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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2014-0054]

Environmental Impact Statement; Introduction of the Products of Biotechnology

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) plans to prepare a programmatic environmental impact statement in connection with potential changes to the regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms. This notice identifies reasonable alternatives and potential issues to be evaluated in the environmental impact statement and requests public comments to further define the scope of the alternatives and environmental impacts and issues for APHIS to consider.

DATES: We will consider all comments that we receive on or before [Insert date 30 days after date of publication in the Federal Register].

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

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0054>.
- Postal Mail/Commercial Delivery: Send your comments to Docket No. APHIS-2014-0054, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0054> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Sidney W. Abel, Assistant Deputy Administrator, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3943.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Plant Protection Act (PPA) authorizes the Animal and Plant Health Inspection Service (APHIS) to protect plant health in the United States. Under that authority, APHIS currently regulates the introduction (movement into the United States or interstate, or release into the environment) of genetically engineered (GE) organisms that may present a plant pest risk through its 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 are intended to protect against plant pest risks to plant health by providing for the safe importation, interstate movement, or release into the environment of certain GE organisms.

APHIS’ regulation of certain GE organisms to protect plant health is aligned with the Federal Coordinated Framework for the Regulation of Biotechnology (henceforth referred to as the Coordinated Framework), the comprehensive Federal regulatory policy for ensuring the

safety of biotechnology research and products in the United States. The Coordinated Framework describes how Federal agencies will use existing Federal statutes to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework sets forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment and describes the roles and responsibilities for the three major Federal agencies involved in regulating biotechnology products: APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). Currently, the Federal agencies are in the process of working with the Executive Office of the President to modernize a number of Coordinated Framework issues and activities; that effort is distinct from and entirely compatible with APHIS' effort to revise its biotechnology regulations at 7 CFR part 340. This notice only addresses proposed changes to the APHIS regulations. It is not intended to circumscribe, restrict, or otherwise preclude future actions taken under other Federal statutes and their respective authorities.

During the past 28 years of APHIS' regulation of certain GE organisms pursuant to the PPA and 7 CFR part 340, advances in biotechnology and new issues raised by a range of stakeholders have emerged. Over this period, APHIS has also gained considerable experience in assessing the plant pest and noxious weed risks of GE organisms. Our evaluations of any potential plant pest risks of APHIS regulated GE organisms have included assessments of weediness of the regulated article or other plants with which it can interbreed. Accordingly, APHIS is considering amending the 7 CFR part 340 regulations pertaining to introductions of certain GE organisms to address the advances in biotechnology and the new issues raised by stakeholders. This update to APHIS' biotechnology regulations will increase the efficiency and

precision of our regulations. The proposed revisions would align the range of potential risks that may be considered under APHIS' regulations in 7 CFR part 340 with both the plant pest and noxious weed authorities of the PPA, to ensure a high level of environmental protection pursuant to APHIS' PPA authorities to regulate plant pest and noxious weeds, improve regulatory processes so that they are more transparent to stakeholders and the public, and provide regulatory relief to the extent possible so that unnecessary regulatory burdens are eliminated. Changes to the regulations would ensure that the Agency can continue to effectively regulate the products of biotechnology that may pose plant pest or noxious weed risks to U.S. agriculture and the environment.

In our current regulations found at 7 CFR part 340, APHIS defines the term “genetically engineered organisms” to mean organisms that have been genetically modified by recombinant DNA techniques.

The following terms are defined by the Plant Protection Act (7 U.S.C. 7701-7772):

Noxious weed: Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

Plant pest: Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

- A. A protozoan.
- B. A nonhuman animal.
- C. A parasitic plant.
- D. A bacterium.

E. A fungus.

F. A virus or viroid.

G. An infectious agent or other pathogen.

H. Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

Under the provisions of the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.), Federal agencies must examine the potential environmental impacts of proposed Federal actions and alternatives. We are planning to prepare a programmatic environmental impact statement (EIS) in connection with the proposed revisions and amendments to APHIS' biotechnology regulations that are being considered. Aspects of the human environment that may be potentially affected by such proposed regulatory revisions and amendments that we have preliminarily identified for evaluation in the EIS will include: Potential impacts on U.S. agriculture and forestry production (e.g., conventional, biotechnology-based, and organic); potential impacts on current and potential future uses of products of biotechnology in agriculture and forestry; agronomic practices employed in biotechnology crop production that may have environmental consequences or impacts (i.e., tillage, crop rotation, and agronomic inputs); potential impacts on aspects of the physical environment that include soil quality, water resources, air quality, and climate change; potential impacts on aspects of the biological environment such as animal and plant communities, weed and insect resistance to herbicides and insecticides (respectively), the potential gene flow and weediness of regulated GE crop plants, and biodiversity; potential impacts on consumer health and agricultural worker safety; animal feed and health; and socioeconomic considerations, to include potential impacts of

regulated GE crop plants on the domestic economic environment, international trade, and coexistence among all forms of U.S. agriculture, conventional, biotechnology-based, and organic, in providing market demand for food, feed, fiber, and fuel.

This notice describes the range of proposed reasonable alternatives that are currently under consideration for evaluation in the EIS and the issues that will be evaluated in the EIS, and requests public comment to further define the issues and scope of the EIS' alternatives. We are also requesting public comment to help us identify other environmental issues that should be examined in the EIS.

The EIS will be prepared in accordance with: (1) NEPA, (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

In considering the envisioned revisions to 7 CFR part 340, APHIS has preliminarily identified possible new definitions to be used in its proposed part 340 biotechnology regulations for consideration and analysis in the EIS:

Biotechnology. Laboratory-based techniques to create or modify a genome that result in a viable organism with intended altered phenotypes. Such techniques include, but are not limited to, deleting specific segments of the genome, adding segments to the genome, directed altering of the genome, creating additional genomes, or direct injection and cell fusion beyond the taxonomic family that overcomes natural physiological reproductive or recombination barriers. This definition does not include and is intended not to include traditional breeding, marker assisted breeding, or chemical or radiation-based mutagenesis.

Product of biotechnology. An organism developed using biotechnology.

Regulated organism. An organism developed using biotechnology that poses plant pest or noxious weed risks as documented in an APHIS risk analysis that APHIS has determined to regulate.

APHIS is considering, and invites public input on, these proposed definitions. Such input should address APHIS' regulatory objectives to safeguard agricultural plants and agriculturally important natural resources from plant pest or noxious weed damage (biological, chemical, or physical) caused by a "product of biotechnology," including its potential, or lack of potential to pose plant pest or noxious weed risks.

These proposed definitions will be used in the four proposed alternatives that are proposed to be examined in the EIS. These proposed alternatives are:

First Alternative: Take no action. Under this "no action" alternative, APHIS would make no changes to the existing 7 CFR part 340 regulations for certain GE organisms that pose a potential plant pest risk and APHIS would continue to regulate certain GE organisms as it does today. APHIS would not revise its current regulations to add the definitions outlined above. The No Action alternative represents the baseline against which the proposed revisions to the regulations will be compared.

Second Alternative: Revise the current APHIS regulations concerning the introduction of certain GE organisms to provide for a process to review and regulate certain products of biotechnology to protect plant health; analyze potential plant pest and/or noxious weed risks first; and thereafter regulate only when appropriate and necessary.

Under this alternative, APHIS would revise its current regulations to implement a two-step process that would ensure a thorough review of a product of biotechnology's potential to pose plant health risks (plant pest and/or noxious weed) - analyze such plant health risks first and

only thereafter determine the use of any regulatory action as appropriate and needed. Such a two-step process will enable the agency to consider and place risk-appropriate regulatory controls on the importation, movement, or “outdoor” use of those products that are determined by the agency to pose actual plant pest or noxious weed risks (regulate only when APHIS has determined that certain plant health risks are appropriate and necessary to require some regulatory action to be taken and implemented).

Analyze First: APHIS would use established and delineated criteria to identify certain products of biotechnology for which the Agency would conduct a review process. The Agency’s review process would be used to determine whether the product of biotechnology poses an actual documented plant pest or noxious weed risk and should therefore be regulated. The criteria that would “trigger” the Agency’s review process are those which would indicate the potential for the product of biotechnology to pose documented plant pest or noxious weed risks, and may include:

1. Whether the recipient organism is a biocontrol organism, a microorganism that has been modified for altered plant-microbe interactions, or a plant; and
2. Whether the product of biotechnology’s donor or recipient organism, or the vector used in its development meet the definition of a plant pest, is included in the list of plant pest taxa, or is unknown or unclassified.

APHIS is considering, and invites public input, on these two proposed regulatory review criteria and also invites public input on proposing other possible regulatory review criteria for APHIS’ consideration.

It is important that the public be aware that the Coordinated Framework has consistently held and proceeded pursuant to the concept and position that the process of genetic modification has not been shown to be inherently dangerous. The Executive Office of the President has,

through the Coordinated Framework, underscored the importance of a risk based, scientifically sound, flexible regulatory approach that balances regulatory oversight with the need to avoid impeding biotechnology research and innovation. With that in mind, APHIS is considering and would like public input on potential justifiable exceptions or exemptions that would exclude certain “products of biotechnology” from APHIS’ regulatory review and oversight because they lack the realistic potential to pose documented plant pest or noxious weed risks. For example, some possible candidates to be exempted from regulation might be:

- a. Plant products of biotechnology in which the genetic modification was obtained through a process of biotechnology including nucleotide deletions, single base pair substitutions, or other modifications that could reasonably be expected to be obtained through mutagenic techniques that have commonly been used for plant development since the early 1900s.
- b. Insects which are not plant pests transformed using the PiggyBac transposon, but not otherwise containing sequences from plant pests.

Those products of biotechnology which APHIS determines do meet the proposed criteria 1 and 2 listed above and will not be exempted, would undergo a regulatory review. This regulatory review would employ a plant pest and/or noxious weed risk analysis process to determine whether the product of biotechnology poses either a plant pest or noxious weed risk, and therefore would be a regulated organism as defined above.

Regulate When Necessary: Once the review process is completed by the Agency, the importation, interstate movement or “outdoor” use of those products of biotechnology that were determined to pose plant pest or noxious weed risks, as documented and confirmed in an APHIS

risk analysis, would be subject to APHIS regulatory controls that ensure the protection of plant health. The regulatory control would typically be the issuance of permits with risk-appropriate conditions to mitigate risks.

Under this second alternative, APHIS proposes to eliminate the notification procedure (currently 7 CFR 340.3), as APHIS anticipates that many GE organisms currently regulated under the notification procedures would not be regulated nor subject to further review under this alternative.

Under this alternative, APHIS also proposes to eliminate the current petition process for non-regulated status (currently 7 CFR 340.6), as APHIS will conduct new risk analyses consistent with the “analyze first, regulate when necessary” when new information is made available.

Under this second alternative, APHIS is considering whether or how products of biotechnology that are developed for pharmaceutical or industrial purposes would be regulated under the proposed revised regulations. APHIS appreciates that there are aspects of its regulatory program that are well suited to address these types of products, and would like public input on how public health and safety objectives might be achieved for pharmaceutical or industrial products of biotechnology that would pose plant pest or noxious weed risks.

Third Alternative: Revise the current APHIS regulations concerning the introduction of certain GE organisms to provide for the regulation of “products of biotechnology” as either plant pests or noxious weeds using the existing plant pest “analysis trigger” or a noxious weed “analysis trigger” that might classify plants produced through biotechnology as potential plant pests or noxious weeds.

Under this third alternative, APHIS' proposed regulations would substantially increase oversight and resources over those currently used to regulate GE organisms. APHIS would not exempt certain "products of biotechnology" from APHIS regulatory oversight if a "product of biotechnology" was developed using a plant pest; or, if it posed a risk as a noxious weed pursuant to the PPA definition of a noxious weed. Introductions of products of biotechnology that posed a plant pest risk or noxious weed risk would require a permit and conditions would be applied for import, interstate movement, or "outdoor" use.

Under this third alternative, APHIS' proposed regulatory scheme would include the range of actions and processes that would enable APHIS to become, to the extent permitted by its PPA authorities, an all-encompassing, wide-scale regulatory permitting authority but still fully comply with the Coordinated Framework and support the continued development of products of biotechnology. APHIS would use its plant pest and/or noxious weed risk analyses to inform the establishment of appropriate permit conditions to protect agricultural plants and agriculturally important natural resources. For example, APHIS' proposed regulatory scheme under this alternative would evaluate and consider agricultural and mitigation practices such as crop exclusion zones, risk appropriate isolation distances, or other measures that would address and mitigate "damage" as included in the PPA definition of a noxious weed (e.g., direct or indirect damage to crops or other interests of agriculture). APHIS requests and would appreciate public input on these practices or others that might be appropriate for this third alternative.

Under this third alternative, APHIS' proposed regulatory scheme would also eliminate the notification (currently 7 CFR 340.3) and petition procedures (currently 7 CFR 340.6) since this alternative's regulatory scheme would propose that all "products of biotechnology" that are plants and are captured by the existing plant pest or noxious weed "analysis triggers," as defined

by the PPA, and currently used and applied by APHIS pursuant to the regulations in 7 CFR parts 340 and 360, would require a permit to enable the agency to establish risk appropriate conditions. APHIS would appreciate public input on its proposal, under this alternative, to eliminate notifications and petitions.

Fourth Alternative: Withdraw the current 7 CFR part 340 regulations completely and implement a voluntary, non-regulatory consultative process for certain products of biotechnology whereby APHIS would document plant pest or noxious weed risks, if any, of certain products of biotechnology as defined above.

Under this fourth alternative, developers would be responsible for ensuring that their respective products of biotechnology do not pose risks as a plant pest or noxious weed pursuant to their respective PPA definitions, and that their activities related to the importation, interstate movement, or release into the environment of their respective products of biotechnology are not in violation of any existing statutes or Federal regulations that relate to plant pests or noxious weeds.

Under this fourth alternative, APHIS would not have a dedicated regulatory scheme to specifically regulate any products of biotechnology that may pose plant pest or noxious weed risks and therefore would not require consultation nor prescribe methods or practices related to any products of biotechnology. Any products of biotechnology that pose plant pests or noxious weed risks would be managed by APHIS using its other existing regulations pursuant to the PPA; e.g., 7 CFR parts 330 and 360. Those existing APHIS regulations relating to plant pests or noxious weeds, would be used as applicable to regulate any products of biotechnology, but would regulate them under their respective current regulatory schemes. Thus this alternative would be using a very different scheme than the current 7 CFR part 340 or the regulatory

schemes proposed in the second and third EIS alternatives since APHIS would not plan on revising, amending, or requiring any regulatory changes to 7 CFR parts 330 and/or 360 to address plant pest or noxious weed risks specifically related to products of biotechnology. However, APHIS would maintain expertise in regulating the products of biotechnology pursuant to its PPA plant pest and noxious weed risks and create a non-regulatory program providing voluntary, non-regulatory consultative services to provide developers with Federal support and services intended to facilitate importation, interstate movement or “outdoor” use of products of biotechnology that do not present PPA plant pest or noxious weed risks. Under this fourth alternative and approach, APHIS would provide, upon request for consultation, for an analysis of PPA plant pest or noxious weed risks as part of its routine and continuing operations, and such analyses might facilitate the commercialization of the products of biotechnology by providing an objective analysis of plant pest or noxious weed risks using APHIS risk analysis processes that document a scientific review of the literature and findings related to plant pest or noxious weed risks. APHIS would appreciate public input on its proposal, under this alternative.

APHIS is requesting comments and information related to the topics and issues presented in this notice so that the scope of the analysis in the draft EIS, including the types and range of reasonable alternatives, is reasonable and appropriate, and proposed revisions to 7 CFR part 340 are well-evaluated. Public input will be helpful in further defining the scope of the issues and

reasonable alternatives under consideration. A notice will be published in the Federal Register to announce the availability of a draft EIS when it is issued and to invite the public to provide comments on it.

Done in Washington, DC, this 1<sup>st</sup> day of February 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.