crops, which APHIS has historically not regulated. These products of biotechnology are likely to pose no greater plant pest risk than their traditionally bred comparators. These exemptions are restricted to plants because the long history of plant breeding gives us extensive experience in safely managing associated plant pest risks. The categories of plants that would be exempted under § 340.1(b) are discussed further below.

Proposed § 340.1(c) would exempt GE plants with plant-trait-mechanism of action (MOA) combinations that we have already evaluated by conducting a regulatory status review and found to be unlikely to pose a plant pest risk. As discussed in further detail later in this document, MOA refers to the biochemical basis for the new trait. The results of all completed regulatory status reviews would be publicly accessible on the APHIS website. The regulatory status review process is discussed in detail below.

Under our proposed new regulatory framework, a developer would have the option to make a self-determination as to whether his or her GE plant belongs to one of the categories listed under § 340.1(b) or (c) and is therefore exempt from the regulations. A developer who determines that his or her GE plant belongs to an exempted category would have the option under proposed § 340.1(d), to request written confirmation from APHIS that the self-determination is valid. These confirmation letters, which would provide a clear and succinct statement about the regulatory applicability of the GE plant and the nexus to plant health, may be useful to developers wishing to market their products domestically or overseas by allowing them to provide verification to an importing country or other party that APHIS concurs with their self-determinations. APHIS anticipates a timely turnaround time in developing and providing these confirmation letters to developers. Allowing for self-determinations would provide developers with regulatory relief and open more efficient and predictable pathways for innovators to get new modified plants that are unlikely to pose a plant pest risk to market, in turn supporting further innovation. APHIS anticipates that benefits will accrue to developers of all sizes, including small and mid-sized ones, as well as academic institutions. At the same time, APHIS would be able to allocate its resources more efficiently than under the current regulations. Because we would no longer have to perform the redundant task of assessing GE plants with plant-trait-MOA combinations that we have already determined are not subject to these regulations, we would be able to devote more attention to assessing and regulating those GE organisms that are likely to be associated with potential plant pest risks.

We would note here that a developer making a self-determination that APHIS determines not to be valid may be subject to remedial measures or penalties in accordance with the compliance and enforcement provisions, which are discussed below, in proposed § 340.6(c) if the organism is moved without proper authorization under part 340. In addition, penalties and remedial measures (including but not limited to, quarantine, seizure and/or destruction) under the authority of the PPA may be exercised.

Under § 340.4 of the proposed rule, the process by which we would evaluate GE plants for plant pest risk would be called a regulatory status review. When evaluating the plant pest risk posed by a newly developed GE plant, APHIS would consider three fundamental elements in combination and individually: (1) The basic biology of the plant prior to modification; (2) the trait that resulted from the genetic modification; and (3) the MOA. Since any one or any combination of these three elements may affect plant pest risk, APHIS would determine the need for regulatory oversight by appraising the risk posed by the plant's unique combination of the three elements.

This proposed rule would define *trait* as an observable (able to be seen or otherwise identified) characteristic of an organism. We would define *mechanism of action* as the ''biochemical process(es) through which genetic material determines a trait.'' For example, a plant may be modified to confer the trait of male sterility by either of two MOAs in pollen: Expression of a protein that is toxic to the pollen grain (barnase system) or expression of a protein which changes deoxyribonucleic acids (DNA) in pollen-producing tissues (DNA adenine methylase system) in a disruptive way that ultimately results in death of those tissues.

For reasons described in greater detail below, the regulatory status review process would apply only to plants and not to genetically engineered plant pests or other genetically engineered non-plant organisms that fall within the scope of the regulations. We are requesting comments from the public, however, on whether the scope of the regulatory status review 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 the Agency should consider in its analyses.

Information pertaining to the results of all completed regulatory status reviews would be publicly accessible on the APHIS website. This information would include a comprehensive list of GE plant-trait-MOA combinations that we have evaluated for plant pest risk via the regulatory status review process under proposed § 340.4. The list would also include GE plants for which we have made determinations of nonregulated status under the petition process. Developers could use the list to aid them in making their self-determinations. For example, if a developer were to find that his or her newly developed GE plant had the same plant-trait-MOA combination as a GE plant previously found by APHIS to be not subject to the Agency's regulations, the developer would know immediately

that the newly developed plant would not be subject to APHIS regulation. We anticipate that should this rule be implemented, this list would grow as new regulatory status reviews are completed.

For GE plants that do not fall into one of the exempted categories and have not previously been assessed through the regulatory status review process, developers would have the option of either requesting an immediate regulatory status review or requesting a permit for the movement of their GE plant in lieu of a regulatory status review. (A developer who initially requests a permit would also have the option of following up with a request for a regulatory status review.) Providing these options would allow for maximum flexibility in the research and development of novel GE plants for all types of developers (multi-national companies, small companies, and public sector researchers). Developers of GE organisms that are plant pests would continue to need permits to move those organisms.

Regulation of Plants That Produce Plant-Made Industrials and Pharmaceuticals

APHIS recognizes that certain plants are genetically engineered in order to produce pharmaceutical and industrial compounds, also known as plant-made pharmaceuticals and industrials (PMPIs). Federal oversight of outdoor plantings of PMPI-producing plants could be necessary to prevent the unlawful introduction into the human or animal food supply of pharmaceutical or industrial PMPI products, even when the principal purpose of the plants is not for human or animal food use. In addition to potential adulteration issues (such as the potential of an unapproved food additive and other food safety risks) posed by such plants should they enter the food supply, a gap in Federal oversight could generate concerns from the general public regarding the safety and wholesomeness of the human or animal food supply, which could adversely impact agricultural interests. Establishing growing and handling conditions to confine such plants, and inspecting to ensure such conditions are followed, may enable corrective actions before material from the plants is inadvertently released and causes public health or economic impacts.

Under the current regulations, APHIS requires permits for the environmental release of all GE plants that meet the definition of a regulated article and produce PMPIs. APHIS exercises oversight of all outdoor plantings of these regulated PMPI-producing plants. This oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring. PMPI-producing plants and the products obtained from them may also be regulated by FDA (authority over food and drugs) or EPA (chemical substances as defined by the Toxic Substances Control Act (TSCA)), depending on their use or intended use. If a PMPI-producing plant or plant product were potentially to be used for human or animal food, food additive approval might be required under the Federal Food, Drug, and Cosmetic Act.

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. However, under the provisions of this proposed rule, a GE plant that is developed using a plant pest as a vector, vector agent, or donor of genetic materials would not necessarily be regulated. Rather, the GE plant would be regulated only if it had a plant-trait-MOA combination that the Agency has not yet evaluated for plant pest risk or if it was evaluated and found to pose a potential plant pest risk. Additionally, APHIS' evaluations of GE plants for plant pest risk would generally not require data from outdoor plantings. Even if the plant represents a new plant-trait-MOA combination not previously reviewed, there is a likelihood that most, if not all, GE PMPI-producing plants that are currently under APHIS permits could be determined to be not regulated under the provisions of the proposed regulations after a regulatory status review because they are unlikely to pose a plant pest risk. Thus, such plants could be grown outdoors without the need for APHIS permits and without APHIS oversight.

One of the reasons APHIS' oversight of such crops has been an important part of the coordinated framework for oversight of GE plants is that companies are not necessarily required to notify FDA or EPA when the developer plants PMPI-producing plants. For example, for PMPI-producing plants whose products are subject to FDA oversight, FDA has no regulations governing planting of such crops. For crops genetically engineered to produce human drugs, companies only have to go to FDA when they have reached the point that they are ready to begin clinical trials with the pharmaceutical derived from the plant. This could be years after they first started growing the pharmaceutical-producing plant in the field.

Under TSCA, EPA has requirements for new chemical substances, including industrial compounds produced in genetically engineered plants. However, given existing APHIS oversight, EPA does not currently have an oversight program nor regulations for genetically engineered plants that produce industrial compounds.

APHIS has identified two options that have the potential for adequate Federal oversight of outdoor plantings of plants engineered to produce PMPIs. Under one option, APHIS would use other authorities (*e.g.,* 7 CFR part 360) to regulate outdoor planting of plants engineered to produce PMPIs. Under a second option, a statute would be enacted, or existing statutory authority amended, to grant one or more Federal agencies explicit authority to provide oversight of outdoor plantings of all GE PMPI-producing plants and to evaluate GE PMPI-producing plants for all possible risks, beyond plant pest and noxious weed risks. APHIS does not prefer one of these options over the other, nor does the Agency consider the two options necessarily to be exhaustive. Rather, we put them forward to indicate that the Agency is aware of the implications of this rule with regard to PMPIs, and to request specific public comment regarding the best manner to address this issue.

Plant-Incorporated Protectant Small-Scale Field Testing

Certain plants are genetically engineered to produce plant-incorporated protectants (PIPs), meaning that they produce pesticides. PIPs fall under the regulatory oversight of EPA. However, currently only APHIS exercises regulatory oversight of PIP plantings on 10 acres or less of land. Under the current regulations, APHIS requires permits or notifications for the environmental release of all GE plants that meet the definition of a regulated article and produce PIPs. APHIS exercises oversight of all outdoor plantings of these regulated PIP-producing plants. This oversight includes the establishment of appropriate environmental release conditions, inspections, and monitoring.

To date, PIP-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. However, under the provisions of this proposed rule, a GE plant that is developed using a plant pest as a vector, vector agent, or donor

of genetic materials would not necessarily be regulated. Rather, the GE plant would be regulated only if it had a plant-trait-MOA combination that the Agency has not yet evaluated for plant pest risk or if it was evaluated and found to pose a potential plant pest risk. Additionally, APHIS' evaluations of GE plants for plant pest risk would generally not require data from outdoor plantings. Even if the plant represents a new plant-trait-MOA combination not previously reviewed, there is a likelihood that many GE PIP-producing plants that are currently regulated under APHIS permits or notifications could be determined not regulated under the provisions of the proposed regulations after a regulatory status review because they are unlikely to pose plant pest risks. Thus, such plants could be grown outdoors without the need for an APHIS permit and without undergoing APHIS oversight.

APHIS understands that this proposal would shift Federal oversight of small-scale (10 acres or less) outdoor plantings of some PIPs to EPA. EPA may decide to require experimental use permits for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under permit. APHIS is fully committed to coordinating with EPA on these issues.

APHIS understands that an MOU and services agreement may be necessary to provide personnel and other resources to assist EPA during the interim period while EPA implements its own program for the oversight of outdoor planting of PIPs 10 acres or less.

APHIS recognizes that there are challenges associated with such a transition that would also require EPA to incur the costs associated with setting up a revised regulatory program. Further, such a transition would require policies, procedures, and guidance regarding APHIS' interaction with EPA. APHIS does not consider the approach listed above necessarily to be exhaustive. Rather, APHIS puts it forward to indicate that the Agency is aware of the implications of this rule with regard to small-scale testing of PIPs and to request specific public comment regarding the best manner to address this issue.

Specific provisions of the proposed rule are discussed in detail below.

Applicability of the Regulations

Proposed § 340.1(a) would refer the reader to § 340.2 for information on what GE organisms would be subject to the proposed regulations.

Under proposed § 340.1(b)(1) through (4), modified GE plants would not be regulated or subject to a regulatory status review in accordance with § 340.4, 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.

As noted above, non-plant GE organisms that are plant pests or pose a plant pest risk would require permits for movement under the proposed regulations; these proposed exemptions would apply only to GE plants.

The exemptions reflect the Secretary of Agriculture's March 28, 2018, statement that USDA does not plan to regulate plants that could otherwise have been developed through traditional breeding techniques. Such products of biotechnology are likely to pose no greater plant pest risk than their traditionally bred comparators, which APHIS does not regulate. All four categories of plants listed in the exemptions above could otherwise have been produced by traditional breeding methods. Traditional breeding techniques generally involve deliberate selection of those plants with desirable traits either from existing population genetic variations or from new genetic variations created through artificial hybridization or induced mutations, and have been used since the advent of sedentary agriculture. Every domesticated crop has been subjected to extensive traditional breeding. Genetic engineering relies on a newer toolset that may be used in addition to traditional breeding practices, including chemical or radiation-based mutagenesis, in order to expedite development of a plant with a desired genotype and/or traits.

In two reports, issued in 1987 and 1989, respectively, by the National Research Council of the National Academies of Science,[6] [7] 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 classical genetic 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 which are introduced. A recent National Academies of Sciences, Engineering, and Medicine report, issued in 2016, reaffirmed this conclusion.[8]

The 1989 report elaborated on the safety of traditionally bred crops, stating that ''plants modified by classical genetic methods are judged safe for field testing on the basis of experience with hundreds of millions of genotypes field tested over decades.'' This does not mean there are no conceivable risks, but rather that those risks are, in the words of the committee, ''manageable by accepted standards.'' Thus, given the accepted safety of traditionally bred crops, and the principle that the use of recombinant DNA does not itself introduce unique risks, it is logical and appropriate to exempt from our regulation plants produced by any method if they also could have been produced by traditional breeding.

APHIS recognizes that there is no universally applicable, sharp delineation between what is and what is not possible to achieve with traditional breeding methods in an agriculturally relevant timeframe. There are many biological and practical factors that affect the likelihood of success in a breeding program. 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. There is such variation in these factors among plant species that the probability of a plant breeding program being able to achieve specific, desired changes in a given species will differ on a case-by-case basis. Developing a standard for all species based on what is possible to achieve with traditional breeding methods in any given species is not a practical measure. Furthermore, plants that qualify for an exemption would not be reviewed by APHIS. For these reasons, the exemptions are based on measures that are easily recognizable and on genetic changes that could be achieved by traditional plant breeding

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

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

[8] National Academies of Sciences, Engineering, and Medicine. 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC: The National Academies Press. doi: 10.17226/23395.

in any system. A single deletion or a single base pair change is a conservative estimate of what could be achieved in any system through traditional breeding. Changes beyond those in the exemptions would be assessed on a case-by-case basis for plant pest risk. We acknowledge there will be examples of plants created that do not qualify for the exemptions that pose little plant pest risk. We believe these examples will be promptly handled through the process of regulatory status review. In this way we believe we can offer both regulatory relief and appropriate regulation as needed.

In general, the natural gene pool of a plant is determined by those plants with which the plant is sexually compatible. This is most typically considered to be restricted to crosses that can take place without human management. However, a number of traditional breeding techniques have been developed to enable wide crosses between distantly related species or plants that would not encounter each other in nature. Where such techniques have been developed for a given plant, distantly related plants are also considered part of the natural gene pool.

In some cases, a GE parent plant will contain inserted donor nucleic acid, but after some number of breeding steps, there are progeny that are produced which contain neither the inserted donor nucleic acid nor any modifications made directly by the inserted nucleic acid. APHIS does not consider the progeny to be associated with a greater plant pest risk. Therefore, such progeny would not be subject to regulation under the fourth exemption.

APHIS requests comment from the public regarding the categories of plants listed under proposed § 340.1 as not subject to the regulations, including their breadth, whether we need to provide greater specificity in the exemptions, and whether additional categories should also be considered for exemption from the requirements of part 340.

In addition to the categories listed in proposed paragraph (b), under proposed § 340.1(c), GE plants that would not be subject to these proposed regulations if they have plant-trait-MOA combinations that are the same as those of GE plants that APHIS has found, after conducting a regulatory status review in accordance with proposed § 340.4, not to be subject to the regulations under part 340. We would list such GE plant-trait-MOA combinations on our website, as noted above, and developers could use this information to aid them in making their self-determinations.

As noted earlier, we would also list GE plants for which we have made determinations of nonregulated status under the petition process,[9] which is described in further detail below. Though the proposed regulatory status review would represent a change in our regulatory approach, GE plants for which determinations of nonregulated status have been made under the current system have been evaluated for the same plant pest risk factors which will be used under the proposed rule. Specifically, both reviews analyze the biology of the GE plant and its non-GE comparator, potential changes in plant pest impacts, impacts on nontarget organisms, and the propensity for increased weediness of the GE plant and any sexually compatible relatives. The initial list of plant-trait-MOA combinations that are not subject to the regulations is available on *Regulations.gov* as a separate document to this proposed rule. The list will include identification of the MOA of nonregulated plants reviewed under the petition process, which can be used for comparisons of future GE plants to determine regulatory status.

Plants produced using biotechnology which were reviewed in response to an ''Am I Regulated?'' (AIR) [10] inquiry were not reviewed using all the plant pest risk factors listed above, but rather were reviewed for regulatory status based on whether the modified plant conformed to the definition of a ''regulated article'' in the current regulations and in a some instances on one or more of the factors, but not all. We know of no plant pest issues raised during the review of the AIR inquiry, and none have arisen from use of any of these plants. GE plants determined not to require regulation pursuant to the current AIR process would retain their nonregulated status under the new regulations to prevent potential market disruptions and provide regulatory certainty for developers. These plants would be listed separately from those evaluated at the MOA level, and this list would not be used for determining regulatory status based on MOA.

We would note again that plants that are not subject to these regulations could still be subject to other APHIS or USDA regulations or to the regulations of the other Federal Agencies functioning within the Coordinated Framework.

Scope of the Regulations

Proposed § 340.2 would set forth general restrictions regarding the movement of GE organisms that would be subject to these regulations. The following categories of GE organisms would be allowed to move only under permit:

- The GE organism is a plant that has a plant-trait-MOA combination that has not been subjected to a regulatory status review in accordance with § 340.4; or
- The GE organism meets the definition of *plant pest* in § 340.3; or
- The GE organism is not a plant but has received 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
- The GE organism 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.

GE plants that have not yet been evaluated for plant pest risk by means of a regulatory status review would be subject to permitting under § 340.2(a). While APHIS has found that most plants evaluated to date do not pose plant pest risks, it is conceivable that some of those produced in the future may. For example, certain modifications may change the relationship of the plant to plant pests. In most cases, this would not be of concern, as APHIS understands that resistance to disease and insects varies widely among varieties. Still, if as a result of the modification, the plant became a reservoir for pests or diseases in such a way that plant pest issues were exacerbated not just for those who used the new variety, but for others in the surrounding area, APHIS might find it appropriate to take regulatory action. For instance, plants and their wild relatives could have increased importance as reservoirs for plant pests if the introduced trait resulted in an increase in their prevalence and/or caused a change in their distribution. For these reasons, APHIS believes it is appropriate to examine novel plant-trait-MOA combinations for plant pest risk. Regulatory oversight is needed for such plants until the level of plant pest risk associated with their movement is known.

As noted earlier, under the current criteria, a GE organism is considered a

[9] Information about determinations of nonregulated status pursuant to the petition process currently in part 340 is available at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status.*

[10] Information about decisions made pursuant to the AIR process is available at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/regulated_article_letters_of_inquiry/regulated_article_letters_of_inquiry.*

regulated article not only if the recipient organism itself is a plant pest, but also if the donor, vector, or vector agent used in the engineering process is a plant pest. This reflects the concern in the 1980s that if an organism was modified using genetic material taken from a plant pest, or a plant pest was used as a vector or vector agent to carry genetic material into an organism, the resulting GE organism could also be a plant pest.

Based on APHIS' experience evaluating field trial data from thousands of authorized environmental releases of regulated organisms, as well as the 130 determinations of nonregulated status for GE plants, this generally stated concern has not proven to be valid. Although a plant pest may contribute or vector genes to a GE organism, the mere presence of plant pest sequences has not been shown in APHIS' evaluation of data to cause a GE organism, particularly if it is a plant, to become a plant pest. Indeed, experience has shown that the use of genes from donor organisms which are plant pests, as well as the use of vectors which are from plant pests, has not to date resulted in plant pest risks of any sort in recipient organisms that are not already plant pests.

The most common use of plant pest components in genetic engineering involve either the use of a disarmed version of the plant pathogenic bacterium *Agrobacterium tumefaciens* to vector genes into a plant or use of genetic material from plant pest donors which function as regulatory sequences in the plant. Currently, methods that use *Agrobacterium tumefaciens* as a vector of genetic material do not leave viable bacteria behind in the recipient organism and do not cause disease. Likewise, regulatory sequences such as the 35S promoter from Cauliflower Mosaic Virus and the nopaline synthase (nos) terminator from *A. tumefaciens* are themselves unable to be expressed and do not confer plant pest traits, though they do facilitate the expression of other genes in the GE organism. The use of plant pests in these ways either as donors of regulatory sequences or for vectoring genetic material into a recipient organism has a long history and has not resulted in disease or injury to the recipient organism or to other organisms.

These advances in our knowledge of biotechnology notwithstanding, under § 340.2(b), we would continue to regulate GE organisms in those cases where the organism which is engineered is itself a plant pest as defined in the PPA.

Our approach to regulating such organisms, however, would differ from that of the existing regulations. In current § 340.2, there is a list of taxa that contain plant pests. Under our proposed regulatory framework, however, we would not use taxonomic classification of donor organisms to determine if a GE organism is regulated. We would, therefore, remove the list from the regulations, along with the procedures described in current § 340.5 for amending this list.

Instead, when determining whether a GE non-plant organism is subject to the regulations, APHIS will assess whether a recipient organism is likely to be a plant pest, based on the most up-to-date pest information maintained by APHIS. This information is more specific than the information in the list of plant pest taxa in the current regulations, and should be more useful and reliable than static lists of taxa, which become outdated. APHIS will maintain a list of taxa that contain plant pests on its website and would be available for consultation by developers to help them determine whether or not their GE non-plant organism is or is not a plant pest. APHIS welcomes public comment on this proposed change.

Under proposed § 340.2(c), we would also regulate GE organisms that are not plants but have received DNA from a plant pest if the DNA from the donor organism is sufficient to produce an infectious entity or encodes a pathogenesis-related compound that is expected to cause plant disease symptoms. DNA from a donor organism that is a plant pest could, when inserted into an organism which is not a plant pest, result in a GE organism that is a plant pest if: (1) The DNA sequence that is encoded in the organism is able to be expressed as a functioning infectious entity capable of causing plant disease; or (2) if the inserted DNA enables the organism to produce pathogenesis-related compounds, that is, compounds that are typically produced by pathogens and involved in producing disease symptoms. Examples of such compounds would include plant degrading enzymes, plant growth regulators, phytotoxins, or compounds that can clog plant vascular systems.

APHIS intends this criterion to be specific to GE organisms other than plants, such as nonpathogenic soil bacteria that through genetic engineering may become capable of producing plant disease symptoms in plants. This contrasts with the current regulations, under which we regulate GE organisms based merely on the presence of DNA from a plant pest.

In addition, under § 340.2(d), we would regulate GE organisms that are microbial pathogens used to control plant pests, microbial parasites used to control plant pathogens, or invertebrate predators or parasites (parasitoids) used to control plant pests if they could pose a plant pest risk. These organisms are generally not plant pests but their potential effects on organisms beneficial to agriculture (referred to below as ''beneficial'') could indirectly affect plant health. The PPA provides the authority to regulate such biological control organisms used to control plant pests to ensure they do not pose a plant pest risk. As with non-GE biological control organisms, the types of GE biological control organisms APHIS would regulate 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 only to consider 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.

APHIS requests comment from the public regarding the categories of GE organisms listed under proposed § 340.2 as subject to the regulations and whether additional categories, such as pollinators, should also be considered.

Definitions

Definitions would be listed in proposed § 340.3. APHIS proposes to retain certain definitions currently found in § 340.1 of the regulations, to change other definitions, to add some new definitions, and to remove definitions that no longer need to appear in the regulations.

APHIS is proposing to retain the following definitions from the current regulations, without change:

Administrator, Animal and Plant Health Inspection Service (APHIS), donor organism, environment, organism, and *person.*

APHIS is proposing to revise the definitions of the following terms from those in the current regulations:

We would define *genetic engineering (GE)* as techniques that use recombinant or synthetic nucleic acids to modify or create a genome. This proposed definition is clearer than the existing one, which refers to modification using ''recombinant DNA techniques,'' a term that is not defined in the regulations. The current definition could also be construed, contrary to our intentions, to exclude the use of synthetic DNA, *in vivo* DNA manipulation, and genome editing. The proposed definition of *genetic engineering* would not cover traditional breeding techniques, such as marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion, or chemical or radiation-based mutagenesis. APHIS has never considered such techniques to constitute genetic engineering. Accordingly, organisms created through such techniques are currently excluded from the definition under part 340, and would continue to be so.

We would define *inspector* as any individual authorized by the Administrator or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in part 340. The current definition predates the establishment of the Department of Homeland Security, as well as the transfer of certain inspection responsibilities for imported organisms from APHIS to U.S. Customs and Border Protection.

The definition of *interstate* would be from one State into or through any other State or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States. This proposed revision aligns the definition of *interstate* in part 340 with the definition used in the PPA.

Move (moving, movement) would be defined as 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. This proposed revision aligns the definition of *move* in part 340 with the definition of *move* used in the PPA.

The definition of *permit* would be a written authorization, including by electronic methods, by the Administrator to move organisms regulated under part 340 and associated articles under conditions prescribed by the Administrator. This proposed revision would generally align the definition of *permit* in part 340 with the definition of *permit* used in the PPA. However, whereas the definition in the PPA mentions that a permit may authorize the movement of plants, plant products, and biological control organisms, plant pests, noxious weeds, and associated articles, our proposed definition would pertain to the movement of organisms regulated under part 340 and associated articles. This change reflects the scope of the proposed regulations.

Additionally, while the PPA allows for the issuance of oral permits, APHIS would not under these regulations. Oral permits do not provide adequate documentation that a responsible person was aware of and understood permitting conditions at the time the permit was issued.

Plant would be defined as 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. This revision is necessary because the current definition of *plant* used in the regulations precedes the issuance of the PPA, and is broader than the PPA definition. The proposed definition would align with the definition used in the PPA. A result of this alignment would be that APHIS would no longer consider ''cellular components,'' such as ribosomes, to be plants. Cellular components are not capable of propagating to cause plant pest risks.

Plant pest would be defined as 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. This proposed definition would generally align the definition of *plant pest* in part 340 with that used in the PPA. However, 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, to be plant pests.

Recipient organism would be defined as the organism whose nucleic acid sequence will be modified through the use of genetic engineering. In contrast, the current definition is ''the organism which receives genetic material from a donor organism.'' This change would differ from the current definition by distinguishing an organism with modified traits from the same organism prior to transformation; in some cases the recipient organism's nucleic acid sequence may be modified using genetic material from the same species.

We propose to define *release into the environment (environmental release)* as the use of a GE organism outside the physical constraints of a contained facility. The existing definition of *release into the environment* refers to the release of a regulated article; however, in this proposed rule we are no longer using the latter term. Our proposed definition of *release into the environment (environmental release),* would also clarify that *release into the environment* and *environmental release* are synonymous terms.

Responsible person would be defined as the person responsible for maintaining control over a GE organism under permit during its movement and ensuring compliance with all conditions contained in any applicable permit as well as other requirements of part 340. The proposed definition would further state that the responsible person may be, but would not be limited to, the signatory of a permit or the institution that the signatory represented at the time of the application. The responsible person must be at least 18 years of age and be a legal resident of the United States.

The current regulations define *responsible person* as the person (at least 18 years of age and a U.S. resident) who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the permit and requirements in part 340 are complied with. We are proposing to replace it with the new definition to clarify that the term refers to both individuals and institutions. That dual responsibility is implied in the existing definition, because we define the term *person* to include institutions, but it is not stated explicitly, potentially resulting in confusion over who ultimately is the responsible party. Attributing responsibility for a regulated organism only to an institution may be problematic for enforcement of the regulations, because such responsibility can be diffused, resulting in no individual being held accountable for violations. Attributing it only to an

individual may be similarly problematic because the signatory of the permit may change his or her institutional affiliation and location. The proposed definition would ensure that some individual or party would be held accountable for violating permit conditions and/or regulatory requirements.

State would be defined as 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, the Virgin Islands of the United States, or other Territories or possessions of the United States. This change aligns the definition of *State* in part 340 with that used in the PPA.

We currently define *State regulatory official* as the State official with responsibilities for plant health, or any other duly designated State official, in the State where the introduction is to take place. We would change the term to *State or Tribal regulatory official.* We would define the *State or Tribal regulatory official* as the 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. Under the proposed definition, the official's responsibilities would not change. The proposed change from the former definition is to acknowledge Tribal authority on Tribal lands.

APHIS proposes to add definitions of the following new terms:

We would define *access* as 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 part 340 and all conditions of a permit issued in accordance with § 340.5. This proposed definition is in line with APHIS' authority under the PPA to conduct inspections and, where necessary, sampling activities to verify that premises associated with permits meet our requirements.

Because the responsible person, as defined above, may have an agent acting on his or her behalf, it is necessary to add to the regulations a definition of the latter term. *Agent* would be defined as ''[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 ensure compliance with all conditions contained in any applicable permit and the requirements in part 340. 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.'' This proposed definition would codify the responsibilities of a designated agent acting on behalf of the responsible person.

We would define *article* as any material or tangible object that could harbor plant pests or noxious weeds. This proposed definition is needed to clarify the meaning of the term as used throughout these proposed regulations and also aligns with the PPA definition of the term.

Contained facility would be defined as a structure for the storage and/or propagation of living organisms designed with physical barriers capable of preventing the escape of the organisms, and that examples include laboratories, growth chambers, fermenters, and containment greenhouses. While the current regulations use the term contained facility, the term is not currently defined. APHIS proposes to add this definition to clarify what constitutes a contained facility.

Import (importation) would be defined as to move into, or the act of movement into, the territorial limits of the United States. This is the definition used in the PPA.

We would define *mechanism of action,* as discussed earlier in this document, as the biochemical process(es) through which genetic material determines a trait. We would add this definition because it is an element that we would consider, along with organism and trait, when evaluating a GE organism for plant pest risk.

As discussed earlier, we would define *plant pest risk* as the possibility of harm to plants resulting from introducing or disseminating a plant pest or exacerbating the impact of a plant pest. It is necessary to add this definition because our regulatory status review process, described below, hinges on our evaluation of the plant pest risk posed by a GE plant.

Parasitic plants can pose plant pest risks directly by injuring plants themselves, while other types of plants pose plant pest risks indirectly, either by serving as reservoirs, which can increase the numbers or distribution of plant pests, or by serving as hosts in which new plant pests can be created.

Non-plant GE organisms may also pose both direct and indirect plant pest risks. Direct plant pests risks are limited to GE organisms which are themselves plant pests, *i.e.,* capable of causing injury of, damage to or disease in plants or plant products. Indirect plant pest risks involve interactions of a GE organism with other organisms or the environment in such a way that injury of, damage to, or disease in plants or plant products by plant pests occurs or is increased. As with GE plants, an important mechanism by which a non-plant GE organism could have an indirect plant pest impact would be the suppression of populations of a beneficial organism which, in turn, suppresses plant pests. With decreased levels of the beneficial organism, injury, damage, or disease from the plant pest it suppresses might be increased.

Plant product would be defined as any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of plant or any manufactured or processed plant or plant part. This matches the definition of *plant products* found in the PPA. This definition is more precise than the current definition of *product* in part 340, which this definition would replace. For example, the current definition of *product* includes ''anything made by or from, or derived from an organism, living or dead.'' APHIS does not plan to regulate dead organisms as APHIS has found that they do not present a plant pest risk.

Secure shipment would be defined as 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. This definition would be used to clarify the container requirements in the proposed rule.

We would define *trait,* as discussed earlier in this document, to mean an observable (able to be seen or otherwise identified) characteristic of an organism. This proposed definition would provide clarity regarding the relationship between trait and MOA.

Unauthorized release would be defined as the intentional or accidental movement of an organism under a permit issued pursuant to part 340 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 part 340. We would add this definition to ensure that the Administrator would have the ability to enforce regulatory requirements that are accidentally or intentionally violated and maintain effective compliance oversight.

APHIS proposes to remove the following definitions from the regulations: *Antecedent organism, courtesy permit, expression vector, introduce or introduction, product, regulated article, Secretary, stably*

integrated, United States, vector or vector agent, and *well-characterized and contains only non-coding regulatory regions.*

These definitions would be removed because the terms would no longer be used in the regulations.

APHIS proposes to remove the definition for *introduce or introduction.* APHIS currently uses the term in part 340 to denote certain kinds of activities that fall within the scope of the regulations, namely importation, interstate movement, and release into the environment. The PPA, however, does not specifically define the term *introduction.* Therefore, to avoid confusion, instead of using the term *introduction* to define the different types of regulated activities, APHIS would refer to these activities in the regulations as *movement* in accordance with the definition of *move* in the PPA. Additionally, as mentioned above, the regulations will specify and define as necessary the types of movements to which the regulations would apply, namely, importation, interstate movement, and release into the environment.

APHIS proposes to remove the definition of *regulated article.* APHIS currently uses the term in part 340 to refer to which organisms fall within the scope of the regulations. A GE organism is considered to be a regulated article under the current definition if the donor, vector, or vector agent is a plant pest. However, GE techniques, such as genome editing and synthetic genomics, have recently been developed that need not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents but that may pose plant pest risks. APHIS proposes to identify the categories of organisms that are subject to the regulations in § 340.2 instead of through the definition of regulated article.

Finally, based on the terms that APHIS is proposing to add or remove from the regulations, as well as the revised scope of the regulations, the Agency would revise the heading of part 340 to ''Movement of Organisms Modified or Produced Through Genetic Engineering.''

Regulatory Status Review

Under the existing regulations, APHIS deems GE organisms ''regulated articles'' based upon the use of a plant pest in the genetic engineering process. APHIS receives requests from developers who wish to ascertain, prior to conducting a potentially regulated activity, whether a specific organism that they have developed meets our definition of *regulated article* and is therefore subject to the regulations. APHIS has been responding to such inquiries from developers since the late 1990's. In 2011, APHIS implemented a formal ''Am I Regulated'' (AIR) process, providing a web page that instructs developers on how to submit an AIR inquiry. We developed the AIR process because we saw an increasing number of such requests. The process was intended to guide developers to provide consistent and predictable information that would enable the Agency to respond to inquiries in a timely manner so as to not inhibit innovation. This process is not codified in the existing regulations, however.

The primary analysis conducted under this process is to determine whether or not the organism described in the AIR inquiry is a regulated article as defined in part 340. The organisms in question have ranged from clearly regulated (*e.g.,* GE plants that DNA that was inserted by the plant pest *Agrobacterium tumefaciens*) to clearly not regulated ones, such as GE organisms that are genetically engineered without the use of a plant pest. Products of new genome editing techniques, such as TALENs and CRISPR, have presented intermediate scenarios that have been evaluated over the past few years. Additional considerations by APHIS under this process include weediness potential. If the organism in question is weedy or has weedy wild relatives, these concerns are also addressed in APHIS' response.

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. Published APHIS decisions made under the current regulations in § 340.6 have used different ways to express the basic standard ''unlikely to pose a plant pest risk'' in determining whether to grant nonregulated status to a specific GE organism. Alternative characterizations that have been used include ''poses no more of a plant pest risk than its non-GE counterpart,'' ''will not pose a plant pest risk,'' ''no plant pest risk,'' and ''no direct or indirect plant pest effects.'' Regardless of the phrases used, APHIS has applied the same basic evaluation criteria, specified in current § 340.6(c)(4), to each determination to conclude that the GE organism is unlikely to pose a plant pest risk and therefore is not subject to the part 340 regulations. Those criteria include, conclusions on the potential of the GE organism to create pest or disease problems, the potential for nontarget effects that might affect organisms beneficial to agriculture, changes in agricultural practices that might exacerbate pest or disease problems, the potential for a GE organism to become a weed or increase its weediness or that of sexually compatible species, and the potential of the GE organism to transmit the introduced trait to organisms with which it does not interbreed.

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, the Agency believes the petition process is no longer necessary and is proposing to remove the petition process from the regulations.

In this document, APHIS is proposing to provide developers of novel GE plants that have not been previously evaluated by APHIS the option of either requesting a regulatory status review by the Agency to determine regulatory status or applying for a permit for movement under the regulations. Developers choosing to apply for a permit would, upon approval of the permit application, be able to immediately import, move interstate, or field test their plant under APHIS-imposed conditions and oversight. If they choose to request a regulatory status review, and the Agency finds that the plant-trait-MOA combination is not likely to pose a plant pest risk and therefore is not subject to the regulations, the developer could proceed with product development and marketing activities free from regulation under part 340.

The current petition process contained in the regulations is only applicable to GE plants; likewise, the proposed regulatory status review described in proposed § 340.4 would apply only to plants and not to GE plant pests or other GE non-plant organisms. The latter two categories would fall within the scope of the proposed regulations in § 340.2 and therefore require permits for movement. Unlike most plants, other organisms described in § 340.2(b), (c), and (d) are either known to be plant pests, engineered in such a way that they are likely to be plant pests, or will be used to control plant pests and therefore need to be regulated for direct or indirect plant pest risks. As noted earlier, we are requesting public comment on whether the regulatory status review process or some equivalent process should apply

to non-plant GE organisms and, if so, what factors should be analyzed.

Proposed § 340.4(a) describes the process for submitting a request for a regulatory status review. Since APHIS may also initiate a regulatory status review, that process is described as well.

Under proposed § 340.4(a)(1), any person could submit a request to APHIS for a regulatory status review of a GE plant that has not previously been reviewed for plant pest risk based on its plant-trait-MOA combination. Proposed paragraph (a)(2) would allow any person to request a re-review of a GE plant listed as subject to part 340, provided that the person making the request can provide new, scientifically valid evidence bearing on the plant pest risk associated with movement of the plant.

Proposed paragraph (a)(3) would state that APHIS could also initiate a regulatory status review or re-review of a GE plant. This provision would provide another means of enabling us to respond quickly to scientific developments when making decisions on whether or not GE plants are subject to the regulations. APHIS could initiate a re-review of a GE plant, regardless of the initial finding, if new information warrants such a reevaluation.

Proposed paragraph § 340.4(a)(4), would state that information submitted in support of a request for a regulatory status review would have to meet the requirements listed in paragraphs (a)(4)(i) through (iii), which are as follows:

- A description of the comparator plant, to include genus, species, and any relevant subspecies information;
- The genotype of the modified plant, including a detailed description of the differences in genotype between the modified and unmodified plant; and
- A detailed description of the new trait(s) of the modified plant.

Additional guidance on how to meet these requirements will be available on the APHIS website and is included below:

I. A description of the comparator plant to include:

a. Common name(s);

b. Genus, species, and any relevant subspecies information (*e.g.,* variety) that would distinguish the plant; and

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

a. If genetic material is inserted into the genome, the following information shall be provided:

i. For gene sequences, the name of the sequence, the donor organism(s) or source, the function of sequence, the nucleotide sequence, and if applicable, the publicly available sequence identification, protein accession number, and enzyme commission number. If genes have been modified (*e.g.,* codon usage efficiency, gene shuffling, etc.), a statement regarding the nature of the modification and its purpose would be needed. The developer would also have to identify and highlight 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 source of each regulatory sequence would need to be described. Promoters must be identified as constitutive, inducible, developmental, or tissue specific. If inducible, known inducers must be described (*e.g.,* chemical, temperature, light, stress, wounding, etc.). If developmental/tissue specific, the stage(s)/tissue at/in which the promoter is intended to be active must be described.

b. If genetic material is not inserted into the genome, and the genome is modified in a way that does not fall under the exemptions in § 340.1(b), the following must be provided:

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

ii. For substituted base pairs, the number of substitutions.

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

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

a. The purpose of the new trait and the expected MOA by which the intended trait is conferred;

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

c. If available, any additional experimental data, publications, and other science-based assessments that are relevant to APHIS' evaluation of the potential of the plant to pose plant pest risks. (APHIS does not intend for submitters to generate experimental data specifically for a regulatory status review. However, if a submitter is aware of information or experimental data in the public domain that may support our assessment, they may include it.)

APHIS considers the categories of information specified above to be sufficient for assessing a GE plant and identifying the plant pest risks, if any, associated with it. That being said, the Agency solicits public comment on the adequacy of the requested information, and whether additional or alternate information requirements would be more appropriate. Specifically, APHIS is interested in whether commenters think the above information requirements may be insufficient to identify whether the plant poses a plant pest risk.

To that end, APHIS wishes to highlight some of the differences between the above information requirements and the information currently required for either a petition for nonregulated status of a GE plant or an AIR inquiry. With regard to the genotype of the GE organism, APHIS would add specific information requirements for gene sequences, regulatory sequences, and genome modifications. The current regulations in § 340.6 require the petitioner to supply a detailed description of the genotype of the GE organism, but do not specify that a description of the gene sequences, regulatory sequences, or genome editing of the organism is required. Operationally, however, APHIS considers this information to be necessary. APHIS anticipates using the information to confirm the intended trait(s) of the GE plant and to assess similarity with previously reviewed plants, which will assist the Agency in understanding the impacts the modification(s) will have on characteristics of the plant.

The current regulations specify that a petition must contain field test reports for all trials conducted under permit or notification procedures involving the regulated organism, including the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, non-target organisms, or the environment. A petition is typically requested after lengthy field testing. Currently, most of the field data submitted are intended to demonstrate that there have not been unintended deleterious effects on plants, non-target organisms, or the environment.

To date, APHIS has authorized more than 100,000 field trials—a single permit or notification may authorize multiple trials—and APHIS has not received a report of unintended deleterious effects on plants, non-target organisms, or the environment. 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, the Agency 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 findings of reports of the National Academies of Science, Engineering, and Medicine.[11] [12]

Accordingly, field test information would not be a generally applicable requirement for the initial regulatory status review and would only be requested on an as-needed basis when further analysis is needed. APHIS considers information from field tests to be unnecessary, in most cases, for a determination of regulatory status under the proposed regulations. The approach APHIS is proposing focuses primarily on evaluating the genetics and characteristics of the GE plant-trait-MOA combination and the likelihood that, based on these genetics and characteristics, the plant will pose a plant pest risk if it is released into the environment for the uses intended by the developer.

This approach would not preclude a developer from providing information from field tests, if he or she considered it to be pertinent to our analysis. For example, if a developer wished for APHIS to reevaluate the status a GE plant that the Agency had previously considered to be subject to the regulations, field-test information demonstrating a lack of direct or indirect adverse effects on plants and plant products 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.

APHIS would also remove a current regulatory requirement that requires the petition to state the country and locality of the donor organism from which a GE organism has received genetic material in order for APHIS to evaluate the genotype of the GE organism. In the Agency's experience, this information has not proven germane to evaluating risk associated with modifying the genome of the GE organism, since it does not provide information regarding the modified genome of the GE organism, or the manner in which the genome was modified.

Information pertaining to the MOA may include, to the extent that it is or could be 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. This information is useful to us because these factors may affect the level of plant pest risk associated with the GE plant.

The above information is needed to allow APHIS to evaluate the plant pest risk posed by the GE plant. The general description of the plant-trait-MOA combination will not be eligible for CBI designation. Making this information available would facilitate APHIS' transparent regulatory approach and thereby increase public understanding of what combinations the Agency has already assessed and the regulatory status of those combinations, aiding developers in making self-determinations as to whether their products would be exempt from the regulations in accordance with § 340.1. Certain technical information that could be used to re-create an organism, however, may be eligible for CBI designation under existing statutory authorities.

Proposed § 340.4(b) would set out the regulatory review process. Under proposed § 340.4(b)(1), upon receiving a request for a regulatory status review of a GE plant, APHIS would 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, based on following factors:

I. The biology of the comparator plant 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.

APHIS uses existing knowledge and information on the biology of the comparator plant and its sexually compatible relatives, including their spatial and temporal distribution in the absence of intentional human assistance and their interactions with or impacts on other organisms and the environment, as the foundation for considering whether alterations in the GE plant are likely to pose plant pest risks.

As noted earlier, the MOA is the specific manner by which the genetic modification of the GE plant confers the intended trait on the plant. It is necessary for a regulatory status review to evaluate both trait and MOA because the same trait may be obtained by different MOAs, which may pose greater or lesser plant pest risks. For example, the trait of coleopteran resistance can result from either of at least two MOAs: Expression of a Cry protein, or expression of a silencing complex targeting ribonucleic acids (RNA) in the coleopteran pest. Plants with insect-resistant traits can potentially cause plant pest risks through harms to organisms beneficial to agriculture, such as predator insects that can suppress pest populations. Though the two MOAs in the example both produce a coleopteran resistant trait, they would need to be evaluated separately for nontarget impacts to beneficial insects. Nontarget impacts related to Cry proteins depend on whether the nontarget insect has the correct protein in its gut to bind the Cry protein. Ribonucleic acid interference (RNAi)-based resistance could, on the other hand, be designed to target RNA encoding for any number of essential proteins in the target insect. The sequence could be very specific to the target insect or widely preserved across varying taxa. Only through extensive testing or bioinformatics analysis could risks to nontarget insects be determined. In summary, because these two MOAs are different, one would not expect the analysis of risks to nontarget organisms for one MOA to be informative in evaluating the risks to nontarget organisms of the other. The important principle is that it is not just the trait, but also the MOA, which is critical for differentiating GE plants in order to determine whether new reviews of plant pest risk are needed.

As in plant pest risk assessments (PPRAs) prepared in response to petitions for nonregulated status under the current regulations, APHIS would evaluate whether planting or release of the GE plant could result in direct or indirect harm to non-target organisms that are beneficial to agriculture, such as pollinators and predators of plant pests. We would also evaluate the potential of the plant to displace native/established organisms or otherwise alter community composition or structure in a manner that harms beneficial non-target organisms.

APHIS recognizes that genetic engineering may be used to introduce a trait that increases the distribution,

[11] See: NRC (National Research Council). 1989. *Field Testing Genetically Modified Organisms: Framework for Decisions*. Washington, DC: National Academy Press.

[12] National Academies of Sciences, Engineering, and Medicine. 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC: The National Academies Press. doi: 10.17226/23395.

density, or development of a plant or the weedy impacts of the plant, factors that are considered aspects of a plant's weediness. As such, we would continue the 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 in the timing during which they serve as a host for plant pests due to the introduced trait. As part of the regulatory status review, 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. Second, 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 and listing as a Federal noxious weed under the regulations in part 360. The proposed regulation does not change this analysis.

Because the initial review is objective, rapid, and based on transparent predetermined criteria, it has functional similarity to the current AIR process. In both processes, the outcome is merely a finding of whether a GE organism is subject to the regulations in part 340. APHIS will maintain on our website a list of all GE plant-trait-MOA combinations which have been evaluated. The list will include the inquiry, and the Agency finding. In cases where no potential plant pest risks are identified, APHIS will conclude that the plant-trait-MOA combination is not likely to pose a plant pest risk, and, therefore, the agency will have no discretion to regulate. As such, and consistent with our current process for AIR inquiries, there will be no comment period or need for publication in the **Federal Register**.

Proposed § 340.4(b)(2) states that if we do not identify potential plant pest risk in the initial review, the GE plant would not be subject to the regulations in part 340, and APHIS would post the finding on its website.

Under proposed § 340.4(b)(3), in cases where the Agency identifies potential plant pest risks, APHIS would conduct a PPRA, a more robust analysis than the initial review, to evaluate the factor(s) of concern and to determine the likelihood and consequences of the potential plant pest risks identified in the initial review. In some cases, the Agency may be able to reach a finding that the plant-trait-MOA combination is not subject to the regulations based on the outcome of the PPRA. In other cases, the Agency may determine that additional information is needed to evaluate the potential plant pest risks and field trials or greenhouse studies may be necessary to collect additional information to inform the risk assessment.

Proposed § 340.4(b)(3) also states that APHIS would make available information on the results of both the initial review and the subsequent PPRA conducted pursuant to this paragraph in a notice in the **Federal Register** and take public comments. After reviewing the comments, we would make a final determination of regulatory status and notify the public via a subsequent notice in the **Federal Register**. If the GE plant were found unlikely to pose a plant pest risk and therefore not to require regulation under part 340, APHIS would post the finding on its website. If the Agency could not reach such a finding, movement of the GE plant would be allowed only under permit.

Along with this proposed rule, we are publishing a document entitled ''Framework for USDA APHIS' Plant Pest Risk Assessment (PPRA) for Genetically Engineered Plants.'' The framework will provide more detailed information on the PPRA process than is contained in this document. We welcome public comment on the framework.

Proposed § 340.4(c) states that APHIS would maintain on its website information on all requests for and results of regulatory status reviews. We would protect CBI associated with individual regulatory status reviews on the website, except that, as noted earlier, plant, trait, and MOA would not be eligible for consideration as CBI.

Permits

The current regulations in § 340.3 provide criteria for a notification procedure whereby certain GE plants may be authorized for introduction in lieu of a permit. Rather than using customized requirements, like the permitting conditions used for the permitting procedure, the notification procedure relies on performance-based standards that are described in the regulations themselves. The use of the performance-based standards that do not vary from one notification to the next facilitates rapid administrative turnaround on notifications. However, in some ways, the term ''notification'' has been misleading to the public, since sending a notification does not mean automatic authorization by APHIS.

In many ways, the APHIS evaluations for notifications 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 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.

Because the notification procedure uses only the performance-based standards in the regulations, it is more administratively streamlined and provides the responsible person with flexibility in how the standard is met, *e.g.,* by allowing for appropriate changes in protocols used during the growing season. There are, however, some disadvantages to this approach. 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 if 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.

The permitting procedure avoids this disadvantage, because the 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. Because of this, APHIS has determined that it would have more risk-appropriate oversight, better regulatory enforcement, and improved transparency if all regulated movements are authorized under the permitting procedure. Therefore, APHIS is proposing to remove current notification provisions from the regulations and require that movement of all GE organisms subject to part 340 be conducted under permit.

The use of the permitting procedure in lieu of notifications is also necessary for APHIS to address a number of the recommendations from the OIG audits and the 2008 Farm Bill. In both the OIG audits and the 2008 Farm Bill, concern was expressed regarding the use of performance-based standards to regulate field tests of regulated articles. It was

recommended that APHIS amend the regulations to exercise greater oversight and enforcement of such field tests and to require more extensive reporting and record retention regarding such tests. These requirements can be added to a permit as permitting conditions, but do not lend themselves to performance-based standards. Some permit conditions, however, are and have always been performance-based. APHIS acknowledges that there is more than one way to manage risk and works with the permit applicant to find a mutually acceptable way to do so. In some instances, permit conditions may allow for the flexibility inherent in performance standards, while ensuring a specific requirement is addressed, something not possible with the notification procedure.

In short, if APHIS were to retain the notification procedure, in order to be responsive to the risk factors that may be associated with certain field trials but not others, to make it easier to assess compliance, and to be responsive to both the OIG audits and the 2008 Farm Bill, APHIS would need to revise the procedure to substantially reduce its reliance on performance-based standards. However, doing so would eliminate the primary benefit of the current notification procedure, which is that it is more administratively streamlined than the permitting procedure. Indeed, a revised procedure which took into consideration all risk factors that may be associated with specific field trials would be overly burdensome. For these reasons, APHIS is proposing to eliminate the notification procedure, rather than revise it.

The permitting procedure found in § 340.4 of the current regulations describes types of permits, information required for permit applications, standard permit conditions, and administrative information (*e.g.,* time frames, appeal procedure, etc.). Permits contain specific conditions that must be followed by the permit holder. Standard permit conditions, or ''general conditions,'' are listed in the current regulations, and APHIS supplements these with additional conditions as necessary. The current regulations specify the amount of time that APHIS is allotted for review of complete permit applications: 60 days for permits for importation and interstate movement, 120 days for environmental release. The current regulations also outline requirements for protecting CBI when submitting a permit application.

APHIS is proposing certain changes concerning permit application information requirements, permit conditions, records, and reports. We are proposing to remove the specified timeframes for APHIS review of permit applications to ensure the Agency has the appropriate time to evaluate each permit application based upon the risk the GE organism poses and the complexity of the permit application. Currently, some permit and notification applications take a minimal amount of time and others take longer, APHIS anticipates this to continue. We are also proposing to reorganize the regulations to improve the clarity of the permit application and evaluation procedures.

As noted earlier, under proposed § 340.2, GE plants that have not undergone a regulatory status review and those that have and were not found to be unlikely to pose a plant pest risk would both be subject to the regulations and could be moved only under permit. In some cases, a developer may opt to move a GE plant under permit initially while also requesting a regulatory status review. If a GE plant is subject to a regulatory status review during the time the permit is in effect, depending on the results, APHIS could amend the permit, or, if the plant is found not to require regulation, terminate the permit and communicate this termination to the permittee.

Paragraph (a) of proposed § 340.5 would state that movement of any GE organism subject to the regulations in part 340 would require a permit issued by APHIS.

Paragraph (b) of proposed § 340.5 would state that the responsible person would have to submit a permit application using a method listed on our website. The permit application would have to contain all the categories of information listed below.

Proposed paragraph (b)(1) would list general information requirements for all types of permit applications. All applications would have to include the name, title, and contact information of the responsible person and agent; the country and locality where the organism was collected, developed, manufactured, reared, cultivated, or cultured; the intended activity (*i.e.,* importation, interstate movement, or release into the environment of the GE organism); and information on the intended trait and genotype of the intended trait. These information requirements would be very similar to those for current permits.

Under proposed paragraph (b)(2), applications for permits for interstate movement or importation would, in addition to meeting the requirements of paragraph (b)(1), have to include 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; the method of shipment, and means of ensuring the security of the shipment against unauthorized release of the organism; and the manner in which packaging material, shipping containers, and any other material accompanying the organism will be disposed of to prevent unauthorized release.

Under proposed paragraph (b)(3), permit applications for release into the environment would have to address the general information requirements in paragraph (b)(1) and provide the following additional information: The location and size of all proposed environmental release sites, including area, geographic coordinates, addresses, 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 would continue the practice of evaluating and amending permits to add new release sites.

Finally, proposed paragraph (b)(4) would state that APHIS would request additional information as needed. Based on APHIS' extensive experience with the current permitting process, there are additional pieces of information that APHIS proposes to routinely request, such as multiple GPS coordinates for requested acreage, as well as multiple GPS coordinates for actual release acreage to appropriately describe the approved area. This information would allow APHIS to fully utilize GIS capabilities to oversee what was released within an authorized area. Additional documentation or notices may be required commensurate with risk of persistence in the environment.

APHIS currently has to follow up with applicants for this information; under this proposed rule, we would obtain it up front, as it would be required to support the permit application.

The categories of information above also align with the recommendations of the 2005 and 2015 OIG audits, and the provisions of the 2008 Farm Bill. For example, the OIG recommendations are reflected in the provisions that would enable APHIS to require geographic coordinates for the locations of environmental releases.

Proposed paragraph (c) of § 340.5 would continue to exempt *Arabidopsis thaliana* from permitting requirements for interstate movement, provided that it is moved in a secure shipment and the cloned genetic material is stably

integrated into the plant genome and does not include the complete infectious genome of a plant pest. This exemption is based on that organism's historically exempt status, which exists because interstate movement of the organism has not resulted in the dissemination of plant pests within the United States. *A. thaliana* has desirable traits (including small size, short generation times, high seed set, and ease of growth) that lend themselves to use in scientific studies. *A. thaliana's* small genome size, lack of repetitive DNA, and ease of genetic modification using *Agrobacterium tumefaciens* make it especially useful for molecular genetic analysis. Though GE *A. thaliana* often needs to be moved interstate between laboratories and other containment facilities as part of scientific studies, safeguards exist which can adequately mitigate the plant pest risk.

Proposed paragraph (d) of § 340.5 would exempt disarmed *Agrobacterium tumefaciens* from permitting requirements for interstate movement, subject to the same conditions as *A. thaliana.* This exemption is granted because, like *A. thaliana,* disarmed GE *A. tumefaciens* often needs to be moved interstate between laboratories and other containment facilities as part of scientific studies, and safeguards exist which can adequately mitigate the plant pest risk. In addition, while some strains of disarmed *Agrobacterium* may cause mild plant disease symptoms in some cases, our extensive experience has shown that given its specific usage in transforming plants and its lack of persistence in the newly transformed plants, there is a very low plant pest risk.

Proposed paragraph (e) of § 340.5 would exempt biological control organism-containing microbial pesticide products that are currently registered with EPA as a microbial pesticide product and that are not plant pests.

Under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, 7 U.S.C. 136 *et seq.*), EPA regulates certain biological control organisms (including eukaryotic microorganisms, prokaryotic microorganisms, and parasitically replicating microscopic elements, including, but not limited to, viruses) as ''pesticides,'' (see 40 CFR 152.20(a)(3)) and has established a regulatory process for their use as microbial pesticides.

Proposed paragraph (f) of § 340.5 would contain specifics regarding APHIS' review of permit applications. Under proposed (f)(1), APHIS would review permit applications to determine completeness. As under the current regulations, if the application is incomplete, APHIS would notify the applicant orally or in writing, and the applicant would be provided a sufficient opportunity to revise the application. Once an application is complete, APHIS would review it to determine whether to approve or deny the permit application.

Paragraph (f)(2) of § 340.5 would contain provisions regarding APHIS' assignment of permit conditions. If a permit application is approved, permit conditions would be assigned to each permit commensurate with the risk of the organism under permit and activity. Under the current regulations, the permitting procedure does not require a formal acknowledgement from the applicant prior to permit issuance that they are aware of and consent to the permit conditions, though it has been our practice to request such acknowledgment. APHIS considers such an acknowledgement to be necessary in order to verify that applicants are aware of and willing to abide by the conditions. Accordingly, we are proposing to codify our current practice by adding to the regulations a requirement that, prior to permit issuance, applicants must agree, in writing and in a manner prescribed by the Administrator, that they are aware of, understand, and will comply with all permit conditions. If an applicant fails to comply with this provision, their application would be denied.

Under paragraph (f)(3) of § 340.5, all premises associated with the permit would be subject to inspection before and after permit issuance, and all materials associated with activities conducted under permit would be subject to sampling. APHIS would require that the responsible person provide inspectors with access, as defined under proposed § 340.3, to inspect any relevant premises, facility, location, storage area, waypoint, materials, equipment, means of conveyance, records, and other articles related to the movement of organisms regulated under part 340. While this requirement is functionally the same as the current one, it clarifies what locations and articles may be subject to inspection. Failure to allow the inspection of premises prior to the issuance of a permit would be grounds for the denial of a permit application. Failure to allow an inspection after permit issuance would be grounds for withdrawal of the permit.

While the current regulations provide for review of permit applications by State regulatory officials, they do not provide for review by Tribal officials. Recognizing that Tribal officials may exercise oversight on Tribal lands equivalent to that of State officials within States, APHIS proposes in § 340.5(f)(4) to submit copies of permit applications to appropriate State and Tribal officials for review. Timely comments received from the State or Tribal regulatory official would be considered by the Administrator prior to permit issuance.

General permit conditions, which APHIS is proposing to list in paragraph (g) of § 340.5, would be assigned to all permits. As under the current regulations, additional or expanded permit conditions may also be assigned if determined by the Administrator to be necessary to ensure confinement of the GE organism. Examples of such supplemental requirements may include, but are not limited to, specific requirements for reproductive, cultural, spatial, and temporal controls; monitoring; post-termination land use; site security or access restrictions; management practices such as training of personnel involved in the movement; and practices to prevent articles associated with the movement of an organism under permit from spreading the organism.

The use of permits and permit conditions gives APHIS and the responsible person an understanding as to what actions must be taken for the permit holder to comply with the regulations. In the current regulations, APHIS also provides a list of general permitting conditions that are assigned to all permits in order to provide as much transparency and predictability as possible about permit conditions. To that end, as mentioned above, APHIS would continue to maintain a list of general conditions that APHIS would assign to all permits issued under the regulations within the regulations themselves. Paragraph (g) of § 340.5 would contain these general conditions. APHIS would require that:

I. 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.

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

III. The organism under permit must be maintained only in areas and premises specified in the permit.

IV. The organism under permit's identity must be maintained and verifiable at all times.

V. Authorized activities may only be done while the permit is valid; the duration for which the permit is valid will be listed on the permit itself.

VI. The responsible person would have to maintain records related to activities performed under permit of sufficient accuracy, quality, and completeness to demonstrate compliance with all permit conditions and requirements under the regulations. APHIS would be allowed access to all records, to include visual inspection and reproduction (photocopying, digital reproduction, etc.). The responsible person would have to submit reports and notices regarding the status of the organism under permit and actions and activities associated with the organism to APHIS at the times specified on the permit and containing the specified information. These reports would include, at a minimum:

a. Environmental release reports:

i. Following an environmental release, environmental release reports would have to be submitted for all authorized release locations where an environmental release occurred. Environmental release reports would have to contain details of sufficient accuracy, quality, and completeness to identify the location, shape, and size of the release and the organisms released into the environment.

ii. In the event no release occurs at an authorized location, an environmental release report of no environmental release would have to be submitted for all authorized locations where an environmental release did not occur.

iii. When the environmental release is that of a plant, reports of volunteer monitoring activities and findings would have to 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 would have to be submitted indicating why no volunteer monitoring was done.

VII. Inspectors would have to be allowed access, during regular business hours, to all locations where the organism under permit is or has been located and any equipment used with the organism under permit.

VIII. The organism under permit would have to undergo the application of remedial measures determined by the Administrator to be necessary to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment.

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

X. The responsible person for a permit remains the responsible person for the duration of 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 part 340.

Most of the conditions listed above are drawn from the current regulations, although APHIS has added some details to clarify their meaning. For example, while the existing regulations provide that APHIS inspectors shall be allowed access to records related to the permit, they do not specify what ''access to records'' means. APHIS would clarify that this includes visual inspection and reproduction (photocopying, digital reproduction, etc.) of all records required to be maintained under the proposed regulations or under the conditions of the permit. APHIS believes that these additional details will better communicate to applicants what the general permitting conditions are and will better support administration of the permitting program, including compliance and enforcement.

The conditions related to permit duration are new. Under the current regulations, notifications for environmental releases and interstate movement are valid for 1 year. Interstate movement permits are only valid for 1 year from the date of issuance, and a new import permit must be obtained for each imported shipment. These permits are referred to as ''limited permits.'' The duration period for a permit issued solely for an environmental release is not currently specified.

APHIS has found that it often takes considerably longer than 1 year for activities authorized under a permit to be completed. For example, with a perennial plant such as a tree, it may take much longer than 1 year to gather relevant data about the plant for the purpose of determining risk. Additionally, monitoring activities may be required for several years after a field test is complete. In other cases, multiyear research projects may require multiple shipments of GE organisms under permit for analysis. APHIS is therefore proposing to eliminate the current limits in the regulations on the duration of permits for interstate movement and importation. APHIS also would continue not to specify in the regulations the duration for which an environmental release permit is valid. The duration for which a permit is valid would instead be specified on the permit itself, although as is currently true, some reporting requirements may extend beyond the expiration of the permit. APHIS would work with the developer to ensure that the duration would be appropriate, so that APHIS would have the flexibility to issue these permits with suitable durations to meet individual circumstances.

APHIS is also proposing to make regular reporting regarding any activities associated with environmental release of a GE organism under permit a general permitting condition. As mentioned previously in this document, the 2005 and 2015 OIG audits suggested that APHIS exercise greater and more coordinated oversight over field tests of GE organisms. APHIS identified regular reporting regarding actual release site coordinates and details of the release as a key means of exercising such oversight. Adding this reporting requirement as a general permitting condition will ensure that it is communicated to all responsible persons.

Similarly, to respond to the recommendations of the 2015 OIG audit, APHIS would add a requirement as a general permitting condition that the responsible person must notify the Agency in writing if any activity associated with environmental release under permit will not be conducted. OIG recommended that APHIS implement improvements to track the status of all authorized test field locations in order to account for and sufficiently monitor all such locations and thereby prevent the inadvertent release of GE organisms into the environment. Thus, APHIS is proposing to require the submission of reports so APHIS knows the status and location of authorized field trials. Specifically, APHIS is proposing to require the submission of a report of no release to account for all approved test fields under an authorization. For example, APHIS may approve 50 test fields within various locations in the United States, but test field releases only occur in 30 of the 50 approved locations. Thus, a report of no release would allow APHIS to account for the 20 other test fields. This will lead to efficient compliance oversight of the 30 test fields that have permitted releases. This general condition would work in tandem with the reporting requirement mentioned above, and help APHIS resolve what could otherwise be considered inconsistencies between the permit conditions and the regular reports.

APHIS recognizes that some of these general permitting conditions pertain only to activities associated with

environmental release under permit of a GE organism. APHIS also recognizes that it is possible that certain permit applications may not include a request to release the organism into the environment. Where conditions apply to a specific activity, *e.g.,* movement into the United States, movement interstate, or release into the environment, the appropriate condition will be acknowledged. However, the permit issued would still contain these general conditions to communicate to the responsible person APHIS' general requirements regarding environmental release of GE organisms under permit. This will ensure that, consistent with the recommendations of the OIG audits, all responsible persons are aware of those requirements. The conditions would also prove useful, should the responsible person subsequently request amendments to the permit to authorize environmental release.

While the general permitting conditions that are currently in the regulations contain a condition that pertains to packing material used to transport the organism under permit, APHIS would not retain this as a general permitting condition. Instead, as discussed below, requirements for shipping under permit would be contained in paragraph (k) of § 340.5.

Conditions for denial of a permit application or withdrawal of an existing permit are contained in current § 340.4(g). We are proposing to amend these conditions to make them clearer and provide additional protection against plant pest risks.

Proposed § 340.5(h)(1) lists circumstances under which a permit application may be denied. An application could be denied either orally or in writing. If the denial is oral, the Administrator will then communicate the denial and the reasons for it in writing as promptly as circumstances allow. A denial may occur when the Administrator concludes that, based on the application or additional information, the proposed actions, *i.e.,* movements under permit, may result in the unauthorized release, spread, dispersal, and/or persistence of a GE organism in the environment. Such a situation would arise if we determined that the possibility of the unauthorized release would exist regardless of any permit conditions we could assign. A second cause for denial would be the failure of the responsible person or any agent of the responsible person to comply at any time with part 340 or any APHIS regulation pursuant to the PPA or with the conditions of any permit that has previously been issued in accordance with the regulations. A previous record of noncompliance would call into question the applicant's ability or willingness to abide by our permitting conditions. Finally, if all other application requirements are met, we would still decline to issue the permit if the applicant does not agree in writing to comply with the permit conditions we assign for movement of the organism or does not allow inspection, in accordance with the regulations, of the premises associated with the permit.

Conditions for the withdrawal of permits would be contained in § 340.5(h)(2). A permit could be withdrawn if, following issuance of the permit, the Administrator receives information that would otherwise have provided grounds for APHIS to deny the permit application; if the Administrator determines that actions taken under the permit have resulted in the unauthorized release, spread, dispersal, and/or persistence in the environment of a GE organism; or if the Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with the regulations in part 340, any other regulations pursuant to the PPA, or any permit conditions. The first two of these proposed conditions are new. They would provide additional protections against plant pest risks that may be associated with the movement of GE organisms under permit. Failure to comply with permit conditions is grounds for withdrawal under the current regulations, but we would provide additional protection against plant pest risks by broadening the provision to include failure to comply with any APHIS regulation as well.

Under proposed § 340.5(h), the Administrator would communicate the denial or withdrawal and the reasons for it in writing as soon as circumstances allow.

Proposed § 340.5(i) would retain the current procedures for appealing the denial of a permit application or withdrawal of a permit, with one modification. Any person whose permit application has been denied or whose permit has been withdrawn could appeal the decision in writing or electronically to the Administrator. Under the current regulations, the appeal must be submitted within 10 days after the applicant receives the written notification of the denial or withdrawal and must state all of the facts and reasons that, in the view of the applicant, demonstrate that the permit was wrongfully denied or withdrawn. The Administrator grants or denies 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 is held to resolve the conflict. Under this proposed rule, we would require an acknowledgment by the applicant of the denial or withdrawal within 10 days after receiving the written notification, along with a statement of the applicant's intent to appeal. The proposed change is intended to allow the applicant adequate time to gather the necessary information and prepare the appeal.

APHIS is also proposing to clarify in § 340.5(j) of the regulations the procedure to be used when amendment of existing permit conditions is sought by the responsible person or required by APHIS. In the current regulations, the administrative practices that APHIS uses to amend permits are not stated explicitly. Adding them to the regulations would provide increased transparency and efficiency.

Proposed paragraph (j)(1) would state that if a responsible person determines that circumstances have changed since the permit was issued, he or she may contact APHIS directly and request an amendment or amendments. Supporting information may need to be submitted to justify the request. APHIS may amend the permit if only minor changes are needed. Requests for more substantive changes may require a new permit application. Prior to issuance of an amended permit, the responsible person or his or her agent(s) will be required to agree in writing to comply with the conditions of amended permit. If the responsible person does not agree to the conditions, the amendment will be denied.

APHIS may also initiate amendments to permits and permit conditions 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 would provide notice to the responsible person of the amendment(s) and, as soon as circumstances allow, the reasons for it. The responsible person and his or her agents would have to agree in writing to comply with the new conditions before APHIS would issue the amended permit. Failure to provide such an agreement may result in the withdrawal of an existing permit.

Section 340.8 of the current regulations lists container requirements for the shipping of regulated articles, *i.e.,* shipping under permit. These requirements are very prescriptive. While they do allow a responsible person to request variances from the requirements, this request process, by its nature, results in a case-by-case determination of whether other types of

containers are acceptable for the transportation of the organism. The current regulations also do not clearly reflect the performance-based standard that APHIS used to develop the requirements, which was that the container should be sufficient to prevent dissemination of a GE organism during movement under permit.

Proposed paragraph (k) of § 340.5 would update the requirements for shipping under permit to resolve the issues discussed above.

Paragraph (k)(1) would state that shipping containers or means of conveyance would have to meet the standards listed under our proposed definition of *secure shipment, i.e.,* would have to be of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation. These requirements would make the performance standard referred to above more explicit in the regulations than it is now, while at the same time making the requirements less prescriptive, thus eliminating the need for a request process for variances.

In that paragraph, we would also retain a provision from the current regulations, currently a footnote to § 340.8, that specifies that all organisms shipped under permit must be shipped in accordance with the regulations in 49 CFR part 178. Those regulations, which are administered by the Department of Transportation (DOT), provide packaging requirements for materials, including organisms that DOT has designated as hazardous materials.

Paragraph (k)(2) would state that the container would have to be accompanied by a document that included the names and contact details for both the sender and the recipient. These details are essential for purposes of enforcement.

Paragraph (k)(3) would list container-labeling and documentation requirements for GE organisms imported under permit into the United States. These requirements are currently found in § 340.7 and would not be changed.

Finally, paragraph (k)(4) would state that following the completion of the shipment, all packing material, shipping containers, and any other material accompanying the organism would have to be treated or disposed of in such a manner so as to prevent the unauthorized dissemination and establishment of the organism. This requirement is currently a general permitting condition, but could more accurately be described as a shipping requirement.

APHIS currently authorizes a small number of permits for commercial production. APHIS has occasionally received inquiries from stakeholders regarding whether a permit could authorize the commercial distribution of an organism subject to the regulations. Currently, most developers of GE organisms do not commercialize their products until after those products are granted a determination of nonregulated status. However, APHIS does not prohibit commercializing GE organisms that have not been granted a determination of nonregulated status.

Under the proposed regulations, there may be some GE organisms that an entity wishes to commercialize or grow on a large scale, under permit. As it does currently, APHIS would evaluate these permit applications on a case-by-case basis to determine whether permitting conditions can be developed that adequately address the risk associated with the organism.

The current regulations in § 340.4(h) provide APHIS with the ability to issue courtesy permits in order to facilitate the movement of GE organisms that are not subject to the regulations in part 340 but whose movement might otherwise be hindered because of their similarity to organisms or articles that are regulated by other APHIS programs. APHIS commits significant resources to the issuance of these courtesy permits.

Courtesy permits have been part of the regulations since their inception in 1987, and have been useful to inform shippers and State and Federal inspectors not yet fully familiar with requirements for GE organisms that the shipments in question were not regulated. However, their continued use has led to the widespread misunderstanding by some researchers that courtesy permits are actually required for the movement of certain organisms or that issuance of a courtesy permit removes the requirement for applicants to follow other applicable regulations, such as the plant pest regulations found in 7 CFR part 330. This confusion partially stems from the similarities between the application form for courtesy permits and those for other types of permits, as well as between the courtesy permit itself and other permits. Therefore, in an effort to alleviate confusion and to better focus and allocate APHIS resources, APHIS would no longer issue courtesy permits. It has been common APHIS practice to facilitate the importation of nonregulated articles through the use of letters indicating that no permit is required; under the proposed regulations, APHIS would move to this approach. APHIS would continue to work with researchers and relevant government regulatory officials to facilitate the transition.

Record Retention, Compliance, and Enforcement

APHIS is proposing to consolidate all record retention, compliance, and enforcement requirements in part 340 into a new § 340.6. APHIS is also proposing to strengthen these provisions in order to manage compliance with the regulations more efficiently, to augment the approaches used to prevent or remediate plant pest risks, and to utilize appropriate enforcement strategies. These proposed regulatory changes also reflect certain provisions of the 2008 Farm Bill and align with recommendations of the 2005 and 2015 OIG audits.

The current regulations require a responsible person to retain for 1 year records demonstrating that an organism that was imported or moved interstate under a permit arrived at its intended destination but contain no record-retention requirements related to environmental release of an organism under permit. While APHIS has frequently added this record retention requirement as a permitting condition, both the 2005 and 2015 OIG audits and the 2008 Farm Bill recommended that the Agency specify the retention requirement in the regulations themselves. These recommendations have been corroborated by the Agency's own experience administering the regulations.

Proposed § 340.6(a) would require that a responsible person and his or her agent(s) would have to establish and keep the following records and reports:

- All records and reports required as a condition of a permit;
- Addresses and any other information, *e.g.,* GPS coordinates and maps, needed to identify all locations where the organism under permit was stored or used, including all contained facilities and environmental release locations;
- A copy of the APHIS permit authorizing the permitted activity; and
- Legible copies of contracts between the responsible person and all agents that conduct activities subject to the regulations for the responsible person and copies and documents relating to agreements made without a written contract.

We are proposing these requirements for compliance assurance, evaluation, and enforcement purposes, including fact findings and investigations into the possible unauthorized environmental release of a GE organism subject to permitting or its escape from a

containment facility. A thorough record of activities taken under the permit is necessary in order for APHIS to assess compliance and determine whether enforcement actions are needed.

Proposed paragraph (b) of § 340.6 lists requirements for record retention. Records indicating that an organism that was imported or moved interstate under permit reached its intended destination would have to be retained for at least 2 years. The current requirement is 1 year. In the event that there is uncertainty regarding whether the organism arrived at this location, it may take APHIS more than 1 year to investigate the matter.

All other records related to the permit would have to be retained for 5 years following permit expiration, unless the Administrator determines that a longer time period is appropriate and documents that determination in the supplemental conditions of the permit.

APHIS recognizes that, in practice, our proposed requirements would require most records associated with activities conducted under permit to be retained for 5 years (or longer), and that this is a significant duration to retain a potentially substantial number of records pertaining to permit activities, especially for a researcher or small company. However, retaining documents for less than 5 years may impede fact findings and investigations into possible compliance infractions. In conducting such investigations, APHIS has found it necessary to obtain information from field trials conducted up to 5 years prior to an investigation. In instances in which the information was not available, APHIS' ability to do an expeditious and thorough investigation was adversely impacted.

The Agency requests specific public comment regarding whether a shorter duration is warranted for certain records pertaining to permit activities and which activities these may be. Additionally, APHIS requests comment on any alternate means that stakeholders may identify for the Agency to obtain necessary information from developers in the event of a fact finding or an investigation of possible regulatory noncompliance.

Proposed paragraph (c) of § 340.6 would state that responsible persons and their agents must comply with the proposed regulations. Failure to comply with the regulations could result in any or all of the following: Denial of a permit application or withdrawal of a permit, application of remedial measures in accordance with the PPA, and criminal or civil penalties in accordance with the PPA.

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. APHIS typically issues an Emergency Action Notification or administrative order to the owner of the organism to specify these remedial measures.

If APHIS intends to issue a civil penalty, the Agency may enter into a stipulation prior to issuance of the complaint seeking the penalty. Our regulations regarding such stipulations are located in 7 CFR 380.10.

Proposed paragraph (d) of § 340.6 would specify that for purposes of enforcing the regulations, 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. We would note, however, that in enforcing the regulations, we will take the least drastic action that is commensurate with the mitigating factors of the noncompliance. It is expected, therefore, that major and/or repeated infractions would be dealt with more harshly than minor ones.

Confidential Business Information

The current regulations contain requirements pertaining to CBI in various sections. APHIS is proposing to consolidate these requirements for protecting CBI into a single section, § 340.7, thereby making it easier for interested persons to find the necessary information. Under proposed § 340.7, 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 CBI must justify how each piece of information requested to be treated as CBI is a trade secret or is commercial or financial information and is privileged or confidential. As noted earlier, in order to facilitate APHIS' transparent regulatory approach, a general description of the plant-trait-MOA combination will not be eligible for CBI designation. Certain technical information, however, such as GPS location data, or data that could be used to recreate an organism, may be deemed as CBI under existing statutory authorities.

Costs and Charges

Proposed § 340.8 would contain APHIS' requirements regarding costs and charges for the services of inspector, which are found in the current regulations in § 340.9. Currently, the section provides that the services of an inspector during regularly assigned hours of duty are provided free of charge, but that APHIS will not be responsible for any other costs or charges incident to inspections or compliance, apart from the services of this inspector. These provisions would remain unchanged in this proposed rule.

Miscellaneous

Because, as described above, we are proposing to eliminate the notification procedure from these regulations, we would also remove language pertaining to notifications from 7 CFR 372.5(c)(3)(iii). Because we are proposing to eliminate petitions for determinations of nonregulated status, we are also removing language pertaining to that process in paragraphs (b)(7) and (c)(4) of § 372.5. These changes would make those regulations consistent with the proposed ones contained in this document.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the revision of our regulations regarding the movement of certain GE organisms, APHIS has prepared a programmatic environmental impact statement (PEIS). The PEIS was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (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). The PEIS may be viewed on the *Regulations.gov* website or in our reading room. (A link to *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Executive Orders 12866, 13563, and 13771 and Regulatory Flexibility Act

This proposed 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. This proposed rule, if finalized as proposed, is expected to be an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the rule's economic analysis.

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). 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 an initial 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 by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the *Regulations.gov* website (see **ADDRESSES** above for instructions for accessing *Regulations.gov*).

We are proposing to revise our regulations regarding the movement of certain genetically engineered organisms in response to advances in genetic engineering and our understanding of the plant pest risk posed by them, thereby reducing regulatory burden for developers of organisms that are unlikely to pose plant pest risks. The proposed rule would provide a clear, predictable, and efficient regulatory pathway for innovators, facilitating the development of new and novel genetically engineered organisms that are unlikely to pose plant pest risks.

The proposed regulations would benefit developers, producers, and consumers of certain GE organisms, public and private research entities, and the Agency. There would not be any decrease in the level of protection provided against plant pest risks. The regulatory framework, including the regulatory status review process used to determine regulatory status of GE plants, established under the proposed rule would provide cost savings to the biotechnology industry and allow APHIS to allocate its resources more effectively than it can under the present regulations.

Under the proposed rule, APHIS regulatory oversight (through permitting) would not be required for GE plants that fall into an exempted category or have been assessed by means of a regulatory status review and found unlikely to pose plant pest risks. Direct regulatory costs to GE plant developers would be reduced for the development of GE plants for which permits are no longer necessary. Savings to the regulated community would 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 would be reduced or eliminated where 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, 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 proposed rule could range from $1.5 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 $538,000 to $924,000 ($730,600 on average). From 1993 through 2017, 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 12 in 1995. As the rule is expected to spur innovation, we expect the number of new organisms developed annually to increase over time. In particular, the proposed rule may provide impetus to the development of new horticultural varieties, where the costs of acquiring non-regulated status may have been high in the past relative to the potential market.

In the following estimate of impacts, we use average cost savings per GE plant developed and assume the annual number of new GE organisms developed under the proposed rule without APHIS permits would range from 5 (the current annual average of processed petitions) to 10 (twice this average). We further assume that about 20 percent of those new GE organisms would have required only APHIS oversight, and the remaining would still require FDA and/or EPA oversight. If 5 new GE plants are developed annually without APHIS permits (all with no APHIS permit, but 4 still with EPA and/or FDA evaluation), the annual savings would be $6.5 million.[13] 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 would be $13.0 million.[14]

There would be some new costs borne by regulated entities under the proposed rule pertaining to rule familiarization and recordkeeping. Annual recordkeeping costs are based on information collection categories in the paperwork burden section of the rule and are estimated would total about $714,000. About 1,100 distinct entities have applied for permits or notifications under part 340. APHIS estimates that those entities would spend about 8 hours becoming familiar with the provisions of this rule at a total one-time cost of about $576,000.

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 $9 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 those GE activities that would be affected by the proposed rule total about $3.5 million. These include compliance activities, inspection activities, AIR process activities, notification activities, permit activities, and petition activities. Under the proposed rule, APHIS' overall annual personnel costs of regulating GE organisms are not expected to change. While the volume of specific activities would change, the overall volume of regulatory activities, the general nature of those activities and level of skill necessary to perform those activities would not. There would be costs to APHIS of implementing the proposed rule, which would include outreach activities, developing guidance documents, training, and adjusting the current permit system. APHIS estimates that the public outreach, guidance and training would cost about $77,000. Requests for regulatory status and response letters under the proposed rule could be handled in a manner similar to the current AIR process outside the electronic permitting system without incurring new costs.

PMPIs are plants genetically engineered in order to produce pharmaceutical and industrial compounds. There is a likelihood that

[13] One × $3,560,245 = $3,560,245. Four × $730,600 = $2,922,400. $3,560,245 + $2,922,400 = $6,482,645.

[14] Two × $3,560,245 = $7,120,490. Eight × $730,600 = $5,844,800. $7,120,490 + $5,844,800 = $12,965,290.

most, if not all, GE PMPI-producing plants that are currently under APHIS permits could be determined to be not regulated under the provisions of the proposed regulations after a regulatory status review because they are unlikely to pose a plant pest risk. Thus, such plants could be grown outdoors without the need for permits and without APHIS oversight. Federal oversight of outdoor plantings of PMPI-producing plants could be necessary to prevent the unlawful introduction into the human or animal food supply of pharmaceutical or industrial PMPI products, even when the principal purpose of the plants is not for human or animal food use. APHIS estimates that current PMPI inspections cost roughly $26,000 in total annually or about $800 each on average. Assuming that oversight continues in the same manner as APHIS oversight, a similar government expenditure could be expected under any Federal PMPI oversight scenario.

PIPs are plants that are genetically engineered to produce plant-incorporated protectants, *i.e.,* pesticides. APHIS regulates those that are captured by our current regulations, *i.e.,* when plant pests are used. PIPs also fall under the regulatory oversight of EPA. However, currently only APHIS exercises regulatory oversight of PIP plantings on 10 acres or less of land. Many GE PIP-producing plants that are currently regulated under APHIS permits or notifications could be determined not regulated under the provisions of the proposed regulations after a regulatory status review because they are unlikely to pose plant pest risks. Thus, such plants could be grown outdoors without the need for an APHIS permit and without undergoing APHIS oversight. This proposal would shift Federal oversight of small-scale (10 or fewer acres) outdoor plantings of some PIPs to EPA. EPA may decide to require experimental use permits for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under permit. As described above, current inspection costs incurred by APHIS average roughly $800 per inspection.

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

GE crop varieties, in general, are not required to be reviewed or approved for safety by the FDA before going to market. However, the developer is responsible for ensuring product safety, and some developers consider voluntary consultations with FDA on food safety to be an absolute necessity for applicable GE products.[15] It would be in a GE plant developer's own best interest to maintain the same level of supervision and control over the development process as at present to prevent undesired cross-pollination or commingling with non-GE crops. Developers also have various legal, quality control and marketing motivations to maintain rigorous voluntary stewardship measures. APHIS therefore believes that developers would continue to utilize such measures for field testing even in cases where USDA would not require a permit.

Farmers who adopt GE crops may benefit from the proposed rule. The adoption of GE crops in the United States has generally reduced costs and improved profitability at the farm level. As mentioned, under the proposed rule, regulatory costs are expected to be lower, thereby potentially spurring developer innovation, especially among small companies and universities. Farmers may benefit by having access to a wider variety of traits as well as a greater number of new GE crop species, affording them a broader selection of crops to suit their particular management needs. 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.

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 otherwise would have 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 foregone benefits stemming from even a relatively brief delay in product release overshadow both research and regulatory costs. It should be noted that while the proposed rule would alter the evaluation process of GE plants for APHIS, it does not affect the evaluation by FDA or EPA, which operate under different authorities and evaluate for different endpoints, or international regulatory agencies, all of whom would have impact opportunity costs. When FDA and/or EPA also have a regulatory role, time savings would only be realized in those instances in which APHIS' process takes the longest time. When APHIS is the only agency with oversight, such as for some new horticultural varieties, there could be significant time savings over the current petition process.

Some farmers (*e.g.,* growers of organic and or identity-preserved crops) could be indirectly negatively impacted by these same innovations. Some consumers choose not to purchase products derived from GE crops and instead purchase commodities such as those labeled ''non-GMO (Genetically Modified Organism)'' or organic. In addition, the organic standard does not allow for the use of GE seeds. When crops intended for the non-GE or identity-preserved marketplace contain unintended GE products, the profitability of the non-GE or identity-preserved product may be diminished. Effects of the proposed 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 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. Unauthorized releases of regulated GE crop plants and the entry of regulated plant material in the commercial food and feed supply can have impacts on domestic or international markets. While such releases have occurred and may occur again, such incidents are expected to be rare.

Entities potentially affected by the proposed rule fall under various categories of the North American Industry Classification System. While economic data are not available on business size for some entities, 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 proposed rule would be small.

[15] *Genetically Engineered Crops: Past Experience and Future Prospects.* Committee on Genetically Engineered Crops: Past Experience and Future Prospects; Board on Agriculture and Natural Resources; Division on Earth and Life Studies; National Academies of Sciences, Engineering, and Medicine.

APHIS welcomes public comment on the proposed rule's possible impacts. The following table provides a summary statement of the expected direct costs and cost savings of the proposed rule:

TABLE 1—EXPECTED COSTS AND COSTS SAVINGS OF THE PROPOSED RULE FOR THE BIOTECHNOLOGY INDUSTRY AND FOR USDA, 2016 DOLLARS

Entity:			
Biotechnology Industry Developer costs (recordkeeping and rule familiarization) [1]	Costs ($1,000). 1,290.		
	Cost savings *per Trait* ($1,000)		
Developer Savings [2]		Proposed Rule, lower bound	Proposed Rule, upper bound
USDA sole regulatory agency USDA with FDA and/or EPA oversight		−1,546 −538	−5,574 −924
APHIS Biotechnology Regulatory Services Costs for public outreach, training, and e-permitting [3]	Costs ($1,000). 77.		

[1] Costs of rule familiarization, one-time costs, would total about $576,000. Annual recordkeeping costs would total about $714,000.

[2] These savings are shown on a per trait basis. On average, if 5 new GE organisms are developed annually without USDA permits (all with no USDA permit, but 4 still with EPA and/or FDA evaluation), the annual savings would be $6.5 million. If 10 new GE organisms are developed annually without USDA permits (all with no USDA permit, but 8 still with EPA and/or FDA evaluation), the annual savings would be $13.0 million.

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

As shown in the economic analysis accompanying this proposed rule, we have some data pertaining to the potential effects of this proposed rule on small entities; however, we do not currently have all of the data necessary for a comprehensive analysis of those potential effects. Therefore, we are inviting comments on the potential effects. In particular, we are interested in additional information on the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

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 proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

The Animal and Plant Health Inspection Service has assessed the impact of this rule on Indian Tribes. APHIS sent a letter to Tribal leaders upon publication of a notice of intent to conduct a programmatic environmental impact statement in support of the proposed rule. In addition, APHIS held a conference call for Tribal leaders to provide information and answer questions regarding our plan to publish a proposed rule.

In an email dated December 21, 2018, one California Tribe contacted APHIS requesting consultation on the proposed rule. This request has led USDA's Office of Tribal Relations (OTR) to determine that the rule has potential tribal implications that require continued outreach efforts to determine if tribal consultation under Executive Order 13175 is required. As of February 2019, APHIS is following up with that Tribe to determine whether formal consultation is warranted or needed. If this or another tribe requests formal 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.*), reporting and recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send comments on the Information Collection Request (ICR) to OMB's Office of Information and Regulatory Affairs via email to *oira_submissions@omb.eop.gov,* Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2018–0034. Please send a copy of your comments to the USDA using one of the methods described under **ADDRESSES** at the beginning of this document.

We are proposing to revise our regulations regarding the movement (importation, interstate movement, and environmental release) of certain GE organisms. The proposed revisions include, but are not limited to, the following new information collection activities: Requests for confirmation from APHIS of developers' self-determinations that the GE plant is not within the scope of part 340, procedures for permits and record reporting, marking and labeling of organisms under permit, State and Tribal regulatory officials' review of permit applications, regulatory status reviews, and recordkeeping. In addition, the proposed revisions would remove the current petition process for

nonregulated status and associated burdens.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses).

Estimate of burden: Public burden for this collection of information is estimated to average 17.73 hours per response.

Respondents: Businesses and State and Tribal regulatory officials.

Estimated annual number of respondents: 321.

Estimated annual number of responses per respondent: 3.

Estimated annual number of responses: 1,097.

Estimated total annual burden on respondents: 19,453 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

A copy of the information collection may be viewed on the *Regulations.gov* website or in our reading room. (A link to *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) Copies can also be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483. APHIS will respond to any ICR-related comments in the final rule. All comments will also become a matter of public record.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the EGovernment 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 proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

List of Subjects

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 proposing to amend 7 CFR parts 340 and 372 as follows:

■ 1. 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 genetically engineered (GE) organisms described in § 340.2.

(b) The regulations in this part do not apply to plants modified such that they belong to one of the categories listed below:

(1) The genetic modification is solely a deletion of any size; or

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

(3) The genetic modification is solely introducing nucleic acid sequences from within the plant's natural gene pool or from editing of nucleic acid sequences in a plant to correspond to a sequence known to occur in that plant's natural gene pool; or

(4) The plant is an offspring of a GE plant that does not retain the genetic modification in the parent.

(c) The regulations in this part do not apply to a GE plant-trait-mechanism of action 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.

(d) Developers may request confirmation from APHIS that the plant is not within the scope of this part.

§ 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

(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.

§ 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 ensure compliance with all conditions contained in any applicable permit 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.

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

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.

Genetic engineering (GE). Techniques that use recombinant or synthetic 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 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, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Mechanism of action. 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 possibility of harm to plants resulting from introducing or disseminating a plant pest or exacerbating the impact of a plant pest.

Plant product. Any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of plant or 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 a GE organism outside the physical constraints of a contained facility.

Responsible person. The person responsible for maintaining control over a GE organism under permit during its movement and ensuring compliance with all conditions contained in any applicable permit as well as other requirements in this part. A responsible person may be, but is not limited to, the signatory of a permit, or the institution the signatory represents at the time of application. A responsible person must be at least 18 years of age and 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, the Virgin Islands of the United States, or 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 an Agency regulatory status review of whether a GE plant is subject to the regulations in this part, based on its plant-trait-mechanism of action combination.

(2) Any person may request re-review of a GE plant previously found to be subject to this part, 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 this paragraph. Additional guidance on how to meet these requirements may be found on the APHIS website.

(i) A description of the comparator plant, 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.

(b)(1) When APHIS receives a request for a regulatory status review of a GE plant, the Agency 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 that of the plant pest risk posed by their respective non-GE or other appropriate comparator(s), based on the following factors:

(i) The biology of the comparator plant 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) If the Agency is unable to identify potential plant pest risks in the initial review, the GE plant will not be subject to the regulations in this part, and APHIS will post the finding on its website.

(3)(i) If the Agency does identify potential plant pest risks in the initial review, APHIS will conduct a more robust evaluation of the factor(s) of concern to determine the likelihood and consequence of the potential plant pest risk posed by the GE plant.

(ii) APHIS will make available information on the results of both the initial review and one conducted pursuant to this paragraph in a notice in the **Federal Register** and will take comments on its findings from the public. After reviewing the comments, APHIS will make a final determination regarding the regulatory status of the GE plant and announce that determination in a subsequent **Federal Register** notice.

(iii) If the GE plant is found unlikely to pose a plant pest risk and, therefore, not to require regulation under this part, APHIS will post the finding on its website.

(iv) If APHIS is unable to find the GE plant unlikely to pose a pest risk it will require regulation under this part and its movement will be allowed only under permit in accordance with § 340.5.

(c) APHIS will maintain on its website information on all requests for and results of regulatory status reviews.

§ 340.5 Permits.

(a) *Permit issuance.* A permit must be issued by APHIS for the movement of all GE organisms subject to the regulations under this part.

(b) *Permit application requirements and permitting exemptions.* The responsible person must apply for and obtain a permit through a method listed on APHIS' website. The application must also include the following information:

(1) *General information requirements.* All permit applications must include the name, title, and contact information of the responsible person and agent; the country and locality where the organism was collected, developed, manufactured, reared, cultivated, or cultured; 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.

(2) *Permits for interstate movement or importation.* Applications for permits for interstate movement or importation of GE organisms must meet the requirements of paragraph (b)(1) of this section and 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 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) *Permits for release into the environment.* Applications for permits for release of GE organisms into the environment must meet the requirements of paragraph (b)(1) of this section and include information on the size of all proposed environmental release sites, including area, geographic 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 continue the practice of evaluating and amending permits to add new release sites.

(4) *Additional information.* APHIS will require additional information as needed.

(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 cloned genetic material is stably integrated into the plant genome, and the cloned material does not include the complete infectious genome of a plant pest.

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

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

(f) *Administrative actions*—(1) *Review of permit applications.* APHIS will review the permit application to determine if 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 in accordance with paragraph (h) of this section.

(2) *APHIS assignment of permit conditions.* If a permit application is approved, the Administrator will issue a permit with conditions as described in paragraph (g) 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.

(g) *Permit conditions.* The standard conditions listed in this paragraph 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. The responsible person, and his or her agents, must ensure compliance with

these conditions, as well as any supplemental conditions listed in the permit:

(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 only be done 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 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 (photocopying, digital reproduction, etc.). The responsible person must submit reports and notices to APHIS at the times specified in the permit and containing the information specified within 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.

(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 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.

(h) *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 the denial and the reasons for it in writing as promptly as circumstances allow. The Administrator may deny a permit application if:

(i) The Administrator concludes that, based on the application or on additional information, 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 at any time with any provision of this part, any permit that has previously been issued in accordance with this part or any other regulations issued pursuant to the Plant Protection Act, 7 U.S.C. 7701 *et seq.;*

(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 (f)(2) of this section, to comply with the permit conditions or, in accordance with paragraph (f)(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 the withdrawal and the reasons for it in writing as promptly as circumstances allow. The Administrator may withdraw a permit if:

(i) Following issuance of the permit, the Administrator receives information that would otherwise have provided grounds for APHIS to deny the 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 provision of this part or 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.

(i) *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. 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.

(j) *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, he or she 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 may amend the permit if only minor changes are necessary. Requests for more substantive changes may 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. 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.

(k) *Shipping under a permit.* (1) All shipments of organisms under permit must be secure shipments. Organisms under permit must also 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 and locality where collected, developed, manufactured, reared, cultivated, or cultured; 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 packing material, shipping containers, and any other material accompanying the organism must be treated or disposed of in such a manner so as to prevent its unauthorized dissemination and establishment in the environment.

§ 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(g);

(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 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 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(h);

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

(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.

§ 340.7 Confidential business information.

Persons including confidential business information 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 is commercial or financial information and 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 without cost.[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.

PART 372—NATIONAL ENVIRONMENTAL POLICY ACT IMPLEMENTING PROCEDURES

■ 2. 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]

■ 3. 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 30th day of May 2019.

Greg Ibach,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2019–11704 Filed 6–5–19; 8:45 am]

BILLING CODE 3410–34–P

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