

August 4, 2019

Regulatory Analysis and Development PPD, APHIS, Station 3A-03.8
4700 River Road Unit 118,
Riverdale, MD 20737-1238

Submitted Electronically via Federal eRulemaking Portal (<http://www.regulations.gov>)

Re: Docket No. APHIS-2018- 0034— Movement of Certain Genetically Engineered Organisms

Dear Sir or Madam:

The Biological Products Industry Alliance (BPIA) promotes the responsible development of safe and effective biological products including biopesticides and biostimulants. These are beneficial tools for commercial agriculture, forestry, golf courses, home gardens, horticulture, ornamentals. The PPIA also supports public health through education, outreach and advocacy activities at the state, federal and international levels.

BPIA is submitting comments as it pertains to the proposed regulation under 7 CFR 340 of genetically engineered (GE) microorganisms.

The existing 7 CFR 340 regulations were promulgated in 1987 under the authority of the Plant Pest Act and the Plant Quarantine Act. The Plant Protection Act (PPA) of 2000 consolidated those and other agricultural laws but also provided some new authority, including the authority to regulate biological control organisms (BCOs). However, this new authority is limited to BCOs used to control plant pests and noxious weeds that may present a plant pest risk.

SEC. 412. REGULATION OF MOVEMENT OF PLANTS, PLANT PRODUCTS, BIOLOGICAL CONTROL ORGANISMS, NOXIOUS WEEDS, ARTICLES, AND MEANS OF CONVEYANCE.

- (a) IN GENERAL.—The Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, **biological control organism**, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction **is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed** within the United States.

In the Findings section of the Plant Protection Act, it states:

“(2) biological control is often a desirable, low-risk means of ridding crops and other plants of plant pests and noxious weeds, and its use should be facilitated by the Department of Agriculture, other Federal agencies, and States whenever feasible;”

Although the PPA does not direct APHIS to consider the benefit of a GE organism, APHIS should consider the Findings Section in developing its regulatory policy, scope and practices. The proposed changes in 7 CFR 340 should reflect the Findings in the PPA to facilitate the use of biocontrol organisms. To be consistent with the Findings and legal authority, APHIS should regulate microorganisms only when needed to prevent the dissemination of a plant pest, as Congress intended, and should not attempt to use the BCO provision to regulate all GE microorganisms.

Regulation of Biological Control Organisms

In Sec 340.2, Scope in Part, the movement of certain GE organisms is prohibited unless a permit is obtained:

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

The term “used to control” is not defined either in the PPA or the proposed regulations but, in plain language and in the context of this regulation, would mean that the intent of moving the GE microorganism is to control a plant pest or noxious weed. This interpretation would be consistent with the coordination with EPA described in a 2012 MOU between APHIS and EPA and as discussed in this proposed regulation. We request that APHIS confirm in a final rule our interpretation of the phrase “used to control” as it is needed for the public to understand which GE microorganisms would be regulated. A lack of clarity could potentially leave any GE microorganism subject to this regulation.

Impacts on Beneficial Non-Target Organisms

Direct Impacts. In the PPA and discussed in the proposed regulation, APHIS has the authority to regulate plant pests that act directly and indirectly to injure, cause damage to, or cause disease in any plant or plant product. For microorganisms that are direct plant pests, those organisms are well-known in the literature based on the disease they cause. We recommend referencing a scientific organization that maintains such as list; for example, Comprehensive List of Names and the List of New Names of Plant Pathogenic Bacteria. If one genetically engineers a microorganism on that list, it would be clear to the public that the taxon may contain strains that are regulated. Alternatively, APHIS could maintain a list on their website, as was done for the current regulations at 7 CFR 340.2. Such a list would be consistent with the approach for a proposed list of GE plants that are not regulated.

Indirect Impacts. It is less clear in what circumstances and to what degree APHIS would consider a GE microorganism to be an indirect plant pest. For GE microorganisms, the use of the “indirect plant pest provision” would seemingly apply solely to biological control organisms. In the proposed rule on page 31 regarding indirect plant pest impacts, APHIS states,

“If the GE organism is known to have harmful impacts on beneficial non-target organisms, it is consistent with APHIS’ authority under the PPA to prohibit or restrict its release. To the extent that we do not know whether a GE biological control organism is

sufficiently specific to avoid harming beneficial non-target organisms, it is also prudent for us to place regulatory controls on the movement and release of the GE biological control organism until the impacts on beneficial non-target organisms and any resulting direct or indirect plant pest effects are better understood.”

Regulating based on direct or indirect impacts to a beneficial organism should be limited to those organisms that would result in an actual plant pest risk. A beneficial organism could be impacted by a BCO but still not result in a plant pest risk.

“To the extent that we do not know whether a GE biological control organism is sufficiently specific to avoid harming beneficial non-target organisms ...” is very subjective and places the burden on the developers of GE microorganism to prove a negative, *i.e.* their GE microorganism is not a plant pest. It is unclear what degree of negative impacts a BCO would need to have on a beneficial non-target organism to represent a plant pest risk. To some degree, all microorganisms compete either actively or passively in the soil and rhizosphere for nutrients. A GE organism could produce in the soil a secondary metabolite, such as an antibiotic, that could impact a beneficial organism in the soil. Similarly, a GE organism could colonize the root surface to the exclusion of a beneficial organism. If using such a standard, all agriculture, soil, and environmental microorganisms could meet the definition of an indirect effect. BPIA requests that APHIS clarify their use of this provision to regulate GE microorganisms and provide a process to remove from regulation GE microorganisms with “unknown plant pest risks”.

Coordination with Other Agencies

APHIS proposed to coordinate with EPA by exempting biological control organism-containing microbial pesticide products that are currently registered with EPA as a microbial pesticide product and that are not plant pests. Additional coordination was also described in a 2012 MOU between APHIS and EPA. Although BPIA supports coordination between the agencies to reduce regulatory burden, it seems unnecessary as described in this proposed rule. As stated in the PPA, APHIS only has authority over BCOs if they also are plant pests. Therefore, the BPIA doesn't foresee an instance where this exemption could apply.

Because BRS and PPQ regulate using the same provisions in the PPA, APHIS should clarify the coordination between PPQ in its part 330 regulations and BRS in its part 340 regulations regarding plant pests and biological control organisms. For example, clarify that if it is regulated under part 340, it is not also regulated under part 330.

In closing, BPIA would like to thank APHIS for the publication of this new draft rule. We encourage APHIS to carefully consider these comments which we believe will increase the transparency and provide clarity regarding permitting and scope of the regulation authorized under the PPA. We would welcome training opportunities from USDA-APHIS-BRS, once these regulations are in place. Please contact BPIA if you wish to discuss these issues further.

Sincerely,
Keith Jones
Executive Director, BPIA