April 21, 2016

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-2014-0054— Environmental Impact Statement; Introduction of the Products of Biotechnology

Dear Sir or Madam:

The Biopesticide Industry Alliance (BPIA) is an organization dedicated to fostering the use of biopesticide technology. Our members include companies that develop biopesticides to control or manage pests, including pests of agriculture. BPIA works to increase the awareness of biopesticides as effective pest control or management products and promote the development and implementation of science-based regulatory processes around the world.

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BPIA welcomes the opportunity to comment on the Notice of Intent (NOI) to prepare an environmental impact statement concerning the introduction of products of biotechnology as announced in the *Federal Register* dated February 5, 2016 (81 FR 6225). We believe that regulations should be based on the best available science, deliver appropriate health and environmental protection, and fully build upon the decades of experience that USDA has in reviewing both genetically engineered (GE) and non-GE microorganisms. Any revisions to the regulations should be appropriate for any identified risk and "maintain sufficient regulatory flexibility to avoid impeding innovation" (OSTP July 2015 memo[1]). BPIA is providing comments on this NOI as it pertains to GE microorganisms, as well as its potential impact on non-GE microbial-based agricultural products.

Microorganisms (plant pathogens and biocontrol organisms) are already regulated by PPQ under 7 CFR Part 330. GE microorganisms that are on the list of plant pests are currently subject to regulation under 7 CFR Part 340. Additionally, certain microbes are already regulated by EPA, FDA, and/or other programs in APHIS, such as Veterinary Services, based on their intended uses. This regulatory regime has adequately protected agriculture and the environment over the

[1]https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

past several decades. The proposed NOI should not impose more stringent regulatory requirements to microbial based agricultural products regulated under 7 CFR Part 340.

APHIS needs to implement a regulatory system that is consistent with the 2011 White House memo[2] that directs agencies to support innovation and reduce regulatory burdens. The proposed expanded definition of "products of biotechnology" would do the opposite. In addition to regulating GE microorganisms that use a known plant pest in their development, this proposal would drastically expand the scope of microbial based agriculture products that would be regulated under 7 CFR Part 340. Included in the definition of "products of biotechnology" are microorganisms produced through laboratory-based techniques, including specific deletions of segments of the genome, adding novel segments to the genome, directed alteration of the genome, creating additional genomes, or direct injection and cell fusion beyond the taxonomic family that overcomes natural physiological reproductive or recombination barriers. The propsed change in regulation, with its overly expansive definition of laboratory-based techniques, would have a dramatic economic impact on BPIA members' development of microbial products, as it would increase the federal regulaty oversight of nearly every microbial agricultural product. This overly expansive definition of laboratory-based techniques would regulate nearly every microbial agricultural product.

Moreover, the NOI proposes broadening the definition of a GE organism to include microbes that "ha[ve] been modified for altered plant-microbe interactions." It is unclear what specific modifications would be subject to additional regulation. This sweeping definition could capture essentially every microbe modified for use in agriculture, regardless of the phenotype or lack of risk to plant health or the environment. Microorganisms that are plant pests or biocontrol agents, including those developed by gene editing, are already regulated by PPQ under 7 CFR Part 330. Therefore, the plant pest risks of any agricultural microorganism are already being addressed.

Furthermore, as stated above, certain GE and other microorganisms are subject to regulation for non-plant pest related risks by several other agencies, such as EPA, CDC, and other programs in APHIS, such as Veterinary Services. These existing regulations provide more than adequate oversight to protect human, plant, and animal health from any risks from microorganisms.

Lastly, it appears that this NOI is intended to address GE crops rather than microorganisms (GE or non-GE). For example, it is unclear how Alternative 3 relates to microorganisms. BPIA requests that APHIS take a careful look at how GE and non-GE microorganisms, and not only GE plants, would be impacted by the proposed change in the regulations. The burdensome

[2] https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf

regulatory framework that would result from implementation of the second alternative will hinder our industry's efforts to develop biopesticides.

For these reasons, BPIA and its members strongly oppose any change in scope for the regulation of microorganisms under 7 CFR Part 340.

Sincerely,

Keith J. Jones
Executive Director

cc: Susan MacIntosh, Chair of BPIA Subcommittee on USDA-APHIS

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