Biotechnology Innovation Organization

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April 21, 2016

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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 Biotechnology Innovation Organization (BIO) is pleased to submit these comments in response to the USDA Animal and Plant Health Inspection Service's (APHIS') request for public input on the agency's Notice of Intent (NOI) to prepare an Environmental Impact Statement in connection with possible revisions to its biotechnology regulations (7 CFR part 340). Thank you for the opportunity to provide input as APHIS considers revision of its regulations. BIO is the world's largest trade association representing more than 950 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 healthcare, agricultural, industrial and environmental biotechnology products, and BIO represents the majority of the biotechnology product developers in North America.

INTRODUCTION

Scientific advancements across the U.S. and global economies are responsible for accelerating economic growth through improved productivity. New technologies, in agriculture and beyond, create new products and processes; stimulate the creation of new companies and new industries; improve existing products; and lower manufacturing costs. They also provide public and private sector researchers with the tools and techniques necessary for discovering new products that hold tremendous potential for society. Over the past two hundred years, the primary scientific drivers of technology development were physics and chemistry. But today, in the 21st century, society is leveraging a deep and rich understanding of the fundamental mechanics of life and its molecular components to drive the development of an array of biologically-based technologies that fuel innovation, stimulate greater economic growth, and transform lives for the better, in the United States and around the world. To remain competitive in the global economy, the U.S. agriculture and technology sectors must continue to lead these efforts.

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Today, biological breakthroughs are enabling farmers to confront the grand challenge for agriculture: doing more with less. Throughout history, as human population growth increased the demand for food, animal feed, fuel and fiber, our agricultural production systems kept pace. In the mid-20th century, fears of a population-driven food crisis led to research and investment to intensify crop production. This "Green Revolution" saved one billion from famine; halved the global percentage of undernourished people; improved rural economies; and protected approximately 2.2 to 3.8 billion acres of land from being cleared for crop production.

Society still faces the challenge of feeding an ever-expanding population, which will reach nine billion by 2050 and require at least a 70 percent increase in food, feed and fuel production. However, this time the challenge of increasing agricultural production is exacerbated by a confluence of interacting pressures in addition to population growth: increased competition for water and land; rising energy prices; a dietary shift from cereals to animal products; diminishing supplies of fossil fuels, the source of most agrochemicals; resource degradation from past activities; and the global effects of climate change. The Green Revolution allowed society to produce more with more inputs, most of which are derived from nonrenewable resources. Our current challenge is to produce more with less, and to do so in a sustainable fashion. Biotechnology provides a set of precise yet flexible tools for meeting that challenge.

For the past two decades, the products of agricultural biotechnology have been commercially available and widely used by a growing number of farmers around the world. In the United States, more than 90 percent of corn, cotton, canola, soybeans, and sugar beets grown contain at least one biotechnology-derived trait. Farmers use these products because they enable the production of more food and feed on fewer acres using less energy and reduced pesticide applications.

The research, development, and widespread commercialization of the current set of agricultural biotechnology products occurred as U.S. government agencies, including APHIS, conducted science-based, pre-market regulatory oversight of these products under the auspices of the Coordinated Framework for the Regulation of Biotechnology.[1] The United States' science-based regulatory approach enabled technology developers to generate and commercialize many highly beneficial products, while assuring consumers and markets that such products received pre-market regulatory scrutiny on a case-by-case basis prior to commercialization. All plants, whether derived from biotechnology or not, are subject to post-commercial regulation based on a variety of federal laws.

APHIS plays an important role in protecting U.S. agriculture by preventing the introduction and dissemination of plant pests and noxious weeds into the United States. Since the late 1980s, APHIS has used its plant pest authority to oversee the products of agricultural biotechnology based on the

[1] 51 FR 23352-23366 (June 26, 1986).

premise that some genetically engineered (GE) organisms might be plant pests. Yet the science of agricultural biotechnology has advanced significantly in the intervening decades since the establishment of APHIS' first biotechnology regulations in 1987, providing a vast body of scientific literature attesting to the safety of products derived from biotechnology. APHIS has overseen tens of thousands of field trials and hundreds of thousands of genetic constructs, and completed in-depth plant pest risk assessments of more than one hundred deregulated products, and yet has never identified a single GE organism to be a plant pest.[2] This long history of safety and APHIS' familiarity with many commonly commercialized agricultural biotechnology products suggests that the current level of pre-market regulatory oversight is now vastly disproportionate to the putative risk that is the basis for such oversight.

In issuing its Notice of Intent, APHIS has noted a need to review the status quo and determine whether changes are needed to better match risk with regulation. APHIS has a tremendous opportunity to modernize its approach to regulating products of agricultural biotechnology. We believe that the agency, by making targeted, strategic changes to its regulatory system, can make significant improvements in focusing its limited resources and maintain a robust system for protecting U.S. agriculture from organisms that may pose a legitimate risk to plant health. Such revisions are important if farmers are to meet the grand challenge of doing more with less as populations soar and pressures on inputs grow.

SUMMARY OF RECOMMENDATIONS

We agree with APHIS that the primary issue that must be addressed in revising its regulatory system for biotechnology is to bring the scope and level of oversight into better alignment with the actual risks that may be posed by biotechnology products. In most cases, the GE organisms under APHIS oversight today do not pose any greater risk to plant health than their non-GE counterparts. We believe that APHIS can significantly improve its oversight of the products of biotechnology by making a few focused, strategic changes:

1. **Clarify specific problems to be addressed, and narrowly tailor proposed regulatory changes to address those specific problems**. APHIS should build on the strengths of its current regulatory system by proposing narrowly-tailored modifications that address specific shortcomings with its current program. There is no need for the agency to replace a mature, well-functioning regulatory system with an entirely new one, in the absence of a clear justification.

2. **Use tools already available.** APHIS may be able to accomplish its goals, at least in part, without rulemaking. APHIS should first use tools that it already has at its disposal– such as

[2] http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml. Similarly, APHIS has never listed a GE organism as a noxious weed.

the extension process— to remove from regulation many of the organisms that APHIS has been repeatedly reviewing and now knows are unlikely to pose a risk to plant health.

3. **Build new tools, if needed.** APHIS could propose revisions to its regulations that incorporate a new, efficient risk-assessment-based mechanism for adding and removing new categories of organisms from its current scope of regulation. This mechanism should be clear, transparent, predictable, and peer reviewed by external experts.

    - APHIS could use this new mechanism to identify new categories of organisms to be excluded from regulatory oversight, more efficiently than with current tools.

    - If APHIS has a reason to believe that certain products *not* captured by the current regulations *do* pose a risk to plant health, APHIS could use the same mechanism to add specific new categories of organisms to regulatory oversight.

4. **Collaborate with scientific experts, stakeholders, and other government agencies.** Throughout the process of considering a new pre-market agricultural biotechnology regulatory system, APHIS should work closely with a broad range of scientific experts, stakeholders, and other government agencies, including EPA and FDA, to clarify, improve, and (as needed) modify and supplement the regulatory alternatives the agency is considering *before* publishing a proposed rule, with an eye to improving clarity, transparency, predictability, and ease of implementation.

We believe APHIS will be best able to successfully improve its pre-market agricultural biotechnology regulatory system by making "surgical" changes, strategically focused on addressing specific issues, rather than by proposing or undertaking a radical departure from the current system. The current regulatory system has operated quite successfully for decades and has resulted in no adverse plant health impacts to U.S. agriculture. We believe that making targeted, strategic improvements to the current regulatory system would engender broader support, prove easier to implement, and have a much more immediate impact with fewer unintended consequences.

In the sections that follow, we lay out our rationale for arriving at these recommendations. First, we describe a set of basic principles of good governance and regulatory policy. Next, we analyze the concepts and regulatory alternatives described in the NOI in light of those principles. Finally, we conclude our comments with a description of the actions that we think APHIS can take to build on the regulatory system it has today, in order to enhance its alignment with those core principles of effective regulation.

GUIDING PRINCIPLES FOR THE REGULATION OF BIOTECHNOLOGY

A diversity of Executive Orders, agency memoranda, and other Executive Branch directives and materials establish best practices and guiding principles for effective rule-making and regulation in general. A number of these are specific to oversight of biotechnology. We briefly describe some of these directives here, and will later use these as benchmarks to discuss the strengths and weaknesses of the concepts and regulatory alternatives that APHIS is considering.

The President has issued several Executive Orders directing agencies to follow certain principles and requirements in rulemaking.[3] In 2011, the White House published a memorandum to the heads of executive departments and agencies, describing guiding principles for regulation of emerging technologies in particular.[4] Based upon these rulemaking principles, regulations should be:

- Protective of health and the environment while promoting innovation.
- Based on the best available scientific and technical information.
- Cost-effective and commensurate with risk.
- Flexible and adaptable to accommodate new evidence and learning.
- Simple, clear, transparent, and with minimal uncertainty.
- Adopted through a public and transparent process.
- Coordinated with other Federal agencies, state authorities, a broad array of stakeholders, and the international community.

We believe strongly that government policy with regard to the products of biotechnology should be based upon these core "good governance" principles.

Regarding oversight of biotechnology in particular, in 1986, the U.S. Office of Science and Technology Policy (OSTP) first published the Coordinated Framework for the Regulation of Biotechnology, which established how Federal agencies would exercise oversight of products of the then-emerging technology.[5] APHIS' current regulatory system in 7 CFR part 340 was built upon that initial policy foundation when the APHIS regulations were first implemented in 1987.

In 1992, OSTP published a memorandum outlining "fundamental scope principles" to aid Coordinated Framework agencies in determining the scope of regulation:

[3] E.O. 12866, E.O. 13258, E.O. 13422, E.O. 13563, E.O. 13497, E.O. 13610.
[4] https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf
[5] 51 FR 23352-23366 (June 26, 1986).

1) A determination to exercise oversight within the scope of discretion afforded by statute should not turn on the fact that an organism has been modified by a particular process or technique, because such a fact is not alone a sufficient indication of risk.

2) A determination to exercise oversight in the scope of discretion afforded by statute should be based on evidence that the risk presented by introduction of an organism in a particular environment used for a particular type of application is unreasonable.

3) Organisms with new phenotypic traits(s) conferring no greater risk to the target environment than the parental organisms should be subject to a level of oversight no greater than that associated with unmodified organisms.[6]

We support these principles. Any regulatory system proposed by APHIS should remain consistent with these core values.

ANALYSIS OF AND SPECIFIC COMMENTS ON APHIS' NOTICE

Identification of Problem-Based Solutions

As described above, the President has directed agencies to follow certain principles in rulemaking. The central "regulatory philosophy" at the heart of the President's directives is as follows:

> Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people.[7]

The first two regulatory principles following from this philosophy are as follows:

(1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.[8]

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[6] 57 FR 6753-6762 (February 27, 1992).
[7] From E.O. 12866 (http://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf).
[8] Ibid.

Consistent with this OMB guidance, we strongly encourage the agency to explicitly prepare and (in any forthcoming notice of proposed rulemaking that follows) publish a detailed and robust account of the clear and compelling public need for revising its regulations; to identify the specific problems in current regulations that the agency intends to address; and to develop regulatory alternatives narrowly targeted to address those issues. This problem formulation step will aid the agency in the development of regulatory alternatives that are strategically designed to address specific issues, and lessen the risk that pursuit of a particular alternative will create unintended additional problems and challenges. Such an exercise will also help the agency articulate the specific "purpose and need" for revising its regulations as it develops a draft EIS in support of a proposed rule, and help the agency choose among reasonable alternatives by judging how they measure up against specific, discrete needs.[9] Further, this will allow interested stakeholders and members of the public to better provide constructive input on the alternatives the agency is considering, as well as to suggest, during the rulemaking process, additional reasonable and appropriate regulatory (and non-regulatory) alternatives that may meet the agency's purpose and need.
Although not stated explicitly in the NOI, two common themes have emerged in recent public statements by agency officials and documents published by the agency, suggesting that the agency seeks to revise its regulations primarily for two reasons:

1) Based upon years of agency experience, the agency has concluded that many (or even the majority) of organisms currently subject to regulation under 7 CFR 340 do not pose risks as plant pests or noxious weeds, and therefore should not be subject to regulation as plant pests or noxious weeds by APHIS.

2) Some organisms not currently subject to regulation under 7 CFR 340 may pose a risk as potential plant pests or noxious weeds, and therefore may warrant new oversight (or clarifications of existing oversight) by APHIS.

We believe that these two concepts warrant serious consideration and exploration, and that regulatory alternatives narrowly tailored to address these points merit careful reflection. We will use these two themes to guide our comments on the regulatory alternatives described in the NOI, as well as additional approaches we suggest below.

[9] "The purpose and need statement is key to developing the NEPA review, as it establishes the scope of the analyses, range of reasonable alternatives, and frames the decision to be made. […] The purpose and need for a PEA [programmatic EA] or a PEIS [programmatic EIS] should be written to avoid eliminating reasonable alternatives and focused enough for the agency to conduct a rational analysis of the impacts and allow for the public to provide meaningful comment on the programmatic proposal. The purpose and need sets the tone for the scoping process and the course for conducting the NEPA review." Michael Boots, Council on Environmental Quality, *Memorandum for Heads of Federal Departments and Agencies: Effective Use of Programmatic NEPA Reviews*, Dec 18, 2014. https://www.whitehouse.gov/sites/default/files/docs/effective_use_of_programmatic_nepa_reviews_final_dec2014_searchable.pdf

Consistency with OSTP Review of the Coordinated Framework

On July 2, 2015, the Executive Office of the President issued a memorandum to FDA, EPA, and USDA, initiating a process to modernize the regulatory system for biotechnology products.[10] Among the primary goals of the directive are:

1) Clarifying the current roles and responsibilities that each agency plays in the regulation of products of biotechnology;

2) Developing a long-term strategy for keeping the regulatory system up to date; and

3) Conducting an external, independent analysis for the future landscape of biotechnology to inform future policy making.

APHIS states in its NOI that the White House-led effort is "distinct from and entirely compatible with APHIS' efforts to revise its biotechnology regulations." We respectfully suggest that these efforts are interrelated, and that proposing expanded definitions and other significant revisions to update APHIS' regulatory scheme should be closely coordinated with the White House-led government-wide effort to modernize the regulatory system for biotechnology products. For example, APHIS notes that "advances in biotechnology" are part of its justification for updating its regulations, while simultaneously the White House has directed the Coordinated Framework agencies to commission an independent study explicitly intended to inform future policy making on such issues.[11] Unless potential changes to the APHIS regulatory process are closely coordinated and integrated with the White House process, regulatory alternatives proposed by APHIS in a notice of proposed rulemaking will not have the benefit of being informed by the not-yet-complete White House review of the Coordinated Framework and will pose a significant risk of running at cross-purposes with that review.

Numerous stakeholders have raised concerns at meetings on the White House-led effort that directly implicate the potential part 340 revisions, including concerns about the interrelationship between APHIS decisions and decisions made by EPA and FDA respectively. For example, comments were made about delays in EPA registrations that occur while APHIS is considering petitions for deregulation. These and other interagency coordination issues will doubtless be considered by the interagency Biotechnology Working Group established by the White House initiative. Part of the working group's mission is to "identify[] changes to authorities, regulations, and policies, if any, that could improve agencies' abilities to assess expeditiously the potential

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

[11] Ibid. "The EPA, FDA, and USDA shall commission an external, independent analysis of the future landscape of biotechnology products that will identify (1) potential new risks and frameworks for risk assessment and (2) areas in which the risks or lack of risks relating to the products of biotechnology are well understood. The review will help inform future policy making."

impacts and risks arising from future products of biotechnology and to ensure the transparency, predictability, and efficiency of regulatory oversight for such products." Accordingly, APHIS must work closely in tandem with other agencies as part of the White House effort as APHIS continues to consider potential changes to its regulations.

The White House-led work on the long-term strategy and on the updated Framework will likely provide useful guidance to APHIS as APHIS proceeds to consider changes to its regulations. By the same token, APHIS' potential changes to its regulations must be coordinated with the White House effort with regard to these issues in order to avoid unnecessary problems and conflicts. Among other things, other Federal agencies will play a crucial role in providing input on the possible implications and consequences of regulatory changes as to product areas over which those agencies exercise responsibility.

The White House also directed the USDA, FDA, and EPA to commission a study by the National Academies of Sciences, Engineering, and Medicine to prepare an expert study on the future landscape of the products of biotechnology.[12] We encourage APHIS to utilize the expertise of the National Academies and consider the findings of that study before making significant changes to its regulatory scope that could include the kinds of products within the scope of the study.

As APHIS considers regulatory revisions, we encourage the agency to continue to work closely with the White House and other executive branch agencies—including, but not necessarily limited to, FDA, EPA, USDA's Foreign Agricultural Service, OSTP, the Office of Management and Budget (OMB), the Council on Environmental Quality (CEQ), and the Office of the U.S. Trade Representative (USTR)—to ensure that any regulatory scheme proposed by the agency is consistent with regulatory best practices.

Definitions

In the NOI, APHIS has preliminarily identified possible new definitions for use in its proposed biotechnology regulations for consideration and analysis in the EIS: definitions for the terms "biotechnology," "products of biotechnology," and "regulated organism."[13] We are unclear as to the justification for using these new definitions to replace or supplement concepts established in the existing regulatory framework. The proposed definitions of "biotechnology" and "products of biotechnology" are very broad relative to the current scope of regulation and are entirely process-based, with no articulated connection to actual risk, thus appearing to depart from the basic

[12] "*Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System.*" http://nas-sites.org/biotech/

[13] An additional new concept introduced in the NOI and used throughout is the phrase *"outdoor" use*. This is a new concept not found in the Plant Protection Act or current regulations. The NOI seems to use the phrase in place of "environmental release," but does not explain the significance of the change in terminology. We welcome further clarification on this issue.

principles underlying the Coordinated Framework.[14] Of course, APHIS has no statutory authority under the PPA to regulate all products of biotechnology, only those that the agency determines, based upon sound science, are plant pests, noxious weeds, or other articles that could lead to the introduction or dissemination of a plant pest or a noxious weed—regardless of whether they are created using biotechnology.

It is unclear whether the agency believes that the proposed broader definition of "biotechnology" will enable it to capture within its regulatory scope additional organisms posing a plant pest or noxious weed risk which are not included within its current scope of regulation. APHIS' current regulatory scope turns on whether the agency has a reason to believe that certain (but not all) GE organisms may pose a plant pest risk.[15] The onus would be on the agency to explain its risk-based justification for proposing to expand its scope of oversight. Broadening regulatory scope without specific justification would be inconsistent with the Coordinated Framework and several executive orders.[16]

With regard to microbes, EPA regulates GE microbes, the products they make and the intermediaries of those products under the Toxic Substance Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). APHIS also oversees certain microbes under the authority of the PPA, as implemented in two different sets of regulations—those produced using "recombinant DNA techniques" (7 CFR 340) and those that are not (7 CFR 330). In 2012, the two APHIS programs with oversight of microbes— Biotechnology Regulatory Services and Plant Protection and Quarantine— committed to a memorandum of understanding with EPA that illustrates the complex and overlapping statutory authorities and regulations of the three programs. APHIS's proposed new definition of biotechnology could significantly complicate oversight of microbes by further expanding oversight into areas already adequately covered by one (or more) APHIS and EPA programs.

Arguably, the kinds of products that might newly fall within the proposed definition of "biotechnology" include organisms created with even more genetic control and precision, making them *less* likely to pose a risk of being plant pests or noxious weeds. As the agency seeks to utilize its 30 years of experience by more narrowly focusing on that subset of organisms posing a legitimate risk to plant health— acknowledging that the vast majority of organisms it currently

[14] "A determination to exercise oversight within the scope of discretion afforded by statute should not turn on the fact that an organism has been modified by a particular process or technique, because such a fact is not alone a sufficient indication of risk" 57 FR 6753-6762 (February 27, 1992).
[15] *"Part 340— Introduction of Organisms and Products Altered through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests."*
[16] "A determination to exercise oversight in the scope of discretion afforded by statute should be based on evidence that the risk presented by introduction of an organism in a particular environment used for a particular type of application is unreasonable". 57 FR 6753-6762 (February 27, 1992). See also E.O. 13563 and E.O. 13610.

oversees are likely neither plant pests nor noxious weeds—the agency should take care to avoid expanding the scope of potential regulation without sufficient scientific justification.

The NOI appears to address this risk by proposing a third definition, "regulated organism." As the rule development process proceeds, care must be taken to provide clarity as to which subset or subsets of "products of biotechnology" would be treated as "regulated organisms" and why. It is crucial to provide a robust description of the risk analysis that APHIS would conduct and the standards and criteria that APHIS would use to define its scope of regulation utilizing this definition.

In addition, we note that there are potential problems in applying the new potential definitions to all four of the regulatory alternatives under consideration. First, it appears that the new definitions cannot be applied to the first alternative (the No Action Alternative), as they are not all used in current APHIS regulations. Secondly, the definition of "regulated organism" appears to be most closely aligned with the two-step process set forth in Alternative 2 (analysis first, followed by determination to regulate), but it is harder to see how this definition is consistent with Alternatives 3 and 4, which do not appear to include such a process. Finally, biotechnology-specific definitions seem to be inconsistent with Alternative 4, as the process by which the products have been developed appears to have no bearing on the decision to regulate under existing plant pest and noxious weed regulations (7 CFR parts 330 and 360).

In the end, it appears that the proposed definitions of "biotechnology," "products of biotechnology," and "regulated organism" may not have much bearing on what is ultimately subject to regulation in the alternatives described by the agency. What may matter more is how the agency identifies the regulatory "triggers" or risk analysis factors that will be used to determine oversight, which categories of products of biotechnology are exempted from oversight, and how clearly these triggers and exemptions are described. These are discussed individually below.

It has long been articulated within the Coordinated Framework and by U.S. regulatory agencies that regulatory policies would focus on the product of GE techniques, and not the process itself. Therefore, we respectfully suggest that the agency should not propose a new scope of regulation based on process-based definitions and instead build on the current scope of the regulatory system by adding and removing specific categories of organisms based upon a scientific, evidence-based assessment of their actual risk.

Scope of analysis

APHIS describes in its NOI a general outline of the scope of the issues it intends to analyze in its programmatic EIS in support of a possible proposed rule. We encourage the agency to follow recent guidance published by the White House Council on Environmental Quality (CEQ) in the

preparation of its programmatic review under the National Environmental Policy Act (NEPA).[17] Further, we encourage the agency to ensure that its analysis of impacts includes both *positive and negative* impacts of the alternatives it considers, including discussion of how overregulation can risk delaying or preventing development and commercialization of products with positive benefits to the human environment. We also encourage the agency to prepare an appropriate economic impact analysis of alternatives under consideration,[18] while of course complying with other relevant laws, regulations, and Executive Orders governing the rule making process.

We understand that the NOI represents a conceptual overview of the alternatives being considered, and that it necessarily does not contain the detail to be provided in an EIS. For some of the alternatives described in the NOI (Alternatives 2 and 3, in particular), the draft EIS may need to provide significant additional clarity and specificity about the categories of organisms that would or would not be subject to regulation, the basis for making regulatory determinations, and the level of oversight that would be imposed on regulated organisms.[19]

The APHIS notice announces the agency's intent to prepare a *programmatic* EIS to support proposed rulemaking. This analysis would include within its scope an analysis of the possible impacts to the human environment of implementing the regulatory alternatives the agency is considering. We would also encourage the agency to address in its review how it will consider the impacts of subsequent *individual actions* that could be taken under the various regulatory alternatives it is considering, consistent with CEQ guidance.[20] Additionally, for all but Alternative 1 (the no action alternative), APHIS would likely need simultaneously to propose accompanying revisions to APHIS NEPA implementing regulations (7 CFR 372) in order to implement changes to 7 CFR 340.

Proposed Regulatory Alternatives

Alternative 1.

APHIS identifies Alternative 1 as the "no action alternative"— i.e. making no revisions to the current regulations in 7 CFR 340. As discussed above, careful attention will need to be given, in the statement of purpose of need for the proposed action, to the question of the specific purposes

[17] *Memorandum for Heads of Federal Departments and Agencies: Effective Use of Programmatic NEPA Reviews*, Dec 18, 2014. https://www.whitehouse.gov/sites/default/files/docs/effective_use_of_programmatic_nepa_reviews_ final_ dec2014 _searchable.pdf
[18] E.O. 12866, 5 USC 601-612.
[19] "The purpose and need for a PEA [programmatic EA] or a PEIS [programmatic EIS] should be written to avoid eliminating reasonable alternatives and focused enough for the agency to conduct a rational analysis of the impacts and allow for the public to provide meaningful comment on the programmatic proposal." Ibid.
[20] "Agencies should clearly communicate the purpose and need for the programmatic and subsequent decisions, clearly state the decisions the agency proposes to make based directly on the PEA or PEIS, and distinguish the analysis of impacts and alternatives of the broad programmatic proposals from project- or site-specific proposals." Ibid.

to be met by potential revisions of APHIS regulations. There is ample evidence that the current regulatory system, as administered by APHIS, has protected plant health, and no persuasive evidence to the contrary. Indeed, that the current regulations have operated since 1987 without the introduction and establishment of a single GE plant pest or noxious weed is a testament to their success and durability. APHIS' very success in this area is a basis for caution in considering potential departures from the existing scheme. That being said, we believe that the current regulatory system could be improved by strategically focusing APHIS oversight on those organisms posing a legitimate risk to plant health. However, attention should continue to be directed to the questions of which specific, compelling needs warrant revisions; whether the problems under discussion are great enough to justify the scale of specific revisions under consideration; and whether the agency's goals can be accomplished by other means, including means other than by rulemaking.

Alternative 2.

Under this alternative, it appears that APHIS would not specify in advance which organisms would be subject to regulation. Instead, for organisms meeting certain "triggers" and not included in certain "exemptions," the agency would prepare an "up front risk assessment" to determine whether the organism would be subject to regulation.

As we understand it, there are aspects of this alternative that appear to represent promising innovations regarding the way APHIS would oversee certain products. Using an efficient, transparent, science-based risk assessment system to inform the agency's decisions about where to focus its limited resources is a principle that we strongly support. If implemented appropriately, such a principle could dramatically enhance efficient decision making and direct APHIS oversight to organisms posing a legitimate risk, while still maintaining a strong science and risk-based foundation for decision making. To inform the EIS, however, APHIS will need to provide significant additional elaboration on how this alternative would result in a workable regulatory system.

APHIS must describe the risk assessment system it envisions in detail and describe the decision making factors or criteria that would be used to make regulatory determinations. If the scope of regulation is defined entirely by the output of a risk assessment model and subsequent agency decision— as opposed to clear, up-front criteria or standards— such a system would provide little if any transparency, clarity, or predictability about what is actually subject to regulation; developers would have no way of knowing the regulatory status of their products without first approaching the agency and asking. Decision-making derived from the risk assessments must be transparent and predictable. We therefore look forward to further elaboration from the agency concerning the concepts described in Alternative 2 and how they would work in practice. We emphasize that regulatory criteria and standards, and predictable processes and timelines for applying these,

would need to be clarified, and clearly understood, in advance in order for the concepts to be workable.

Alternative 2 includes proposed "criteria that would 'trigger' the Agency's review process" – step one of the two-step process described in that alternative. In other words, these "trigger" criteria would describe the subset of "products of biotechnology" that would be expected to undergo an up-front risk assessment. By contrast, "exemptions" would describe those organisms that would be excluded from the need for such an assessment. We believe that this potential approach merits further consideration.

At the same time, we have a number of questions about the specifics relating to the descriptions of these exempted categories set forth in the NOI, and the specifics of what the agency envisions would be subject to regulation. The potential "exemptions" described in the NOI appear to describe categories of organisms that are already largely excluded from the potential triggers described in the NOI. For example, many organisms carrying the genetic modifications described in the first exemption[21] would not meet the second regulatory trigger[22] unless the recipient or vector happened to be a plant pest. That is because the relatively simple genetic alterations included in the exemption are already of a kind different than those in which genetic sequences are derived from a "donor," as described in the second trigger. Similarly, most insects meeting the second exemption[23] would already not be captured by the first trigger[24] unless the insect happened to be a "biocontrol organism."

The agency seeks public input regarding possible additional triggers and exemptions that should be considered. Rather than proposing specific triggers and exemptions, we suggest that if the agency is considering a regulatory system in which a new risk assessment mechanism is used to inform agency determinations about scope of regulation, then the agency should consider using the same system to identify categories of organisms that should be included ("triggers") or excluded ("exemptions") within its scope. We suggest that this approach would create a logical consistency and would prevent triggers and exemptions from being created using different, and possibly inconsistent, rationales. The agency also seeks public input regarding possible oversight of crops developed for pharmaceutical or industrial purposes. On the general concept, we would reiterate the point that any agency oversight under the PPA must spring from the agency's statutory authority to regulate plant pests or noxious weeds, and that decisions about regulatory scope and

[21] "Plant products of biotechnology in which the genetic modification was obtained through a process of biotechnology including nucleotide deletion, single base pair substitutions, or other modifications that could reasonably be expected to be obtained through mutagenic techniques that have commonly been used in plant development since the early 1900s."
[22] "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."
[23] "Insects which are not plant pests transformed using the PiggyBac transposon, but not otherwise containing sequences from plant pests."
[24] "Whether the organism is a biocontrol organism, a microorganism that has been modified for altered plant-microbe interactions, or a plant."

level of oversight should be consistent across all organisms regardless of the process used to develop them.

Additionally, depending on the specifics of how the system would operate in practice, we are extremely concerned about capacity constraints on the agency's ability to make "assess first" regulatory determinations, given the scale and diversity of products being developed by our members every year. Our member companies regularly conduct confined, regulated field trials of tens of thousands of individual GE organisms annually. As breeding programs improve plant varieties year to year, many, if not most, of those varieties are different from year to year. We assume that the agency does not propose to prepare thousands— if not tens of thousands— of individual risk assessments that would be required annually if an individualized agency determination of the status of all of these organisms were to be required on a real-time basis.[25] In addition, agricultural research is highly seasonal, so the bulk of any queries regarding regulatory status would not be distributed evenly throughout the year, but would instead be concentrated in the few months prior to planting season, as company researchers decide which breeding lines to select from the previous year's research and carry into the next year. While the agency has recently made great progress in process improvements, the new system under consideration could result in a significant increase in workload that may be beyond the agency's capacity.

Accordingly, we submit that great care must be taken in delineating how an "assess first" regime would work— including how much self-assessment work would be done by developers, and how much of the potential burden would be mitigated by predetermined categorical assessments that avoid burdensome organism-specific assessments on a case by case basis. A key goal would be to avoid overburdening the agency and clogging the regulatory system with individualized determinations that may be beyond the existing system's capacity to handle. If broad categories of no-risk or low-risk organisms are exempted "on the front end" from the review process with little or no demands on agency staff time, it seems more likely that the system as outlined in Alternative 2 would be more workable. We await further elaboration on this crucial issue.

We also seek clarification on the regulatory status of products *before* APHIS completes an up-front risk assessment. The proposed definition in the NOI of a "regulated organism" seems to suggest that until APHIS reaches a determination to regulate, the organism is *not* regulated.[26] On the other hand, Alternative 2 implies that products meeting the regulatory triggers (and not exempted)

[25] APHIS annually oversees field trials of 100+ species carrying tens of thousands of individual traits. APHIS officials have recently publicly estimated that the risk assessment model in development has the capacity to conduct a "baseline" risk assessment (i.e. for an individual crop species) in about one week, and an additional "trait specific" risk assessment would take an additional day or so for each trait. These estimates do not appear to account for time necessary for documenting, internally reviewing, and publishing individual determinations. Assuming that they do so, it seems unlikely that the agency would have the capacity to confirm the regulatory status of all of these products on an individualized basis, much less in a timely manner.

[26] "An organism developed using biotechnology that poses a plant pest or noxious weed risks as documented by an APHIS risk analysis that APHIS has determined to regulate."

would be expected to undergo the up-front risk assessment in order to determine their regulatory status. The NOI does not explain the regulatory status of the (potentially tens of thousands of) organisms before APHIS reaches a regulatory determination. Clarification must be provided in the proposed rule to avoid the risk of creating an untenable regulatory limbo that could be compounded by a lack of capacity to clarify the regulatory status of products in development. Certainty about the regulatory status of individual products is crucial to the functioning of the system for all stakeholders. This is true not only of products already developed and awaiting their status for field trial purposes, but of products not yet developed— potentially impacting research priorities within companies and universities and the ability of companies and universities to attract resources for new areas of research and development.

As a related point, we believe it is crucial that before any change of this nature is made, clear guidance be provided to the regulated community, other stakeholders, and the public concerning the regulatory status of organisms during any transition periods. Surprise determinations without prior notice, and "gap periods" of uncertainty or confusion, should be avoided at all costs. Thus, for example, any proposed new system should preserve (or "grandfather") determinations made under the current regulations, to avoid regulatory uncertainty. These considerations may counsel in favor of introducing any new regulatory changes incrementally (step-wise), as improvements to the current, relatively stable regulatory regime.

We believe that Alternative 2 would be improved if it were to explicitly state that specific organisms may be removed from permit requirements if advances in knowledge determine that those organisms do not pose plant pest or noxious weed risks. In particular, the PPA provides a mechanism by which anyone may petition the USDA to add or remove a plant pest or noxious weed from regulation.[27] In other words, some equivalent or analogue to the deregulation process provided under current regulations would likely be needed. As a related (but distinct) point, we are not in agreement with the proposition that elimination of the petition process for non-regulated status under 7 CFR 340.6 is warranted because "APHIS will conduct new risk analyses consistent with the 'analyze first, regulate when necessary' [principle] when new information is made available." It seems to us that new information demonstrating that a permitted organism presents no plant pest risks would warrant a conclusion that a permit for that organism is no longer required.

In short, Alternative 2, as described, contains promising concepts aligned with the regulatory guiding principles and Executive Orders summarized above, but more specificity would be needed before we could conclude whether adoption of the described alternative would be likely to result in a workable and improved regulatory system that would warrant a change in regulations. We particularly appreciate the concept of utilizing a rigorous, science-based risk assessment system to

[27] 7 U.S.C. 104 §7711(c)(2) and §7712(f)(2).

inform regulatory decision making. At the same time, we are concerned about the agency's capacity to implement such a system, and would need to gain more clarity about what would actually be subject to regulation. Any lack of clarity on this issue could complicate the agency's efforts to prepare an EIS.

In our recommended actions below, we describe how we believe APHIS could use the best elements of the Alternative 2 approach to create a path forward that would help the agency to meet its goals, while still addressing some of the concerns we have identified concerning this regulatory alternative as we understand it.

Alternative 3.

Under Alternative 3, APHIS would regulate certain "products of biotechnology" using a plant pest or noxious weed "analysis trigger," and impose an "all-encompassing, wide-scale regulatory permitting authority." Alternative 3 does not define the new term "analysis trigger" (quotation marks in original). Alternative 2 describes a regulatory process in which organisms meeting a regulatory trigger undergo additional analysis before the agency makes a determination to regulate; Alternative 3 seems to imply a similar or analogous process, but there is little information provided to distinguish between Alternatives 2 and 3 with regard to scope of regulation.

The NOI seems to suggest that the "trigger" and "analysis" under Alternative 3 may be different from the trigger(s) and analysis described under Alternative 2, but the NOI provides no description of what those triggers and analyses would be. Without additional clarification, it is difficult to speculate regarding the kinds of organisms that could be subject to regulation under Alternative 3, and how the alternative is different from the other alternatives under consideration.

It is further unclear how the "all-encompassing, wide-scale regulatory permitting authority" envisioned under this alternative is different from the existing permitting system (aside from elimination of the notification process). The agency already has permitting authority under existing regulations to prevent the introduction and establishment of plant pests and noxious weeds (included in both Alternative 1 and 4). Further, the NOI provides no explanation for why the existing petition process would be revoked under Alternative 3. This appears to be inconsistent with the PPA, which explicitly includes mechanisms by which any person may petition the agency to add or remove plant pests or noxious weeds from regulation[28]. Relatedly, the regulatory status of products previously deregulated under the current regulatory system appears to be unclear under this alternative.

[28] 7 U.S.C. 104 §7711(c)(2) and §7712(f)(2).

In short, Alternative 3 is insufficiently specific for us to provide input on whether this represents a workable regulatory alternative, how it might meet the agency's goals, what would be subject to regulation, how it differs from the other alternatives, and whether it is fully consistent with the statutory authority of the PPA. We are concerned that this lack of clarity could render it difficult for the agency to prepare an EIS with regard to this alternative.

Alternative 4.

Alternative 4 describes a regulatory system in which APHIS would revoke 7 CFR part 340 altogether— i.e., APHIS would have no biotechnology-specific regulations. Instead, APHIS would oversee any plant health risks potentially posed by products of biotechnology using other existing APHIS regulations developed to prevent the introduction and establishment of plant pests and noxious weeds (7 CFR parts 330 and 360, respectively).[29]

This alternative seems appealing for several reasons. First, this system may be the alternative most consistent with the original principles underlying the Coordinated Framework, because oversight would be based entirely on the actual risk posed by the product, without regard for the particular process used in its development. This alternative would hold products of biotechnology to the same standard or level of oversight as other organisms posing similar risks. This approach would also be consistent with U.S. obligations under international sanitary/phytosanitary (SPS) agreements. For these reasons, Alternative 4 appears to represent a regulatory scheme that would be scientifically and logically coherent, providing valuable transparency and clarity, because products of biotechnology would always be held to the same standards as any organism that might be a plant pest or noxious weed.

Further, there would be a large body of information to support the agency's analysis of (and public input concerning) possible impacts to the human environment under NEPA if such a system were adopted, because noxious weed and plant pest regulations have been in operation in the United States for many decades (federal noxious weed and plant pest lists; existing regulations and the operation of the APHIS programs implementing them; published risk assessment systems and the precedents they have already established; etc.). That is, the impacts on the human environment of this alternative would be expected to be very similar to the impacts of the already-existing plant pest and noxious weed programs at APHIS.

Yet despite the potentially appealing aspects of Alternative 4, repealing APHIS biotechnology regulations would seem to fail to capitalize upon the strengths of the current regulatory system and could have significant unintended consequences, making the alternative too disruptive to be

[29] Of course, APHIS plant pest regulations in 7 CFR 330 currently exclude all genetically engineered organisms (as defined by 7 CFR 340.1) from regulation as plant pests for purposes of 7 CFR 330 (see 7 CFR 330.100: Definition of *plant pest*). APHIS would thus need to revise 7 CFR 330 in order to adopt Alternative 4.

practical. Instead, we encourage APHIS to think of Alternative 4 as containing potential benchmarks relevant to the goals of any regulatory revisions. APHIS *should* develop a regulatory system that does not single out products merely because of the process by which they were created, and *should* focus narrowly on only those products that do legitimately pose a risk to plant health. Based upon the agency's experience and data, most products of biotechnology do not pose any such risk. Therefore, as further explained below, we are proposing a series of practical actions that the agency could take to continue to gradually transition its current regulatory system to one that more appropriately further focuses limited agency resources on those products which could pose a plant health risk, reallocating resources that currently are given over to products that pose little or no such risks.

RECOMMENDED ACTIONS: A PATH FORWARD

As the agency moves forward with its consideration of improvements to the current regulatory process, we recommend that the agency take the following actions in order to develop regulatory alternatives that meet the agency's need and are consistent with the principles described above:

1. **Clarify specific problems to be addressed, and narrowly tailor proposed regulatory changes to address those specific problems**. APHIS should begin by clarifying its focus on the specific problems in the current regulatory system that it intends to address through rulemaking or otherwise, and (if needed) to develop alternatives narrowly tailored to address those issues, including alternatives that do not require amendments to Part 340. We believe that the primary issue that APHIS must address in considering revisions to its regulatory process is to bring the scope and level of oversight into better alignment with the actual risks posed by these products. Crafting a detailed statement of purpose and need, which focuses on specific issues to be solved, will enhance the chances of regulatory success, and help avoid the unintended effect of creating additional new problems that had not been considered.

2. **Use tools already available.** APHIS should utilize its nearly 30-year experience regulating GE organisms to remove from regulation many of the organisms that it has been repeatedly reviewing and now knows are unlikely to pose a risk to plant health. APHIS should use tools it already has at its disposal to address this issue. This can be done with little or no need for rulemaking.

    - APHIS should use the extension process, described in 7 CFR 340.6(e), to grant nonregulated status to broad categories of organisms similar to those that APHIS has already reviewed and deregulated. This change could be made under the current regulatory framework. Historically, APHIS has implemented this mechanism relatively sparingly, interpreting "similarity" narrowly (in most cases, to mean reinsertion of identical or nearly-identical genetic sequences in the same crop species as previously

considered). We commend the agency for recently publishing new guidance that expands the use of the process.[30] At the same time, this new guidance is conservative relative to the regulatory alternatives APHIS is proposing in its NOI. APHIS could go a long way toward utilizing its nearly 30-year experience in regulating products of biotechnology, and providing regulatory relief for products with which it is has a great deal of experience, by utilizing the extension process much more broadly— for example, by applying it to corn, soy, and cotton varieties with particular herbicide tolerance or insect resistance traits; virus resistant papaya and squashes; and apples, potatoes, and tomatoes with enhanced shelf-life and storage properties. This strategic move would result in immediate resource savings and enhanced regulatory efficiency.

- Over the course of the last several years, APHIS has published a series of letters clarifying the regulatory status of individual products.[31] While this process has been helpful in building up a body of precedents to illustrate how the agency interprets its regulatory scope, to date the agency has not published more generalized guidance articulating how the agency determines what is or is not subject to current regulation. We encourage APHIS to develop such guidance to provide additional clarity and transparency about which products the agency believes pose a plant health risk and are subject to regulation.

- APHIS should also provide guidance on how to petition the agency to create new categories of products that are or are not subject to regulation as plant pests or noxious weeds. The PPA already authorizes such a process. This system of building exclusions could be used by the agency to gradually winnow the agency's effective scope of regulation. This would allow the agency to retain those categories of organisms with which it has little experience or familiarity, or for which there is legitimate scientific evidence to suggest they may pose a risk to plant health.

3. **Build new tools, if needed.** If APHIS ultimately decides that revisions to its regulations are necessary, the agency could propose revisions to its regulations in order to incorporate a new, efficient risk-assessment-based mechanism, which could be similar in some respects to aspects of the option described in Alternative 2, for *adding and removing* new categories of organisms to and from its *current* scope of regulation. Because this mechanism could be effectively utilized to keep APHIS' scope of regulation current into the future, we note here that this new mechanism would have the added benefit of supporting the White House directive for agencies "to develop a long-term strategy to ensure that the Federal Regulatory system is equipped to assess efficiently the risks, if any, associated with future

[30] https://www.aphis.usda.gov/brs/aphisdocs/guidance_ext_nonreg.pdf
[31] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated

products of biotechnology".[32] However, APHIS should take a number of actions before implementing such a system.

- Any proposed risk assessment model should be made available for external peer-review by scientists with expertise in weed and pest risk assessment to ensure its scientific rigor and consistency with other credible, published weed and pest risk assessment models. If different parts of APHIS use different risk assessment models to assess the same kind of risk (e.g. whether an organism is a plant pest or noxious weed), the outcomes of the different models should invariably reach the same conclusion. For example, conclusions about what is determined to be a "noxious weed" by the APHIS biotechnology program should be consistent with conclusions reached by parts of APHIS that assess noxious weed risk unrelated to biotechnology.

- The agency should establish clear and objective criteria that would define how the conclusions of a risk assessment model would be used to reach regulatory determinations. Both the risk assessment model(s) and decision-making criteria should be clear and transparent, so that affected stakeholders would be able to reliably reach the same conclusions as the agency, in order to predict whether products will be subject to regulation. This provides necessary predictability to developers, and will help to ensure that regulatory decision-making is consistent.

- APHIS should publish any proposed risk assessment model in peer-reviewed scientific literature and subsequently publish its decision-making criteria for public review and comment in advance of, or in conjunction with, any proposed rule or draft environmental analysis. Providing this information to the public is essential to ensure that stakeholders understand what would actually be subject to regulation under such a scheme, and that regulatory decisions are based on scientifically rigorous standards. In this way, the public can have a meaningful and effective opportunity to comment on such a system and its potential impacts.

Create new exclusions/exemptions. Once APHIS follows the steps above to ensure the scientific rigor, transparency, and predictability of any new risk assessment model, APHIS should utilize the new model to identify broad categories of products that do not pose a risk to plant health, and therefore could be excluded or exempted from regulation. This would enable the agency to remove from regulation organisms beyond those that could be deregulated using the existing extension process. For example, the risk assessment system might show that crops such as broccoli, lettuce, or peas, when altered to carry certain traits, would be highly unlikely to be plant pests, and therefore,

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

are not subject to regulation as plant pests. Some of these excluded categories could be incorporated into a proposed rule, whereas other categories could be added later as the agency gains additional knowledge and experience.

Add to scope where needed. If APHIS has reason to believe that there are certain products *not* captured by the current regulations that *do* pose a legitimate risk to plant health, APHIS could also use its new risk assessment system to identify specific subsets of products (if any) that should be brought into the scope of its regulatory system. Presumably, the APHIS risk assessment model will define the characteristics of organisms posing a legitimate plant health risk of concern to the agency. APHIS could use these characteristics to define specific new categories of organisms to *add* to the current regulatory scope. This approach would be scientifically and logically rigorous, because the same criteria would be used to determine both what should be and what should not be subject to oversight. This also would help the agency avoid having to define an overly-broad regulatory scope (under which the vast majority of products captured by the system would be organisms that do not pose any risk to plant health), and would help the agency focus its limited resources on products that do pose a legitimate plant health risk.

Add a new mechanism to verify status. If APHIS revises its regulations to incorporate a new, risk-based mechanism for adding and removing new *categories* of organisms to its scope of regulation, as described in the steps above, APHIS would also have to create a fast and efficient secondary mechanism to confirm whether *individual* organisms belong to the categories of organisms that APHIS has determined to regulate or not. Even though regulatory determinations under this system would now be based upon general categories, developers, growers, distributors, and a variety of other stakeholders would likely need an efficient, accurate mechanism to obtain confirmation of the regulatory status of individual products.

4. **Collaborate with scientific experts, stakeholders, and other government agencies.** We strongly encourage the agency to work closely with a broad range of stakeholders and scientific experts to clarify, improve, and (as needed) modify and supplement the regulatory alternatives the agency is considering *before* publishing a proposed rule, with an eye to improving clarity, transparency, predictability, and ease of implementation. Once APHIS publishes a proposed rule, the agency's ability to interact with stakeholders to refine its proposal will be significantly diminished, and the range of regulatory alternatives the agency can consider will be more limited.

CONCLUSION

BIO welcomes the opportunity to provide APHIS with feedback on the functioning of its regulatory system and how it may be improved in the future. We strongly encourage APHIS to utilize its nearly 30-year experience to ensure that APHIS' oversight remains consistent with APHIS' statutory mission of protecting agriculture from the impacts of plant pests and noxious weeds, that APHIS' level of oversight is proportionate to the degree to which particular products of biotechnology may pose such risks, and that APHIS' continuing oversight is based on sound scientific principles.

We commend APHIS for thinking "outside the box" by considering bold, new improvements to its existing system of regulation. We believe that APHIS will be best able to successfully improve its regulatory system in the first instance by making focused, "surgical" changes, strategically focused on addressing specific issues, rather than by first undertaking a radical departure from the current system. Many of these changes could be implemented immediately via policy, while other changes can be implemented through rule making. It is worth repeating that the current regulatory system has operated successfully for decades and has resulted in no adverse plant health impacts to U.S. agriculture. In the end, making targeted strategic improvements to the current regulatory system will engender broader support, prove easier to implement, and have a much more immediate impact with fewer unintended consequences.

Thank you for your time and consideration.

With Sincerest Regards,

James C. Greenwood
President and CEO