Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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Docket No. APHIS-2008-0023
Regulatory Analysis and Development
PPD
APHIS
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-12308

Re: Comments to Docket No. APHIS-2008-0023

To whom it may concern:

These comments are submitted by the Biotechnology Industry Organization (BIO), in response to the proposed rule entitled "Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms," published by the Animal and Plant Health Inspection Service (APHIS or the Agency) of the United States Department of Agriculture (USDA) in the Federal Register on October 9, 2008.[1] BIO appreciates this opportunity to provide comment on the proposed rule.

BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,200 members worldwide. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology. Corporate members range from entrepreneurial companies developing their first product to Fortune 100 multinationals. We also represent state and regional biotechnology-derived associations, service providers to the industry and academic centers.

BIO greatly appreciates the time and effort that has gone into the drafting of these proposed regulations. Although the agency has done an outstanding job of administering a challenging regulatory program that has enabled the safe development of valuable agricultural products, BIO shares the Agency's expressed goals of more efficient regulation of the products of genetic engineering and a continuation of a high level of protection against any potential risks to health or the environment that may be associated with these products. However, as drafted, several aspects of the proposed regulations are simply unworkable.

As APHIS has repeatedly stated, much has been learned regarding safety and risk in over twenty years of field testing and commercialization of genetically engineered (GE) plants and other organisms. Much has also been learned about the proven environmental and economic benefits

[1] 73 Fed. Reg. 60008 (Oct. 9, 2008).

of biotechnology-derived crops already on the market, and about the promise shown by plants and plant products still in development. Many early concerns regarding this technology have proven to be unfounded.

BIO and its members are proud of this record of safety and of benefit to growers and the environment. This record supports amendments to the regulatory oversight of GE organisms that recognize the years of safety of products currently commercialized or under development. However, new regulations must also account for the possibility, however small, that future GE organisms may need closer regulatory scrutiny. Unfortunately, as drafted, the proposed regulations fail in both respects – they would impose greater regulatory burdens on all products that undergo regulatory review while, inexplicably, appearing to make the regulatory process voluntary.

Because of the wide range of products, posing a wide range of potential risks, that could be under development around the world at any given time, the regulations in 7 C.F.R. Part 340[2] that implement the provisions of the Plant Protection Act (PPA) must reflect that diversity and avoid, wherever possible, a one-size fits all approach. As discussed in greater detail below, the absence of a clear regulatory mandate under Part 340 coupled with the imposition of unnecessary regulatory burdens on the vast majority of developers that would voluntarily undergo regulation is contrary to the public interest that Part 340 has come to serve since 1987. Establishing a long list of recordkeeping and other requirements and conditions for all regulated GE organisms and all activities associated with those organisms, largely irrespective of actual risk posed, ignores twenty years of safety, sound science, the diversity of ongoing research and development efforts, and the realities of agricultural production. The regulations must continue to be mandatory and must allow gradations of risk to drive gradations of meaningful, science-based regulatory requirements. Specific recordkeeping provisions and other recommended practices should be issued in the form of guidance. In so doing, APHIS will continue to provide appropriate protections for health and the environment, while allowing for the continued development and commercialization of products that benefit consumers, farmers, health, agriculture and the environment.

1. Regulatory Scope

a. Plant Protection Act Authority

Currently APHIS regulates certain GE organisms as potential plant pests. This regulatory approach was adopted in 1986 under the auspices of the Coordinated Framework for Regulation of Biotechnology[3] (Coordinated Framework) and the authority of the Federal Plant Pest Act and Plant Quarantine Act, two statutes that were repealed when the PPA was enacted in 2000. Under this approach, APHIS authorizes permitted activities with GE organisms that may pose potential plant pest risks (importation, interstate movement, and field release) and grants nonregulated status to GE organisms based upon a determination that such organisms are not likely to pose a plant pest risk.

[2] Hereafter, unless otherwise noted, all references to "Part 340" or to specific regulations apply to 7 C.F.R. Part 340.
[3] 51 Fed. Reg. 23302 (June 26, 1986).

Relying on the broader authorities of the PPA, proposed § 340.0(a) defines the scope of Part 340 to be prevention of the "unauthorized introduction or dissemination of a plant pest or noxious weed." The breadth of the definitions of "plant pest" and "noxious weed" in the PPA,[4] which apply to GE and non-GE organisms alike, reflects Congress' awareness of the broad range of potential threats from plant pests and noxious weeds to agriculture, the environment and human health, and Congress's intent that APHIS enjoy the authority to address these threats as the Agency deems appropriate.

BIO supports APHIS' exercise of its broader statutory authority over GE organisms and agrees that this will better align the Part 340 regulations with the Agency's PPA authorities to guard against the possibility, however remote, that the environmental release, importation, or interstate movement of GE organisms may pose a risk of introducing or disseminating a plant pest or noxious weed. BIO would like to underscore APHIS' assertion in the draft Environmental Impact Statement (EIS)[5] that, merely because an organism is subject to APHIS' regulatory oversight under Part 340, it is not necessarily a plant pest or noxious weed. In fact, after twenty years of reviewing studies and other data submitted by developers, including the results of thousands of field tests conducted under permit, there is no evidence that biotechnology-derived plants or plant products currently on the market present either plant pest or noxious weed risks. Moreover, APHIS has carefully developed permit requirements and performance standards to ensure that, under the conditions of those permits and performance standards, these field trials themselves do not pose plant pest or noxious weed risks.

b. Noxious Weed Determinations

BIO agrees that APHIS' current program has been effective in ensuring the safe environmental release, interstate movement, importation and commercialization of GE organisms. However, it is at least theoretically possible that GE plants could be developed that do not fit within the plant pest definition, but could conceivably be covered by the PPA's definition of "noxious weed." This may particularly be the case if the donor or recipient organism already possesses noxious weed characteristics. Basing its regulatory determinations firmly within APHIS' full PPA authority will provide clarity and additional assurances to the public, users and other industry stakeholders, the United States' trading partners, and the regulated community that APHIS is addressing the full range of potential agricultural and environmental risks.

As discussed in the preamble to the proposed rule, APHIS' determination that a plant is a noxious weed is based on notable physical harm or injury caused by the plant. This would be the case for GE and non-GE plants alike. To determine if a plant poses a noxious weed risk, the first consideration is identifying what direct injury or damage (physical harm) the plant causes. Once direct injury or damage has been identified, additional consideration evaluates any indirect damage the plant may cause to interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

As APHIS has set out in the preamble to the proposed rule, the physical harm or injury caused by a noxious weed is often quantified in terms of economic losses. As an example, loss in the value

[4] 7 U.S.C. §§ 7702(14) (plant pest), 7702(10)(noxious weed).
[5] 72 Fed. Reg. 39021(July 17, 2007).

of a commodity due to the presence of noxious weeds in seeds is a consequence of the anticipated physical damage that would be caused if the seed containing a noxious weed were distributed and planted. In this context, economic loss is never simply the result of market preferences. This means that a desire to have commodities free of a certain type of seed or other plant material, in and of itself, in the absence of any potential physical damage or harm, would not be a sufficient basis for a determination that a plant is a noxious weed.

BIO strongly supports the longstanding regulatory policy under which APHIS does not consider significant economic effects alone, i.e., economic effects that are not linked to physical damage, to be sufficient in determining if a plant is a noxious weed. This position is consistent with international standards for plant pest and noxious weed risk identification as established by the International Plant Protection Convention (IPPC), to which the United States is a signatory. The IPPC is the convention by which phytosanitary matters are regulated at the international level, ensuring compliance with World Trade Organization (WTO) agreements, while ensuring appropriate national phytosanitary protections. Indeed, basing a noxious weed or plant pest risk on purely economic bases would risk violation of WTO agreements.

c. Implementation

APHIS has proposed to remove the original list of plant pest taxa that is included in § 340.2. BIO appreciates the Agency's need for flexibility to discern circumstances when agricultural or environmental damage could occur, to identify species that are likely to cause those types of damage, and then create appropriate permit conditions to make such damage unlikely to occur without reference to a static regulatory list. However, in order to make the definition of "regulated article" workable, BIO urges APHIS to make readily available on its website and elsewhere guidance that includes those taxa or any other appropriate categories or criteria that APHIS concludes are likely to raise plant pest concerns. Such guidance would be far easier to keep current than a list incorporated in the Code of Federal Regulations and should be made available concurrent with removal of the list of plant pest taxa.

As APHIS has stated, "most GE plants that APHIS has been regulating in the past, such as varieties of GE corn and soybeans modified with common agronomic traits, do not qualify as "noxious weeds."[6] Moreover, APHIS has stated that "in practice, when APHIS assesses a GE plant it has always evaluated the potential weediness of the GE plant in relation to its plant pest potential," despite the fact that, [i]n the context of the PPA, 'weediness' is more properly a noxious weed risk characteristic than a plant pest one."[7] As APHIS also stated, "[c]urrent APHIS regulations and guidance directly address the importance of including weediness when evaluating risks associated with GE organisms."[8] Accordingly, substantive changes to Part 340 to address APHIS' noxious weed authority do not appear necessary.

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[6] 73 Fed. Reg. at 60014.
[7] *Id.* at 60029.
[8] *Id.*

d. Determination of Regulatory Scope

The proposed rule, § 340.0(b)(3), provides that "[a]ny person may contact APHIS to discuss how the criteria of this paragraph apply in the case of a particular GE organism or group of organisms." The preamble interprets this new provision by saying "[u]nder the proposed regulations, the responsible person for a GE organism could correctly apply the criteria in §340.0 to determine whether the GE organism is subject to the regulations."[9] APHIS goes on to note that "in many cases, it will be very straightforward for a responsible person to apply these criteria," while in other cases, where application of the criteria is not readily apparent, "persons who are not sure . . . may consult with APHIS."[10] Together, these statements could be read to suggest a radical departure from APHIS' longstanding approach to the regulation of GE organisms that may pose a plant pest risk, because these statements suggest that anyone, without Agency oversight, can determine whether a particular GE organism is a regulated article.

Of course, if the person decides that a GE organism is a regulated article, all the provisions of the proposed Part 340 would be brought to bear on this organism, and APHIS oversight covers that organism from its first field test through to a possible grant of nonregulated status. Records will be kept, data will be shared with APHIS, field trials will be carefully executed and inspected, regulatory processes will be undertaken with public scrutiny, and agricultural safety will be demonstrated before the organism is allowed to enter the domestic and global marketplace. Almost two decades of public confidence is based on the power of the APHIS Administrator to be the sole arbiter of which GE organisms are regulated by the Agency.

However, if anyone developing a GE organism, or anyone merely possessing a GE organism, is allowed by APHIS to unilaterally determine the regulatory status of that organism, it is possible that none of the protections provided by the proposed rule will be triggered. Theoretically, a developer could release GE organisms into the environment without APHIS permission, with no provisions made for the confinement of the organism, and with no obligation to inform APHIS as to the safe completion of the field test. GE organisms could be imported or developed domestically and released as commercial products without ever having gone through APHIS review. GE crops, released without APHIS' knowledge, could intermingle with existing crops, potentially causing chaos in domestic and global markets.

Simply put, self-determination of regulatory status would make APHIS' entire regulatory scheme voluntary. BIO has never supported, and does not now support, a voluntary process for federal oversight of GE organisms. BIO and its members have always supported rigorous, science-based regulations. A voluntary program is, by definition, not rigorous, and a voluntary program undermines the global confidence in United States biotechnology-derived products that has been earned by the regulated industry, under APHIS oversight, for almost twenty years. While, at some point in the future, APHIS may well have sufficient experience with various categories of GE organisms to allow developers to decide for themselves whether they will be subject to the regulatory process, that time has not yet arrived.

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[9] 73 Fed. Reg. at 60030.
[10] *Id.* at 60012.

For these reasons, while BIO supports consultation with APHIS, the regulations cannot imply that a determination of regulatory status can be made by anyone other than the Administrator. Therefore, the following addition to proposed § 340.0(b) must be made:

> Only the Administrator can determine how the criteria in this paragraph, and whether the regulations in this part, apply to a particular GE organism or group of organisms.

Despite the specific language used in the regulation, BIO also urges APHIS to confirm unequivocally that a GE organism that meets the definition of a regulated article is subject to Part 340 unless and until APHIS determines otherwise.

e. Exclusions from Regulatory Oversight

As recognized in the draft environmental impact statement (EIS) issued in conjunction with the proposed revision of Part 340, [11] APHIS is in a position to identify certain well-defined exclusions from regulation. BIO continues to support the alternative proposed by APHIS in the draft EIS that would allow the Agency to make a decision to exclude specific classes of organisms from regulatory oversight and create a mechanism to exclude additional organisms from regulation after a safety review. As discussed in greater detail below, BIO agrees with APHIS that sound science and sound regulatory policy support the Agency's ability to exclude classes of organisms that APHIS determines do not pose a significant risk or that are adequately regulated by another federal agency. This approach would allow APHIS resources to be focused on those organisms that have a greater potential for risk or are not otherwise regulated by another agency.

As outlined in the draft EIS, APHIS would have allowed for the exclusion of specific classes of organisms from regulatory oversight and the creation of a mechanism to exclude additional organisms after a safety review.[12] Although the preamble to the proposed regulations does not address why APHIS chose not to pursue this alternative, sound science and sound regulatory policy continue to support the Agency's ability to exclude classes of organisms that do not pose a significant risk or that are adequately regulated by another federal agency. Certainly the movement of small quantities of research material constitutes one such class of organisms. An exclusion mechanism would allow APHIS' resources to be focused on those organisms and activities that have a greater plant pest or noxious weed potential or that are not otherwise regulated by another agency. BIO encourages APHIS to re-visit this issue and include a transparent exclusion mechanism for GE organisms that meet criteria such as the following:

- history of safe use of the engineered trait (e.g., organisms in which the only transgene expressed is a common marker gene such as *nptII* or "GUS"), recognizing also the

[11] APHIS, "Introduction of Genetically Engineered Organisms: Draft Programmatic Environmental Impact Statement – July 2007." *See* 72 Fed. Reg. 39021 (July 17, 2007) (announcing availability of draft EIS and requesting comments). A link to the Draft EIS is available at http://www.aphis.usda.gov/brs/pdf/complete_eis.pdf (last viewed Nov. 19, 2008).

[12] Draft EIS at 189.

history of safe use of other common components of widely used transformation systems, T-DNA borders, common promoters and gene terminators, etc.;

- use of intragenic DNA (i.e., a genetically engineered organism as described in the previous bullet but with the inclusion of a gene or genes from the host species, its relatives within the same genus, or other sexually compatible species); and

- membership in a class of events that are similar to one or more events that have been the subject of a determination of nonregulated status by APHIS.

In addition, the need for administrative flexibility argues in favor of providing a transparent mechanism for researchers, developers and other interested parties to request exclusions on an ongoing basis for both classes of organisms and individual organisms. An approval of such a request would always be premised on either a satisfactory demonstration of safety to APHIS or a showing of adequate regulation by another federal agency. APHIS should have the ability to define the precise circumstances and conditions under which an organism or class of organisms would be excluded from regulation. Exclusions for these types of organisms could be based on reduced data requirements due to the well-understood lack of risks such organisms pose. If this approach is adopted, the Agency should explain the opportunity to pursue these paths to interested researchers.

f. Basis for Regulatory Decision-Making

BIO agrees with APHIS that the current regulations do not limit APHIS to one particular approach (e.g., event-by-event) to regulatory decision-making and supports the Agency's decision to continue this approach in the proposed regulations. APHIS recognized in the draft EIS that neither regulation by event nor by trait should increase the potential for impacts to the environment.[13]

BIO agrees with APHIS' statement in the preamble to the proposed regulations that any evaluation of risk should be based on the biology of the product.[14] Such a focus on plant phenotype in the evaluation process will further a stated purpose of the rule, to reduce the regulatory burden when doing so will not increase any potential plant pest or noxious weed risk.[15]

In its 2002 report, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, the National Research Council (NRC) stated that using genetic transformation alone is a practical and useful trigger for regulation.[16] Once that threshold determination is made, however, the NRC has consistently stated that the focus should be on the assessment of the phenotype of the organism (*i.e.*, the trait) that results from the genetic engineering process.[17] Any risk that might be associated with environmental introduction of the organism should be

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[13] Draft EIS at 168.
[14] *See* 73 Fed. Reg. at 60030.
[15] *See id.* at 60009.
[16] NRC 2002 at 82, 83, Findings 2.9, 2.10; *see also* NRC, Field Testing Genetically Modified Organisms; Framework for Decisions (National Academy Press 1989).
[17] NRC 1989; NRC 2000; NRC 2002.

assessed based on the nature of the organism and introduced trait and the environment into which the organism is introduced, not the method by which the organism was produced.[18]

While appropriate and amenable to a wide variety of plant species, including commodity crops, other approaches, such as trait-by-species or construct-by-species, would be particularly beneficial for vegetatively propagated crops, so-called "minor" crops (*e.g.*, lettuce, tomatoes, strawberries and squash), and non-food/non-feed plants including bioenergy crops. As biotechnology research and development expand beyond commodity crops to a wide variety of fruits, vegetables, trees and ornamentals, different plant biology and smaller acreage can make extensive event-specific data collection prohibitive. For example, vegetatively propagated plants are often more difficult to breed than commodity crops, and thus may require multiple primary genetic transformation events in a broad variety of germplasm in order to develop suitably adapted cultivars for different regions. Under appropriate testing protocols and permit conditions, a single body of data should be sufficient to enable APHIS to analyze the agricultural and environmental safety of these "sister" events. In addition, for minor crops, a requirement for each combination of germplasm and event to undergo extensive regulatory requirements can be prohibitive for small developers and public sector researchers, with no gains in agricultural or environmental safety.

Similarly, non-food/non-feed plants grown to produce biomass in order to meet increasing energy needs should not automatically require the same scope of data required of certain other plants. An initial safety review and environmental assessment on a particular plant-trait combination can often serve as the basis for subsequent confirmatory reviews of "sister" events based on a more limited data set.

g. Regulation of Nonviable Plant Material

As an initial matter, the regulation should provide a definition of the term "viable" so as to make clear, by comparison, the distinction between viable and nonviable plant material. To address the overall concern regarding survival of regulated material in the environment, BIO recommends defining "viable" to mean "capable of regeneration or breeding outside of a laboratory or greenhouse setting."[19]

The PPA provides ample authority for the regulation of nonviable plant material by defining "noxious weed" as encompassing both plants and plant products.[20] "A plant product" is defined as "any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of plant; or any manufactured or processed plant or plant part."[21] As noted in the preamble, "APHIS has regulated GE organisms under part 340 for over 20 years, and there is no strong evidence to suggest the need to regulate nonliving (nonviable) plant products in most cases."[22] However, if in a specific case the importation, interstate movement, or environmental

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[18] *Id.*

[19] Using this approach, an example of nonviable plant material would be isolated leaves shipped on dry ice for analysis.

[20] 7 U.S.C. § 7702(10).

[21] *Id.* at § 7702(15).

[22] 73 Fed. Reg. at 60015.

release of nonliving products of a GE plant may pose noxious weed risks, APHIS has clear authority to address those risks by imposing permit conditions on the handling of nonliving products of the GE organism.

Proposed § 340.3(b) allows APHIS to assign supplemental permit conditions addressing nonliving plant materials associated with or derived from GE organisms when such conditions are needed to make it unlikely that the nonliving materials would pose a noxious weed risk. BIO supports APHIS' proposal, which includes a case-by-case determination, based on a scientific evaluation of noxious weed risks, and which provides a flexible process imposing appropriate conditions to reduce those risks.

BIO notes that issues associated with nonviable plant materials may occasionally arise with respect to imports as well as to domestic materials. As APHIS acknowledges in the preamble, "some noxious weeds can cause physical harm to the health of humans or livestock and other animals."[23] BIO requests a clear statement from APHIS that the rule's requirement for a permit (or conditional exemption) extends to imports for food or feed, or processing or refinement, as well as to domestic plant material. Where nonviable plant material presents a food or feed safety concern, APHIS may be in a position to assist FDA and/or EPA in carrying out their regulatory and enforcement authorities, as appropriate.

BIO requests that APHIS prepare guidance to help applicants, including importers, anticipate types of nonviable GE material that might be subject to permit conditions and to provide examples of appropriate permit conditions designed to minimize potential noxious weed risks from nonviable material. Guidance would also be appropriate to clarify those situations in which regulatory oversight would not be required to move nonviable plant material without an environmental release. Movement of non-viable material via secure shipment will, in many cases, pose no noxious weed risk and repeated consultation on each movement of such material would be an undue burden on both the Agency and the regulated community.

h. Support for Exclusions Based on Other Statutory Authority

BIO supports the Agency's decision to specifically exclude from regulatory scope those organisms regulated primarily by sister agencies and/or under other statutory authority. For example, GE microorganisms that are regulated as biological control organisms[24] and GE vertebrates.[25] Accordingly, BIO's comments here are not directed at either of those classes of organisms.

2. Permitting and Permit Conditions

a. General

BIO sees merit in a risk-based approach as described in the draft EIS. Unfortunately, as currently drafted, the proposed permit scheme would not improve on the current process. The

[23] 73 Fed. Reg. at 60014.
[24] *Id.* at 60012.
[25] *Id.* at 60014.

preamble describes the proposed permitting system as "more a reorganization than substantive change."[26] However this characterization fails to recognize the significant negatives associated with the proposed regulatory system that would impose unwarranted and unduly burdensome requirements for application information, permit conditions and recordkeeping, create an unprecedented two-stage permitting process, abandon mandatory deadlines for agency decision-making and, thereby, dramatically increase regulatory uncertainty and costs for large and small researchers and developers alike, without any meaningful gain in health or environmental protection. In short, the proposed changes are essentially unworkable.

As discussed more fully below, both the application requirements, set forth in proposed § 340.2 and the permit conditions, set forth in proposed § 340.3, impose mandatory requirements for all permits and applications. Although the proposed regulations and preamble go to great lengths to distinguish among different categories of risk associated with different permits, the proposed regulations then require identical information from all applications and impose almost exactly the same requirements on all permit categories. Moreover, the preamble makes plain that the placement of a release in a particular category does not presuppose the same risk level across permits in that category. As drafted, the proposed regulations create a case-by-case permitting system following an extraordinarily detailed application process. Such a system would provide no additional agricultural, health or environmental benefits or transparency, and would impose significant regulatory burdens on a technology that has established a twenty-year track record for the safe development and commercialization of beneficial plants and plant products.

BIO appreciates the mandates issued by Congress through the "Lessons Learned" provisions in the 2008 Farm Bill.[27] However, BIO and its members strongly oppose any movement away from a science-based and performance-based regulatory system towards a regime overly-focused on paperwork that ignores biological timetables and other practical realities of agricultural production. While BIO and its members consider the extensive application and permit requirements overburdensome in the extreme considering the proven record of safety evidenced by the technology, the regulated community would be eager to work with the Agency to develop a more science- and experience-based set of requirements that would protect against the relevant potential risks, while enabling research, development and commercialization of valuable new food, feed, fuel, fiber and pharmaceutical products to continue at a meaningful pace.

b. Application Requirements

The preamble states that "the current program has been effective in ensuring the safe environmental release, interstate movement, and importation of genetically engineered organisms."[28] This statement is consistent with APHIS' long-standing position, also expressed in the draft EIS, that the notification system ensured safety while reducing regulatory burdens for both the Agency and the regulated community: "The notification option has been an effective regulatory tool: the process features a simplified submission format, expedited agency review, and reduced regulatory burdens for both applicants and the agency while still ensuring safety."[29]

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[26] *Id.* at 60016.
[27] Section 10204 of Title X of the Food, Conservation, and Energy Act of 2008.
[28] 73 Fed. Reg. at 60009.
[29] Draft EIS at 26.

It is critical to the continued and timely development of safe and beneficial products that the proposed permit categories contain at least one category that preserves these features. As currently drafted, no permit category does so.

The list of information required for all permit applications under proposed § 340.2(c) appears to assume that every application will be for a high-risk species-trait combination. These proposed requirements unintentionally call into question the Agency's statement, quoted above, assuring the public of the safety of the current notification system. The preamble states that a tiered risk system was rejected because it "would essentially require a full risk assessment prior to assigning a proposed release to the appropriate risk category."[30] As currently drafted, the proposed regulations request enough information to allow APHIS to do just that.

Also, as discussed more fully below, the creation of four new categories and a decision matrix to place organisms into the categories appears unnecessary if all permits require identical application data and impose nearly identical permit conditions. If APHIS intends to require this additional information for all permit applications, it must justify the increased regulatory burden associated with its information collection activities under both the Administrative Procedure Act and the Paperwork Reduction Act by explaining how the information will improve on a process the Agency has previously and consistently found to be adequate to address the relevant risks.

A more science-based and experience-based system would provide for a list of informational requirements appropriate to the potential risk posed by the GE organisms assigned to each category. For example, agency review of organisms placed into Category A should rely heavily on years of past experience garnered from thousands of notifications successfully and safely completed.

All permit application requirements should recognize the value APHIS places in past scientific experience and familiarity. Application requirements should reflect the fact that, for most of the plants currently introduced under notification and permit, APHIS already has much of the information for which it is asking. This information includes plant biology, phenotypic differences between the GE and conventional plant, sexually compatible species, etc. Agricultural and environmental safety are not better served by re-submitting information that APHIS already possesses. An individual permit applicant should be allowed, if not encouraged, to refer to information that the developer has previously submitted to APHIS in order to reduce the size of applications and expedite review.

At a minimum, the regulations should make plain that all permit application information identified in proposed § 340.2 will not automatically be required for every application. To provide additional transparency and certainty, the Agency should, by regulation or contemporaneous guidance, link specific application requirements to particular categories of permits in a science-based manner.

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[30] 73 Fed. Reg. at 60018.

c. Agency Action on Permit Applications and Timelines

As drafted, the permit application requirements set forth in proposed § 340.2 simply cannot be met and analyzed at the scope and in the timeframes in which this industry operates. As the preamble states, APHIS has typically authorized 700-1200 notifications per year over the past decade.[31] This figure represents approximately 90% of APHIS field trial authorizations.[32] Using the high end of this estimate, and assuming 20 working days in a month, APHIS processes 5 notifications *per day*. Not surprisingly, developers rely on these established regulatory timeframes to schedule field trials and set product development timelines. The proposal now provides for a 75 or 150 day turnaround *goal for each permit*. The regulations must be sufficiently clear and succinct to allow processing at the customary rate. As the preamble to the proposed regulations states, this can be, and has been accomplished, while ensuring agricultural and environmental safety. The new process must allow for a similar pace of permitting approval.

Even the proposed expanded timeframes are not mandated by the proposed rule, but merely a general estimation.[33] For example, in § 340.2(d), APHIS proposes that there will no longer be *any* fixed time frames for Agency action on any permit application. Based on risk categories, APHIS should allow for shorter, *mandatory* time periods for review for those permits that do not pose novel questions or significant risks. BIO asks that fixed time frames be used throughout the proposed rules. BIO also requests that time frames be added to all decisions by the Administrator, such as the decision to amend or transfer a permit.[34]

The need for mandatory timeframes is critical. Because the vast majority of the regulated activities at issue here involve seasonal planting and harvesting of crops, permit applications are carefully timed to allow for well-planned planting schedules. A long, or worse – uncertain – permit approval schedule can play havoc with the tight schedule on which field trials must be planted. A regulatory delay of weeks could result in a planting delay of an entire year.

Mandatory timetables provide necessary structure in other ways, as well. As discussed below, BIO fully supports the involvement of state and tribal government in the review of these permits. A mandatory timetable helps these governments to set their own schedules for providing comments on the permit applications.

Additionally, the approach taken by the United States to the regulation of biotechnology-derived products serves as a model to many other countries. Adherence to predictable time frames in the United States is crucial to maintaining parity among all the various regulatory schemes worldwide—a necessity in future trade negotiations. If the United States' regulatory system becomes less predictable, we can expect other countries' systems will follow.

The timing of any permit approval appears to be further slowed by means of a two-step approval process, whereby APHIS would undertake an initial review to ensure that the permit application

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[31] *Id.* at 60010.
[32] *Id.* at 60017.
[33] 73 Fed. Reg. at 60026.
[34] *See* proposed § 340.2(h).

is complete, and only then determine permit conditions.[35] While there is merit in assuring the adequacy of the application information, as drafted, the procedure simply allows for additional delay in processing permits. As discussed above, for some risk categories, less information should be required and less time needed for initial review and complete analysis.

Finally, the proposed regulations only vaguely describe the process by which a permittee would accept the terms of each permit. As drafted, the proposal provides that "Prior to the issuance of a permit, the responsible person must agree . . . that the responsible person and all agents of the responsible person will comply with the permit conditions."[36] However, the proposed rule does not clearly state that the permittee will have the opportunity to see, understand and, if appropriate, discuss appropriate modifications of these terms prior to making such a significant commitment. While the Agency has the final word on the terms and conditions of any permit, the extent to which the current process provides room for discussion has consistently resulted in well-informed, science- and risk-based permit decisions. The regulations must explicitly provide these opportunities to permit holders prior to any acceptance of permit terms.

d. Risk-based Categories

The multiple-layer permit review process also imposes significant uncertainty among permit applicants by creating multiple opportunities within the review process for changes in permit conditions. Proposed § 340.2(d)(1)(i) lays out an "initial sorting" system, which appears to be intended as a guide for permit applicants: "APHIS will clarify which species fall into each group by publishing lists in guidance."[37] However, a permit applicant cannot rely on permit conditions that may be linked to a particular risk category. Applications will be further evaluated beyond this "initial sorting."[38] Only following this second sorting will APHIS conduct its final review and assign permit conditions.[39]

As mentioned above, this proposal effectively creates a multi-stage, case-by-case permitting regime at a time when the majority of field trials can continue to be safely conducted under a single-stage process based on established and transparent performance standards and criteria. Despite the extensive discussion of risk categories and risk factors, and the creation of the risk category matrix, the proposal provides no assurances for the regulated community that the submission of a specific crop-trait combination will receive permit conditions similar to those imposed under the current system. In fact, the proposal goes to great lengths to state that no assumptions of permit conditions should be made in *any* instance: "there is no prior conclusion that every release within the same category poses the same level of risk. Likewise, releases in different categories do not necessarily pose greatly different risks."[40] As such, the proposal fails to meet the intent expressed in the preamble of a "clearer understanding as to what actions must be taken" and "as much transparency and predictability as possible."[41] The proposal offers no transparency as to how the conditions will be applied in practice and, therefore, no predictability.

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[35] Proposed § 340.2(d).
[36] Proposed § 340.2(d)(6)(i).
[37] 73 Fed. Reg. at 60018.
[38] Proposed § 340.2(d)(2).
[39] Proposed § 340.2(d)(3).
[40] 73 Fed. Reg. at 60018.
[41] *Id.* at 60020.

Like permit timing, the predictability of permit conditions is critical to this industry. If, for example, multiple field trials are planned in a specific plot, each with set isolation distances, a change in the isolation distance requirements of any one of those field trials could put all of the other field trials in jeopardy. Specific requirements for various categories of permits must be adopted and maintained.

BIO agrees with comments in the preamble that a permit for a particular regulated article may move from category to category. However, the examples provided in the preamble discuss specific permits moving to permit categories offering more stringent permit conditions. The regulations should state that a permit for a particular regulated article may move to a category requiring less stringent permit conditions if science, experience and data would support such a move.

The proposed regulation provides little explanation for the distinctions made by the proposed categories. BIO has reviewed the section of the preamble describing how GE plants would be assigned to categories A-D, and although the Agency has provided a limited number of examples, these examples provide very little guidance as to how the Agency will actually assign plants into the various categories. One of the chief reasons for switching from a 2-level system to a 4-category system, as discussed in the draft EIS, was to increase transparency, for both the regulated community and the public. With virtually no guidance as to how the new system will work, that transparency is lacking.

BIO and its members are particularly troubled by changes in position APHIS has taken on specific crops and the risks they pose under the current Part 340 standards and under those proposed. One particularly confusing example is tomato. Tomato was one of the first six species allowed to be introduced under a notification, because the Agency saw no increase in plant pest risk arising from the decision.[42] Now, under the proposed categories, tomato would fall into Category B, an elevated risk category. When reversing position in such a way, it is incumbent upon an agency such as APHIS to provide a science-based justification for the reversal.

The mandatory language of proposed § 340.3(a) implies that the permit conditions set forth will be imposed on all permits, regardless of risk level. Indeed, the only differences in permit conditions for *any* risk categories appear to be additional reporting requirements for categories C and D.[43] As mentioned above, this identical treatment appears to negate the efforts made to place permits in specific categories at all. While proposed § 340.3(b) states that APHIS will assign permit conditions "in a manner that is commensurate with the risk," the mandatory language of proposed § 340.3(a) precludes a great deal of flexibility. Specific, science-based permit conditions should be established for specific categories of field trials. A one-size-fits-all approach is neither science-based nor transparent.

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[42] 58 Fed. Reg. 17044 (March 31, 1993) (amending Part 340 to allow field trials of six crops under notification process).

[43] *See* proposed §§ 340.3(a)(4)(iii)(F) and (G).

BIO is keenly aware that different types of GE plant research may pose different levels of plant pest and noxious weed risk, and BIO fully supports APHIS' authority to impose significant restrictions on the release of GE plants (and other organisms) when circumstances and science so dictate. However, BIO members know from their own experience that the majority of the field trials being conducted in the United States pose minimal risks, and permit applications and conditions should reflect this reality.

APHIS shares these years of experience. Accordingly, it is troubling that proposed § 340.3(b) does not explicitly list Agency familiarity as a modifying factor in setting permit conditions. As APHIS set forth in the draft EIS, familiarity is one of the primary, if not the primary, means by which the Agency evaluates the potential agricultural and environmental risk posed by a particular species-trait combination. In addition, the proposal fails to recognize the role that familiarity in the broader scientific community plays in its current decision making. These key considerations cannot be omitted and should be added as the first modifying factors listed in proposed § 340.2(d)(2).

BIO's positions on the use of risk-based categories for purpose of establishing permit conditions have been expressed to APHIS in the past, but bear repeating in light of the proposed changes to Part 340.

- Criteria for the categories must be science-based and the assignment of organisms to the tiers must be consistent with current, accepted science.

- Organisms must be assigned to categories based on the potential risk of the organism itself, not its intended function or any name that is given to that function (e.g., phytoremediation, PMP, classes of organisms such as trees, grass, etc.).

- Organisms posing little or no risk should move through the permitting process in an expedited way, as is currently done under notification.

- The primary factor in assigning an organism to a category should be the overall risk posed by the trait-species combination, rather than any single factor, such as the source of the transgenes.

e. Draft EIS Table 4-2

A more detailed analysis of permit categories is not new to APHIS. In fact, APHIS described just such a concept in the draft EIS. There, APHIS provided "Table 4-2" as an example of a 4-tiered plant permitting scheme.[44] That table made it relatively clear where individual species-trait combinations would fall, what permit requirements would be imposed, and how compliance would be verified. In addition, that table incorporated a permit "type" clearly analogous to the current notification process. Permit requirements and inspection frequencies were keyed to the

[44] Draft EIS at 140.

risk posed by the specific species-trait combinations in each type of permit. That table proposed a transparent, workable, science- and risk-based process that enabled the regulated community to predict, with reasonable certainty, how its products would be regulated. The proposed 4-category approach lacks most of these benefits, and BIO therefore urges that the Agency reconsider the approach laid out in Table 4-2 of the draft EIS and return to a comparable scheme.

Table 4-2 was accompanied by a list of criteria, similar to the criteria for a notification, by which an applicant could determine whether a particular species-trait combination could be introduced under a "Type 1" permit. BIO reminds the Agency that the vast majority of introductions of GE plants are authorized under notification. Therefore, it is crucial that the Agency explain, to the regulated community as well as the public, how the Agency will determine what GE plants will fall into proposed Category A. Without such guidance the four categories proposed provide little additional transparency. For Category A to be a true expedited permit category, guidance should be in the form of crop-specific protocols deemed sufficient to minimize the likelihood that the introduction of a GE plant would pose a plant pest or noxious weed risk. To provide flexibility to applicants, the protocols should allow the responsible party to employ whichever confinement strategies are appropriate for the crop, trait, and growing condition in question, provided those strategies provide adequate confinement.

f. Plant-made Pharmaceuticals and Plant-made Industrial Compounds

Consistent with international scientific standards, APHIS has set forth assessment methodology for all proteins regardless of their intended use.[45] There is no scientific reason that, under appropriate conditions, food crops should not be used for the development of pharmaceutical or industrial compounds, or that either food or non-food crops used for these purposes should not be grown outdoors.

Plants have been used for industrial and medical uses for millennia. Plant remedies were being used by Sumarians 5000 years ago.[46] As of 2002, human medicines contained phytochemicals valued at more than $30 billion, and since the 1940s, 47% of the 155 small molecules approved for cancer treatment were products either extracted or derived from plants.[47] Vitamin E is extracted from wheat germ oil and industrial lubricants are extracted from high erucic acid rapeseed. (Low erucic acid rapeseed varieties are known as "canola," a specific edible type of rapeseed.) Genetic engineering of plants to produce pharmaceutical and industrial proteins is not a radical departure from accepted practice, but simply an application of modern biotechnology to continue the important role plants have played in the development of important pharmaceutical and industrial products.

Plants that also can be used for food crops are a natural choice for these types of production because researchers have extensive agricultural knowledge and familiarity of these plants, as well as experience with their growth. Scientists have an extensive understanding of genetics,

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[45] *See* Draft EIS, Appendix F-5.
[46] Pujol, M. *et al.*, "Fighting Cancer with Plant-Expressed Pharmaceuticals," *TRENDS in Biotechnology*, Vol. 25 No. 10, 455 at 456.
[47] *Id.*

agronomics and the environmental impact these plants have, as well as their composition. This information is crucial in developing methods for confining and managing these plants.

The preamble implies that APHIS will continue to impose strict permit conditions on plants that produce pharmaceutical and industrial compounds. BIO reminds APHIS that this type of sweeping characterization of products that fall into broad categories would be inconsistent with the science- and risk-based approach endorsed by international scientific bodies, adopted by the United States, and required by the PPA[48] for regulating products of biotechnology. Imposing inappropriately stringent confinement measures or placing entire broad categories of products in risk tiers prior to an evaluation of product and permit-specific risks would be arbitrary and restrictive to a degree not supported by the available science or the law. As discussed above, a demonstration of safety satisfactory to the Agency should allow products to move between categories.

Given the expanded statutory authority APHIS proposes to exercise, it is appropriate that the Agency consider food safety in setting permit conditions for food-use plants that produce pharmaceutical or industrial compounds. However, no scientific assessment of any potential risks posed by these plants would justify extreme categorical restrictions on the field testing of these plants. Moreover, such categorical restrictions would ignore the long-time use of food crops for a wide variety of medicinal and industrial uses with well-established means of identity preservation and the maintenance of food safety and purity.

g. Stewardship

The 2008 Farm Bill specifically directs APHIS to take action designed to enhance standards for quality management systems, and proposed §§ 340.2 and 340.3 appear to reference major components of these stewardship plans, such as communication, training and contingency plans. The value of stewardship in achieving regulatory compliance is recognized by APHIS, the biotechnology industry, the food and commodity groups, and the public, and it seems an oversight for the rule and preamble to make no direct mention of stewardship programs.

BIO is one of the founding members of Excellence Through Stewardship[SM] (ETS), an initiative providing stewardship and quality management programs for the full product life cycle of biotechnology-derived plants. APHIS has developed its own voluntary stewardship program, Biotechnology Quality Management Systems, with similar goals to those of ETS. The ETS principles integrate management practices for communication, training, recordkeeping, and incident response, all verified via third-party audits. The implementation of stewardship practices will ensure that technology developers and other researchers will have already developed the data, procedures, and documents required by APHIS' proposed rules and permit conditions.

BIO urges the Agency to recognize the important role that quality management and stewardship systems play in fostering compliance with regulatory requirements and good agricultural practices and the significant extent to which quality management and stewardship systems address the majority of issues covered in the 2008 Farm Bill's "Lessons Learned" provisions.

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[48] 7 U.S.C. § 7701(4).

One of the great virtues of stewardship and quality management programs is that they can be adopted and implemented by a diverse universe of researchers and developers – a vital consideration for APHIS in implementing the provisions of the PPA as amended by the 2008 Farm Bill. APHIS should also provide guidance as to how stewardship implementation can streamline permit application processes, minimize the imposition of burdensome permit conditions, and simplify the granting of nonregulated status and conditional exemptions.

h. Shipping Container Requirements (Proposed § 340.3(a)(2))

BIO strongly supports the safe transport of GE organisms, and BIO agrees with APHIS' decision to employ performance-based standards for shipping containers rather than rely on prescriptive container requirements. Performance-based standards recognize technological and manufacturing advances, allow researchers to use containers appropriate for the needs of the organisms being shipped, and avoid the current practice of applying for, and obtaining, variances from APHIS. The implementation of the performance-based standards via "secure shipments" is a simple, logical, and flexible means to include shipping conditions in the terms of APHIS permits.[49] BIO would offer one suggestion to the proposed regulations, however. In proposed § 340.2(c)(2)(iii), APHIS discusses the disposition of shipping containers. The regulations should make clear that shipping containers can be cleaned and reused, when appropriate, under approved permit conditions.

i. State and Tribal Review

BIO continues to support APHIS' sharing of permit applications with the appropriate state and tribal governments for their notice and review. However, the proposed § 340.2(d)(4) does not specify a time limit for this review. The United States demands that our trading partners implement regulatory processes without "undue delay" when those processes impact the importation of U.S. products. By the same token, U.S. regulatory processes must have predictable time frames. The rule must set out a specific number of days during which state and tribal officials can review APHIS permits. APHIS should make clear, through regulations or in the preamble, that if that time limit is exceeded, APHIS will exercise its jurisdictional authority to make the permitting decision without the state or tribal input.

BIO supports the ongoing efforts of APHIS to encourage state and tribal governments to provide for the protection of confidential business information to the same extent provided at the federal level.

j. Multi-year Permits

The preamble to the proposed regulations states that the Agency "propose[s] to allow multi-year permits for any type of regulated activity, when we determine that appropriate risk-related conditions can be prescribed for those activities."[50] BIO supports this position and urges APHIS to expressly authorize multi-year permits in the regulations themselves. No science-based justification supports a yearly permitting system as a matter of course.

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[49] Proposed § 340.1.
[50] 73 Fed. Reg. at 60031.

3. "Approvals with Conditions" (described as conditional exemptions from the requirement for a permit in proposed regulations)

BIO supports the creation of a new mechanism that could be used in a variety of circumstances to authorize certain activities to be carried out with respect to a regulated GE organism that would ordinarily require either a permit or a determination of nonregulated status. The process would be appropriate for a number of activities, including commercialization. Such a process would be appropriate where a GE organism's development or use requires greater regulatory flexibility. BIO does not believe that the use of such a process would sacrifice APHIS oversight or create a plant pest or noxious weed risk. This is because APHIS would have the ability to impose appropriate conditions to minimize those risks with respect to all regulated articles that fall within the scope of the authorization.

a. Nomenclature

American agricultural products, including GE plants and products derived from those plants, are routinely traded in the global market. For that reason, APHIS' regulatory decision-making should be easily understood and transparent to our global trading partners. While BIO supports the concept of what APHIS has termed "conditional exemptions," and understands that the exemption is from the requirement of a permit, BIO fears that this terminology may not be translatable to countries with different regulatory frameworks for products of biotechnology, including our trading partners, thereby resulting in widespread confusion as to the status of products granted an exemption.

For this reason, BIO recommends the use of the term "approval with conditions" for a specific activity – import, interstate movement, environmental release or commercial use. Commercial use could include the commercialization of either seed intended for commercial sale and planting, or commercial sale of harvested or imported plant material to be used for food, feed, processing or refinement (*see* further discussion of this later option below). BIO understands that such "approvals" will be subject to specific conditions, but believes that the use of the term "approval" will more easily translate to trading partners than "conditionally exempted from regulation." We understand that APHIS intends to continue use of the term "non-regulated status" for those products that have been approved for non-regulated status under the separate petition process under proposed § 340.6.

b. General Comments

BIO supports the Agency's focus on plant phenotype in its decision-making regarding "approvals with conditions." Such a focus on plant phenotype in the evaluation process will further a stated purpose of the rule, to reduce the regulatory burden when doing so will not increase the plant pest or noxious weed risk.[51] However, as drafted, proposed § 340.5(b)(1) includes extensive and detailed mandatory application requirements. A requirement for an identical data set to "approve with conditions" either the interstate movement of a small quantity of research materials or nationwide planting of a commodity crop is neither science- nor risk-

[51] *See* 73 Fed. Reg. at 60009.

based. The regulations should state that data required for different types of "approvals with conditions" would be based on the nature of the product and activity for which "approval with conditions" is sought.

Similarly, to increase both regulatory certainty and transparency, the regulations should require that all conditions imposed on these "approvals with conditions" be set using the best available science, and be no more burdensome or restrictive than necessary to make a plant pest or noxious weed risk unlikely. To this end, conditions should be appropriate for the type of "approval with conditions" requested. For example, an interstate movement "approval with conditions" would require fewer and less burdensome conditions than an environmental release "approval with conditions." Clarification and/or examples would be helpful to explain how conditions would be applied to the import, transport, storage and use of products subject to these "approvals with conditions," as well as how such conditions would be enforced.

The activity "approved" and the conditions associated with an "approval with conditions" should be a matter of public record. The proposed § 340.5(b)(4)(i) describes the administrative action in response to a petition, but the rule does not clearly describe what the petitioner will receive from the Administrator should a petition be granted. BIO requests that APHIS issue a document, affirmatively stating that the GE organism is "Approved with Conditions." Such documentation would be extremely helpful to resolve questions regarding the status of the organism as it moves through the channels of trade. For example, if the organism is "approved with conditions" for interstate movement, a copy of the "approval" statement could be enclosed with all shipments of the organism. If seed, for example, is sold under a commercial "approval with conditions," the "approval" statement will assure trading partners that the plant was affirmatively cleared by APHIS for the designated activities (e.g., interstate movement, environmental release and placing on the market). BIO also requests that all "approvals with conditions" be published, in a timely way, on the APHIS website.

Finally, APHIS regulations and policy should provide that certain "approvals with conditions," such as the interstate movement of well-understood research materials, would be categorically excluded from further environmental review under the National Environmental Policy Act (NEPA) pursuant to APHIS regulations implementing NEPA.[52] As discussed more fully below, an "approval with conditions" of the interstate movement of certain discrete research shipments, for example, may easily fall within the regulatory parameters of NEPA's categorical exemptions.

c. Interstate Movement of Common Research Organisms

BIO is extremely disappointed that the Agency missed an opportunity to provide real regulatory relief in the proposed revision to § 340.4. In the draft EIS, the Agency mentioned several traits, such as common genetic markers and flower color, that raised no possibility of significant agricultural or environmental impacts and considered adding these traits, and possibly others, to the current list of organisms or types of traits exempted from the need for an interstate movement permit.[53] As the Agency has mentioned on numerous occasions, past Agency experience and familiarity with a host of species and traits have demonstrated that they pose no plant pest or

[52] 7 C.F.R. Part 372.
[53] *See* current § 340.2(b).

noxious weed risk. However, in its proposed rule, APHIS made no additions to the list at all. BIO urges APHIS to reconsider expanding the list of common research organisms exempt from interstate movement permits. Moreover, as suggested in BIO's comments on the draft EIS, APHIS should exempt all GE plants that fall under category A from interstate movement permits.

The concept of an "approval with conditions" for shipment of these materials could serve universities and other members of the research community well. However, as currently drafted, the process for applying for what APHIS describes as a "conditional exemption" appears no different, in terms of data requirements and regulatory burden, from a petition for nonregulated status.[54] Moreover, the timing for all such decision making is anticipated at 180 days. This much time is simply unnecessary when deciding whether to allow research materials to be shipped interstate.

Information requirements and other regulatory burdens should be proportionate to the risk posed by the activity. The interstate movement of small quantities of research materials containing familiar plants or traits poses virtually no plant pest or noxious weed risk to agriculture or the environment, and APHIS' regulatory requirements for granting an exemption or "approval with conditions" for this activity should be proportionately small.

d. Food, Feed, Processing or Refinement

Currently, under APHIS regulations, GE organisms intended for food, feed, processing or refinement (FFPR) can be imported only under a permit or following approval of a determination of non-regulated status. Under the proposed rule, APHIS could instead grant a conditional exemption or, as described above, a commercial use "approval with conditions."

BIO agrees that an alternative to the current reliance on permits or deregulation for the importation of FFPR materials is necessary. Valuable GE products will increasingly be developed oversees, and our markets will demand these products. APHIS' current system is overly burdensome and may function as a deterrent to international trade, contravening Congress' mandate in the Plant Protection Act.[55] Safe GE commodities could be expediently cleared for importation into the United States through a science- and risk-based system – an FFPR commercial use "approval with conditions."

An FFPR commercial use "approval with conditions" would allow for different activities beyond those allowed under either an import or an interstate movement permit. As drafted, the proposed rule defines "environmental release" as any movement of a GE organism outside of a secure shipment, as those terms are defined by the proposed rule.[56] An FFPR commercial use "approval with conditions" should allow the shipment, use and consumption of FFPR materials outside the strict confines of "secure shipment" to include placement on a display case or dinner plate, for example.

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[54] *Compare* proposed § 340.5(b)(1) *with* proposed § 340.6(b)(1).

[55] 7 U.S.C. § 7701(3)("it is the responsibility of the Secretary to facilitate exports, imports, and interstate commerce").

[56] Proposed § 340.1.

An FFPR commercial use "approval with conditions," with a smaller data set requirement than would be required for deregulation, would be consistent both with APHIS' position regarding the potential risks posed by potentially non-viable products and with international positions on the subject. In the draft EIS, APHIS discussed the fact that a GE product imported for FFP purposes does not raise a significant risk of escape and establishment in the environment when compared with the importation of GE seed for the purpose of planting. This position is also supported by the simplified procedure for FFP imports outlined in the Cartagena Protocol on Biosafety.

An FFPR commercial use "approval with conditions" would equally serve the needs of GE plants grown in containment (such as vegetables grown in greenhouses) that are then placed on the market for commercial sale and consumption. In each of these instances, the extensive data set necessary to support approval for deregulation or environmental release would not be necessary, but certain data and "approval" conditions would be appropriate.

FFPR materials being imported into the United States through an FFPR commercial use "approval with conditions" would likely have been the subject of risk assessments required by the material's country of origin. Such a risk assessment is likely to be analogous to APHIS risk assessments required for environmental release, as well as risk assessments developed by international organizations to which the United States is a party, such as the Codex Alimentarius Commission (Codex) or the Organization for Economic Cooperation and Development (OECD). APHIS referral to this type of analysis would assist in addressing potential environmental concerns, while helping to promote international harmonization of these types of risk assessment. In addition to compliance with regulations in effect in the country of origin and any authorizations afforded a particular FFPR product intended for importation, BIO encourages APHIS to also weigh the availability of documented stewardship practices used by the developer in the country of origin when determining appropriate, risk-based conditions for an FFPR commercial use "approval with conditions."

The FFPR commercial use "approval with conditions" for FFPR imports must be no more burdensome than for FFPR materials developed from GE plants grown domestically under containment and released for FFPR purposes. Such equitable treatment will provide an example to other countries in their own treatment of GE products. If the United States requires more regulatory requirements for importation, foreign countries may consider raising the bar for U.S. products as well, resulting in increased delays and costs for U.S. growers, traders and developers of GE products, and negatively affecting U.S. agricultural exports. Further, many countries have no regulations at all specific to GE organisms; others are struggling to create regulatory systems in conformity with guidance provided by international fora such as Codex and the Cartagena Protocol on Biosafety. APHIS should expect these countries to look to the United States as an additional source of guidance in regulatory development.

By the same token, the proposed system for GE imports must be no less rigorous than for GE products developed domestically. BIO cautions against creating a means to import materials developed outside the oversight of the United States government that makes it more attractive to develop GE products overseas. BIO realizes the delicate balance between these two factors. However, the reaction of the global marketplace to these proposed rules cannot be overstated.

BIO encourages APHIS to specify in its regulations both the availability and the requirement for FFPR commercial use "approvals with conditions" for imports and plants grown domestically in containment.

4. Compliance, Enforcement and Remedial Action

In an attempt to implement provisions of the PPA and the 2008 Farm Bill, the proposed regulations impose uniform requirements on an extremely broad range of people. In many cases, this broad scope renders many of the requirements both impractical for the regulated entity and, more importantly, unnecessary for the Agency. As outlined in greater detail below, the regulations should more carefully limit the application of these requirements. Although specific topics discussed below may not be addressed directly in proposed § 340.7, all of these topics could be included in activities subject to the proposed regulations' compliance provisions.

a. Enforcement

BIO members are committed to complying with all applicable provisions of the PPA and the 2008 Farm Bill, and assisting APHIS in any necessary investigations into possible regulatory violations. Proposed §§ 340.7(a) and (b) provide a useful summary of the access to premises and records that APHIS inspectors may need to carry out the Secretary's enforcement responsibilities under the PPA. BIO recommends, however, that the regulation clarify that access must be provided in accordance with the Subtitle B of the PPA, §§ 421-423.[57]

b. Training and Communication

The proposed rule and the preamble address communication and employee training numerous times in the context of permitted activities and permit conditions, and BIO agrees that effective internal communication practices and appropriate training can foster regulatory compliance and reduce the need for remedial action. However, proposed § 340.3(a)(1)(ii) requires extensive communication of "all conditions, activities, actions, and contingency plans associated with the permit to all his or her agents and any other persons participating in permit-related activities." Such communication includes, among other things, "[p]roviding a copy of the permit and conditions to all agents involved in a permit."[58]

Because of the wide variety of employees, contractors and agents that may be involved in the carrying out of activities under an APHIS permit, the diversity of expertise of such persons, and the wide range of potential activities involved, this provision imposes a tremendous, and unnecessary, burden. First, specific tasks a particular employee or agent may perform under a permit can be conveyed without requiring communication of the entire contents of the permit. Indeed, a directed communication would likely be more effective. Next, it would serve no purpose for a field employee to be trained in the permit requirements for import, for example. Finally, because of such wide distribution, developers would need to provide permits to employees on a redacted basis to protect confidential business information, adding additional

[57] 7 U.S.C. §§ 7731-7733.
[58] Proposed § 340.3(a)(1)(ii)(B).

complexity. This provision should be rewritten to require appropriate training only for those specific activities the employee or agent is authorized to perform.

Similarly, proposed § 340.2(c)(1)(v) seeks information from a permit applicant regarding "how permit requirements will be communicated to persons having contact with the GE organism under permit." As mentioned above, BIO fully supports the communication of relevant permit requirements to those bound by those requirements. However, this requirement should not be interpreted as a requirement to share permit requirements with neighbors, passersby, or others who may only come "in contact" with the GE organism under the broadest sense of the term. The term "having contact with the GE organism under permit" in this provision should be replaced with language such as "having obligations under permit conditions."

Finally, proposed § 340.3(a)(1)(i)(A) requires the "[m]arking, labeling, or otherwise identifying all GE organisms during the course of the permit...." This suggests that individual GE organisms or fields in which permitted GE plants are grown must be somehow labeled or otherwise physically identified as "GE". Such an interpretation would provoke needless public concern and could lead to property destruction or even violence. Moreover, such a requirement is unjustified based on twenty years of safe and responsible development of these products. BIO urges that APHIS make it clear that, while appropriate labeling or marking to ensure proper handling and delivery may be required, such physical identification, in field or otherwise, that would lead to product disparagement or destruction is neither required nor justified in any way. Identification of GE organisms through appropriate recordkeeping remains, of course, an appropriate regulatory practice.

c. Recordkeeping for Permits (Proposed § 340.3(a))

BIO members are committed to maintaining records needed to demonstrate compliance with applicable permit conditions. However, much of the information sought by APHIS under this proposal provides no value in the protection against threats of plant pests or noxious weeds. The permit application itself and any associated permit conditions should provide all the information regarding the procedures involved in carrying out the permitted activity, and these records will already be in the possession of APHIS. Records, reports, and notices either kept by the responsible party or submitted to APHIS will demonstrate compliance with the permit conditions.

These permit-related records are required by proposed § 340.3(a)(1)(iii), which provides that records must be maintained sufficient to demonstrate compliance with permit conditions. BIO supports this performance-based approach in the rule. Specific recordkeeping requirements beyond this would best be addressed in guidance so as to avoid a "one size fits all" approach in the rule itself.

For example, proposed § 340.3(a)(2)(ii) requires the maintenance of a variety of records. The intent of this section seems to be to provide APHIS with shipping information. However, many of these requirements would provide no useful or relevant information, and the collection and maintenance of these records, amounting to tens of thousands of pages, would be unreasonably burdensome. BIO suggests that the rule simply require that the applicant maintain sufficient

records to document what GE organisms were shipped and whether they were properly received at the intended destination.

A specific requirement from this provision is illustrative. Proposed § 340.3(a)(2)(ii)(F) requires the permit holder to maintain "a copy of any label used on these containers [used to transport GE organisms] during transport." Retaining a copy of the label accompanying every shipment will impose a significant paperwork burden on the permit holder without meaningfully reducing risk. As discussed above, for compliance purposes, BIO supports a requirement that records be kept describing what was shipped and whether it was received at the destination. However, if APHIS imposes a requirement that shipping labels be maintained for compliance purposes, APHIS should provide guidance describing information that should appear on those labels.

The proposal could also be read to place unreasonable recordkeeping requirements on the hundreds or thousands of agricultural workers who may be assisting with the development of these plants. Although BIO fully supports the maintenance of appropriate records regarding permitted activities by the responsible person, proposed § 340.7(c) would also require agents to keep duplicates of these records. If proposed § 340.7(d) were interpreted to require that each of these thousands of employees then maintain these records for up to five years, the requirement would be impossible for permittees to meet or the Agency to enforce.

The nature of agricultural research and product development can often involve facilities, employees, contractors and cooperators in multiple locations, performing a wide variety of tasks directly or peripherally related to the permitted activities. Moreover, these processes may span multiple months or even years, even though a particular worker might only be employed for a season. Requiring such workers to then maintain permits and other records for five years would be impossible for regulated entities to require and would serve no meaningful purpose.

APHIS also proposes to require that records be kept of all contracts between the responsible party and "all agents that conduct activities subject to this part for the responsible person" for as long as 5 years.[59] As drafted, this requirement could be interpreted to include employment contracts of every employee who participated in any permitting activity. Similarly, "activities subject to this part" could amount to hundreds of documents per permit for activities with only tangential relation to Part 340. To avoid the public release of personal information and confidential business information, redacted copies of these documents would likely be needed, further adding to the burden this requirement imposes on regulated entities. These provisions should be rewritten to require the proposed records be kept only by the responsible person.

It is one of the primary duties of the responsible person to maintain such records. As discussed above, numerous staff members and agents will often perform permitted activities at the direction of a responsible person, and it is common business practice for any records created in the course of a field test by staff to be compiled and forwarded to the responsible person where the records can be stored in centralized locations. For these reasons, BIO suggests that the phrase "and their agents" be struck from proposed § 340.7(c).

[59] Proposed §§ 340.7(c)(5); 340.7(d).

Limiting recordkeeping to the responsible person is consistent with the PPA's theory of agency.[60] The requirements for recordkeeping should only be imposed on the responsible person, and should be limited to those records necessary to establish compliance with relevant regulatory requirements.

d. Recordkeeping for "Approvals with Conditions"

As currently drafted, recordkeeping obligations under proposed § 340.7(c)(2) would render the use of the "conditional exemption" or "approvals with conditions" unworkable for the vast majority of uses. The proposed recordkeeping obligations would apply to activities "subject to the regulations of this part."[61] As such, all recordkeeping requirements would apply equally to activities undertaken under permit and under an "approval with conditions." Recordkeeping is appropriate under an "approval with conditions" only to record those activities that relate to the specific conditions required by the "approval with conditions," not, for example, for every release into the environment.

Proposed § 340.7(c)(2) would require responsible persons to maintain records regarding, *inter alia*, "all locations where the GE organism was released into the environment."[62] As proposed, a GE organism regulated under an "approval with conditions" would be subject to this recordkeeping. However, the preamble states that an "approval with conditions" (described there as a "conditional exemption") could be used "for the importation of certain GE commodities. A person could petition for an exemption from all permits for shipments of a particular GE commodity grain under the condition that the grain is not grown, but will only be moved for direct use as food, feed, or for processing."[63]

As discussed above, BIO fully supports the use of an FFPR commercial use "approval with conditions" in such circumstances. However, as currently proposed, the recordkeeping burden that would be associated with such an "approval with conditions" would be impossible. In the example given above, proposed § 340.7(c)(2) would require that, despite the FFPR commercial use "approval with conditions," every contained facility through which that grain passed, and its every release into the environment, must be recorded. The very nature of commodity shipment would render it impossible to document this information. The regulations must clarify that documentation is only required for those specific activities required as a condition of the "approval with conditions."

e. Low-Level Presence of Regulated Biotechnology Materials (Proposed § 340.7(g)(2))

As discussed above in references to stewardship, BIO strongly endorses continued implementation of measures aimed at preventing, in commercial seed lots, bulk commodities, and processed food and feed, the occurrence of intermittent, low levels of genes and gene products from biotechnology-derived crops under development for food and feed use until all

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[60] 7 U.S.C. § 7734(c).
[61] Proposed § 340.7(c).
[62] Proposed § 340.7(c)'s imposition of this requirement on the agents of responsible persons is addressed in section 4.c. of these comments.
[63] 73 Fed. Reg. at 60023.

applicable regulatory reviews have been completed. As discussed above, BIO and its members are involved in the first industry-coordinated effort to address product stewardship and quality management that are intended, in part, to minimize this occurrence.

Despite the best stewardship efforts of all parties to ensure adequate confinement of field trials, however, 100% genetic confinement is impossible to guarantee. APHIS has consistently recognized this reality of growing commodity crops in a biological system. It would be helpful for APHIS to include a short discussion of these biological realities in the preamble to the regulations to provide context for its treatment of this issue.

To address the low-level presence (LLP) of regulated biotechnology materials in commercial crops, food, feed, or seed of genetically engineered plant material that has not completed the required regulatory review processes, APHIS has proposed, under § 340.7(g)(2), regulatory provisions that are essentially the same as those set out in its "Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials," which BIO has consistently supported.[64] BIO supports the adoption of science-based criteria by which regulated material, present as LLP, would be considered "non-actionable." In other words, the material would still be subject to APHIS regulation, but the Agency could decide not to take any remedial action authorized under the PPA against the material.

In proposed § 340.7(g)(2), APHIS applies several criteria for non-actionable determinations. The potential risks that might be posed by the LLP of plant material meeting these criteria would not be expected to pose any significant environmental impact. BIO would like to underscore that the factors set forth in the proposed regulations are not exclusive, and that other factors may be considered. The language of the proposed regulation states: "The factors the Administrator will consider that would support a decision not to order LLP remedial action include, but are not limited to..."[65] If particular plant material does not meet all of the enumerated criteria, APHIS could still consider taking no remedial action based on a showing of safety. BIO supports the consideration of all appropriate factors in making a finding of safety to minimize both plant pest and noxious weed risks, as well as market disruption, in making decisions regarding remediation.

BIO continues to support a pragmatic approach to LLP that is coordinated between APHIS, FDA, and EPA and is in keeping with the Coordinated Framework and the Office of Science and Technology Policy's "Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants and to Establish Early Food Safety Assessments for New Proteins Produced by Such Plants."[66] If the LLP occurs in a product intended for food or feed, it is important to remember that, as confirmed by FDA and numerous other scientific bodies, DNA is safe. Accordingly, APHIS should confirm that food safety evaluations are only intended to address proteins and other expressed substances (non-nucleic acid substances) produced in food and feed, and that the introduced genetic material (DNA) itself does not warrant a food safety assessment. Also, although biotechnology-derived genetic material might be detected at trace levels in food or feed, this is not a definitive indication that an expressed substance is also present. The mere presence of such DNA should not trigger federal action.

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[64] 72 Fed. Reg. 14649 (Mar. 29, 2007).
[65] Proposed § 340.7(g)(2).
[66] 67 Fed. Reg. 50578 (July 2, 2002).

If an expressed substance is found, then BIO supports the proposed consideration of established EPA tolerances or exemptions from tolerances when deciding whether to remediate a particular LLP occurrence in the case of a Plant Incorporated Protectant (PIP). For expressed substances not considered PIPs, as proposed, the existence of an appropriate assessment of key food safety issues of the new expressed substance should be considered. This food safety information is critical to deciding whether an LLP occurrence poses any risks to humans or non-target organisms.

BIO was extensively involved in negotiations that led to the successful adoption of Codex's "Annex on Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food." This Annex provides guidance on food safety assessment of LLP to the global community, and it relies on a process of food safety evaluation with which FDA's own food safety reviews are in conformity. BIO shares APHIS' concerns regarding the potential for occurrences of LLP to impact international trade and the acceptance of biotechnology-derived products in the global marketplace. For the purposes of LLP remediation under the proposed Part 340 rules, food safety issues must be resolved consistently in a manner accordant with FDA and the Codex guidelines.

Because the term "new" (as used in proposed § 340.7(g)(2)(ii)(F)(3)) is subject to a range of interpretations, BIO urges APHIS to adopt the relevant provisions of the definition of "new" used by FDA in its Guidance for Industry on early food safety evaluations[67] and the characterization of "new" expressed substances by Codex in its Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.[68] Specifically, under APHIS' food safety criterion for non-actionable LLP, a "new" expressed substance should refer to "any non-nucleic acid substance produced in a new plant variety that is new to the plant species, or is a native substance that has been produced at a significantly elevated level, or is a native substance from a part of a plant that is not normally ingested, and will now be produced in a part of the plant that is normally ingested." An expressed substance that is not "new" under this definition would meet APHIS' non-actionable criterion.

BIO strongly supports the inclusion of the concept of familiarity in the LLP decision-making process, but BIO wants to emphasize that familiarity is based on the state of scientific knowledge and is not limited to the prior experience of the regulatory agency involved with a particular protein, transformation event or gene. Not every biotechnology-derived expressed substance will require a unique food safety assessment. For example, BIO supports the adoption of science-based categories of expressed substances for which individual LLP evaluations will not be required based on prior food safety evaluations, similarity to a deregulated product, a history of safe use, or a lack of new exposure. Expressed substances that have previously been cleared for food and feed use in the United States, have a known history of safe use, or are closely

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[67] FDA, "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use" (June 2006). A link to the guidance is available at http://www.cfsan.fda.gov/~dms/bioprgu2.html (last visited Nov. 19, 2008).

[68] A link to the guidelines is available at ftp://ftp.fao.org/docrep/fao/007/y5819e/y5819e00.pdf (last viewed Nov. 21, 2008).

related to an expressed substance that meets these criteria (i.e., "familiar" expressed proteins) should not need to undergo a second food safety evaluation for purposes of LLP remediation.

One of the LLP enumerated criteria addresses persistence.[69] The regulation should clarify that this determination should correlate directly with the "persistence" determination made under proposed § 340.2(d)(1)(i)(A), but will also depend on the amount and viability of the LLP plant material found.

Finally, with regard to both LLP and other issues that could potentially involve the need for remediation, APHIS should make plain that it retains all authority to take any action necessary to protect the environment or public health, whether or not the plant material giving rise to such a threat is viable or not.

5. Due Process

Although the proposed rule provides minimal due process protections, further procedural protections would provide both certainty and transparency to the permitting, deregulation and "approval with conditions" processes, as well as ensure that an appropriate record exists for any judicial review.

a. Standards for Agency Action

Under the proposed regulations, APHIS may revoke a permit or deregulation, and may revoke or amend an "approval with conditions," based on receipt of information subsequent to the decision that the decision is likely to result in the introduction or dissemination of a plant pest or noxious weed.[70] Because there are currently no standards applied to this "information," BIO suggests that any information sufficient to alter an APHIS decision must meet minimum standards of scientific rigor. For example, the regulation could state: "Such information must consist of validated tests or other significant evidence raising prudent concerns that the decision is likely to result in the introduction or dissemination of a plant pest or noxious weed."

Similarly, as drafted, the proposal would allow APHIS to amend permit conditions at any time "upon determining that the amendment is needed to make it unlikely that actions under the permit would result in the introduction or dissemination of a plant pest or noxious weed, or to ensure that the permit is in compliance with all of the requirements of this part."[71] BIO proposes that any such permit amendment be based on new science- or compliance-based information subject to the same higher standard proposed above: "Such information must consist of validated tests or other significant evidence raising prudent concerns that the decision is likely to result in the introduction or dissemination of a plant pest or noxious weed."

With regard to denials or revocations based on the actions of a responsible person, under the proposed rules, APHIS has the discretion to deny or revoke a permit or revoke a conditional exemption if the responsible person or an agent "has failed to comply at any time with any

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[69] Proposed § 340.7(g)(2)(ii)(D).
[70] Proposed §§ 340.2(e)(2), 340.5(d) and (e), 340.6(d).
[71] Proposed § 340.2(h)(2).

provision of" Part 340 including any permit condition.[72] This language is overly broad and could jeopardize the ability of any permittee to operate. BIO proposes that the test for denial or revocation should be: "material noncompliance and substantial evidence that the responsible person has failed to take appropriate and available corrective action." Such a standard would ensure that APHIS decision-making is based on factors likely to prevent the introduction or dissemination of a plant pest or noxious weed, but would provide the regulated community with certainty that instances of noncompliance that are non-material and have been promptly corrected, where possible, would not jeopardize a development program.

b. Appeal

In contrast to the administrative appeal rights granted to petition denials, no such right is provided for the revocation of deregulation or broad revocation of a "conditional exemption," despite the fact that such action would likely have far greater impacts on channels of trade. BIO requests an administrative appeal right for any party adversely affected by the revocation of a conditional exemption or deregulation. Pending any such appeal, the GE organism should remain on the market in the absence of a demonstrated, significant and immediate plant pest or noxious weed risk.

c. Protection of Channels of Trade

For the first time, the proposal provides for the revocation of an approval of nonregulated status.[73] However, the proposed regulations fail to provide adequate certainty as to the effects of such a decision, which could have catastrophic impacts on trade and consumer confidence. For example, if APHIS determined that planting of a deregulated crop endangered the habitat of an endangered species in one county in Washington State, the proposal would authorize the Agency to revoke the determination without taking further action. This could result in disruption of commerce in seed, produce and processed goods made from the crop, all for no health-related reason.

While the proposed language of the regulation attempts to address this issue, it does not go far enough. Upon revocation of a deregulation, the proposed rule states that the Administrator "may approve for the same GE organism" a conditional exemption (or, using BIO's terminology, an "approval with conditions").[74] This discretionary language does not provide adequate protection for product already in the channels of trade. To avoid unnecessary trade disruption and public concern, the regulation should state that any revocation of either a deregulation or conditional exemption ("approval with conditions") must include provisions that allow products to clear the channels of trade and be minimally disruptive to the marketplace while ensuring appropriate protection of public health, agriculture and the environment.

6. Confidential Business Information (CBI)

BIO supports the efforts made by APHIS to balance the competing interests of transparency in

[72] Proposed §§ 340.2(e)(1)(iii), 340.4(e), 340.5(f) and 340.7(e).
[73] Proposed § 340.6(d).
[74] Proposed § 340.6(d).

Agency decision-making and the need to protect CBI and other information in accordance with the protections afforded under the Freedom of Information Act (FOIA). Procedurally, the vast majority of permit applications are submitted to APHIS electronically through the ePermits portal. Although petitions for the granting of non-regulated status are not currently submitted through ePermits, APHIS has indicated on several occasions that it is the Agency's intention to enable ePermits to accept petitions. Except for the first sentence of proposed § 340.8, the remaining text does not represent the current state of the art in submitting CBI to the Agency. BIO recommends that all but the first two sentences of proposed § 340.8 be struck and that APHIS produce appropriate guidance for the submittal of CBI. The second sentence should read: "Persons wishing to protect confidential business information in permit applications, petitions, or other submissions to APHIS under this part should do so in a manner approved by APHIS."

7. Regulatory Impact, Paperwork Reduction and Environmental Impact

Given the significant differences in the data required for permit applications, and the significant increases proposed in recordkeeping and reporting, BIO and its members have no confidence in the Agency's cost and paperwork requirement estimates. Statements such as "it is not anticipated that there would be any efficiency loss during the transitional period" is simply an inaccurate description of a process that changes a mandatory thirty-day response deadline for 90% of Agency actions to 150 day goals.[75] Similarly, in the face of the tremendous increase in recordkeeping, the preamble's statement that the rule could decrease the regulatory burden appears careless, at best.[76] At least one BIO small company member has estimated that it would require approximately 50 hours to collect the information required for a permit application under the proposed regulations, compared to the two hours estimated in the preamble.[77] The Agency should provide greater detail as to how it reached its conclusions, or provide more realistic estimates of the time needed to meet the proposed regulatory requirements. The time estimates outlined in the preamble simply cannot include the time required to track, record and maintain employment records of all those involved in permitting activity, nor can they include the time required by all those involved in permitting activity to obtain, record and maintain all permitting records. The Paperwork Reduction Act analysis included in the preamble does not mention the new recordkeeping burden imposed on what could be thousands of individuals.

The preamble to the proposed regulations analyzes the proposal within the framework of the draft EIS. However, this analysis fails to consider the potential environmental impacts that could result if APHIS were to adopt a self-determination approach to regulation as suggested in the preamble. The preamble accurately outlines the tremendous beneficial effects for the environment of GE plants in commercial production.[78] Slowing the development and commercialization of future products, such as the delays inherent in the proposed revisions to permitting requirements, would impact the rate at which future benefits can be achieved, and, if these aspects of the rule are not changed, these impacts must be reflected in the final EIS.

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[75] *See* 73 Fed. Reg. at 60017.
[76] *Id.* at 60036.
[77] *Id.* at 60038.
[78] 73 Fed. Reg. at 60033.

8. Preemption

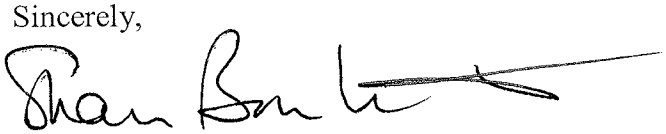
On November 10, 2008, APHIS published a correction to the preamble to the proposed rule. The correction stated that: "if this proposed rule is adopted, all State and local laws and regulations that are inconsistent with this rule will be preempted."[79] This correction conforms the language of the preamble to the express preemption language of the PPA and to APHIS' well-reasoned discussion of the preemptive nature of these regulations set forth in the preamble to an earlier amendment to Part 340.[80] BIO supports APHIS' position as published in the corrected publication.

9. Implementation

In every case in which substantive changes are made to recordkeeping requirements or to permit requirements or conditions, the Agency should provide for an orderly phase-in of implementation dates so as to account for the ongoing nature of permit and petition applications, and the advance planning required to schedule field tests and commercial plantings.

BIO appreciates the opportunity to provide comments on this proposed rule, and again thanks the Agency for its work and attention to this issue.

Sincerely,



Sharon Bomer Lauritsen
Executive Vice President
Food and Agriculture

[79] 73 Fed. Reg. 66563 (Nov. 10, 2008).
[80] 58 Fed. Reg. 17044, 17053-54 (March 31, 1993) (finalizing "Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status").