September 15, 2017

Office of Budget and Program Analysis
United States Department of Agriculture
Jamie L. Whitten Building, Room 101-A
1400 Independence Ave SW
Washington DC 20250

Re: Identifying Regulatory Reform Initiatives

Dear Ms. Adcock:

The Biotechnology Innovation Organization (BIO) is pleased to submit these comments in response to the USDA's request for information on "Identifying Regulatory Reform Initiatives," published in the *Federal Register* on July 17, 2017.[1] Thank you for the opportunity to provide input as the U.S. Department of Agriculture (USDA or the Agency) considers opportunities to improve customer service and remove unintended barriers to participation in its programs in ways that least interfere with its customers and allow USDA to accomplish its mission.

BIO is the world's largest bioscience trade association representing nearly 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO represents the majority of agricultural biotechnology product developers in North America, including companies developing products subject to USDA oversight. We focus our comments here on the regulatory oversight of products of agricultural biotechnology by USDA's Animal and Plant Health Inspection Service (APHIS). BIO may submit additional comments on other aspects of USDA programs in future segments of this comment period.

Over the past two decades, commodity crops improved with biotechnology have been integrated into agricultural systems so completely that in countries where they are available, biotech seeds are viewed as the routine choice, not the exception; 18 million farmers in 26 countries grew biotech crops in 2015.[2] The economic and societal impacts of using biotech seeds have been considerable and entirely positive. Biotechnology enhanced seeds have added $72.9 billion in agricultural value to the global economy, to date, and $6.9 billion in 2015 alone.[3] Globally, their use has reduced the use of pesticides by 37%; increased crop yields by 22%; and improved farmer incomes by, on average, 68%.[4]

[1] 82 FR 32649-32650 (July 17, 2017).
[2] James, C. 2016. *Global Status of Commercialized Biotech/GM crops*. ISAAA Brief 52-2016. http://www.isaaa.org/resources/publications/briefs/52/default.asp
[3] *Ibid.*
[4] Qaim, M and W. Klumper. 2014. *A Meta-Analysis of the Impacts of Genetically Modified Crops*. PLoS ONE 9(11): e111629.

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USDA plays a significant role in the pre-market oversight of products of agricultural biotechnology via its regulations in 7 CFR Part 340, implemented by APHIS. However, the U.S. pre-market regulatory system for biotechnology-derived products, originally established three decades ago, continues to be out of synch with the overwhelming body of scientific evidence affirming the safety of such products. Overly conservative regulatory systems that have little connection to actual risks have had the unintentional consequence of stifling innovations which benefit growers, consumers, public health, and the environment. The most recent analysis to date puts the average cost of developing a new biotechnology crop at approximately $136 million over 13.1 years, more than one third of which is consumed by pre-market regulatory requirements.[5] Smaller seed companies, land-grant universities, and USDA's Agricultural Research Service—traditionally the developers of small acreage crops and solvers of local production problems—have effectively been prevented from developing these technological tools to improve plants by a regulatory system where the degree of regulation is unrelated to the degree of risk.

While the Agency has taken steps in recent years to improve its regulatory system, regulatory oversight remains disproportionate to actual risk, creating unnecessary barriers to innovation for both large and small product developers, and reducing access to the economic and environmental benefits of biotechnology. USDA recently proposed updating 7 CFR Part 340 with the goal of better aligning the level of oversight with actual risk. BIO submitted comments to the docket expressing concerns with the proposed updates. As part of its regulatory reform initiatives, we urge USDA to continue its efforts to improve 7 CFR Part 340. Instead of the proposed revisions, as discussed in detail below USDA should focus on a few key improvements to better align pre-market oversight with risk. Doing so will help accomplish USDA's mission of protecting plant and human health without creating unnecessary and unintended barriers to important innovation.

Finally, USDA has a unique opportunity to provide strong leadership to other U.S. regulatory agencies having pre-market oversight of these important products, such as the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), and to other governments globally, as it champions the importance of regulatory reform and fostering important innovation. Because consistent policies domestically and globally for products of agricultural biotechnology are essential to advancing agriculture, promoting innovation, and harmonizing trade regimes, we urge the U.S. government agencies to actively engage with our trading partners as soon as possible to work toward consistent, science-based policies across countries.

IMPLEMENTATION OF CURRENT APHIS REGULATIONS IN 7 CFR PART 340

APHIS is to be commended for making significant improvements to its regulatory program under 7 CFR Part 340 in recent years. In late 2011, APHIS launched an overhaul of the "petition" process,[6]

[5] Phillips McDougall, "The Cost and Time Involved in the Discovery, Development and Authorisation of a New Plant Biotechnology Derived Trait," A Consultancy Study for Crop Life International, September 2011, at https://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf; Agnes E. Ricroch and Marie-Cécile Hénard-Damave, "Next Biotech Plants: New Traits, Crops, Developers and Technologies for Addressing Global Challenges," Critical Reviews in Biotechnology, (February 2, 2015), http:dx.doi.org/10.3109/07388551.2015.1004521.

[6] 7 CFR 340.6

the process by which the Agency determines whether to grant new products of agricultural biotechnology nonregulated status. More recently, it published updated guidance on the "extension" process,[7] a more streamlined version of the petition process for products similar to those already reviewed and deemed safe. Both of these actions have resulted in significant improvements to the timeliness and predictability of Agency determinations of nonregulated status. However, these improvements do not go far enough because data demands continue to be unrelated to risk, resulting in wasted government resources in reviewing data.

Despite APHIS's improvements to the deregulation processes in 7 CFR Part 340, regulatory requirements imposed on pre-market activities— regulated activities such as field trials conducted under notification or permit[8]— have expanded dramatically in recent years. New impositions take the form of: increased specificity and variety of information required to apply for a permit or notification; increased number, variety, frequency, and specificity of required supplemental reports; and increased number and variety of records required to be maintained and provided to support APHIS inspection of field trials.[9] Among the many types of documents now required by APHIS are:

- Design protocols, increasingly lengthy documents describing management of a field trial, required for application for both notification and permit
- Monthly planting reports
- Volunteer monitoring reports
- Final field trial reports
- Documents created to facilitate APHIS inspection of field trials
- Documents created in response to inspections

With the exception of the paper-based permit application form (APHIS Form 2000) and a handful of rarely used forms,[10] none of the specific reports and records required by APHIS have been reviewed by OMB and assigned a control number. We believe that the most recent information collection review[11] submitted to OMB significantly underestimates the information collection burden imposed by APHIS in implementing 7 CFR Part 340.

In 2013, in response to an OMB information collection review,[12] BIO submitted comments[13] calling into question the Agency's estimations of information collection burdens associated with implementation of 7 CFR Part 340. Largely as a result of BIO's comments, OMB extended APHIS's information collection for one additional year (as opposed to the usual three) and directed the Agency to "provide a written response to all comments received during this period of Notice and

[7] 7 CFR 340.6(e)
[8] 7 CFR 340.3 and 7 CFR 340.4, respectively.
[9] In addition to the expanding regulatory requirements, in recent years APHIS has repeatedly narrowed the eligibility criteria for the more-streamlined notification process, thereby shifting a wider range of regulated products into the more onerous permit process.
[10] OMB Control No. 0579-0085.
[11] ICR Reference No. 201411-0579-002.
[12] 77 FR 238 (December 11, 2012)
[13] https://www.reginfo.gov/public/do/DownloadDocument?objectID=39767600

the next period of Notice and explain what, if any changes it has made to the collection to reduce burden or increase practical utility."[14] In turn, APHIS committed to conducting a survey of respondents to better estimate burdens and identify opportunities to reduce them.[15] To our knowledge, APHIS never conducted such a survey, and in early 2017, OMB extended APHIS's information collection request for an additional three years (through 2020), with no opportunity for stakeholder input.[16]

In our assessment, the regulatory and information collection requirements imposed by APHIS on field trials have increased significantly since BIO submitted its comments in 2013. This expansion in oversight runs contrary to the Agency's recent statements that most of the products of agricultural biotechnology it currently oversees pose no greater risk of being plant pests or noxious weeds than plants not subject to APHIS oversight.[17] The growing incongruity between level of regulatory requirements and the actual risk posed by regulated activities suggests that there are significant opportunities to increase the efficiency of APHIS's regulatory program and provide relief to its customers (by both rulemaking and non-rulemaking means).

We respectfully request that USDA impose a moratorium on new categories of information collection required by APHIS under 7 CFR Part 340 until USDA can review APHIS's current information collection procedures and practices. The review should provide a more accurate accounting of regulatory and information collection burdens imposed on customers, identify opportunities for the Agency to improve its efficiency and effectiveness by reducing unnecessary requirements, and implement appropriate and meaningful mechanisms by which customers can provide the Agency with feedback regarding the impact, feasibility and implementation of proposed new information collections. Such a review would also inform the Agency's ongoing consideration of regulatory revisions to 7 CFR Part 340 (see next section).[18]

In addition to APHIS's unnecessarily increasing regulatory requirements imposed on products of agricultural biotechnology, such products are in many instances also subject to overlapping and somewhat redundant oversight by FDA and EPA. Regulatory dossiers submitted to APHIS for the petition process, for example, contain much of the same data and information submitted to FDA for its pre-market consultation process and to EPA for plant-incorporated protectant (PIP) registration reviews. Similarly, field trials of PIP-containing plants are overseen by both APHIS and EPA, with each agency having its own separate, but significantly overlapping, application requirements and oversight conditions. Agencies may be able to reduce unnecessary regulatory oversight by identifying means to eliminate unnecessarily duplicative processes.

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[14] OMB Terms of Clearance. https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201305-0579-004
[15] IRC Supporting Statement (Nov 2014). https://www.reginfo.gov/public/do/DownloadDocument?objectID=51957702
[16] ICR Reference No. 201411-0579-002.
[17] "…GE [genetically engineered] plants as a class, which constitute the vast preponderance of GE organisms to date, pose no greater plant pest or noxious weed risk than their counterparts developed through traditional breeding techniques or chemical or radiation-cased mutagenesis." 82 FR 7008-7039 (January 19, 2017).
[18] APHIS is also in the process of developing a new "eFile" system for electronic submission of permit applications and required reporting. We encourage APHIS to evaluate whether and how the new submission system could affect, positively or negatively, information collection burden.

PROPOSED REVISIONS TO 7 CFR PART 340

In January 2017, APHIS proposed major revisions to its biotechnology regulations in 7 CFR Part 340 (the Proposed Rule), the first major revision of the regulations since the late 1990s.[19] BIO supports APHIS'S efforts to achieve a better regulatory system for agricultural biotechnology and for recognizing the long history of scientific evidence and safety associated with agricultural biotechnology and plant breeding. We agree with the Agency that most products of genetic engineering pose no more plant pest or noxious weed risk than products developed by traditional plant breeding or other methods— a conclusion that demonstrates the current regulatory regime imposes unnecessary costs that exceed its benefits and is in need of significant reform.

We fully support the intent of APHIS's proposed revisions to 7 CFR Part 340 in establishing broad predictable categories of crop-trait combinations that do not require pre-market review, based on APHIS's 20+ years of experience with such products and the repeated finding that they do not pose plant pest risks. We also fully support APHIS excluding certain products of plant breeding innovation, like gene editing, from pre-market regulation when they do not pose any different risks from products of conventional breeding or plant traits that are found in nature. However, we have identified unintended consequences with the way APHIS has devised the proposed revisions to 7 CFR Part 340 that are significant enough that we are unable to support the revisions as proposed. Our close examination of the Proposed Rule reveals issues that run counter to the Agency's regulatory reform goals and could have significant unintended consequences.[20] Some of those issues include:

- Lack of predictability and clarity in scope of regulation
- Increased regulatory burden and uncertainty imposed on research and development phases of product innovation arising from upfront risk assessment of new products
- Challenges for the Agency in implementing the proposed regulatory system on a scale compatible with current research and development activity, potentially leading many products to be trapped in regulatory limbo
- Potential inconsistency and redundancy with APHIS's regulatory oversight of noxious weeds under 7 CFR Part 360
- Unintended consequences for other regulatory agencies in the Coordinated Framework (FDA and EPA) and for domestic and international markets

If the Proposed Rule moves forward as is, these issues will have a significant negative impact on innovation, particularly for small and medium-sized companies and universities hoping to develop agricultural products that are important domestically and internationally. We believe that problems with APHIS's proposed regulatory system are significant enough that APHIS will need to substantially revise the Proposed Rule and solicit additional public input before adopting a final rule.

[19] 82 FR 7008-7039 (January 19, 2017).
[20] BIO submitted more detailed comments to the proposed Part 340 revisions, available here: https://www.regulations.gov/document?D=APHIS-2015-0057-0133

We believe that APHIS will be best able to improve its regulatory system successfully, with fewer risks and disruptions, by making more focused changes to the current regulatory framework under 7 CFR Part 340, strategically focused on addressing specific issues, rather than by undertaking a radical departure from the current system. Our key recommendations for APHIS include:

- Abandon the opaque and burdensome "up front" regulatory status evaluation concept.
- Retain the "notification" process, the streamlined version of the permitting process, and identify means to implement the process such that oversight is proportional to actual risk.
- Add a new mechanism to its regulations to allow the Agency to assess and potentially remove from regulation broader categories of familiar species-trait combinations or organisms that meet certain criteria.
- Rather than incorporating redundant noxious weed provisions into 7 CFR Part 340, if necessary propose revisions to APHIS noxious weed regulations (7 CFR Part 360) to identify specific categories of GE plants (if any) that pose a noxious weed risk and need further evaluation.

BIO strongly encourages the Agency to continue to make clear, positive statements on the importance of, and the Agency's support for, innovation in agriculture, including innovations in plant breeding. It is critical that the US Government take a leadership position and actively engage with other governments, particularly among our trading partners, with the goal of working toward internationally consistent, science-based policies, for both transgenic crops and products of newer plant breeding techniques like gene editing. Further, USDA should have a clear policy statement regarding products that could have been produced via traditional breeding methods, using the rationale described in the preamble to the Proposed Rule for the exclusions to the definition of "genetically engineered organism." In the absence of a final rule, the plant breeding community needs certainty regarding the regulatory status of new varieties of plants developed using innovative methods such as gene editing.

We believe that revision of 7 CFR Part 340 should continue to be a high priority for USDA, and look forward to continuing to work with the Agency to help refine its proposed revisions to expand the benefits of agricultural biotechnology to the US economy, while improving resilience of US food production systems to pests and environmental challenges.

APHIS NEPA-IMPLEMENTING REGULATIONS (7 CFR 372)

In July 2016, APHIS proposed revisions to 7 CFR 372,[21] its regulations for implementing the requirements of the National Environmental Policy Act (NEPA). NEPA implementing regulations have a critical impact on the efficiency of regulatory programs because they describe the kinds of NEPA-related environmental analysis— environmental impact statement, environmental analysis, or categorical exclusion from a need for analysis— that an agency will need to prepare before

[21] 81 FR 47051-47071 (July 16, 2016).

taking action. We supported APHIS's 2016 proposed revisions, in part because they provided significant streamlining of the NEPA analysis associated with the "extension" process of 7 CFR Part 340.[22] BIO recommends that APHIS proceed with finalizing the revised NEPA implementing regulations due to the immediate regulatory relief they provide for both APHIS and the regulated community under the current Part 340 regulations.

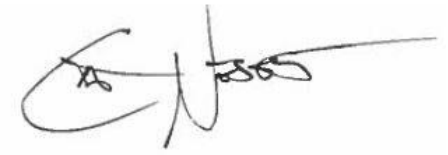
In early 2017, when APHIS proposed revisions to 7 CFR Part 340, the Agency did not propose accompanying NEPA-implementing regulations, and did not articulate how it intended to implement the requirements of NEPA under the Proposed Rule. Appropriate implementation of NEPA requirements will be critically important to the functioning and efficiency of any revised Part 340. While we continue to fully support the 2016 proposed revisions to Part 372, APHIS must ensure that any final revisions to Part 340 (or Part 360) are accompanied by matching revisions to Part 372.

CONCLUSIONS

The current regulatory system for products of agricultural biotechnology has operated quite successfully for decades and has resulted in no adverse plant health impacts to U.S. agriculture. USDA has an opportunity to incorporate its 30 years of experience and make its oversight more risk-proportionate and remove unnecessary or unintended barriers to innovation. Making targeted strategic, but significant, improvements to the current regulatory system, by both rulemaking and non-rulemaking means, is achievable in the near term and will engender broad support, with immediate positive impact on US agriculture.

Thank you for the opportunity to provide comments on opportunities for new regulatory reform initiatives. Please feel free to contact me directly if you have any questions about our comments.

Sincerely,



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[22] https://www.regulations.gov/document?D=APHIS-2013-0049-0007