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Animal and Plant Health Inspection Service

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Regulatory Impact Analysis and Final Regulatory Flexibility Analysis

Final Rule
APHIS 2018-0034
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Movement of Certain Genetically Engineered Organisms (7 CFR part 340)

Policy & Program Development

Policy Analysis & Development

Summary

Under the Plant Protection Act (PPA, 7 USC 7701-7772), the Secretary of Agriculture is authorized to regulate the movement into and through the United States of plants, plant products, and other articles to prevent the introduction or dissemination of plant pests. As one part of its implementation of the PPA, APHIS regulates the safe introduction (environmental release, interstate movement, and importation) of certain genetically engineered (GE) organisms that might be plant pests (7 CFR part 340). APHIS is revising its regulations of GE organisms to respond to emerging trends in genetic engineering, to more efficiently use APHIS resources, and eliminate unnecessary regulatory burdens.

The revisions to 7 CFR part 340 create the framework for more focused, risk-based regulation of the GE organisms that pose plant pest risk. Under this rule, certain categories of plants are exempted from the regulations in part 340. Developers are able to determine, when appropriate, whether their products fit into one of the exempted categories and are therefore not subject to APHIS' regulations.

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

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

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

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

Cost savings for these entities are expected to more than offset the new costs. APHIS estimated the cost savings for two regulatory oversight scenarios where USDA either has sole

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

In the following estimate of impacts, we use the average cost savings reported above per GE plant developed and assume the annual number of new GE plants developed under the rule without APHIS permits ranges from 5 (the current annual average number of processed petitions) to 10 (twice this average). We further assume that about 20 percent of those new GE plants are solely within the purview of APHIS oversight, and that the remaining 80 percent will also be under the purview of FDA and/or EPA oversight. If 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.[1] If 10 new GE plants are developed

[1] One x $3,573,500 = $3,573,500. Four x $744,000 = $2,976,000. $3,573,000 + $2,976,000 = $6,549,500.

annually without APHIS permits (all with no APHIS permit, but 8 still with EPA and/or FDA evaluation), the annual savings would be $13.1 million.[2]

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

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

[2] Two x $3,573,500 = $7,147,000. Eight x $744,000 = $5,952,000. $7,147,000 + $5,952,000 = $13,099,000.

$13,000 to $671,000, depending on recordkeeping, reporting, stewardship and testing requirements.[3]

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

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

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

Certain plants are genetically engineered in order to produce pharmaceutical and industrial compounds, also known as plant-made pharmaceuticals and industrials (PMPIs). To

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

date, PMPI-producing GE plants regulated by APHIS have been genetically engineered using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current regulations in 7 CFR part 340. In this rule, APHIS will maintain its oversight of PMPI-producing plants. In this final rule, we are adding this requirement to §340.2, as a paragraph (e) which states that a permit is required for the movement of a plant that encodes a product intended for pharmaceutical or industrial use.

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

A quicker APHIS evaluation process will mean a shorter period of regulatory uncertainty that may facilitate developers' ability to raise venture capital. Reduced regulatory requirements may also lead to greater participation by public and private academic institutions in GE research and product development. These indirect benefits of the rule may spur GE innovations,

particularly in small acreage crops where genetic engineering has not been widely utilized due to the expense of regulation.

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

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

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

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

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

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

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

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

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

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

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

Table A. Expected Costs and Costs Savings of the Rule for the Biotechnology Industry and for APHIS, 2016 dollars

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

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

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

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

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Introduction

Under the Plant Protection Act (PPA, 7 USC 7701-7772), the Secretary of Agriculture is authorized to regulate the movement into and through the United States of plants, plant products, and other articles to prevent the introduction or dissemination of plant pests. As one part of its implementation of the PPA, USDA's Animal and Plant Health Inspection Service (APHIS) administers 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." These regulations govern the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered (GE) organisms. APHIS is revising these regulations in response to advances in genetic engineering and our understanding of the plant pest risk posed by certain GE organisms, thereby reducing regulatory burden for developers of organisms that are unlikely to pose plant pest risks. This rule marks the first comprehensive revision of the regulations since they were established in 1987.

Under this rule, certain categories of plants are exempted from the regulations in part 340. Developers are able to determine, when appropriate, whether their products fit into one of the exempted categories and are therefore not subject to APHIS' regulations. This rule also provides for a process to determine the regulatory status of a plant under part 340. GE plants having the same plant-trait-mechanism of action (MOA) combination as those previously found by APHIS to be not subject to the regulations will not be regulated, nor will they be required to undergo a regulatory status review (RSR). GE organisms found likely to pose a plant pest risk and GE plants that are not eligible for an RSR, will be allowed to move only under permit. For plants that do not fall into any of the exempted categories and are eligible for an RSR, developers will have the option of either requesting a review or requesting a permit for the importation,

interstate movement, or environmental release of their GE plants in lieu of an RSR. Developers of GE organisms that are plant pests will continue to need permits to import, move interstate, or environmentally release those organisms.

The framework in this rule provides 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. The revised regulatory framework codifies in the regulations, via rulemaking, the Secretary of Agriculture's March 28, 2018, statement that provided clarification on APHIS' oversight of plants produced through plant breeding innovations. The framework is also consistent with OIG recommendations, requirements of preexisting Farm Bill statutory language, and with the guiding principle of the Coordinated Framework for Regulation of Biotechnology.

This document provides a benefit-cost analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity considerations). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This document also examines the potential economic effects of the rule on small entities, as required by the Regulatory Flexibility Act, and addresses the Executive Order 13771 requirement to provide the agency's best approximation of the total costs or savings associated with each new regulation or repealed regulation.

Background

Modern Plant Breeding

Conventional plant breeding methods include cross- and selective-breeding to develop new varieties with specific desirable characteristics. (The term "conventional breeding" may generally be used interchangeably with "traditional breeding." In the June 2019 proposed rule, APHIS used both terms, with "traditional breeding" appearing more frequently in the text. Based in part on dialogue with other agencies involved in regulating biotechnology, we have elected to use the term "conventional breeding" throughout this document, except when the need to quote directly indicates otherwise. For purposes of this document, "conventional breeding" has the meaning it is understood to have within the context of part 340, based on the examples provided in the final rule. Other Federal or State regulations may use the term "conventional breeding" in the context of their regulations and attribute slightly different meanings.) Selective breeding involves choosing traits with desired characteristics and propagating them repeatedly over several generations. Because the genes that contribute special characteristics are not explicitly identified in most cases, the desired characteristic is usually achieved through time-consuming trial and error. The most notable limitation of this method is that two species can be cross-bred only if they are closely related (Subramaniam and Reed 2015). Conventional breeding also uses chemical and radiation mutagenesis to introduce variation that increases the desirable characteristics that can be selected. Thousands of varieties have been created using mutagenesis, and these varieties are not excluded from use in organic and non-GE production systems (Joint FAO/IAEA Mutant Variety Database https://mvd.iaea.org/; 7 CFR part 205.2).

Modern gene technologies in conjunction with deeper understanding of gene function allow scientists to identify specific genes associated with desirable characteristics and to create valuable new phenotypes in GE organisms.[4] These technologies accelerated development of new transgenic products in many fields, including the pharmaceutical, manufacturing, and agricultural sectors. In the agricultural sector, plants have been developed that are resistant to pests and disease, fruits and vegetables have been developed with increased shelf life, and plants have been developed with increased productivity, altered nutritive values, and other characteristics (Subramaniam and Reed 2015).

It has been more than 20 years since GE varieties with pest management traits first became commercially available for major crops in the United States. Adoption rates for GE crops increased rapidly following their commercial introduction in 1996. Soybeans and cotton have been among the most widely adopted GE crops in the United States, followed by corn (USDA-ERS 2018). The area of GE crops planted in 2017 in the United States was the highest globally at 185.4 million acres; the average adoption rate for GE soybeans, corn and canola is 94.5 percent (ISAAA 2017). In 2017, soybeans valued at $41 billion were harvested from 90.1 million planted acres, of which 92 percent were in GE varieties (USDA–NASS 2019). The harvested value of corn was $48.6 billion from 90.2 million planted acres with 94 percent in GE varieties in 2017 (USDA–NASS 2019). There was $7.2 billion in cotton harvested in 2017 on 11.1 million planted acres, $1.5 billion in sugar beets produced on 1.2 million planted acres in 2016, $532.7 million in canola produced on 2 million planted acres, and $11.7 million in papayas produced from 1,500 planted acres in 2017 (USDA–NASS 2019). Most if not all of the planted

[4] Phenotype is the set of observable characteristics of an individual resulting from the interaction of its genotype (DNA) with the environment.

acres in these crops were GE varieties (ISAAA 2017). There were also $4 billion in potatoes produced on 1 million planted acres, $3.1 billion in apples produced from 323,000 bearing acres, $178.5 million in squash produced from 35,500 planted acres, and $50 million in alfalfa produced from 12.4 million harvested acres in 2017 (USDA–NASS 2019). About 0.7 percent of the potato acres, 0.6 percent of the apple acres, 5.6 percent of the squash acres, and 24.2 percent of the alfalfa acres were in GE varieties (ISAAA 2017). Planting of GE crops increased by 68 percent between 2000 and 2005, and by another 45 percent between 2005 and 2013 (Fernandez-Cornejo, *et al*. 2014).

On a global scale, approximately 470 million acres of GE crops were planted in 24 countries in 2017, an increase of nearly 112-fold since 1996. Soybeans, maize (corn), cotton, and canola are the major GE crops worldwide. Based on the global crop area for individual crops, 77 percent of soybeans, 80 percent of cotton, 32 percent of corn and 30 percent of canola were GE crops in 2017. U.S. acreage accounted for approximately 40 percent of the planted area; Brazil, 26 percent; Argentina, 12 percent; Canada, 7 percent; and India, 6 percent. (ISAAA 2017).

U.S. Regulation of Agricultural Genetic Engineering

The Federal government has a coordinated, risk-based system to ensure that new GE organisms and/or products are safe for the environment and human and animal health. Established as a formal policy in 1986, the Coordinated Framework for Regulation of Biotechnology describes the policy of the Federal agencies involved with the review of GE products. The Coordinated Framework is based upon existing laws designed to protect public health and the environment. Under the Coordinated Framework, Federal regulatory policy to ensure the safety of GE products is carried out by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA). Products

are regulated according to their nature, characteristics, and application, with some products regulated by more than one agency for complementary non-duplicative purposes.

EPA uses a registration process to regulate the sale, distribution, and use of pesticides in order to protect health and the environment, regardless of how the pesticide was made or its mode of action. This includes regulation of pesticides produced by an organism through genetic engineering. FDA is responsible for ensuring the safety of human and animal foods, including those produced using genetic engineering. FDA encourages developers of new plant varieties to participate in its voluntary consultation process to ensure that human and animal food safety and related regulatory issues for a new plant variety are resolved prior to commercial distribution. A recent amendment to the Agricultural Marketing Act of 1946 requires the Secretary of Agriculture to establish a national mandatory bioengineered (BE) food disclosure standard. On December 21, 2018, USDA's Agricultural Marketing Service (AMS) published a final rule that requires food manufacturers and other entities that label foods for retail sale to disclose information about BE food and BE food ingredient content.[5]

USDA APHIS is responsible for protecting U.S. agriculture against threats from pests and diseases. The Secretary of Agriculture's authority under the PPA to restrict importation, interstate movement, and release into the environment of plants, plant products, biological control organisms, or other articles when necessary, to prevent the dissemination of plant pests, includes GE organisms that may pose plant pest risk.

APHIS regulates the introduction of GE organisms as set forth 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." These regulations

[5] https://www.ams.usda.gov/rules-regulations/be

govern the introduction (importation, interstate movement, or release into the environment) of certain GE organisms. Under APHIS' current regulations, a GE organism is considered to be a regulated article if the donor organism, recipient organism, vector, or vector agent[6] is a plant pest or if the Administrator has reason to believe the GE organism is a plant pest. For the introduction to take place, as defined above, of a GE organism that is a regulated article, a permit must be issued, or the introduction must occur under an acknowledged notification (collectively known as "authorizations"). For both permits and notifications, applicants provide information on the organism, the proposed activity, and the proposed starting dates of the activity.

The introduction of regulated articles may be authorized under permit, under which developers must 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 of all packing material, shipping containers, and any other material accompanying the regulated article to prevent the dissemination and establishment of plant pests.

The notification procedure is an administratively streamlined alternative to the permitting process for certain GE plants. For authorizations under notification, the regulations contain performance-based standards applicable to shipping, environmental release, and field trials of GE organisms. These standards are aimed at preventing the unwanted dissemination of such

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

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.

As of July 2018, APHIS had 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 (table 1). Additionally, APHIS had 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 had denied slightly more than 1,600 requests for authorizations, many of which were denied because APHIS ultimately decided that the requests lacked sufficient information on which to base an Agency decision. Release authorizations allowed plantings at more than 125,000 sites.

In addition to issuing permits and acknowledging notifications, APHIS has responded to petitions requesting non-regulated status under these regulations. Under the petition procedure, which is described in § 340.6, any person may submit a petition to APHIS seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of current § 340.6 describe the form that a petition for a determination of non-regulated status must take and the detailed information and scientific data needed to support the petition.

Environmental Releases

Most authorized field trials have involved major crop plants. For example, from 1988 through September 2019, GE corn was approved for 8,980 field releases; GE soybeans for 2,711 field releases; GE cotton for 1,264 field releases; and GE potatoes for 989 releases. In terms of GE traits, the majority of the applications approved have been for herbicide tolerance (23%), followed by agronomic properties such as drought resistance (21%), product quality

(17%), insect resistance (16%), "other" traits (8%), marker gene (7%), virus resistance (4%), and fungal resistance (4%).[7]

While the annual number of approved crop releases has declined from a high of 1,194 in 2002, the number of associated phenotypic designations[8] reached a high of 50,963 in 2013 (table 1). A single permit or notification can include many sites and authorize many different phenotypic designations to be tested at each site. Authorizations have been for acreages ranging from 0.001 up to 100,000 acres. An authorized field trial may have one site or multiple sites. The median size of an authorized field trial site is approximately 5 acres, and average size is about 20 acres. Some field trials, particularly for corn, soybean, cotton, rice, and potato, can range from several hundred to a few thousand acres in size. While APHIS authorizes a specific amount of acreage and the number of sites for field testing of GE organisms, not all field tests are actually conducted. The acreage utilized for field tests is commonly less than that authorized under the notification or permit. Field trials are typically smaller during the research and development phases and increase in size when seed production is expanded in anticipation of commercialization. Authorization requests are typically submitted months in advance of planting in anticipation of research and development needs.

[7] Compiled from Virginia State and Polytechnic University data: http://www.isb.vt.edu/search.aspx?CommandName=search&searchterm=environmental+releases&sort=relevance

[8] A phenotypic designation or gene construct is the functional unit necessary for the transfer or the expression of a gene of interest. Apart from the gene of interest, itself, a so-called promoter ("starter") and a terminator ("stop signal") are required for expression. In most cases, additional sequences are included, e.g. marker genes, which are also accompanied by a promoter and a terminator. The name "construct" is used because the sequences normally do not exist in this combination, but must be "put together". (http://www.gmo-safety.eu/glossary.html)

Table 1: Number of Releases, Sites, Acres and Phenotypic Designations authorized by APHIS, 1987-2019

Year	Releases	Release Sites [1]	Acres [1]	Phenotypic Designations
1987	11	---	---	5
1988	16	---	---	16
1989	30	---	---	30
1990	51	---	---	50
1991	90	---	---	89
1992	160	---	---	160
1993	301	508	948	306
1994	579	1,731	8,117	585
1995	711	3,683	62,394	710
1996	612	2,742	7,084	604
1997	763	3,474	23,817	761
1998	1,071	5,099	89,620	1,075
1999	983	3,973	56,959	1,005
2000	925	3,708	40,199	904
2001	1,083	5,765	54,195	1,083
2002	1,194	5,130	139,023	1,191
2003	813	2,976	24,713	810
2004	893	4,421	58,809	891
2005	955	4,961	99,510	956
2006	865	4,256	84,061	2,149
2007	932	3,605	45,931	4,920
2008	871	7,878	182,964	8,581
2009	751	6,724	166,315	16,650
2010	660	6,683	139,517	30,770
2011	792	10,384	235,226	35,186
2012	665	8,652	374,338	38,795
2013	602	10,725	368,384	50,963
2014	557	10,561	365,089	39,382
2015	467	8,274	447,631	46,214
2016	453	5,019	234,492	37,505
2017	379	3,799	152,417	35,659
2018	382	4,481	246,481	37,744
2019[2]	330	3,196	173,484	24,342

[1] Records of the release sites and authorized planting acreages prior to 1993 are not complete and are not included here.

[2] Through September 2019.

Releases, Importations, and Interstate Movements

APHIS regulates the movement into and through the United States of plants, plant products, and other articles to prevent the introduction or dissemination of plant pests. In FY 2017, there were 47 import permits, 149 interstate movement permits, and 139 release or interstate movement and release permits issued for GE organisms. There were also 116 import

notifications, 306 interstate movement notifications, and 240 release or interstate movement and release notifications for GE organisms acknowledged in 2017.

Overview of the Action and affected Entities

Consistent with its authorities under the PPA, APHIS regulates GE organisms that pose plant pest risk. These regulations are contained in 7 CFR part 340. As described, APHIS currently requires issuance of a permit or authorization of a notification for the importation, interstate movement, or environmental release of organisms regulated under part 340. A developer can petition APHIS to grant non-regulated status to a particular GE organism. If such status is granted, the GE organism can be moved or released into the environment without permit or notification. APHIS' determination of non-regulated status applies to both the GE plant and its progeny; the GE plant can be used in plant breeding programs and in agriculture without further oversight from APHIS. As of December 2018, APHIS has granted non-regulated status for GE plants 130 times since the inception of the program. Many of these GE plants have been commercialized and are available to U.S. growers.

While the current regulations have been effective in ensuring the safe introduction of GE organisms during the past 30 years, advances in genetic engineering make it necessary for us to revise the regulations in accordance with a regulatory framework that will provide a clear, predictable, and efficient regulatory pathway for innovators while facilitating the development of new and novel GE organisms that are unlikely to pose a plant pest risk.

The rule streamlines APHIS' GE regulatory process by, among other things, exempting certain organisms from the regulations and changing the way we evaluate GE organisms for plant pest risk. While the rule will relieve regulatory burden on developers and spur innovation, it will not diminish the protection against plant pest risk that the current regulations provide.

Under this rule, certain categories of plants are exempted from the regulations in part 340 because they could be produced through conventional breeding techniques and thus are unlikely to pose a greater plant pest risk than conventionally bred crops, which APHIS has historically not regulated. Additionally, those specific plants that we have assessed under the existing regulations or that will be reviewed under the RSR procedure and are have been found to be unlikely to pose a plant pest risk will be exempted from further regulation. Developers will be able to determine, when appropriate, whether their plants fit into one of the exempted categories.

A developer who determines that his or her plant belongs to an exempted category has the option to request written confirmation from APHIS that the determination is valid. These confirmation letters, which will provide a clear and succinct statement about the regulatory applicability of the organism, 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 determinations. Under this rule, APHIS will provide a written response within 120 days of receiving a sufficiently detailed confirmation request. A developer making a determination that APHIS finds to be not valid may be subject to remedial measures or penalties if the organism is moved without proper authorization under this part.

A GE organism is subject to regulation if it is a plant that has not been evaluated for plant pest risk; or an organism that meets the definition of plant pest; or is not a plant but has received DNA from a plant pest, and the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound that is expected to cause plant disease symptoms; or is determined by the Administrator likely to pose a plant pest risk. Such a GE organism requires a permit for movement (importation, interstate movement, or release into the environment). In the case of GE plants that are voluntarily subjected to

permitting requirements for field release without a request for RSR, developers may request such a review anytime.

This rule provides for a new process, under which a GE plant will be evaluated for plant pest risk to determine the regulatory status of the organism under part 340. Plant pest risk will be evaluated based on a consideration of the plant-trait-MOA combination that produced the modified organism. We define *plant pest risk* as "the potential for direct or indirect injury, damage, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest." We define *mechanism of action (MOA)* in this rule as the "biochemical process(es) through which genetic material determines a trait" and *trait* to mean "the observable (able to be seen or otherwise identified) characteristic of an organism." It is necessary to consider these elements because, singly or in combination, they may affect plant pest risk. If the results of the RSR indicate that the GE organism is unlikely to pose a plant pest risk, it can be moved without restriction under part 340. If we are not able to reach such a determination, the organism requires a permit to be moved.

Under the RSR, permitting for movement requirements will be based on the characteristics of the organism itself or the types of genetic modification it contains rather than on an evaluation of the method by which the organism is genetically engineered. The current petition process stems from the manner in which *regulated article* is defined. Based on the change in approach, the petition process has been removed from the regulations with this rule.

Previously, the 'Am I Regulated' (AIR) process allowed a biotechnology developer who is not sure whether his or her GE organism falls under our regulations to ask us to evaluate whether the GE organism meets our definition of a regulated article prior to conducting a regulated activity. This process is not codified in the existing regulations, however. We believe

that the RSR process will be more efficient than the existing processes, which can be slow and cumbersome depending on the GE organism under consideration and the amount and type of information that must be submitted to enable APHIS to make its determination.

In addition to the new definitions of *plant pest risk*, *trait* and *MOA*, as described above, this rule retains certain definitions currently found in § 340.1 of the regulations, changes other definitions, adds new ones, and removes others.

Some definitions were altered for consistency with the PPA or to reflect the scope of this regulatory framework. In particular, the definition of *genetic engineering* will be clearer than the existing definition, which, for example, refers to modification using "recombinant DNA techniques," a term that is not defined in the regulations. The previous definition could also have been construed, contrary to our intentions, to exclude the use of synthetic DNA and all genome editing, among other things. We will continue to exclude from the definition of *genetic engineering* conventional breeding techniques or chemical or radiation-based mutagenesis. APHIS does so because the Agency has never considered such techniques to constitute genetic engineering. Accordingly, organisms created through such techniques were previously excluded from regulation under part 340, and will continue to be excluded.

Among the terms removed from the regulations under this rule, the most significant is *regulated article*. APHIS previously used this term to refer to organisms that fell within the scope of part 340. A GE organism was considered to be a regulated article under the previous definition if the donor, vector, or vector agent was a plant pest or sequences from a plant pest. However, GE techniques 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.

Therefore, the definition was outdated. This rule specifies the organisms that are subject to the regulation in § 340.1 instead of using *regulated article*.

This rule eliminates the notification procedure and requires permits with specific conditions for movement of all GE organisms that are subject to the regulations. During the first six years of APHIS' regulation of GE organisms (1987 to 1992), all field trials of GE plants were authorized through APHIS' permit process. APHIS introduced the notification process in 1993, initially for six crops (corn, soy, cotton, potato, tobacco, tomato). Importation, interstate movement, or environmental release could be authorized through notification by finding that six eligibility requirements were met, as described in § 340.3(b) and six performance standards could be met, as described in § 340.3(c).

APHIS favors regulation through permitting rather than notification because issuance of permits allows for the application of specific permit conditions. Permitting allows for increased monitoring of the environment and additional reporting during and after plantings to reduce the likelihood of incidents where unauthorized GE organisms persist in the environment.
We have made a number of changes to the permitting requirements. These changes apply to the application process; permit conditions; permit denial, revocation, and amendment; and shipping under permit.

While many of the permit conditions in this rule are drawn from the previous regulations, with details sometimes added to clarify their meaning, we made some substantive changes as well. Under the previous regulations, notifications for environmental release and interstate movement were valid for 1 year. However, it often takes considerably longer than 1 year for activities authorized under a permit to be completed. This rule eliminates time limits for permits. Instead, the period for which a permit is valid will be specified on the permit itself. APHIS will

work with the developer to ensure that the length of time is appropriate. APHIS will have the flexibility to issue permits for periods of time suitable to meet individual circumstances.

This rule also makes explicit APHIS' authority to deny or revoke a permit or to amend permit conditions, either at the request of the permittee or upon the Agency's own initiative. In the previous regulations, the administrative practices that APHIS used to amend permits were not stated explicitly. Adding them to the regulations will provide increased transparency and efficiency. We are also adding provisions for appealing a denial or revocation of a permit.

Under this rule, APHIS will no longer issue courtesy permits. APHIS previously issued courtesy permits for items that were not covered under part 340, in order to facilitate the movement of organisms that are outside the scope of these regulations, but whose movement might otherwise be hindered because of their similarity to regulated organisms. While courtesy permits were useful to show that the shipments in question were not regulated, their use led to widespread misunderstanding by some researchers that a courtesy permit removes the requirement for applicants to follow all applicable regulations, including the plant pest regulations found in 7 CFR part 330.

The previous requirements for the shipping of regulated articles were very prescriptive. While they did allow a responsible person to request variances from the requirements, this request process, by its nature, resulted in a case-by-case determination of whether other types of containers were acceptable for the transportation of the organism. The process could be onerous and also did not clearly reflect the performance-based standard that APHIS used to develop the requirements, namely, that the container should be sufficient to prevent dissemination of a GE organism during movement under permit. We are amending the shipping requirements to reflect that standard, thus allowing for greater flexibility in meeting safeguarding objectives, while

maintaining proper identification and containment of GE organisms during shipment. This revision is expected to yield modest benefits for the regulated community.

APHIS is consolidating recordkeeping, compliance, and enforcement requirements in 7 CFR part 340 into a new § 340.5. This rule also changes recordkeeping requirements to ensure that APHIS has sufficient information to monitor compliance with its regulations and maintain effective oversight of regulated GE organisms, in accordance with provisions of the 2008 Farm Bill and recommendations of the 2015 USDA OIG report on GE organisms.

The records required to be maintained under this rule are necessary for effective enforcement of the regulations. The maintenance and retention of these records should not significantly affect permit holders. While some of the specific records required under this rule were not explicitly included in the previous regulations, they have been required as part of the supplemental permit conditions that accompany an issued permit. These records include reports and notices such as volunteer monitoring reports, pre-planting notices, and flowering notices. These records are integral to the activities under the permit and should already be maintained by the permit holder as a normal part of business operations and therefore readily be accessible.

APHIS is also increasing the length of time required for the responsible person's retention of records. Previously, the required length of time was 1 year. APHIS will require under this rule that records indicating that a regulated organism was imported or moved interstate and reached its intended destination be retained by the responsible person for at least 2 years after completion of the importation or interstate movement. We are also requiring that all other records be retained for 5 years following permit expiration unless determined otherwise by the Administrator and indicated in supplemental permit conditions or other regulatory requirements.

This change is not expected to significantly impact permit holders. The requirements are not increasing the type of records that must be maintained, just how long those records must be kept. As one commenter on the proposed rule noted, the five-year timeframe in this rule is commensurate with the length of time other types of records are stored. Thus, record retention should not create an undue burden. And as another commenter noted, any responsible developer will generate and maintain records relating to a permit not only to comply with regulatory obligations, but also for stewardship purposes.

This new section of the regulations also clarifies what locations and articles may be subject to inspection. These changes should have, at most, a minor impact on permit holders. The clarifications are functionally the same as previous inspection requirements.

Finally, we are consolidating existing confidential business information requirements contained in various places in part 340 into a single section, § 340.6, and incorporating the existing provisions pertaining to costs and charges for an inspector's services into § 340.7.

The amendments in this rule will benefit developers, producers, and consumers of certain GE organisms; public and private research entities; and the Agency. There will not be any decrease in the level of protection provided against plant pest risks. The regulatory framework, including the RSR process used to determine regulatory status, established under the this rule will provide cost savings to some plant developers and will allow for reallocation of APHIS resources to Biotechnology Regulatory Services (BRS) priorities.

In addition to regulatory compliance costs, there are opportunity costs of delayed innovation when the approval process for a plant takes longer than it should 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 forgone benefits stemming from even a relatively brief delay in product release can overshadow both research and regulatory costs.

Some farmers (e.g., growers of identity-preserved crops, including organic, other non-GE and other agricultural commodities segregated for specific purity and quality tolerances) could be indirectly negatively impacted by these same innovations. Identity preservation (IP) refers to a process or system of maintaining the segregation and documenting the identity of a product. Crops with unique product quality traits, such as low linolenic canola require IP to capture the added value. Similarly, organic commodities must be produced according to specific criteria and segregated in the marketplace in order to receive premium prices. Some consumers choose not to purchase products derived from GE crops and instead purchase commodities such as those labeled "non-GMO" (food made without ingredients from genetically engineered organisms). In addition, the USDA organic standard does not allow for the intentional use of GE seeds. In cases where crops intended for the non-GE or other identity-preserved marketplace contain unintended GE products, their profitability may be diminished. Diminished profitability may occur for identity preserved crops that have special attributes because of the unintended presence of products not having the special attributes. Such crops are more likely to be developed under the new rule.

Expected Benefits and Costs of the Rule

Expected benefits of this rule include more efficient regulation of entities by APHIS under part 340. By implementing risk-based regulation, this rule will reduce the burden associated with the regulation of organisms that are unlikely to pose a plant pest risk, thereby reducing costs for the biotechnology industry. The regulatory framework in this rule will

provide a clear, predictable, and efficient regulatory pathway for innovators while facilitating the development of new and novel GE organisms that are unlikely to pose a plant pest risk. In particular, the RSR process and allowing developers to determine the appilicibility of the exemptions will provide developers with regulatory relief and open, more efficient and predictable pathways for innovators to market new products that are unlikely to pose a plant pest risk, in turn spurring 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 will be able to allocate its resources more efficiently than currently. Because we will no longer have to perform the redundant task of assessing GE plants with plant-trait-MOA combinations that we have already determined do not need to be subject to these regulations, we will be able to devote more attention to assessing and regulating those products that are likely to be associated with potential plant pest risks.

Based on APHIS' experience evaluating field trial data from thousands of permits that authorize environmental release of regulated organisms, as well as petitions for non-regulated status, APHIS has determined that most of the GE plants evaluated by the Agency do not merit continued regulatory oversight under the PPA. There will be both direct and indirect economic benefits of not subjecting the majority of these plants to permitting requirements. First, direct regulatory costs to some plant developers will be reduced for those plants that are not under permit. Second, a reduced regulatory burden and a more clear, predictable, and efficient APHIS regulatory pathway may facilitate developers' ability to raise venture capital and increase participation by public and private academic institutions in GE research, thereby spurring innovation. Producers who adopt new technologies will benefit as lower costs and increasing

supplies can lead to increased income. Consumers will benefit as they get more for their money when price decreases and/or quality increases (Just, *et al*. 2004).

To the extent that this rule reduces regulatory delays for GE traits, the negative consequences of such delays will be reduced. Regulatory delays mean that both producers and consumers see the benefits of innovation later than they otherwise would have and most likely, at lower levels. The forgone producer and consumer benefits constitute costs of regulatory delays on innovation (Kalaitzandonakes, *et al*. 2015). One study of regulatory costs and delay on agricultural biotechnology in the Philippines showed that while the specific impact of regulatory costs were relatively small—for example, a four-fold increase in regulatory costs led to a 7 percent decrease in net present value for multiple virus resistant (MVR) tomato—a three-year regulatory delay led to a 93 percent decrease in net present value using a 5 percent discount rate. Delays in regulatory approval play an important role in a firm's net returns and can have drastic effects on investment decisions (Bayer, *et al*. 2010).

On the other hand, an increased rate of GE crop innovation may have an indirect, negative effect on growers of identity preserved crops, including organic, other non-GE crops, and other crops segregated for specific traits. Some consumers choose to avoid GE commodities by purchasing products such as those labeled "non-GMO" or organically grown. In addition, the organic standard does not allow for the use of GE seeds. Other buyers are looking for products with specific identity-preserved traits. When these products are found to have unintended GE traits, their value may be diminished.

Innovation is expected to increase under this rule. However, a plant developer's control over the development process is not expected to be materially altered as a result of this rule. It is in a plant developer's own best interest to maintain the same level of supervision over the

development process as under the previous regulations. APHIS therefore believes that rigorous stewardship measures will continue to be utilized for field testing even in cases where APHIS does not require a permit. Undesired cross-pollination or commingling:

1) introduces unwanted characteristics and variability that diminishes the value of a seed crop;
2) increases legal exposure from unauthorized use of intellectual property (if another developer's traits are inadvertently incorporated into their lines);
3) increases legal exposure if unapproved GE plants are detected in crops; and
4) introduces the possibility of the loss of intellectual property and/or confidential business information (if a trait were to escape a developer's control).

Breeding lines are routinely subjected to genome analysis to confirm genetic identity. Even after deregulation, seed companies are motivated to adhere to strict stewardship requirements to maintain the integrity of their crops and reduce legal exposure. Best management practices include maintaining appropriate isolation distances from sexually compatible crops; monitoring and removing volunteers in production fields and the local environments; using color tagging and traceability systems for visual identification of GE plants; and using production best practices regarding equipment monitoring, treatment and cleaning procedures for crop production equipment, seed cleaning, storage, shipping container and screenings disposal requirements, grower guidelines, record keeping, inspections, training, and maintaining a continual review and improvement process.[9]

While the aforementioned measures represent the best practices followed by the sugar beet seed industry, similar stewardship measures have been followed in other instances such as the production of GE alfalfa seed and Enogen® corn, where as little as 1 seed in 10,000 can affect the

[9] Loberg, G to: United States District Court for the Northern District of California, San Francisco Division. 2010. Declaration of Greg Loberg in Support of Intervenors' Opposition to PL. Permanent Injunction Case no. 08-0000484, Regarding Center for Food Safety, *et al*., Plaintiffs, v. Thomas J. Vilsack, *et al*., Defendants. United States District Court for the Northern District of California, San Francisco Division. Case No. 3:08-cv-00484 JSW.

characteristics of processed corn.[10] In the case of alfalfa seed production, the National Alfalfa Forage Alliance has implemented a non-regulatory coexistence strategy, based on grower opportunity zones. A locality can focus on either GE alfalfa seed production or alfalfa seed production targeted for GE sensitive markets, depending on whether the growers on 80 percent or more of the alfalfa seed acres choose production of GE or non-GE seed.[11] In the United States, there are currently 6 grower opportunity zones catering to GE sensitive markets and 21 opportunity zones where GE alfalfa is produced.[12]

GE crop varieties 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 for consumption. Developers are encouraged to make use of FDA's voluntary consultation process prior to marketing GE crops, and it is common practice for them to do so. Because developers want to ensure the safety of their products before they are commercialized, some consider voluntary consultations with FDA on food safety to be an absolute necessity for applicable GE products.[13] Just as there are outside motivations for voluntary consultations on food safety, developers also have various legal, quality control, and marketing motivations to maintain rigorous voluntary stewardship measures for field trials, as described above. For these reasons, APHIS believes that developers will continue to use rigorous voluntary stewardship measures in field testing even when APHIS has determined that an organism does not pose a plant pest risk.

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[10] https://www.alfalfa.org/pdf/CSBMPForRRA.pdf; http://www.syngenta-us.com/corn/enogen/grower; http://nabc.cals.cornell.edu/Publications/Reports/nabc_27/NABC27Report.pdf p.97

[11] https://www.alfalfa.org/pdf/GOZseed.pdf

[12] https://www.alfalfa.org/bio_growerzones.php

[13] 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.

The rest of this section broadly describes expected direct impacts for the entities that are principally affected by the regulations, the biotechnology development community and the government (primarily APHIS), and possible indirect effects for farmers who grow GE crops, consumers, farmers who grow organic, non-GE or other identity preserved crops, and international trade.

Direct Effects – Biotechnology Development Community -- Innovators

The agricultural biotechnology industry is highly concentrated. Since 1990, global market concentration in agricultural input industries has increased significantly. The four firm concentration ratio for the seed and biotechnology industry, for example, increased from 32.5 percent in 2000 to 53.9 percent in 2009, an increase of 66 percent (Fuglie *et al*. 2011). Increasing regulatory compliance costs and the risks associated with successfully getting a product through development, approvals, and market introduction have forced small biotechnology companies to either exit from the business or merge with other companies. Between 1996 and 2006, the number of independent biotechnology companies decreased from 600 to 250 (Subramaniam and Reed 2015). In 2018 there were about 80 institutions with more than 4,300 authorized release sites under APHIS permits (APHIS Form 2000).[14] Just two companies had nearly 80 percent of those sites, and 8 companies had about 93 percent of those authorized release sites. (APHIS internal data).

Strong competition among a reduced number of biotechnology firms can jeopardize potential benefits. For example, if two companies compete in the development of a new trait at the same time, the company with the product less suited to the market could find it has no return from R&D expenditures, and may be less able to make future investments in R&D. To avoid

[14] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_permits_notifications_and_petitions/sa_permits

such pitfalls, agriculture biotechnology firms choose two strategies: (1) collaboration with other firms so they are not competing directly and (2) acquisition of or mergers with firms that hold biological patents in order to hinder the development of similar products by other firms (Subramaniam and Reed 2015).

In the current industry structure, some small biotechnology companies conduct research and establish patents with the sole purpose of being purchased by a large multinational company. These acquisitions and mergers not only protect large firms against competition from new products, but also encourage small companies to develop new products that they do not intend to take all the way through the approval process. Small, nimble biotechnology startups with lower operating costs assume the risks of product development, and the large companies acquire the technology when they purchase the smaller company, taking the product through the regulatory approval and marketing process. Slow regulatory approvals and other delays are more likely to deter smaller firms than larger firms (Subramaniam and Reed 2015).

Under this rule, products that fit into one of the exempted categories are not subject to APHIS' regulations. This rule also provides for an RSR process whereby GE plants found by APHIS to be unlikely to present a plant pest risk are not regulated. When an APHIS permit is not necessary, developers avoid certain regulatory compliance costs. Specifically, costs associated with reporting requirements, some analytical tests and assessment studies, and regulatory management costs, including preparing USDA dossiers and permit documents, are reduced or eliminated when APHIS permits are no longer necessary. We believe that this rule will have a particularly positive impact on small-scale developers, university researchers and spur innovation by new start-up companies. Costs now associated with petitions for non-regulated status will be reduced or eliminated when APHIS permits are no longer necessary.

There will be some new costs borne by regulated entities under the rule, including rule familiarization and recordkeeping. Annual recordkeeping costs are based on the information collection categories in the paperwork burden section of the rule, and are estimated to total about $1,070,000.[15] There have been about 1,250 unique entities that have applied for permits or notifications under part 340, and APHIS estimates that each of those entities will spend a total of about 24 hours becoming familiar with the provisions of this rule, at a total one-time cost of about $1.5 million.

Below, we first discuss the areas of regulatory compliance costs commonly incurred by developers; we then discuss a breakdown of those costs based on which agency or agencies have oversight of a particular trait; and finally we discuss the specific regulatory compliance costs that some developers will no longer bear under this rule.

Regulatory Compliance Costs

GE plants are subject to regulatory scrutiny and a battery of tests before commercialization. The process of experimentation, submission of experimental results, and regulatory review undertaken by biotechnology firms translates into compliance costs.

There is significant variation in current regulatory compliance costs because the requirements tend to vary from one regulatory submission (dossier) to another, depending on the crop modified, the novel trait introduced, and the type of regulatory approval pursued. These considerations drive differences in the number and type of field trials, analytical tests, bioinformatic analyses, animal studies and other comparative safety assessments (Kalaitzandonakes, *et al*. 2007).

[15] Estimated average hourly wage of $33.28 multiplied by 1.4706 to capture employee benefits. U.S. Department of Labor, Bureau of Labor Statistics Occupational Outlook Handbook, 2019 Report - Occupational Employment and Wages in the United States.

A difficulty in estimating the impact of this rule for plant developers is the fact that information on compliance costs is closely guarded and not publicly available (Phillips 2014; Kalaitzandonakes, *et al*. 2007). Two surveys provide estimates of the regulatory costs to the biotechnology industry of governmental oversight of new GE crop development in key producing and importing countries: Kalaitzandonakes, *et al*. (2007) and McDougall (2011). Both surveys were based on confidential data obtained from major biotechnology developers: Bayer CropScience, Dupont/Pioneer Hi-Bred, Monsanto Company, and Syngenta AG. In addition, Kalaitzandonakes, *et al*. (2007) included BASF Corporation data and McDougall (2011) included Dow AgroSciences data.

The McDougall (2011) study was designed to determine the cost and period of time associated with the discovery, development, and authorization of a new GE plant trait. The study reported costs in six main categories: discovery, construct optimization, commercial event production and selection, introgression breeding and wide area testing, regulatory science, and registration and regulatory affairs. For each category, the mean values of the company costs were determined based on survey responses. The entire process up to commercialization was taken into account. Information on four GE crops was collected: canola, cotton, soybean, and corn. The findings indicated that the average time required to discover, develop and authorize a new GE trait was 13.1 years, with an average cost of $147.2 million in 2016 dollars. Collectively, the costs of meeting all regulatory requirements amounted to $38 million in 2016 dollars, or 26 percent of the total.

Kalaitzandonakes, *et al*. (2007) estimated regulatory costs incremental to R&D expenses, providing greater insight to the potential cost savings for developers associated with this rule. The estimated regulatory costs were found to be highly variable depending on the company,

ranging in 2016 dollars from about $8.3 million to $18 million for insect-resistant corn and from about $7.2 million to $17 million for herbicide-tolerant corn (table 2). These estimates are roughly one-half of the regulatory costs estimated by McDougall (2011).[16] In research supported by the National Institute of Food and Agriculture (NIFA), Kalaitzandonakes also found that for the period 2009-2014, regulatory compliance costs had roughly doubled, potentially in line with McDougall (2011), although the size and structure of those compliance costs have not yet been published (Kalaitzandonakes 2014).

It should be noted that the above studies are based on surveys of private sector corporations, and involve the development, deregulation, and release in developed countries of high-value trait products such as herbicide-tolerant corn. The costs to not-for-profit institutions in development of GE crop plants with traits of low economic value can be substantially lower. For example, the cost to not-for-profit institutions in developing a GE potato variety resistant to late blight disease, for release in one developing country, was estimated at under $2 million over eight to nine years (Schiek, *et al*. 2016).

Ranges of estimated costs for regulatory categories used in this analysis are shown in table 2. These are based on the detailed component regulatory compliance cost categories published in Kalaitzandonakes, *et al*. (2007). These cost estimates were based on activities associated with both insect-resistant and herbicide-tolerant corn authorizations. In addition, three studies were unique to insect-resistant corn and one study was unique to herbicide-tolerant corn.

[16] APHIS does not have access to information that would account for this discrepancy.

Table 2. Developer Costs for Insect-Resistant Corn and Herbicide-Tolerant Corn, 2016 dollars

Cost Categories	Range of Costs Incurred ($) (1)
General costs	
Preparation for hand-off into regulatory process	23,400 - 58,500
Molecular Characterization	351.000 - 1,404,000
Compositional Assessment	877,500 - 1,755,000
Animal Performance and safety studies	351,000 - 988,650
Protein production and characterization	189,540 - 2,018,250
Protein safety assessment	228,150 - 1,000,350
Agronomic and phenotypic assessment	152,100 - 538,200
Production of tissues	795,600 - 2,574,000
ELISA development, validation and expression analysis	485,550 - 713,700
EU specific import (detection method, fees)	269,100 - 473,850
Canada specific costs	46,800 - 228,150
Stewardship	193,050 - 1,170,000
Toxicology (90 day rat — when done) (2)	292,500 - 351,000
Facility and Management overhead costs	655,200 - 5,265,000
Costs specific to Inspect resistant Corn	
Non-target organism studies	117,000 - 702,000
EPA expenses for Plant-incorporated protectants (PIP) (e.g., Experimental use permit tolerances)	175,500 - 836,550
Environmental fate studies	37,440 - 936,000
Total Insect-resistant Corn	8,260,200 - 18,064,800 (3)
Costs specific to Herbicide Tolerant Corn	
Herbicide residue study	122,850 - 643,500
Total Herbicide Tolerant Corn	7,230,600 - 16,976,700 (3)

Source: Kalaitzandonakes, *et al*., Compliance Costs for Regulatory Approval of New Biotech Crops. Nature Biotechnology 25 (5), pp 509; May 2007.

The costs of withdrawn events are not included in the figures. To preserve the confidentiality of firm-level data used, the means of the individual cost categories and total costs were not presented.

(1)Adjusted to 2016 dollars.

(2) These tests have not been conducted to date (FDA personal communication) and are therefore not included in the estimates in Tables 3 and 4.

(3) Because an individual firm could have costs anywhere within the range of each cost category, the totals do not sum from the individual cost category figures shown.

Where the estimated cost for a general cost category differed between insect-resistant and herbicide-tolerant corn, we included the entire range.

The costs shown in table 2 vary widely. Much of the difference among firms for the individual cost categories and total costs is the result of varying strategies followed by biotechnology developers as they pursue regulatory authorization of their innovations. Strategies

are shaped by the developers' expectations of the appropriate number and types of field trials, analytical tests and assessment studies, and the number of events advanced through various regulatory stages to manage uncertainty.

Regulatory Compliance Costs Under USDA Oversight Alone and Under USDA and FDA/EPA Oversight

As mentioned, APHIS, FDA, and EPA regulate GE plants and/or their products under the Coordinated Framework for Regulation of Biotechnology. For GE plants and/or their products such as insect-resistant corn, all three agencies have oversight. For a GE plant and/or its product used in human and animal food that does not include a plant-incorporated protectant (PIP), such as a variety of soybeans producing oil with altered fatty acid composition, APHIS and FDA have oversight. A GE plant and/or its product not used for human or animal food but that contains a gene that confers resistance (such as to an insect) is regulated by both APHIS and EPA.[17] In some cases, neither FDA nor EPA has oversight of a GE plant or its product. Examples of articles regulated exclusively by APHIS include horticultural plants such as petunias or carnations modified to produce different flower color, morphology, or longevity. Thus, we can consider two regulatory oversight scenarios: APHIS either has sole regulatory authority or shares oversight with EPA and/or FDA. Following, we describe expected effects of this rule on regulatory costs under both scenarios.

Estimates of current developer costs under the two regulatory oversight scenarios are shown in table 3. We note that the actual costs incurred by a specific firm are shaped by that developer's expectations of the appropriate number and types of field trials, analytical tests and assessment studies needed to advance through the various stages of consultation, deregulation

[17] While not all inclusive, this includes resistance to bacteria, fungi, virus, insects, and herbicides.

and/or registration. Where a given plant trait is under the sole oversight of APHIS, compliance costs are estimated to range from $2.4 million to $13 million for a given GE plant. When APHIS and also EPA and/or FDA have regulatory oversight of a given GE plant, costs are estimated to range from $4.7 million to $18.5 million for an herbicide-tolerant trait, and $4.9 million to $20.3 million for an insect-resistant trait.

Table 3. Estimated Current Regulatory Compliance Costs under Two Oversight Scenarios for Herbicide-tolerant Corn and Insect-resistant Corn, per trait, 2016 dollars

Activity	APHIS	APHIS & EPA and/or FDA
	($1,000)	
Preparation for hand-off into regulatory process	23-58	23-58
Molecular characterization	351-1,404	351-1,404
Compositional assessment	N/A	878-1,755
Animal performance and safety studies	N/A	351-989
Protein production and characterization	190-2,018	190-2,018
Protein safety assessment	N/A	228-1,000
Agronomic and phenotypic assessments	152-538	152-538
Production of tissues	796-2,574	796-2,574
ELISA development, validation and expression analysis	N/A	486-714
Stewardship	193-1,170	193-1,170
Facility and Management overhead costs	655-5,265	655-5,265
Subtotal (1)	**2,360-13,028**	**4,302-17,485**
Herbicide residue study	N/A	123-644
Total for Herbicide resistance	N/A	**4,425-18,129**
non target organism study	N/A	117-702
EPA expenses for PIPs (e.g., EUPs, tolerances)	N/A	176-837
Environmental fate studies	N/A	37-936
Total for Insect resistance	N/A	**4,632-19,960**

(1) This subtotal represents the sum of costs for all activities that were in common between insect and herbicide resistant corn.

N/A: Not applicable

Under this rule, APHIS regulatory oversight (through permitting) will not be required for plants that fall into one of the exempted categories or has been assessed by means of an RSR and

has been found unlikely to pose plant pest risks. When a permit from APHIS is no longer required for the development of particular trait and APHIS is the only agency with a regulatory interest in that trait, four activities associated with permitting will no longer need to occur:

1. Preparation for hand-off of events into the regulatory process
2. Protein production and characterization
3. Agronomic and phenotypic assessments
4. Production of tissues

The first activity involves the administrative work preparing samples in the R and D department and transferring those samples to the regulatory group within the company or to a third party contractor. The second activity is extraction of protein from the GE plant or from a bacterial or insect expression system to measure properties of the protein. The third activity involves field studies to collect data on the GE plants growing in greenhouses or the field. The fourth activity is growing large amounts of tissue for measuring the composition of the plant and other characterization assays. Under this rule, when APHIS is the only agency with oversight, plants that are exempt from the regulation or are not regulated based on an RSR will not require these four activities.

Currently, APHIS typically receives data based on each of these activities, although the information gained from the third activity is the primary means by which APHIS evaluates whether a plant is unlikely to pose a plant pest risk in accordance with its oversight authority. Based on the risk assessments that APHIS has performed in accordance with the petition process over 30 years, we have determined that in many cases we are able to evaluate the plant pest risks associated with a GE organism without field-test data. Accordingly, APHIS considers

information from field tests to be unnecessary, in most cases, for a determination of regulatory status and, therefore, will not require the submission of such data for an RSR.

Under this rule, if EPA and/or FDA also have regulatory oversight of a particular trait, but a permit from APHIS is not required, agronomic and phenotypic assessments (third activity) will not be necessary as these data are not relevant to assessing food or environmental safety, the objectives of FDA and EPA oversight, respectively. EPA and FDA will likely still require activities 1, 2, and 4, and associated costs of these activities will still be incurred under this rule in cases where either of these agencies also has regulatory oversight. EPA and FDA evaluate data obtained from feeding studies and compositional analysis performed on protein and tissue samples.

Furthermore, costs of preparing APHIS dossiers and permits (included within facility and management overhead costs) will be reduced when APHIS permits are no longer necessary. These cost savings will come mainly from a reduction in time spent managing the process. We estimate that the reduction in management and administrative costs will be about $385,000 per trait, as shown by the difference in facility and management overhead costs in tables 3 and 4. This estimate is based on the assumption that two mid-level and one upper-level management employees work full-time conducting these processes for each plant.[18]

We assume that even in cases where APHIS as the sole regulatory agency concludes that regulation is not necessary, some plant developers would still incur costs for GE plant development. These costs would include molecular characterization, regulatory costs for

[18] May 2017 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics. Based on North American Industry Classification System 541700, Scientific Research and Development Services management occupations, general and operations managers and administrative service managers.

international markets, stewardship, and facility and management overhead.[19] Table 4 shows estimated regulatory compliance costs under this rule for the two oversight scenarios.

Table 4. Estimated Regulatory Costs with the Rule under Two Oversight Scenarios, per GE plant not regulated by APHIS, 2016 dollars

Activity	APHIS	APHIS & EPA and/or FDA
	($1,000)	
Preparation for hand-off into regulatory process	0	23-58
Molecular characterization	351-1,404	351-1,404
Compositional assessment	N/A	878-1,755
Animal performance and safety studies	N/A	351-989
Protein production and characterization	0	190-2,018
Protein safety assessment	N/A	228-1,000
Agronomic and phenotypic assessments	0	0
Production of tissues	0	796-2,574
ELISA development, validation and expression analysis	N/A	486-714
Stewardship	193-1,170	193-1,170
Facility & management overhead costs	270-4,880	270-4,880
Subtotal (1)	**814-7,454**	**3,765-16,562**
Herbicide residue study	N/A	123-644
Total for Herbicide resistance	N/A	**3,887-17,206**
non target organism study	N/A	117-702
EPA expenses for PIPs (e.g., EUPs, tolerances)	N/A	176-837
Environmental fate studies	N/A	37-936
Total for Insect resistance	N/A	**4,094-19,037**

(1) This subtotal represents the sum of costs for all activities that were in common between insect and herbicide resistant corn.
N/A: Not applicable

Estimated cost savings with this rule for the some plant developers under the two regulatory oversight scenarios are shown in table 5. APHIS estimates that plant developers

[19] For APHIS' risk assessment process for determining regulatory status, a plant developer is responsible for validating that the biotechnology organism corresponds to the intended genotype. Therefore, molecular characterization would need to be performed even though the results would not need to be sent to APHIS. Similarly, companies still need to bear stewardship costs to maintain best practices for field trials to maintain varietal purity and protect intellectual property interests.

could save from $551,000 to $937,000 per GE trait ($744,000 on average) when EPA and/or FDA also have oversight, and from $1.6 million to $5.6 million per GE plant ($3.6 million on average) when APHIS is the only agency with oversight under current regulations.

Table 5. Estimated Regulatory Cost Savings per Trait not regulated by USDA with the Proposed Rule under Two Oversight Scenarios, per trait, 2016 dollars

Activity	APHIS	APHIS/EPA/FDA
	($1,000)	
Preparation for hand-off of events into regulatory	23-58	0
Protein production and characterization	190-2,018	0
Agronomic and phenotypic assessments	152-538	152-538
Production of tissues	796-2,574	0
Facility & management overhead costs	386	386
Required recordkeeping & reporting costs (1)	13	13
Total	**1,559-5,588**	**551-937**

(1) APHIS permits. Estimated average hourly wage of $33.28 multiplied by 1.4706 to capture employee benefits ($48.94). U.S. Department of Labor, Bureau of Labor Statistics Occupational Outlook Handbook, 2019 Report - Occupational Employment and Wages in the United States.. Permitting procedure requires 20 hours per response (20 hours x $48.94 = $978.80). Permit recordkeeping requires 10 hours per response and 25 responses (25 responses x 10 hours = 250 hours. 250 hours x $ = $12,235). $978.80 + $12,235 = $13,123.80.

From 1992 through September 2019, an average of just under 5 petitions were processed (granted non-regulated status or the petition withdrawn) in a given year, with a high of 14 in 1995. Because the rule is expected to spur innovation, we expect the number of new plants developed annually to increase over time. Because of the larger regulatory cost savings for GE crops that require only APHIS oversight, the rule may provide impetus to the development of new horticultural varieties. Very few such crops have acquired non-regulated status. In the last 30 years there have only been a couple horticultural varieties for which deregulation was pursued, with thus far only one (blue rose) deregulated.

In the following estimate of impacts, we use the average cost savings reported above per GE plant developed and assume the annual number of new GE plants developed under the rule without APHIS permits ranges from 5 (the current annual average number of processed

petitions) to 10 (twice this average). We further assume that about 20 percent of those new GE plants are solely within the purview of APHIS oversight, and that the remaining 80 percent will be also be under the purview of 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.[20] 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 $13.1 million.[21]

In addition to the compliance costs associated with regulation, there are opportunity costs associated with missing out on innovation if the approval process for a trait is longer than necessary to ensure safety with reasonable scientific certainty (Bradford, *et al*. 2005; Van Eenennaam, 2013). Regulatory delays mean that the benefits of innovation occur later than they otherwise would have and most likely, at lower levels (Kalaitzandonakes, *et al.* 2015). The forgone benefits due to delayed innovation can be substantial, and developers, producers and consumers all lose from regulatory delays. The forgone benefits stemming from even a relatively brief delay in product release overshadow both research and regulatory costs (Bayer, *et al*. 2010; Phillips 2014; and Pray, *et al*. 2005). Regulatory delays have the potential to slow down the biotechnology innovation process in general (Kalaitzandonakes, *et al*. 2015). In the short run, such delays mean that innovations ready to be marketed to agricultural producers are sitting idle. During this time, the welfare of both producers and consumers is less than it would be otherwise. Operating costs and market prices are both higher than they would be without such innovations on the market (Huang and Yang 2011). In the long run, regulatory delays may

[20] One x $3,573,500 = $3,573,500. Four x $744,000 = $2,976,000. $3,573,500 + $2,976,000 = $6,549,500.
[21] Two x $3,573,500 = $7,147,000. Eight x $7440,000 = $5,952,000. $7,147,000 + $5,952,000 = $13,099,000.

exert an overall dampening effect on the innovation process. Long-run costs take the form of research programs not undertaken, innovations not developed, firms not started, jobs not created, and products not reaching producers or consumers (Bastiat 2007).

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

This rule may also benefit agricultural GE research at public and private academic institutions. University researchers have often commented that the cost of regulation thwarts their ability to use modern methods to innovate and improve crop varieties (Bradford 2005). This rule is expected to lower the cost of conducting field trials and completing APHIS' regulatory process. To that extent, it may spur innovation by university researchers. Such innovation may ultimately benefit private sector biotechnology companies, farmers, and consumers.

Benefits may also accrue from the greater regulatory certainty that would result from the risk assessment process used to determine regulatory status under APHIS. Biotechnology developers, particularly start-up companies, depend on raising venture capital at the onset to fund their innovations. Raising venture capital is especially difficult if regulatory concerns remain an obstacle. A clear, predictable, and efficient regulatory pathway for innovators under this rule will facilitate the development of new and novel GE organisms that are unlikely to pose a plant

pest risk. Under the RSR process, companies should need fewer resources to conduct APHIS specific tests and to prepare APHIS dossiers and should be better able to raise venture capital to pay for field trials where an APHIS permit is not required. In this way, the rule is expected to spur innovation. Because regulatory costs can be a barrier to entry into the biotechnology industry for small firms and a barrier to the introduction of products with small potential markets, the advantages gained from the regulatory framework may be particularly evident in those instances.

In sum, under this rule fewer newly developed GE plants will require an APHIS permit than under the current process. We therefore anticipate both direct and indirect economic benefits for the biotechnology industry. First, direct regulatory costs to biotechnology developers will be reduced for the development of GE plants where APHIS permits are no longer necessary. Savings to the regulated community will result from a reduced need to collect field data, fewer reporting requirements, and lower management costs. Costs now associated with petitions for non-regulated status will be reduced or eliminated where APHIS permits are no longer necessary. Second, indirect benefits are expected to result from a clear, predictable, and efficient regulatory pathway for innovators that facilitates the development of new and novel GE plants that are unlikely to pose a plant pest risk. These benefits include reduced regulatory uncertainty that may facilitate small companies' ability to raise venture capital, and reduced regulatory requirements that may increase greater participation by the public sector in GE research. The latter effects can be expected to spur GE innovations.

Some plants that would not have been regulated under previous 340 regulations because there was not a plant pest used in their development will now be under the purview of APHIS oversight. This change in scope was made because plants engineered without a plant pest can

still pose plant pest risks. If such plants become widely distributed, they potentially could lead to increased management costs for farmers. APHIS believes that the number of plants that fit this category is likely very small. For a nine-year period (2011-2019), APHIS authorized activities for about 346,000 plants (phenotypic designations) under the current regulations (Table 1). We expect that all but about 5 of the plants that completed the AIR process over that same time period would have qualified for exemptions or moved through the RSR process without the need for additional data under this rule. This is an average of considerably fewer than 1 per year. Some of the development costs associated with these newly regulated products (i.e., ones exempted or moved through the RSR process) are regulatory costs. We estimate that gathering the information necessary and preparing an exemption or RSR inquiry takes about 4 hours for a developer, and would therefore cost about $400 based on a salary of $100 per hour. Those costs are, however, likely to be very similar to the costs of the current non-regulatory AIR process. We do not expect the change in scope to change developers' regulatory burden.

For GE plants that will require an APHIS permit, compliance costs for the developer will include permitting, reporting, and recordkeeping. Fewer than 1 in 10 concepts are ever tested in the field. And of these, fewer than 1 in 100 demonstrate sufficient commercial viability to warrant further data collection necessary to address questions raised in the RSR process (McDougall 2011 and Prado, *et al*. 2014). If we nonetheless assume that one plant per year fits this category of expanded APHIS purview and goes under permit, the additional recordkeeping and reporting costs could be about $13,000 annually for a field trial that requires 25 reports per year.[22] Because few plants tested in the field are likely to demonstrate commercial viability, we

[22] Estimated average hourly wage of $33.28 multiplied by 1.4706 to capture employee benefits ($48.94). U.S. Department of Labor, Bureau of Labor Statistics Occupational Outlook Handbook, 2019 Report - Occupational

expect that those plants would be tested on a limited number of sites. If a developer incurs additional stewardship costs under regulation for that plant, those costs could range from about $20,000 to $120,000.[23] Most developers are, however, already incurring stewardship costs in order to protect their intellectual property; to prevent commingling, so as to maintain varietal purity; and to avoid risks related to potential trade disruptions. In the rare case in which a plant demonstrates commercial viability and therefore warrants further data collection necessary to address questions raised in the RSR process, the developer could incur additional testing costs. Under the current regulations, testing costs are estimated at between about $152,000 and $538,000.[24] Since the data required under the RSR process are more targeted than under the current process, those costs are expected to be closer to the lower bound.

Direct Effects -- Government

The rule will streamline APHIS' GE regulatory process by, among other things, exempting certain plants from the regulations and changing the way we evaluate GE plants for plant pest risk. While the rule relieves regulatory burden on developers and could spur innovation, it does not diminish the protection against plant pest risk that the previous regulations provided.

Employment and Wages in the United States.. Permitting procedure requires 20 hours per response (20 hours x $48.94 = $978.80). Permit recordkeeping requires 10 hours per response and 25 responses (25 responses x 10 hours = 250 hours. 250 hours x $ = $12,235). $978.80 + $12,235 = $13,123.80.

[23] A detailed study of component regulatory compliance cost categories included stewardship costs throughout the development and petition process of between $4,000 and $24,000 per site year. For most products this would be a maximum of 5 site years (5 x $4,000 = $20,000, 5 x $24,000 = $120,000). Kalaitzandonakes, *et al.*, Compliance Costs for Regulatory Approval of New Biotech Crops. Nature Biotechnology 25 (5), pp 509; May 2007.

[24] Agronomic and phenotypic assessments are the primary means by which APHIS evaluates whether a plant is unlikely to pose a plant pest risk in accordance with its oversight authority under the permit and petition process. Kalaitzandonakes, *et al*. (2007). Because these plants are likely to also fall under the regulatory oversight of FDA and/or EPA, other regulatory costs are likely to be incurred by developers regardless of whether they are also under the oversight of APHIS.

At present, costs to the Agency associated with the activities related to GE plants covered in this rule are incurred in reviewing and issuing permits and notifications, reviewing petitions and developing environmental impact statements, conducting environmental assessments, and conducting field inspections and compliance actions. In FY 2018, APHIS processed 48 import permits, 150 interstate movement permits, and 140 release or interstate movement and release permits for GE organisms. There were also 103 import notifications, 216 interstate movement notifications, 242 release or interstate movement and release notifications for GE organisms processed, 708 courtesy permits issued and 13 "Am I Regulated" (AIR) inquiries completed in FY 2018.[25] There were 706 inspections completed in FY 2018.[26] There were also 256 compliance letters completed/sent by BRS Compliance Evaluation and Enforcement Branch (CEEB).[27] This includes warning letters, notices of non-compliance, notices of finding, notices of compliance with comments and notices of compliance.

Current annual APHIS personnel costs of conducting GE activities that will be affected by the rule total about $3.4 million: about $185,000 from conducting compliance activities (appendix table 1), about $641,000 from conducting inspection activities (appendix table 2), about $57,000 from conducting AIR process activities (appendix table 3), about $163,000 from conducting notification activities (appendix table 4), about $208,000 from conducting permit activities (appendix table 5), and about $2.1 million from conducting petition activities (appendix table 6).

[25] "Am I Regulated" is a process whereby the biotechnology industry can determine whether a specific trait is regulated by APHIS by entering information in BRS' permit system.
[26] Inspections under 7 CFR part 340 occur throughout the year. Some are conducted by BRS Regulatory Analysts as one part of their compliance oversight work, some are conducted by Plant Protection and Quarantine (PPQ) inspectors as part of their primary jobs, and some are conducted by State inspectors. In FY2017, 495 inspections were done by BRS, 213 by PPQ, and 53 by States.
[27] One letter may be used to close out more than one incident.

Under this rule, APHIS' overall annual personnel costs of regulating GE organisms are not expected to change. While the volume of specific activities are likely to change, the overall volume of regulatory activities, the general nature of those activities and the level of skills necessary to perform those activities will not.

The rule provides for a new RSR process, to evaluate whether an organism requires a permit for movement based on the characteristics of the organism itself or the types of genetic modification it contains rather than on an evaluation of the method by which the organism is genetically engineered. The rule eliminates the petition process as well as the notification procedure but will still require permits with specific conditions for movement (importation, interstate movement, or release into the environment) of all GE organisms that are subject to the regulations. Developers of GE plants that have not previously been evaluated for plant pest risks will be given the option of requesting an RSR to determine the regulatory status of their product. A developer of GE plants who makes a determination will have the option to request written confirmation from APHIS that the determination is valid. A confirmation letter will provide a clear and succinct statement about the regulatory applicability of the organism. The current courtesy permit and accompanying Letter of No Jurisdiction, valid for three years and country-specific, will be replaced by a Letter of No Permit Required. Letters of No Permit Required are commonly issued by APHIS programs to facilitate the importation of non-regulated articles. As these letters apply to non-regulated materials, they are not described in the rule. However, these letters are mentioned in this analysis because over time, savings are expected. APHIS resources needed to issue these letters will be about the same as required currently to issue a courtesy permit; however, there will be savings realized over time, as fewer are issued.

APHIS will likely incur modest additional costs in conducting outreach activities for the rule, developing guidance documents to ensure that the regulated community is familiar with the requirements of the rule, updating the inspection manual, and providing certain staff training in regard to the regulatory revisions. APHIS estimates that the public outreach, guidance, and training will cost about $77,000. Requests for regulatory status and response letters under the rule will be handled in a manner similar to the current 'Am I Regulated' process, that is, outside the electronic permitting system and without new costs.

Plants that Produce Plant-Made Industrials and Pharmaceuticals

Certain plants are genetically engineered in order to produce pharmaceutical and industrial compounds, also known as plant-made pharmaceuticals and industrials (PMPIs). 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, which to date includes all PMPI-producing plants. 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.

Federal oversight of outdoor plantings of PMPI-producing plants helps prevent the 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 this rule, APHIS will maintain its oversight over PMPI-producing plants. In this final rule, we

are adding this requirement to §340.2, as a paragraph (e) which states that a permit is required for the movement of a plant that encodes a product intended for pharmaceutical or industrial use.

Plant-Incorporated Protectant Small-Scale Field Testing

Certain plants are genetically engineered to produce plant-incorporated protectants (PIPs), meaning that they produce pesticides. APHIS regulates plants that produce PIPs when plant pests are used. PIPs also fall under the regulatory oversight of EPA. However, only APHIS has exercised regulatory oversight of PIP plantings on fewer than10 acres of land.

Under the provisions of this rule, a GE plant will be regulated only if it has a plant-trait-MOA combination that the Agency has not yet evaluated for plant pest risk or if it has been evaluated and found to pose a plausible pathway of increased plant pest risk relative to its comparator. Additionally, APHIS' review of GE plants for plant pest risk will 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 would be determined not regulated after an RSR, because the Agency found no plausible pathway of increased plant pest risk relative to its comparator.

Under this rule, Federal oversight of those GE PIPs will rest solely with EPA. EPA may decide to require experimental use permits (EUP) for all, some, or none of such PIPs for test plantings on 10 or fewer acres, and may conduct inspections of all, some, or none of those PIPs that are under permit. EPA would need to develop a program to oversee small-scale testing of PIPs and to issue regulations if warranted. As described above, current inspection costs incurred by APHIS average roughly $800 per inspection.

APHIS is fully committed to coordinating with EPA in this matter. 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 on 10 or fewer acres. APHIS puts forward this possible scenario only to indicate that the Agency is aware of the implications of this rule with regard to small-scale testing of PIPs.

Summary of Expected Direct Impacts

Table 7 provides a summary statement of the expected direct benefits and costs of the rule: compliance costs and cost savings for the biotechnology industry, and a reallocation of APHIS Biotechnology Regulatory Services staffing resources.

Table 7. Expected Annual Costs and Costs Savings of the Rule for the Biotechnology Industry and for APHIS, 2016 dollars

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

[1] The number of plants in this category is expected to be very small, likely less than 1 per year based on historical activity. The range in cost shown is for one permit. The actual cost will depend on additional recordkeeping, reporting, stewardship, and testing requirements.
[2] These savings are shown on a per trait basis. On average, if 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 will be $6.5 million. If 10 new GE plants are developed annually without APHIS permits (all with no APHIS permit, but 8 still with EPA and/or FDA evaluation), the annual savings will be $13.1 million.
[3] Requests for regulatory status and response letters under the rule will be handled in a manner similar to the current 'Am I Regulated' process, outside the electronic permitting system and without incurring new costs.

Indirect Effects -- Farmers who grow GE Crops and Consumers

If the regulatory relief expected under the rule spurs innovation, farmers who adopt GE crops may benefit by having access to a wider variety of traits to meet their specific needs in managing agricultural pests and diseases, as well as to additional new GE crop species. When farmers adopt a new GE variety, they typically expect benefits like increased farm net returns, time savings (by making farming less effort intensive), or reduced exposure to chemicals. Net

benefits are a function of farm characteristics and location, output and input prices, existing production systems, and farmer abilities and preferences (Fernandez-Cornejo, *et al*. 2014).

Systematic reviews and formal meta-analyses of the performance of GE crops have consistently shown reductions in yield damage by insects, reductions in insecticide applications for target insect pests, decreases in management time and increases in flexibility related to herbicide resistant crops, increases in gross (in some cases net) margins due to the adoption of GE crops, or combinations of all the above (Areal *et al*. 2013; Finger *et al*. 2011; Klümper and Qaim 2014; Mannion and Morse 2013; Qaim 2009; Racovita *et al*. 2015; Raney 2006; Sexton and Zilberman 2012; Smale *et al*. 2009; Tripp 2009).

Studies specific to the United States have shown reduced costs and improved profitability at the farm level with the adoption of various GE crops (Brookes and Barfoot 2013 and 2015; Klümper and Qaim 2014). Fernandez-Cornejo, *et al*. (2014) found that the adoption of insect-resistant crops increases yields by mitigating yield losses from insect damage, although empirical evidence regarding the effect of herbicide tolerant crops on yields is mixed. Also, planting insect-resistant cotton and corn seeds is associated with higher net returns when pest or drought pressure is high, but the extent to which herbicide-tolerant adoption affects net returns depends primarily on how much weed control costs decline and seed costs increase.

U.S. farmers have realized higher incomes due to their use of GE crops, totaling approximately $58.4 billion in extra income between 1996 and 2013 (Brookes and Barfoot 2015). Herbicide-tolerant soybean adoption is associated with an increase in total household income because such plants require less management and enable farmers to generate income via off-farm activities or by expanding their operations (Fernandez-Cornejo, *et al*. 2014).

In comparison to the status quo, we expect the revisions to APHIS' regulation of GE organisms will more readily help expand this history of improved farm-level profitability to include a number of crop species for which GE varieties have yet to be developed. As we mentioned above, some plant developer regulatory costs are expected to be lower than the status quo under the rule, potentially spurring innovation, especially for traits where regulatory costs are high relative to the size of the potential market. This offers opportunities to smaller companies and institutions with fewer financial resources. Among the types of innovations expected are crops with greater resistance to disease and insect pests, and with 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, consumers will benefit from a wider variety of available products, including ones with improved taste, storage longevity, or nutritional content. Innovations may also benefit consumers through lower prices for existing products.

Indirect Effects – Organic, Other Non-GE, and Other Identity-Preserved Crops

Because of producer and consumer preferences, supply chains for GE crops are separate from those for non-GE crops, which may or may not be produced with synthetic fertilizers and pesticides. Production of GE crops and nonorganic, non-GE crops both may use synthetic fertilizers and pesticides; USDA distinguishes them as GE conventional production and non-GE conventional production. For the third category, organic production, producers grow non-GE crops and do not use synthetic fertilizers or pesticides (Greene *et al*. 2016).

Identity preservation (IP) refers to a system of production, handling, and marketing practices that maintains the integrity and purity of agricultural commodities. In its simplest form,

IP has been employed since the beginning of agriculture when the seeds and grain of different crops were first traded separately. As crops and production systems have diversified to meet market demands, the need for segregation and identity preservation of agricultural commodities has increased (Sundstrom, *et al*. 2002). Farmers growing high-value specialty crops—such as popcorn, soybean for tofu, and low-linolenic acid canola—have long protected their crops from accidental mixing with lower-value crops to prevent unintended low levels of impurities. Farmers who grow crops for seed production also isolate their crops from related crops to ensure the purity of the seed variety (National Academies of Sciences 2016). Similarly, organic commodities must be produced according to specific criteria and segregated in the marketplace in order to receive premium prices. The segregation of end-use markets for organic, non-GE, and GE crops because of consumer preferences has created a price premium for organic and other non-GE crops (Sundstrom, *et al*. 2002). When crops intended for the non-GE or other identity-preserved marketplace contain unintended GE products, their value may be diminished.

There is relatively little information detailing the economic harm incurred by growers of non-GE crops because of the unintended presence of GE products. In the United States, organic certification is process-based, and therefore low-level presence of GE content in organic food products does not threaten a grower's certification or prevent the end product from being marketed as "USDA organic" (USDA–AMS 2011). However, the private sector may impose standards that go beyond USDA's requirements. U.S. food retailers, restaurants, and food manufacturers are also requiring non-GE products to support "non-GMO" marketing and labeling campaigns. Through contract requirements, growers of organic or non-GE crops may have to supply products that do not exceed a threshold of GE content set by a private company, a strict export market, or a voluntary certifier. The grower bears the risk of losing the market

premium if the supplied crop is rejected because it does not meet a contractually established standard. However, because contracts between growers and buyers are private, it is difficult to find documented information about how extensively growers are contracting to meet specific non-GE standards or to what extent farmers of organic or non-GE crops are incurring economic losses as a result of being unable to meet contracts because of commingling with non-GE crops. (National Academies of Sciences 2016).

Losses reported by organic farmers in the United States were reported in the (2014 USDA Organic Survey).[28] The survey showed that the percentage of organic farmers reporting economic losses due to the unintended presence of GE materials in their crops varied by region and by the extent of GE crop varieties grown in their area. Between 2001 and 2005, one farm in Iowa and one in Utah reported losses due to the presence of GE organisms. The economic value of the losses was not reported. Between 2006 and 2010, nine farms reported losses due to the presence of GE organisms. These reported losses totaled $68,974, with an average reported loss per farm of $7,664. Three of the farms were in Wisconsin, two were in Iowa, and one each were in Illinois, Kansas, Missouri and Nebraska. Between 2011 and 2014, 87 farms reported an average farm loss of $70,099 for a total of $6.1 million.[29] In 2015, 32 farms reported a total of $520,671, with an average reported loss of $16,271. In 2015, the total value of sales of certified organic field crops was $660 million.[30] Data on such reported losses were not collected in the

[28]Organic Survey (2014) Vol. 3 Special Studies Part 4 2012 Census of Agriculture, Updated April 2016.
[29] 2012 Census of Agriculture. Organic Survey (2014) Vol. 3 Special Studies Part 4, Table 45. Value of Organic Crops Loss from Presence of Genetically Modified Organisms (GMOs) -- Certified Organic Farms: 2014 and Earlier Years http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Organics/organics_1_045_045.pdf
[30]Certified Organic Survey, 2015 Summary (September 2015). Table 15. Value of certified Organic Crop Loss from Presence of Genetically Modified Organisms (GMOs) and Genetically Engineered (GE) Material: 2015 and Earlier Years. And Table 9. Certified Organic Field Crops Harvested and Value of Sales: 2015.

Certified Organic Survey in 2015 or 2016.[31]. According to a 2016 study, 1 percent of all U.S. certified organic farmers in 20 States reported that they experienced economic losses (amounting to $6.1 million, excluding expenses for preventative measures and testing) due to GE commingling during 2011-2014. The percentage of organic farmers who suffered reported economic losses would be higher if calculated only for those organic farmers growing the nine crops with a GE counterpart (commodity-specific estimates could not be reported due to data limitations and concerns about respondents' privacy). While less than 1 percent of all organic farmers in California, Indiana, Maine, Minnesota, and Michigan reported losses due to the unintended presence of GE material in their crops, 6 to 7 percent of organic farmers in Illinois, Nebraska, and Oklahoma reported losses (Greene, *et al*. 2016).

Both organic and other non-GE producers use practices to minimize the presence of GE traits. These practices include using third parties to test and verify non-GE seed, and the use of buffer strips and delayed planting to segregate their non-GE crops spatially and temporally. Some of the avoidance practices used by organic and other non-GE farmers raise the cost of producing those crops. For example, delaying planting can reduce yields. Using non-GE seed with GE exclusion traits, and GE testing for seeds and crops, can increase input costs. Buffer zones take land out of production. Also, some organic and GE farmers may alter cropping patterns or the mix of crops, or discontinue the use of inputs and growing of crops that are at risk of containing GE material, raising management and production costs. Beyond the farm gate, shipment testing and labeling costs are also borne by organic and other non-GE processors,

[31]Certified Organic Survey, 2015 Summary. September 2016. USDA, National Agricultural Statistics Service; Certified Organic Survey, 2016 Summary. September 2017. USDA, National Agricultural Statistics Service.

manufacturers, and retailers. These higher costs at various points in the supply chain can increase prices for consumers (Greene, *et al*. 2016).

Cost estimates that include testing, segregation, and identity preservation vary widely. Comparisons are difficult because assumptions are often unstated. Many U.S. processors and retailers that buy and sell organic and non-GE products are now requiring verification that GE avoidance protocols were observed. As part of non-GE verification, testing of both organic and non-GE products has become more frequent. USDA has not collected data on the cost of avoidance practices. Teisl and Caswell (2003) noted in their review of cost studies that estimates range "from very modest to significant increases in costs" in part because of different assumptions and different kinds of costs. A recent study of organic grain producers showed the total median annual cost of practices to avoid GE material in their crops was $6,532 to $8,500 per farm (Food & Water Watch and OFARM 2014).[32,33] However, it is not possible to determine whether these estimates are representative of costs incurred by nonrespondents (Greene, *et al*, 2016).

GE traits can be acquired through pollination of non-GE flowers by GE pollen produced in neighboring fields of GE varieties. Vegetable seed production usually takes place in limited areas where large isolation distances are employed to preserve varieties. For example, pollination of non-GE sugar beets, table beets, and Swiss chard by GE pollen has to our knowledge not been a recurring problem because of the stewardship and best practices employed

[32] Findings on the costs of practices were reported as median costs per farm rather than the more standard costs per acre

[33] Including the cost of buffer strips ($2,500) with a median size for survey respondents of approximately 5 acres, delayed planting ($3,312 to $5,280), testing ($200), and other measures ($520).

by the industry. Other field crops such as beans, lentils, and peas are self-fertilizing and therefore unlikely to be affected by cross-pollination.

Unintended presence can also result from harvested GE grains becoming commingled with non-GE grain crops. Commingling of seed can occur through use of the same equipment or conveyances not thoroughly cleaned. Vegetable crops are unlikely to present a commingling issue because the crops are harvested prior to flowering and the harvested materials are large (carrots, lettuce, cabbage), typically identity-preserved, and not likely to be commingled accidentally through use of the same equipment or conveyances.

Farmers catering to the non-GE market (growers of organic or other identity-preserved crops) for crops with no current commercialized GE varieties could be negatively impacted by the rule if it contributes to an increase in the variety of GE plant species grown in the United States. The non-GE crops most likely to be negatively impacted are grain crops such as wheat, rice, barley, sorghum, and oats, for which no GE varieties have been commercialized to date.[34] Other crops such as hops and peanuts could also be affected.[35] Table 8 shows the quantity and value of certain organic field crops produced on certified organic farms in 2016. For crops such as corn, soybean, cotton, sugar beet, and canola, GE varieties already represent greater than 90 percent of the planted acreage in the United States, and the rule is unlikely to spur innovation in new varieties that would significantly alter these percentages.

It is difficult to predict the economic impact of genome-edited varieties on the non-GE and organic markets. Specifically, it remains to be determined whether genome editing would be allowed under the National Organic Standard.

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[34] A variety of GE rice has been deregulated but not commercialized.
[35] The extent to which some crops are harvested after flowering affects how much of the crop would be potentially affected by the unwanted presence of GE traits.

Table 8. Organic Field Crops susceptible to Cross Pollination or Commingling for which there are no commercialized GE Varieties, Number of Farms, Quantity Harvested, and Value of Sales – Certified Organic Farms, 2016

Crop	Farms	Quantity Harvested (million)	Value of Sales ($ million)
Barley for grain or seed (bushels)	510	2.7	16.9
Buckwheat (bushels)	97	0.1	2.5
Flaxseed (bushels)	40	0.1	2.3
Hops (pounds)	37	1.0	8.6
Oats for grain or seed (bushels)	1,206	3.1	13.3
Peanuts (pounds)	35	21.7	13.4
Proso millet (bushels)	37	0.2	1.2
Rice, all (hundred weight)	109	1.4	42.7
Rye for grain or seed (bushels)	243	0.3	2.0
Sorghum for grain or seed, including milo (bushels)	60	0.6	4.0
Sorghum for silage or greenchop (tons)	123	0.1	0.3
Sunflower seed (pounds)	80	8.3	3.6
Wheat, all (bushels)	1,139	10.6	107.1
TOTAL	***3,716***	***n/a***	***218.1***

Source: Certified Organic Survey, 2016 Summary. September 2017. USDA, National Agricultural Statistics Service.
n/a - not applicable.

Non-GE products that are kept separate from their GE equivalents and organic crops are treated as value-added crops commanding premiums that vary according to prevailing supply and demand conditions. This is to be expected, especially for organic crops, because some consumers strongly prefer them over their conventional counterparts (Loureiro, *et al*. 2001). Organic price premiums are also expected because organic production involves additional risks (Klonsky and Greene 2005) and higher costs (McBride and Greene 2008). The premiums compensate farmers and traders for incremental costs they incur, including those imposed by the segregation of non-GE from GE crops (through buffer zones, spatial and temporal isolation, etc.) throughout the supply chain. In the United States, the management of coexistence between GE and non-GE production systems has been left to market forces. Non-GE growers assume the costs of coexistence and, in turn, pass those costs on to purchasers of non-GE crops (Kalaitzandonakes

and Magnier 2016). Born (2005) noted that "prices for organic grains and oilseeds were about double the conventional prices from 1995 to 2003." More recently, Greene *et al*. (2016) reported that U.S. organic corn and soybean prices are generally two to three times higher than the prices of non-GE varieties.

Crowder and Reganold (2015) examined the financial performance of organic and conventional agriculture by conducting a meta-analysis of data from 44 studies involving 55 crops grown on 5 continents over a 40-year period. They found that median premiums were 32 percent for organically grown crops and 29 percent for organic systems (averaged across all crops in the system). Carlson and Jaenicke (2016) found premiums for fresh organic vegetables ranging from 7 to 44 percent, with many around 30 percent. It is the premium above the price for conventional crops that can be lost by the unintended presence of GE traits. U.S. organic farmers and farmers who produce IP non-GE crops must meet the tolerance levels for accidental GE presence that are set by domestic buyers, foreign buyers, and some foreign governments. Processors and handlers reject the products when GE traits test above the buyer's GE tolerance level (Carter and Guillaume 2003). If their crops test over the expected tolerance level, farmers may lose their organic (or non-GE) premium and incur additional transportation and marketing costs to sell the crop at a discount in alternative markets (Greene *et al*. 2016). If the rule leads to the development and adoption by growers of new varieties of GE crop plants, there may be an increase in the potential for incidents of unintended presence of GE crop material in non-GE crops or crop products. This possibility is due to more crop types in production that would be targeted for specific markets and need segregation. An increase in development and adoption of new varieties of GE crops would entail maintaining supply chains that segregate GE crop products from those produced via non-GE conventional, organic, or identity-preserved cropping

systems. Any increased risk to organic and other non-GE growers from cross-pollination or commingling will depend on the extent to which new GE varieties of crops that could result in cross-pollination or commingling are commercialized, the type of trait, the degree to which those new varieties are adopted, post-harvest handling, and the proximity of fields where the new GE crops are grown to organic or other IP crops. If a trait is value-added, its intellectual property would be protected. Such protection already exists for certain plant products, where varietal identity is important for marketing (apples and pears, for example). The developer's control over and responsibility for the development process is not expected to change. However, innovation in the agricultural biotechnology sector is expected to increase under the rule, and there could be seen a wider variety of GE crop plants in commercial production, and associated increased costs for organic or other IP versions of those crops.

Unauthorized Releases

The rule is expected to spur innovation, and therefore increase the number of new GE plants developed over time, while not diminishing the protection against plant pest risk that the current regulations provide. With a wider variety of GE crop plants in commercial production, the possibility of unauthorized releases also increases. While not a direct effect of this rule, unauthorized releases of regulated GE crop plants can affect growers of that crop. Unauthorized releases of regulated GE crop plants and the entry of regulated plant material in the commercial human and animal food supply are rare, but such incidents have occurred and may occur again in the future. When such accidental releases are detected, they can lead to both domestic market turmoil and international trade disruptions. All growers of the same crop in which the unapproved trait has been found—whether GE, non-GE, or organic—face substantial costs of testing to ensure that the unapproved trait is not present in their production. If the unapproved trait is discovered at any level, the human or animal food is likely to be destroyed because the

sale of any human or animal food with an unapproved GE trait would be unlawful. Such incidents also disrupt trade, because importers are unlikely to want to buy crops with any levels of GE traits that have not yet been approved for commercialization (National Academies of Sciences 2016).

Financial losses resulting from unauthorized releases are difficult to quantify due to a variety of factors that determine the market price of agricultural commodities. However, a couple of examples are provided. One example is that of the well-publicized StarLink corn incident. While not explicitly an unauthorized release for APHIS, it serves as an example of potential costs. StarLink corn was deregulated by APHIS, yet did not have an EPA established tolerance for human food consumption. In 1998, EPA registered StarLink corn for commercial use, provided that all grain derived from StarLink corn was directed to domestic animal food or to industrial uses (e.g., biofuels). It was not authorized for human food uses, and there were no established tolerance limits for human food. In September 2000, residues from StarLink corn were detected in taco shells, indicating that it had entered the human food supply.

It is estimated that this incident resulted in $298 million to $964 million in lost revenue for producers in market year 2000/2001 (Lin, *et al.* 2003). A separate study estimated that the presence of StarLink in the food supply caused a 6.8 percent drop in the price of corn, lasting for 1 year. In total, nearly 300 food products were taken off the market (Lin, et al. 2003), not necessarily because StarLink corn had been detected in all of the products, but as a precaution taken by the manufacturers of the products. The U.S. share of corn imports by Japan for starch use declined from 93 percent to 62 percent from November 2000 through March 2002. South Korea's imports of U.S. corn for food manufacturing during the same year-and-a-half period

were down 53 percent from the comparable period before the incident, a decline of about 1.2 million tons (Lin, et al. 2003).

Similarly, GE Liberty Link rice 601 (LLRICE 601), which was regulated by APHIS, was detected in samples taken from commercial long grain rice. While both APHIS and FDA reviewed the available scientific data and concluded that there were no human health, food safety, or environmental concerns, the economic consequences of the unauthorized release were substantial. The market costs of commingling of APHIS regulated LLRICE 601 with non-GE rice, worldwide, including the costs associated with the loss of export markets, seed testing, elevator cleaning, and food recalls in countries where the variety of rice had not been approved, are estimated to have ranged from $741 million to $1.3 billion (US-GAO 2008).

While the framework in this rule provides 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 is not expected to affect the commercialization of GE traits that require multi-agency oversight, nor the overall risk of unauthorized releases.

A major obstacle to the commercialization of new GE crops intended for export is acquiring international approvals. Foreign approvals of commercialized GE traits are critical to minimizing trade disruptions. In order for a new GE trait to enter the market, it must first gain regulatory approval in countries where it might be produced or marketed. This approval process can slow down commercialization. Regulatory requirements can and do vary from country to country, and in some cases specific requirements can build in additional delays (Kalaitzandonakes, *et al*. 2015).

Asynchronous approval occurs when adoption of a GE trait takes place in the United States prior to approval of that trait in an export market.[36] Even the trace presence of a GE trait in U.S. exports to markets for which it has not been approved can result in market disruptions and corresponding producer losses, as have happened with U.S. exports of corn, soybeans, and alfalfa. Asynchronous approvals can lead to trade delays, shipment rejection, and costs to traders (FAO 2014). They can also result in the diversion of shipments to other markets by some exporters, and rejection of agricultural products by importers due to policies of zero tolerance for the presence of unauthorized GE materials in shipments (Frisvold 2015). The challenges associated with maintaining variety identity in international trade can increase costs as well as the premiums paid for some crops. Consumers in importing countries can also potentially face higher domestic commodity prices when an import is deterred or directed to another trading partner (Atici 2014). Asynchronous approvals can have multisector effects tied to restrictions on imports and increases in costs and prices. Asynchronous approvals may also deter the development and adoption of new GE traits or new GE crops because farmers producing for an export market may be reluctant to grow varieties that carry the risk of not gaining regulatory approval (National Academies of Sciences 2016). Stein and Rodríguez-Cerezo (2009) and Parisi *et al*. (2016) posited that problems posed by asynchronous approval are likely to worsen as more traits are introduced into a wider variety of crops and as the gaps between regulatory approval processes grow.

As an example, China refused entry of corn with trace amounts of a variety called Syngenta MIR-162 that it had not approved. The embargo, from November 2013 until China

[36] There is no unified definition of the term asynchronous approval; different countries and organizations have similar but not the same definition (FAO, 2014).

ultimately approved the use of MIR-162 on December 16, 2014, affected corn sales and prompted extensive litigation, including class action lawsuits, where U.S. corn producers and U.S. grain merchants sued Syngenta (now owned by ChemChina) (Chaney, et al. 2015). In 2017, a $1.51 billion settlement was reached with Syngenta to resolve the complaints of more than 100,000 U.S. farmers. The settlement does not include Canadian lawsuits (Smethie and Heilshorn 2019). Archer Daniels Midland Co. reached a confidential settlement with Syngenta in 2018 (Begemann, 2018). A grain and feed industry study of the MIR 162-induced trade disruptions on the U.S. corn, distillers dried grains with solubles, and soybean sectors of the U.S. grain industry claimed estimated losses of up to $3 billion during the 2013/14 marketing year (Fisher 2014). Disruptions in international trade can be minimized, albeit at substantial cost (as noted below), by delaying commercialization of new GE traits until regulatory approval has been secured in all major markets. Some biotechnology firms have self-regulated toward that end by not releasing new GE traits until they have been approved for use in major import markets (CropLife International 2020).

When regulatory approvals are delayed, the benefits accrue to producers and consumers at a later time and at lower levels. Cost savings and market effects (e.g., production increases, price changes) realized are smaller (Kalaitzandonakes, *et al*. 2015). The forgone benefits stemming from even a relatively brief delay in product release overshadow both research and regulatory costs (Bayer, *et al*. 2010; Phillips 2014; and Pray, *et al*. 2005). The opportunity costs of the regulatory process include both the out-of-pocket expenses and the associated expense of delays in commercialization, both for biotechnology companies and consumers. In addition to the costs associated with regulatory processes, biotechnology companies also incur debt servicing charges while revenues are delayed. These regulatory hurdles often eliminate smaller

companies and institutions from the development process. Growers forgo income that could be earned, and consumers similarly forgo benefits of lower priced or higher quality products (Phillips 2014).

Environmental Implications

Insect and disease resistant GE cropping systems are, for the most part, considered more environmentally benign than cropping systems utilizing traditional insecticides, bactericides, and fungicides (Gatehouse *et al*. 2011; Brookes and Barfoot 2013), and are highly effective in controlling target plant pests and diseases. Based on data from 1995 through 2014, there has been a pronounced reduction in pesticides used over the top on GE insect resistant crops; by one estimate the reduction is approximately 41.7 percent (Klümper and Qaim 2014). For both GE insect resistant and herbicide resistant crops, pesticide use was found to be reduced by 37 percent (Klümper and Qaim 2014). Cultivation of GE insect resistant crops can also suppress plant pest populations on the landscape scale, which benefits surrounding crops and reduces the need for insecticide use in nearby fields, including ones that have non-GE cropping systems (Carpenter 2011). Less obvious environmental benefits conferred by such reductions in pesticide use include reduced exposure of farmworkers to pesticides and consequently less risk of pesticide poisoning (Kouser and Qaim 2011). A further benefit realized with adoption of GE crop varieties is improved food safety from reduced post-harvest infection of grains by fungi and from reductions in the concomitant production of toxins.

Historically, conventional tillage has served as a primary tool for incorporating crop residues, controlling weeds, and suppressing soil-borne diseases. This practice does not always result in effective soil management and has contributed to substantial soil erosion in some areas of the United States. No-till systems leave the crop residue on the production area unless it is removed for other reasons, such as biomass production (USDA-ERS 2000). Conventional tillage

is associated with greater amounts of soil erosion and run-off than conservation tillage, resulting in reduced soil quality and diminished water resources (USDA-ERS 2000).

Reduced tillage lessens soil disturbance and erosional potential, and can in some cases improve soil quality. Conservation tillage provides a variety of agronomic and economic benefits, such as reduced fuel use due to fewer tillage passes over the field, preservation of soil organic matter, and reduced soil erosion and water pollution (Fernandez-Cornejo *et al*. 2012; Roth 2015). Effective herbicide control is an important factor for farmers to employ when using conservation tillage. GE herbicide resistant cropping systems improve weed management using herbicides and not surprisingly, a higher percentage of growers who have adopted GE herbicide resistant crops use conservation tillage compared to non-adopters (Horowitz *et al*. 2010).

Insect and disease resistant GE crop plants are well recognized as providing agricultural and environmental benefits while meeting market demand for food and fiber. There are however concerns among EPA, developers, and producers regarding the development of resistance to PIPs among target pest populations and resistance to various herbicides. There also is the potential for adverse impacts on non-target species. In response to the potential for development of PIP-resistant populations, industry and EPA measures to inhibit the development of resistant populations primarily involve implementation of recommended insect resistance management practices, and best practices for management of herbicide resistance (US-EPA 2015. US-EPA 2017).

As the rule is expected to spur innovation, we expect the number of new GE plants developed annually to increase over time. In particular, the rule may provide impetus to the development of new horticultural varieties, where the costs of acquiring non-regulated status may have been high relative to the potential market. While the trade-off between positive and

negative consequences associated with such expansion is not quantified, we do not expect that the nature or balance of the trade-off will be materially affected by this rule.

Alternatives to the Rule

APHIS considered alternative regulatory approaches to revising 7 CFR part 340. In addition to a no-action alternative and the rule, APHIS also considered expanded regulation of GE organisms during the development of the proposed rule.

APHIS also identified several other potential alternatives, but, after evaluating them relative to the Agency's PPA authorities, as well as their potential efficacy and feasibility in fulfilling the purpose and need for revisions of the regulations, dismissed these other alternatives and did not consider them further. A discussion of these dismissed alternatives is found in the draft programmatic environmental impact statement prepared for the rule.

An overview of expanded regulation of GE organisms is presented below.

Expanded Regulations

Under one version of such an alternative, APHIS would substantially increase oversight of GE organisms relative to no action and the rule. This alternative would incorporate noxious weed authority and expand the scope of regulation to encompass the potential economic impacts of GE plants on producers of non-GE plants. The mere presence of GE plant materials (e.g., pollen, seed, grain dust) in non-GE plants and their products would be considered a harm to agricultural interests and subject to regulation under 7 CFR part 340; there would not need to be evidence of biological harm. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE plants currently grown, and those that would be grown under this alternative, including GE organisms regulated under the rule.

Hence, the concept of plant pest harm would be expanded, or augmented, to include economic harm from the unintended presence of GE traits in other plants, especially resulting from cross-pollination. GE organisms that are unlikely to pose a plant pest risk under current regulations would be evaluated for potential economic harm. Organisms with the potential to cause such harm would require a permit for environmental release, to include commercial crop production. The permit conditions for these organisms would be specifically designed to limit cross-pollination between GE organisms and non-GE plants by specifying isolation distances; would require management of volunteer plants to prevent GE plants from flowering in abandoned, fallow, and rotated fields; and would ensure that only GE plants that have been granted approval in the major export markets are grown in the United States.

Registration and Pinning System: All non-GE plant producers (conventional, organic, and other identity-preserved) that wish to receive protections from injury or harm due to the mere presence of GE traits under the regulations would need to be registered with APHIS to confirm that they are legitimate business entities. A registration system for non-GE plant producers would be developed, and non-GE plant producers would need to register their production systems with APHIS to establish authenticity and qualify for protections under 7 CFR part 340. In addition, a voluntary national web-based pinning map would need to be developed to identify the location and acreage of GE and non-GE plants cultivated in the United States. Registered non-GE plant producers would also need to provide the GPS coordinates of their crop fields using this system in order to receive the protections provided under 7 CFR part 340.

Further, the only GE plants that would be permitted for commercial-scale cultivation in the United States would be those plants that have been granted approval in major export markets.

This requirement would be instituted to reduce the potential for low level presence (LLP) of unapproved plants in shipments exported to other countries.[37]

Tracking and reporting: GE plant developers would be required to maintain and provide to APHIS a list of GE crop plants they offer for sale each year and to verify whether these crops have been approved for import into major international export markets. Developers and producers of regulated GE plants would be required to track and record the planting locations and acreage of all regulated crop plants and to submit that information to APHIS as requested. All registered producers of non-GE plants would likewise need to track, record, and report the location and acreage of their crops on a voluntary national pinning map in order to receive protections under 7 CFR part 340.

Isolation distances: GE developers and producers would need to verify that all regulated GE plants maintained the isolation distances from non-GE plants specified in the permit. Permits would specify the isolation distance necessary to separate the GE and non-GE plants to achieve less than 0.1 percent cross pollination for seed production and 1 percent for grain production. Producers of regulated GE plants would share the responsibility for meeting the isolation distance with non-GE plant producers; producers of both non-GE and regulated GE plants would need to contribute equally to the isolation distances required for maintenance of registration and permit requirements, respectively. USDA organic standards require that organic farmers use certain preventative measures to minimize the risk of commingling, including maintaining buffer zones adequate to protect crops from chemical spray drift or cross-pollination

[37] Low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) in one or more countries that may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined (Codex, 2009).

(7 CFR Part 205, National Organic Program). GE plant developers would have responsibility for obtaining permits and ensuring that isolation distances and volunteer plant management requirements were met. Similarly, non-GE plant producers would be required to maintain their registration with APHIS and to adhere to registration requirements.

Volunteer plant management: Permits would require volunteer plant management plans to be developed and implemented to prevent regulated GE plants from flowering in abandoned, fallow, and rotated fields. All land used for GE plant production would have to be monitored pursuant to permit requirements to ensure that crops are harvested and that volunteers are managed in abandoned, fallow, and rotated fields.

Compliance: Under this alternative, developers and growers of GE plants could be held accountable for harm to non-GE producers if isolation distances and other permit conditions are not followed. Non-GE plant producers who believed that isolation distances were not maintained could request an inspection by APHIS. If the APHIS inspection revealed that the isolation distance was in violation of permit requirements, the GE developer would be subject to penalties as described in the PPA (§ 7734). If required isolation distances were found to be maintained and all other permit conditions were followed, the GE developer would not be subject to penalties.

Under this alternative, the importation, interstate movement, and environmental release of all regulated GE organisms would be conducted solely under APHIS permit; the notification procedure and courtesy permits would be eliminated as with the rule. Permitting procedures and requirements for environmental releases would be the same as that described for the rule for those organisms that posed plant pest risk as defined under the rule. Requirements for the importation and movement of regulated organisms would be the same as those under the rule.

Costs and Benefits of the Alternative: This alternative would assign liability on strictly economic terms for products that do not demonstrate plant pest risk. It would provide some protection to organic and other non-GE plant growers against losses from the unintended presence of GE traits. It would also provide producers with protection against export market disruptions and associated losses that may occur when adoption of a GE trait occurs in the United States prior to its approval in an export market.

This alternative would affect GE plant developers, firms that market GE seed, growers of GE and non-GE crops, and APHIS. Crops produced on approximately one-half of the arable land in the United States, 170 million acres, could be affected. GE plant developers would have increased tracking and monitoring responsibilities, and the collection and monitoring of planting data could be intrusive and burdensome for affected GE plant producers. GE plant developers would also have greatly increased liability exposure. In cases where the permit conditions are not followed and a non-GE plant producer suffers a demonstrated loss, the GE plant developer would be subject to penalties as described in the PPA (§ 7734). In addition, this alternative would delay the launch of GE plants until approvals have been granted in major export markets. Such delays in commercialization of a GE trait could substantially impact the returns to the GE plant developer and the growers who adopt that trait (Phillips 2014). GE growers would be responsible for removing farmland from production or at least for growing non-GE plants on a portion of the isolation buffer areas. This would decrease the profitability of those acres for GE adopters, and potentially decrease the adoption and planting of GE crops overall and increase consumer prices. To the extent that this alternative would increase buffer areas, the cost of providing those areas is a net loss to society regardless of who pays for them. Grass buffers are often not harvested, so farmers lose all of the value that could have been gained from growing

crops on that land. Organic farmers who grow conventional crops as buffers are able to sell the harvested buffer to the conventional market, but they lose the value of the organic premium for those acres. Farmers of GE crops who grow conventional crops as buffers are also able to sell the harvested buffer to the conventional market, but they similarly lose the benefits of the adoption of GE crops on those acres. All of the above factors may also reduce GE innovation and the associated benefits to GE crop developers, GE crop growers, and consumers.

Organic and non-GE crop growers would also be impacted by this alternative. They would receive some protection against losses from the unintended presence of GE traits. However, in order to receive protection, organic and non-GE crop growers would need to record their crop locations, and take part in a certification program to establish authenticity. Certification of non-GE crop producers would be necessary to prevent non-legitimate interests from spuriously claiming non-GE status in order to impose requirements on neighboring GE producers. Some costs for non-GE crop producers may decline because GE adopters would absorb some of the cost of reducing the risk of unintended cross-pollination.

APHIS would need to develop a national system to identify the location of non-GE plants, and a system to certify non-GE plant producers. APHIS would also need to provide a large number of additional inspectors and devote increased resources for the testing of GE plants that may grow within the isolation buffer areas. APHIS would also need to provide a large number of additional inspectors and devote increased resources to the administration of compliance and response to complaints of noncompliance, such as with required crop isolation distances. These costs are expected to be significant, considering that APHIS inspections currently administer around 400,000 acres and that this alternative would increase the scope of potentially permitted area to about 170 million acres.

APHIS has never regulated based on economic effects alone in the absence of any actual biological, chemical, or physical damage. Such a regulatory role would be inconsistent with the limits on APHIS' statutory authority and with current APHIS programs which are aimed at preventing the introduction and spread of plant pests.

E.O. 13771 Cost Savings from the Rule

Table 9 shows annualized primary, low, and high estimates of cost savings associated with this rule discounted at 7 and 3 percent, in 2016 dollars. In accordance with guidance on complying with E.O. 13771, the primary estimate of the cost savings for this rule is $8.3 million, the mid-point estimate of cost savings annualized in perpetuity using a 7 percent discount rate.

Table 9. Annualized value of the primary, low range and high range estimates of cost savings in perpetuity; discounted at 7 and 3 percent, 2016 dollars

	Primary Cost Savings Estimate (1)		Low Range Estimate		High Range Estimate	
	7 %	3 %	7 %	3 %	7 %	3 %
	Million $					
Annualized Cost Savings:	8.3	8.4	4.7	4.8	12.0	11.9

(1) Mid-point of the range of cost savings estimated in the analysis.

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to evaluate the potential effects of their proposed and final rules on small businesses, small organizations and small governmental jurisdictions. This final regulatory flexibility analysis describes expected impacts of this rule on small entities, as required by section 604 of the Act.

Need for and Objectives of the Rule

APHIS is amending 7 CFR part 340, which regulates the interstate movement, importation, and environmental release of GE organisms that may be plant pests or that there is reason to believe are plant pests. The regulations in 7 CFR part 340 were promulgated in 1987 under the authority of the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912. These acts, and others, were subsequently subsumed within the Plant Protection Act (PPA) of 2000. The PPA authorizes the Secretary of Agriculture to implement programs and policies designed to prevent the introduction and spread of plant pests and diseases. This rule draws upon experience gained during more than 30 years of regulating GE organisms. The comprehensive revisions are the first of this sort undertaken since enactment of the PPA. Advances in genetic engineering and oversight experience gained by APHIS underlie the decision to revise and update the regulations. The changes will improve the regulatory process by providing greater transparency, flexibility, and efficiency.

Significant Issues raised by Public Comment in response to the Initial Regulatory Flexibility Analysis

Comments: A commenter stated that APHIS leaves unaccounted the numerous other costs borne entirely by organic farmers to avoid or manage GE commingling with non-GE crops: loss of production and revenue from the planting of non-organic buffer strips, yield losses from delayed planting (for temporal isolation), costs of testing for GE content, and loss of sales due to the increased risk of commingling, among others. From a different perspective, another commenter stated that those marketing "non GMO" products have sought to transfer their identity preservation costs onto the shoulders of neighbors growing legal, safe, environmentally beneficial "GMO" varieties, and that this phenomenon is a "negative impact" that should be considered.

Several commenters suggested that this rule would dramatically increase the frequency of GE commingling with non-GE or organic crops, and associated economic damages. A commenter stated that ending regulation of many experimental GE crops would sharply increase harms to farmers, markets, and the environment from GE escapes and commingling with non-GE crops. Another commenter stated that APHIS dramatically underestimates the frequency and economic impacts of GE commingling with non-GE crops, and that APHIS improperly limits its assessment of harm of commingling to the organic sector. The commenter also stated that APHIS fails to assess the full costs of GE commingling even to the organic sector, which include numerous costly measures to mitigate GE commingling, and lost market opportunities. The commenter further stated that APHIS also fails to assess the past and current, or project the future, impacts and costs of GE organisms that escape into wild or semi-natural habitats via seed dispersal, cross-pollination with sexually compatible relatives, or by other means. That same commenter stated that APHIS fails to account for or analyze the substantially increased harm to the U.S. agricultural economy from increased transgenic commingling episodes. Another commenter stated that APHIS fails to account for the costs of commingling to the "non-organic, non-GMO" sector, beyond anecdotal descriptions of a few high-profile commingling episodes involving unauthorized releases.

Response: APHIS in this Regulatory Impact Analysis has expanded the discussion of the various costs, including the costs associated with buffer strips, spatial and temporal isolation, and the loss of premiums associated with the risk to organic and non-GE growers from cross-pollination or commingling. We note that organic crops and non-GE products that are kept separate from their GE equivalents are treated as value-added crops commanding premiums that vary according to prevailing supply and demand conditions. Organic and other identity-preserved

crops generally receive a price premium, a premium adversely impacted by the unintended presence of GE traits. The premiums compensate farmers and traders for incremental costs they incur, including those borne to maintain the segregation of non-GE and other IP production from GE crops throughout the supply chain (through buffer zones, spatial and temporal isolation, etc.). In the United States, the coexistence of GE and non-GE production systems has been left to market forces. Non-GE growers bear costs of coexistence and, in turn, pass those costs on to purchasers of non-GE crops (Kalaitzandonakes and Magnier 2016).

APHIS did not limit assessment of impacts to the organic sector in the Regulatory Impact Analysis. The discussion of impacts included organic, other non-GE, and other identity-preserved crops. Potential impacts on the organic sector were highlighted because there is relatively little information detailing the economic harm incurred by growers of other non-GE crops because of the unintended presence of GE products. Losses reported by organic farmers in the United States were reported in the 2014 Organic Survey. Through contract requirements, growers of organic or other non-GE crops may supply products that do not exceed a threshold of GE content set by a private company, a strict export market, or a voluntary certifier. Because contracts between growers and buyers are private, it is difficult to find documented information about how extensively growers are contracting to meet specific non-GE standards or to what extent farmers of organic or other non-GE crops are incurring economic losses as a result of being unable to meet contracts because of commingling with non-GE crops (National Academies of Sciences 2016). APHIS is unaware of studies documenting harm to the non-GE food chain from commingling of GE with non-GE food. Furthermore, products bearing the Non-GMO Project Verified seal claim compliance with the Project's standards, but the seal is not a "GMO

free" claim (https://www.nongmoproject.org/product-verification/verification-faqs/). It is not clear to what extent non-GE food producers that are not organic are harmed by commingling.

Innovation in the agricultural biotechnology sector is expected to increase under this rule, and there could be a wider variety of GE crop plants in commercial production. However, plants that are exempted from, or not covered under, this regulation are still subject to oversight by FDA and EPA as appropriate. Many of the new GE traits are expected to be introduced into crops that are already predominantly GE. Also, from our experience with the 'Am I Regulated' program, there have been 80 cases of plants that came through the AIR process since 2011, but to our knowledge only two are being grown in the United States for commercial purposes. In addition, a developer's control over the development process is not expected to change. They will still need to follow best stewardship practices to maintain varietal purity and protect their intellectual property interests.

Comment: Several commenters stated that if traits approved in the U.S. are grown while not fully approved globally, trade issues emerge that can close markets. Additionally, they commented that farmers and processors who rely on sensitive international markets must adapt their practices, including monitoring and testing to comply with international market requirements. Other commenters stated that APHIS failed to account for or analyze the substantially increased harm to the U.S. agricultural economy from lost foreign markets.

Response: APHIS acknowledged the impacts of asynchronous approvals on international trade and has expanded the discussion of those potential impacts in this Regulatory Impact Analysis. We acknowledge that asynchronous approvals can lead to trade delays, shipment rejection, and costs to traders. Asynchronous approvals can result in the diversion of shipments to other markets by some exporters, rejection of agricultural products by importers, and

increased costs associated with maintaining variety identity for some crops. Asynchronous approvals can have multisector effects tied to restricted imports and higher costs and prices. Asynchronous approvals may deter the development and adoption of new GE traits or new GE crops because farmers producing for an export market may be reluctant to grow varieties that jeopardize access to export markets. We acknowledge that problems posed by asynchronous approval can worsen as more traits are introduced into a wider variety of crops and as gaps between regulatory approval processes grow.

However, there are too many unknowns to predict future instances of asynchronous approvals. One unknown factor is whether the approval process in other countries will change following the implementation of this rule. Another unknown is the extent to which modifications made by U.S. developers will be recognized by international regulators.

Innovation in the agricultural biotechnology sector is expected to increase under this rule, and there could be a wider variety of GE crop plants in commercial production. However, plants that are exempted from or not covered under this regulation are still subject to oversight by FDA and EPA as appropriate. Many of the new GE traits are expected to be introduced into crops that are already predominantly GE. Also, from our experience with the 'Am I Regulated' program, there have been 80 cases of plants that came through the AIR process since 2011, but to our knowledge only two are being grown in the United States for commercial purposes. Also, a developer's control over the development process is not expected to change. They will still need to follow best stewardship practices to maintain varietal purity and protect their intellectual property interests.

Comment: One commenter stated that APHIS did not present supporting evidence for the claim that the forgone benefits due to delayed innovation can be substantial and that developers, producers, and consumers all lose from regulatory delays.

Response: APHIS did present citations as to the forgone benefits of regulatory delays in the Regulatory Impact Analysis. Those citations were – Kalaitzandonakes, N., Zahringer, K. and Kruse, J. "The Economic Impacts of Regulatory Delays on Trade and Innovation" Journal of World Trade, 49(6): 1011-1046, 2015; and Bayer, C., Norton G., and Falak-Zepeda, J. "Cost of biotechnology regulation in the Philippines: Implications for developing countries." AgBioForum 13(1) 53-62. 2010.

Comment: A commenter stated that a possible result of the USDA proposal is that there will be a patchwork of state regulations of GE plants with each state having different requirements. This will raise the cost of carrying out confined field trials and commercial release by public and private seed developers and could lead to "forum shopping," where seed developers conduct their field trials in states with lax regulation or no regulation at all.

Response: For purposes of the relationship between State and Federal regulation, the regulations proposed under this part are functionally equivalent to the rules under which APHIS has been operating for essentially three decades. Under the existing regulations, APHIS communicates with and cooperates with state and local governments as appropriate and as circumstances warrant, including for coordination of enforcement and permitting activities. APHIS does not anticipate that the working relationship with state and local governments will be changed in any way based upon issuance of this rule. With respect to GE plants subject to regulation, field trials in all States will continue to be regulated under federal law, and uniform

federal standards will apply to the determination of whether a GE plant should be subject to regulation.

Comments: Several commenters specifically responded to APHIS' request for public comment regarding whether a shorter duration is warranted for certain records pertaining to permit activities. One commenter stated that the five-year timeframe in this rule is commensurate with the length of time other types of records are stored that record retention should not be an undue burden, as long as electronic copies may be used, and that APHIS should specify that records may be retained as backed-up electronic copies. Another commenter expressed support for the time period that APHIS proposed for developers to maintain records for movements and releases under a permit. They stated an expectation that any responsible developer would generate and maintain permit records not only due to regulatory obligations but also for stewardship purposes. One commenter urged us to ameliorate the burden of retaining records of permitted activities for 5 years by offering small entities an option to deposit such records electronically with APHIS for retention.

Response: Records are often reviewed during or after a trial as part of an on-site inspection, or compliance audit, to verify that all conditions have been followed and to verify the fate of the regulated material (e.g., devitalized/disposed of, stored, or shipped). APHIS needs to know where regulated material is maintained in order to perform effective compliance oversight. Further, this requirement satisfies recommendations issued by USDA's Office of Inspector General following audits performed in 2015. APHIS agrees that the five-year timeframe for retaining records following permit expiration in this rule is commensurate with the length of time other types of records are stored, and therefore that record retention should not be an undue burden. APHIS also agrees that any responsible developer would generate and maintain records

relating to a permit not only for regulatory compliance but also for stewardship purposes. Functionally, the record retention requirement in this rule does not increase the type of records that must be maintained, just how long those records must be kept. Certain records are not required to be submitted to APHIS but are to be kept by permitted entities regardless of size. Large and small entities alike have the option to retain such records electronically. APHIS does not agree with the recommendation that APHIS give small entities the option to deposit their records with APHIS. This option would require that APHIS develop a process for companies to send the records and for APHIS to receive and store the information, which seems unnecessarily burdensome as compared to the fairly modest burden for developers of keeping their own records.

Comments: Several commenters stated that APHIS needs to establish reasonable timeframes in this rule. Specifically, commenters noted that time frames for review of permit applications (including state and tribal review), RSRs, and confirmation letters will better facilitate predictable business planning.

Commenters suggested that including timeframes for the completion of RSRs in the regulation would require the Agency to make timely decisions and prevent the excessively long reviews that, according to some commenters, have occurred in previous petitions for deregulation. Several commenters also recommended that APHIS include timelines for APHIS responses to requests for confirmation.

Under the June 2019 proposed rule, timeframes for APHIS to conduct reviews of permit applications would have been removed from the regulations. Some commenters opposed the change and requested that we retain those requirements in the regulations or otherwise incorporate into this final rule "reasonable" timeframes to provide greater certainty for

developers about the length of the process. Commenters had various suggestions as to the length of the timeframe(s). One commenter, for example, recommended that APHIS be allowed 10 days to review applications for permits for interstate movement and 30 days for release permit applications. It was also recommended that we establish timeframes for making determinations on permit amendments and for review and comment by State and Tribal officials on permit applications.

Response: APHIS agrees with the comments on RSR timeframes. We are revising § 340.4(b)(2) to include a statement that APHIS will complete the initial review within 180 days of receiving a request that meets the requirements specified in this section. We are revising § 340.4(b)(3)(ii) by adding a statement that when a more in-depth review is necessary, APHIS will make a final determination regarding the regulatory status of the GE plant within 15 months of receiving a request that meets the requirements specified in this section.

In response to the comment regarding timelines for APHIS responses to requests for confirmation, we are adding a sentence to § 340.1(d), which states that APHIS will provide a written response within120 days of receiving a sufficiently detailed confirmation request.

In response to the comments on permit timeframes, we are adding a new § 340.5(f)(5), which states that APHIS will approve or deny the permit within 45 days of receipt of a complete application for a permit for interstate movement or for importation; or within 120 days of receipt of a complete application for a permit for release into the environment. The 120-day period will be extended if preparation of an environmental assessment of environmental impact statement is necessary.

Comments: Commenters expressed concern over the regulatory oversight of PMPIs. One commenter stated that the lack of clarity on the approach to regulatory oversight of PMPIs

may result in unnecessary costs and time delays to bring new products to market, which would disproportionately impact smaller innovation companies and limit the availability of new opportunities for farmers.

Response: We have decided to maintain regulatory oversight of PMPI-producing plants by continuing to require permits for their movement. The intended use of PMPIs makes them differently situated than other GE plants regulated by APHIS, such that additional evaluation beyond RSR may be needed. We therefore consider it appropriate to maintain the status quo and continue to require permits for PMPI-producing plants. In such instances when the risks associated with a plant or organism are not fully understood, APHIS has interpreted its authority under Sections 7711 and 7712 of the Plant Protection Act to provide a basis for regulating the plant or organism based on our best understanding of the risks presented. APHIS will continue to exercise its authority under the Plant Protection Act to maintain regulatory oversight of PMPI-producing plants. In this final rule, we are adding this requirement to §340.2, as a paragraph (e) which states that a permit is required for the movement of a plant that encodes a product intended for pharmaceutical or industrial use.

Comments filed by the Small Business Administration in response to the Proposed Rule

There were no comments filed by the Small Business Administration in response to the proposed rule.

Potentially Affected Small Entities

The rule is expected to benefit a variety of small entities, directly and indirectly, including GE-related public and private research facilities, seed and crop producers, food processors, grain processors, and paper producers. By implementing risk-based regulation, this

rule directly reduces the regulatory costs for affected plant developers, some of whom are considered small.

Indirect benefits may include more timely foreign regulatory approvals, facilitation of small companies' ability to raise venture capital, and increased participation by public and private academic institutions in GE research. The latter effects can be expected to spur GE innovations, in particular benefiting producers of specialty crops which typically have not benefited from GE plant innovation, including small entities. On the other hand, an increased rate of GE crop innovation may indirectly negatively affect growers of organic or other identity-preserved crops because of the increased possibility of unintended presence of GE traits. Most of the growers of non-GE crops are small entities.

Entities potentially directly affected by this rule are included within the North American Industry Classification System (NAICS) category 541714, Professional, Scientific and Technical Services, as establishments in the sub-category of Research and Development in Biotechnology. By implementing risk-based regulation, this rule reduces the burden associated with the regulation of organisms that are unlikely to pose a plant pest risk, thereby reducing costs borne by some plant developers, some of which are considered small.

Establishments in this industry category are considered small if they employ not more than 1,000 persons. According to the 2012 Economic Census, there were 2,901 establishments in this category, and 2,754 (95 percent) had fewer than 100 employees. Thus, at least 95 percent can be considered small. The specific cost savings to any developer under this rule depends on several factors: the number of new GE plants that a particular producer develops under the regulatory requirements of this rule; whether there already is an APHIS permit for a particular GE plant developed; the number and types of field trials, analytical tests and assessment studies

conducted for a particular GE plant that would have been used to meet previous regulatory requirements; and whether USDA alone has a regulatory role with regard to a particular GE plant.

Farmers may indirectly benefit from this rule by having access to a wider variety of GE crop species, affording them a broader selection of crops to suit their particular management needs. Also, by reducing the cost of regulation, this rule may enable university researchers to increase their use of modern methods to innovate and improve crop varieties. Such innovation may ultimately benefit private sector biotechnology companies, farmers, and consumers. On the other hand, an increased rate of GE crop innovation may indirectly negatively affect growers of organic, other non-GE, and other identity-preserved crops, or producers otherwise catering to GE sensitive markets, because of the increased possibility of unintended presence of GE traits. The extent of any indirect effects depend, among other factors, on the number of new GE plants developed, their rate and extent of adoption, and their proximity to other crops. Entities potentially indirectly affected by this rule are classified within the following NAICS sectors: Agriculture, Forestry, Fishing and Hunting (Sector 11), Manufacturing (Sectors 31-33), Wholesale Trade (Sector 42), Retail Trade (Sectors 44 and 45), and Transportation (Sectors 48 and 49).

The Small Business Administration (SBA) has established guidelines for determining which entities are to be considered small. Table 10 provides a summary of potentially directly and indirectly affected industries, the SBA size standard, the number of establishments in those industries, revenues, and the percentage of establishments considered small.

Table 10. Potentially Affected Entities. Industry (by NAICS code), SBA Size Standard, Number of establishments, Revenue and Percentage considered small.

Industry (NAICS)	Size Standard	Number	Sales		Percent Small		
			Total ($ million)	Average ($million)			
Agriculture, Forestry, Fishing and Hunting (Sector 11)							
Oilseed & Grain Farming (1111)	annual sales ≤ $1 million	369,332	132,008	0.4	at least	80%	(1)
Vegetable & Melon Farming (1112)	annual sales ≤ $1 million	43,021	16,794	0.4	at least	92%	(1)
Fruit & Tree Nut Farming (1113)	annual sales ≤ $1 million	93,020	25,558	0.3	at least	92%	(1)
Greenhouse & Floriculture Production (1114)	annual sales ≤ $1 million	52,777	14,761	0.3	at least	92%	(1)
Cotton Farming (11192)	annual sales ≤ $1 million	8,915	4,910	0.6	at least	67%	(1)
All other crop Farming (11193, 11194, 11199)	annual sales ≤ $1 million	482,790	20,409	0.0	at least	98%	(1)
Beef Cattle Ranching & Farming (112111)	annual sales ≤ $1 million	619,172	33,900	0.1	at least	98%	(1)
Cattle Feedlots (112112)	annual sales ≤ $8 million	13,734	38,264	2.8	at least	70%	(2)
Dairy Cattle & Milk Production (11212)	annual sales ≤ $1 million	46,005	41,477	0.9	at least	73%	(1)
Hog & Pig Farming (1122)	annual sales ≤ $1 million	21,687	22,737	1.0	at least	65%	(1)
Poultry & Egg Production (1123)	annual sales ≤ $1 million	52,849	43,773	0.8	at least	63%	(1)
Sheep & Goat Farming (1124)	annual sales ≤ $1 million	73,272	796	0.01	at least	99.7%	(1)
Animal Aquaculture & Other Animal Production (1125, 1129)	annual sales ≤ $1 million	227,597	6,019	0.03	at least	99%	(1)
Timber Tract Operations (113110)	annual sales ≤ $12 million	394	n/a	n/a		n/a	(3)
Forest Nursery and Gathering of Forest Products (113210)	annual sales ≤ $12 million	182	n/a	n/a		n/a	(3)
Logging (113310)	No more than 500 employees	8,151	n/a	n/a		100%	
Cotton Ginning (115111)	annual sales ≤ $12 million	242	n/a	n/a		n/a	(3)
Soil Preparation, Planting, and Cultivating (115112)	annual sales ≤ $8 million	2,193	n/a	n/a		n/a	(3)

Crop Harvesting (115113)	annual sales ≤ $8 million	333	n/a	n/a		n/a	(3)
Postharvest Crop Activities (except cotton ginning) (115114)	annual sales ≤ $30 million	1,062	n/a	n/a		n/a	(3)
Farm Management Services (115116)	annual sales ≤ $8 million	513	n/a	n/a		n/a	(3)
Support Activities for Animal Production (115210)	annual sales ≤ $8 million	4,359	n/a	n/a		n/a	(3)
Support Activities for Forestry (115310)	annual sales ≤ $8 million	1,691	n/a	n/a		n/a	(3)
Manufacturing (Sectors 31-33)							
Ethyl Alcohol Manufacturing (325193)	No more than 1,000 employees	223	42,649	191		100%	
Pesticide and Other Agricultural Chemical Manufacturing (325320)	No more than 1,000 employees	210	15,176	72		99%	
Pharmaceutical Preparation Manufacturing (325412)	No more than 1,250 employees	1,165	136,453	117	at least	98%	(8)
Medicinal and Botanical Manufacturing (325411)	No more than 1,000 employees	427	12,583	29		98%	
Wholesale Trade (Sector 42)							
Fresh Fruit and Vegetable Merchant Wholesalers (424480)	No more than 100 employees	4,859	74,572	15		96%	
Other Grocery and Related Products Merchant Wholesalers (424490)	No more than 250 employees	13,758	286,631	21	at least	96%	(7)
Grain and Field Bean Merchant Wholesalers (424510)	No more than 200 employees	4,889	231,415	47	at least	99%	(7)
Other Farm Product Raw Material Merchant Wholesalers (424590)	No more than 100 employees	643	15,781	25		99%	
Farm Supplies and Merchant Wholesalers (424910)	No more than 200 employees	8,548	129,772	15	at least	99%	(7)

Flower, Nursery Stock, and Florists' Supplies Merchant Wholesalers (424930)	No more than 100 employees	3,482	9,929	3		98%	
Retail Trade (Sectors 44 and 45)							
Nursery and Garden Centers (444220)	annual sales ≤ $12 million	13,928	33,038	2	at least	96%	(5)
Supermarkets and Other Grocery Stores (445110)	annual sales ≤ $35 million	66,343	537,322	8	at least	90%	(6)
Fruit and Vegetable Markets (445230)	annual sales ≤ $8 million	2,761	3,584	1	at least	94%	(2)
All Other Specialty Food Stores (445299)	annual sales ≤ $8 million	5,524	2,765	1	at least	99.5%	(2)
Food (Health) Supplement Stores (446191)	annual sales ≤ $16.5 million	9,060	5,810	1	at least	99.8%	(5)
Warehouse Clubs and Superstores (452910)	annual sales ≤ $22 million	5,114	406,309	79	less than	3%	(6)
Florists (453110)	annual sales ≤ $8 million	12,476	4,482	0.4	at least	99.8%	(2)
Transportation (Sector 49)							
Farm Product Warehousing and Storage (493130)	annual sales ≤ $30 million	525	738	1	at least	98%	(6)
Professional, Scientific and Technical Services (Sector 54)							
Research and Development in Biotechnology (541714)	No more than 1,000 employees	2,901	16,851	6	at least	95%	(7)

(1) Establishments with no more than $500,000 in sales, the closest size category for which data are available.

(2) Establishments with no more than $5 million in sales, the closest size category for which data are available.

(3) Neither the Census of Agriculture nor the Economic Census tracks revenue for these establishments.

(4) Establishments with no more than 500 employees, the closest size category for which data are available.

(5) Establishments with no more than $10 million in sales, the closest size category for which data are available.

(6) Establishments with no more than $25 million in sales, the closest size category for which data are available.

(7) Establishments with no more than 100 employees, the closest size category for which data are available.

(8) Establishments with no more than 1,000 employees, the closest size category for which data are available.

Sources: 2012 Census of Agriculture and 2012 Economic Census.

Projected Reporting, Recordkeeping, and Other Compliance Requirements

APHIS is consolidating recordkeeping, compliance, and enforcement requirements in 7 CFR part 340 into a new § 340.5. This rule also changes previous recordkeeping requirements to ensure that APHIS has sufficient information to monitor compliance with its regulations and to maintain effective oversight of regulated GE organisms, in accordance with provisions of the 2008 Farm Bill and recommendations of the 2015 USDA OIG report on GE organisms.

There will be some new costs borne by regulated entities under the rule, including rule familiarization and recordkeeping. Reporting and recordkeeping requirements associated with this rule are further discussed in the rule under the heading "Paperwork Reduction Act." The public reporting burden for this collection of information is estimated to average 17.73 hours per response. The estimated total annual burden on respondents (Businesses; State and Tribal Regulatory Officials) is 21,853 hours. This total burden assumes a total of 1,337 responses per year, based on an estimated 321 respondents and an estimated 3 responses per respondent. (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.) Those annual recordkeeping costs are estimated to total about $1,070,000, or about $3,300 per respondent. [38] There have been about 1,250 unique entities that have applied for permits or notifications under part 340 since 1987, and APHIS estimates that each of those entities will spend about 24 hours becoming

[38] Total burden hours (21,853) multiplied by the respondents' estimated average hourly wage of $33.28, and then multiplying the result by 1.4706 to capture benefit costs. The wage estimated was obtained from the U.S. Department of Labor, Bureau of Labor Statistics Occupational Outlook Handbook, 2019 Report - Occupational Employment and Wages in the United States. https://www.bls.gov/ooh/healthcare/veterinarians.htm. According to DOL BLS news release USDL-18-1499, dated September 18, 2018 benefits account for 32% of employee costs, and wages account for the remaining 68%. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.4706. A total of 321 respondents.

familiar with the provisions of this rule at a total one-time cost of about $1.5 million, or about $1,174 per entity. The regulatory compliance costs that are associated with this rule only occur in conjunction with activities that occur under permit. This rule provides ways, such as through exemptions and the RSR process, that APHIS permits will not be necessary for the development of certain GE plants. Small entities, including small-scale biotechnology developers as well as land-grant and other public university researchers, are most likely to develop GE plants that do not require APHIS permits, and thus will face lower regulatory compliance costs under this rule.

The cost savings under this rule are expected to more than outweigh the new costs associated with this rule. Developers who are not required to have permits under this rule will realize cost savings in comparison to the current regulatory process. Savings to the regulated community will result from a reduced need to collect field data, fewer reporting requirements, and lower management costs. Costs previously associated with petitions for non-regulated status will be reduced or eliminated where APHIS permits are no longer necessary. 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 rule could range from $1.6 million to $5.6 million ($3.6 million on average) for the development of a given GE plant. If EPA and/or FDA also have an oversight role in the development of a given GE plant, compliance cost savings could range from $551,000 to $937,000 ($744,000 on average). From 1993 through September 2019, an average of just under 5 petitions were processed (granted non-regulated status or the petition withdrawn) in a given year, with a high of 14 in 1995. As the rule is expected to spur innovation, we expect the number of new GE plants developed annually to increase over time. In particular, the rule may provide impetus to the development of new

horticultural varieties, where the costs of acquiring non-regulated status may have been high relative to the potential market.

Steps Taken by APHIS to Minimize Significant Economic Impacts on Small Entities

This rule reduces costs and streamlines regulatory compliance for small and large businesses alike. The rule provides for a number of exemptions from regulation and an RSR process whereby plants will not be regulated if they are found by APHIS to be unlikely to present a plant pest risk. When APHIS permits are not necessary, developers will forgo regulatory compliance costs associated with those APHIS permits. Based on stakeholder engagement and public comments on the proposed rule, we expect that small entities, including small-scale biotechnology developers as well as land-grant and other public university researchers, are most likely to develop GE plants that do not require APHIS permits, and thus forgo regulatory compliance costs under this rule.

Some of the specific records required under this rule are not explicitly included in the current regulations; however, they are required as part of the supplemental permit conditions that accompany an issued permit. Additional compliance costs that are associated with this rule, only occur in conjunction with activities that occur under permit. This rule provides ways that APHIS permits will not be necessary for the development of GE plants. Through the use of exemptions and the RSR process, entities can avoid certain regulatory compliance costs.

One commenter on the proposed rule urged us to ameliorate the burden of retaining records of permitted activities for 5 years by offering small entities an option to deposit such records electronically with APHIS for retention. APHIS does not agree with the recommendation. The five-year timeframe for retaining records following permit expiration is commensurate with the length of time similar types of records are stored. Other commenters

noted and APHIS agrees that a responsible developer generates and maintains records relating to a permit not only for regulatory compliance but also for stewardship purposes. The record retention requirement in this rule does not increase the type of records that must be maintained, just how long those records must be kept. Large and small entities alike have the option to retain such records electronically. The change in the length of time records are kept should not present a significant burden for permit holders.

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Appendix Tables

The tables in this appendix show the derivation of APHIS staffing expenditures expected to be affected by the rule, in regulating GE organisms. The costs are based on the time required per task, multiplied by the number of employees and their grade-level salaries in 2016. Total costs include benefits and overhead of 31.7 percent. The General Schedule salary table is included as appendix table 9.

Appendix Table 1: Calculation of current costs associated with compliance, 2016 dollars

	Time (hours) per letter per person	Frequency – per letter OR actual number for CAs and EANs	Number of people	GS Level	Total Costs
Documentation and Analysis					
a. Documentation and processing	0.25 -0.75	Per letter	1	12 to 13	23
b. Incident Analysis	0.5-8	Per letter	1 to 2	12 to 13	289
Writing/revising analysis and letters	0.5-2	Per letter	1	12 to 13	85
Quality Assurance Quality Control Review of Analysis/Letter					
a. Initial	0.75-1.75	Per letter	1 to 2	12 to 13	85
b. Final	0.25 - 0.75	Per letter	1 to 2	14	44
Total costs per letter					**526**
Total costs for 256 letters					**134,678**
Other actions (EANs, CAs, etc.)(1)	2 to 5	12 per year	2 to 4	12 to 13	5,720
Total compliance costs					**140,398**
Total compliance costs with overhead and benefits					**184,904**

(1) Emergency Action Notifications (EANs) and compliance agreements (CAs).

Note: GS salaries are calculated at a step 5 level.

Appendix Table 2: Calculation of current costs associated with inspections, 2016 dollars

	Time (hours)	Average Time	Frequency	Number of People	GS Level	Total Costs
Inspection Selection FY17						
a. Standard Inspection Selection Preparation	9.6	9.6	Per inspection selection/12 times per year	1	11	3,986
b. Post-Harvest Inspection Selection Preparation (GIS Mapping)	1.75	1.75	Per inspection selection/12 times per year	1	13	1,036
c. Select sites	1-3	2	Per inspection selection/12 times per year	3 to 4	13-14	4,519
d. Assigning Inspections	0.2-0.25	0.23	1 per inspection	1	13-14	43
e. Reviewing & Processing Assignments						
i. To BRS/PPQ	0.1-0.25	0.18	1 per BRS/PPQ inspection	1	13	9
ii. To States	1	1	1 per State inspection	1	13	49
f. Oversight of Inspections	0.5	0.5	1 per inspection	1	13	25
g. Processing Assignment Changes (only as required)	0.5-1	0.75	.2 per inspection	1	13-14	11
Conducting Inspections						
a. Prepare/Revise Worksheet	0.25 -1	0.625	1 per inspection	1 per inspection	11 to 13	26
b. Review Worksheet/associated information	1 to 2	1.50	1 per inspection	1	13	74
c. Arrange travel, expenses (total time)	0.25-1	0.63	1 per inspection	1 per inspection	8 to 13	22
d. Approve travel, expenses	0.1-0.25	0.18	1 per inspection	2	14-15	23
e. Prepare for Inspection	1	1	1 per inspection	1	11-13 (11 PPQ; 12-13 BRS)	41.8
f. Travel time	1 to 4	2	1 per inspection	1	11-13 (11 PPQ; 12-13 BRS)	83.6
g. Conduct inspection	1	1	1 per inspection	1	11-13 (11 PPQ;	41.8

					12-13 BRS)	
Inspection Reports						
a. Writing/revising inspection reports (includes Map and Photo documentation)	2	2	1 per inspection	1	11-13 (11 PPQ; 12-13 BRS)	83.6
b. Review inspection reports	1 to 3	2	1 per inspection	1 per inspection	12 to 13	90.8
c. Enter State reports into ePermits	1 to 2	1.5	1 per State-conducted inspection	1	8 to 13	53
d. Closeout inspection (non-incident letter or referral)	0.1-1	0.55	1 per inspection	1	12 to 13	25
Total Costs without overhead and benefits						**487,032**
Total Costs with overhead and benefits						**641,422**

Notes: A total of 706 inspections were conducted in FY 2018. GS salaries are calculated at a step 5 level.

Appendix Table 3: Calculation of current costs associated with "Am I Regulated" (AIR) process, 2016 dollars

Activity	Time (hours)	Number of people	GS level	Times per year	Total Cost per Year
Inquiry Intake and CBI Issues	6	2	1 GS08 and 1GS14	12	12,122
Analysis and Drafting of Response	16	2	GS12 to 14	12	19,082
Review and Clearance of Response					
Policy and Technical Review	2	2	GS13 to 14	12	2,582
Program Directors meeting	2	7	GS15 to SES,SL	3	3,037
Office of Deputy Administrator	2	2	GS15 to SES,SL	12	3,470
Total costs without benefits and overhead					**43,398**
Total costs with benefits and overhead					**57,156**

Note: SES and SL salaries are calculated at a GS 15 step 10 level, GS salaries are calculated at a step 5 level.

Appendix Table 4: Calculation of current costs associated with notifications, 2016 dollars

Activity	Time (hours)	Average Time (hours)	Number of people	GS level	Times per year (2018)	Total Cost per Year
1. Notification - Import						
a. Total time spent by Program Specialist	2	2	1	13	103	10,160
b. Total time spent by Biotech	1.25	1.25	1	13- 14	103	6,927
1. Notification -movement						
a. Total time spent by Program Specialist	1.5	1.5	1	13	216	15,980
b. Total time spent by Biotech	1.25	1.25	1	13 - 14	216	14,526
2. Notification – Release and Movement/Release						
a. Total time spent by Program Specialist	2	2	1	13	242	23,871
b. Total time spent by Biotech	4 (2 - 8)	4	1	13 - 14	242	52,078
Total Cost per year						**123,542**
Total Cost per year with benefits						**162,704**

Notes: GS salaries are calculated at a step 5 level

Appendix Table 5: Calculation of current costs associated with permits, 2016 dollars

Activity	Time (hours)	Average Time (hours)	Number of people	GS level	Times per year (2018)	Total Cost per Year
1. Permits – Import						
a. Total time spent by Program Specialist	2	2	1	12	48	3,982
b. Total time spent by Biotech	(1 to 10)	2	1	13-14	48	5,165
c. Branch Chief	0.25	0.25	1	14	48	699
1. Permits - Movement						
a. Total time spent by Program Specialist	1.5	1.5	1	12	150	9,333
b. Total time spent by Biotech	(1 to 10)	2	1	13-14	150	16,140
c. Branch Chief	0.25	0.25	1	14	150	2,186
2. Permits – Release + Movement/Release						
a. Total time spent by Program Specialist	2	2	1	12	140	11,614
b. Total time spent by Biotech	(5 - 42)	12	1	13-14	140	90,384
c. Branch Chief	0.5 to 2	1	1	14	140	8,159
EA for Permits	160	160	1	13-14	1.5	9,955
Total without benefits and overhead						**157,618**
Total with benefits and overhead						**207,582**

Note: GS salaries are calculated at a step 5 level.

Appendix Table 6: Calculation of current costs associated with petitions, 2016 dollars

Activity	Time (hours)	Number of people	GS level	Times per year	Total Cost per Year
1. Petition Completeness review					
a. Administrative processing of incoming petition	2	2	5 to 13	6	789
b. Team assigned, reviews petition, and preps deficiency letter	363	5	12 to 15	6	541,160
c. Review and send deficiency letter	24	4	12 to 14	6	28,623
d. Administrative processing of deficiency letter response	2	2	5 to 13	6	789
e. Review of response, draft letter of completion	37	4	12 to 14	6	44,128
f. Review, clear and send letter of completion	3	2	13 to 14	6	1,937
g. Publish petition	10	2	12 to 14	6	5,963
2. Plant Pest Risk Assessment (PPRA)					
a. Draft and clear PPRA	360	2	12 to 14	6	214,675
3. Environmental Assessment (EA)					
Final EA and FONSI – path 1	360	3	12 to 14	3	161,006
Draft EA – path I2	600	4	12 to 14	3	357,792
Final EA, RTC, and FONSI – path 2	144	4	12 to 14	3	85,870
4. Publish EA (Path 1)					
i. Develop and clear determination	7	3	15 - SES	3	4,791
ii. Approval of Final EA and supporting documentation	21	3	15 - SES	3	14,372
iii. Regulatory workplan for EA (draft and clear)	15	4	14 - SES	3	12,033
5. Publish EA (Path 2)					
i. Approval of EA for publication	20	3	15 - SES	3	13,687
ii. Regulatory workplan for EA (draft and clear)	15	4	14 - SES	3	12,033
viii. Develop and clear Determination	4	3	15 - SES	3	2,737
ix. Approval of Final EA and supporting documentation	24	3	15 - SES	3	16,425
6. All docket related items (workplans, 4 point memo, Office of General Counsel waiver, Federal Register)	8	1	12 to 14	8	3,180
7. Environmental Impact Statement (EIS)					
a. draft EIS	600	3	12 to 14	0.5	44724
c. final EIS and RTC	144	3	12 to 14	0.5	10734
d. Record of Decision (ROD)	144	1	12 to 14	0.5	3578
5. Publish EIS				0.5	

i. Approval of EIS for publication	20	3	15 - SES	0.5	2,281
ii. Regulatory workplan for EIS (draft and clear)	15	4	14 - SES	0.5	2,006
viii. Develop and clear ROD	4	3	15 - SES	0.5	456
ix. Approval of Final EIS and supporting documentation	24	3	15 - SES	0.5	2,737
8. Extension					
a. Draft and clear extension cat ex documentation	80	1	12 to 14	2	7,951
Total without benefits and overhead					**1,596,458**
Total Cost Per Year with Benefits and Overhead					**2,102,535**

Note: GS salaries are calculated at a step 5 level.

Appendix Table 7: Other Developer Costs associated with the part 340 Regulations, 2016 dollars

Section of the Regulations	Number of Respondents	Hours Per Year	Cost ($1,000) (1)
340.1 – Confirmation Letters and Expanded Exemptions Requests	220	4,400	215
340.5 – Procedure for Permits (new community of permittees only)	10	200	10
340.5 – Procedure for Permit Record Retention (new community of permittees only)	10	2,500	122
340.5 – Marking/Labeling (new community only)	1	1	0.05
340.5 – Procedure for Permit Appeal	5	100	5
340.5 – State and Tribal Review (State, Local and Tribal Government)	1	1	0.05
340.4 – Regulatory Status Review	100	1,800	88
340.4 – Reconsider Regulatory Status Review	5	50	2
340.6 – Record Retention	320	12,801	626
Total Record Keeping Costs (2)			**1,070**
Costs of Rule Familiarization (3)	1,250	24	**1,468**
Total Additional Costs			**2,420**

(1) Estimated average hourly wage of $33.28 multiplied by 1.4706 to capture employee benefits. The wage estimated was obtained from the U.S. Department of Labor, Bureau of Labor Statistics Occupational Outlook Handbook, 2019 Report - Occupational Employment and Wages in the United States. https://www.bls.gov/ooh/healthcare/veterinarians.htm. According to DOL BLS news release USDL-18-1499, dated September 18, 2018 (see https://www.bls.gov/news.release/pdf/ecec.pdf), benefits account for 32% of employee costs, and wages account for the remaining 68%. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.4706. May not sum due to rounding.

(2) Recordkeeping cost tabulations are based on the information collection categories from the paperwork burden section of the rule.

(3) This is a one-time cost. There have been about 1,250 unique entities who have applied for permits or notifications under part 340.

Appendix Table 8: Other APHIS' Costs Associated with the Rule, 2016 dollars

Activity	Time (hours)	GS Level	Cost ($1,000)
Outreach (1)			
Develop guidance documents	160	14	12.3
	40	15	3.6
Develop and deliver 3 public webinars	48	12	2.6
	48	13	3.1
	48	14	3.7
	24	15	2.2
Total Outreach Activities			27.5
Training	640	14	49.1
Adjusting the permit system (1)			0
Total Additional Costs			76.6

(1) Requests for regulatory status and response letters under the rule can be handled in a manner similar to the previous 'Am I Regulated' process outside the electronic permitting system without new costs.
Note: GS salaries are calculated at a step 5 level..

Appendix Table 9: General Schedule (GS) Salary Table, 2016 dollars, Washington, DC area										
GS Level	**Step 1**	**Step 2**	**Step 3**	**Step 4**	**Step 5**	**Step 6**	**Step 7**	**Step 8**	**Step 9**	**Step 10**
1	10.97	11.33	11.7	12.06	12.43	12.64	13	13.36	13.38	13.72
2	12.33	12.62	13.03	13.38	13.53	13.93	14.33	14.72	15.12	15.52
3	13.45	13.9	14.35	14.8	15.25	15.7	16.14	16.59	17.04	17.49
4	15.1	15.61	16.11	16.61	17.12	17.62	18.12	18.63	19.13	19.63
5	16.9	17.46	18.02	18.59	19.15	19.71	20.28	20.84	21.4	21.97
6	18.84	19.46	20.09	20.72	21.35	21.98	22.6	23.23	23.86	24.49
7	20.93	21.63	22.33	23.02	23.72	24.42	25.12	25.82	26.51	27.21
8	23.18	23.95	24.73	25.5	26.27	27.04	27.82	28.59	29.36	30.13
9	25.6	26.46	27.31	28.16	29.02	29.87	30.72	31.58	32.43	33.28
10	28.2	29.14	30.08	31.01	31.95	32.89	33.83	34.77	35.71	36.65
11	30.98	32.01	33.04	34.08	35.11	36.14	37.17	38.21	39.24	40.27
12	37.13	38.37	39.61	40.84	42.08	43.32	44.56	45.79	47.03	48.27
13	44.15	45.62	47.1	48.57	50.04	51.51	52.98	54.46	55.93	57.4
14	52.17	53.91	55.65	57.39	59.13	60.87	62.61	64.35	66.09	67.83
15	61.37	63.42	65.46	67.51	69.56	71.6	73.65	75.69	76.81	76.81

Source: Office of Personnel Management (OPM): https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/16Tables/html/DCB_h.aspx