BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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Docket No. APHIS-2008-0023

Regulatory Analysis and Development
PPD
APHIS
Station 3A-03.8
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**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 reopened and extended comment period regarding 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). Existing APHIS regulations for genetically engineered (GE) organisms are codified in part 340 of title 7 of the Code of Federal Regulations (Part 340). The notice for the reopened comment period was published in the Federal Register on January 16, 2009, and extended by notice in the Federal Register on March 11, 2009.[1] These comments supplement BIO's comments submitted on this same docket on November 24, 2008. BIO appreciates this opportunity to provide additional 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.

Before addressing the substantive issues on which APHIS has requested comments, BIO would like to address two overriding issues. First, as APHIS recognized during the April 29-30, 2009 public meeting on this proposed rule (the Public Meeting), concern has been expressed from a cross-section of interested parties regarding various elements of the proposed rule that could have a serious adverse impact on the effectiveness of the Part 340 regulations, both in the short and long

[1] 74 Fed. Reg. 2907; *id.* at 10517.

terms. Given the extent of these concerns, and the anticipated degree to which the rule is likely to be revised to address these concerns, BIO strongly encourages APHIS to issue a new proposed rule, rather than to move directly to a final rule. The issuance of a new proposed rule would allow interested stakeholders the opportunity to comment on the changes that APHIS has made in response to their comments and to continue to work with APHIS to develop a rule that provides appropriate safety to the public, agriculture and the environment, within the context of a science- and risk-based regulatory structure, while not imposing unnecessary burdens on or providing disincentives to the development of new products.

Second, the proposed rule contains a number of significant changes to longstanding APHIS policies and procedures. At such time as APHIS promulgates a final rule adding new requirements, including permit and recordkeeping requirements, or making substantive changes to current policies and procedures, an orderly phase-in of implementation dates will be necessary so as to account for: (a) the ongoing nature of product research and development activities, including the preparation and submission of permit applications and petitions and the processing of pending permit applications and petitions, and (b) the advance planning required to schedule field trials and commercial plantings and introduce new procedures to licensees and cooperators. In establishing the effective dates for various provisions of a final rule, the Agency should give careful consideration to the relationship between the date of the rule's promulgation and planting schedules and other activities taking place during the same time period in the agricultural sector. An orderly phase-in of new requirements will also give APHIS time to issue guidance needed for the proper implementation of these requirements.

In its January 16 Federal Register notice, the Agency asked commenters to provide more specific information and detailed suggestions on four issues identified by the Agency in the notice. An additional issue was raised at the Public Meeting. BIO staff and member company representatives participated in this Public Meeting. The following comments provide more specific information and suggestions to the Agency on all five issues. These comments supplement and do not supersede BIO's previous comments.

**1) The scope of the regulations and which GE organisms should be included or excluded from the proposed regulations**

*GE Organisms Subject to Regulation*

The proposed rule at § 340.0(b)(3) together with statements made by APHIS in the preamble to the proposed rule could be interpreted to suggest a radical departure from APHIS' longstanding approach to the regulation of GE organisms that may pose a plant pest risk. These statements suggest that anyone, without Agency oversight, can determine whether a particular GE organism is regulated, thereby creating the appearance of a voluntary regulatory scheme. Although BIO supports clear Agency guidance regarding the scope of the regulations, 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.

At the Public Meeting, APHIS recognized that the proposed rule's scope criteria, determining which GE organisms are likely to fall within the jurisdiction or scope of the regulation, could be refined and clarified. APHIS-2008-0023-5409.4. BIO fully supports such clarification and repeats here the language originally suggested in BIO's November 24, 2008 comments to be included in proposed § 340.0(b):

> 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.

Whatever the precise language used in the regulation to convey this important message, 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.

APHIS has also proposed to remove the original list of plant pest taxa that is included in § 340.2. BIO appreciates the Agency's need for flexibility in discerning circumstances when agricultural or environmental damage could occur, identifying species that are likely to cause those types of damage, and creating appropriate permit conditions to make such damage unlikely to occur, without reference to a static regulatory list. However, in order to make the system 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. The guidance needs to be made available concurrent with removal of the list of plant pest taxa.

*GE Organisms Excluded from Regulation*

With twenty years of Agency experience regulating genetically engineered organisms, APHIS is in a position to identify specific organisms that are excluded from the regulations. BIO continues to support the alternative proposed by APHIS in the draft Environmental Impact Statement (EIS) that would allow the Agency to make a decision to exclude specific organisms and classes of organisms from regulatory oversight and create a mechanism to exclude additional organisms from regulation after a safety review. 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. BIO therefore makes the following suggestions:

The new regulations must include a transparent mechanism to exclude GE organisms from regulation, if they 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 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

- similarity to one or more GE organisms or events already granted nonregulated status by APHIS.

The Agency should also exclude from regulation those organisms already adequately regulated under statutory authority other than the Plant Protection Act (PPA), including regulation by sister agencies. For example, this exclusion would cover GE microorganisms regulated as biological control organisms and GE vertebrates.

Discussion of exclusions from regulation raises an important question of nomenclature. Although the proposed rule outlines APHIS's desire to cease using the term "regulated article," the proposed rule uses the terms "GE plants" and "GE organisms" as the subjects of regulation (e.g., proposed 7 C.F.R. § 340.2(b)(3) "Environmental release permits are for the environmental release of GE organisms."). This nomenclature ignores the fact that some GE organisms may be excluded from regulation and many GE plants already have obtained determinations of nonregulated status. Some term should be used to identify those GE plants subject to APHIS regulation so that the term "GE plants" is not considered to be regulated by default.

*Regulation of Nonviable Plant Material*

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.[2] However, if in a specific case the importation, interstate movement, or environmental 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. BIO makes the following suggestions regarding the regulation of nonviable plant products.

- The regulations should clearly define "viable" to mean "capable of regeneration or breeding outside of a laboratory or greenhouse setting."

- The Agency must create guidance as to nonviable plant material that is likely to raise noxious weed concerns and publish this guidance on its website and elsewhere prior to the effective date of a final rule. This guidance should include examples of appropriate supplemental permit conditions designed to mitigate any significant noxious weed risks posed by these materials.

[2] 73 Fed. Reg. 60008, 60015 (Oct. 9, 2008).

- All regulatory provisions applied to domestic nonviable plant material must apply equally to imported nonviable plant material.

- Any provisions in the regulations to assign supplemental permit conditions addressing nonviable plant material must provide for case-by-case determinations, based on a scientific analysis of the potential risks, and provide for a flexible mechanism to impose appropriate conditions to manage any significant risks.

**2) Incorporation of the noxious weed provisions of the Plant Protection Act into the proposed regulations**

BIO supports APHIS' exercise of its full statutory authority over GE organisms, because this will better align the Part 340 regulations with the Agency's PPA mandate to guard against the possibility, however remote, that the environmental release, importation, or interstate movement of a GE plant or other organism may pose a risk of introducing or disseminating a plant pest or noxious weed. Basing its regulatory determinations firmly within APHIS' full PPA authority in a manner consistent with the Agency's longstanding policies and procedures 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.

Finally BIO would like to underscore APHIS' assertion in the draft Environmental Impact Statement (EIS) 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. As APHIS has indicated, in regulating GE organisms under Part 340, the Agency "takes a 'safeguarding' approach."[3] 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."

BIO strongly supports the statements made by APHIS at the Public Meeting on the topic of its noxious weed authority. APHIS-2008-0023-5409.2. Specifically, the Agency stated:

> APHIS must consistently apply its PPA noxious weed authority and thus its noxious weed assessment of GE plants under the proposed regulations must be similar to and consistent with the way that APHIS has in the past and continues to evaluate the noxious weed risk of non-GE plants. It is not justifiable either from a regulatory or a scientific perspective to hold GE plants to a different standard than non-GE plants for risks regulated under the same statutory authority by the very same agency.

[3] 74 Fed. Reg. 26832, 26834 (June 4, 2009).

*Id.* at 2. BIO also agrees with the Agency's statement that "the specifics of *how* APHIS will evaluate the noxious weed risk of GE plants may require some additional development and clarification." *Id.* (emphasis in original). As APHIS implements the noxious weed authority, the Agency must uphold the longstanding regulatory policy under which a plant must cause direct injury or damage (physical harm) to a protected interest in order to be considered a noxious weed. This means that APHIS does not consider purely economic effects (i.e., commercial, marketing or economic effects that are not linked to physical damage) to be sufficient in determining if a plant or plant product is a noxious weed.[4] 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.

BIO makes the following suggestions regarding the Agency's adoption of the noxious weed authority:

- In determining whether a plant poses a noxious weed risk, the Agency must first identify any direct injury, damage, or physical harm the plant causes to interests of agriculture, irrigation, navigation, U.S. natural resources, public health, or the environment. If direct injury is identified, the Agency may then identify and evaluate any indirect damage the plant may cause to these same interests.

- Economic effects that are not directly linked to previously identified physical damage are not sufficient to determine that a plant is a noxious weed.

- Any conditions placed on plants granted nonregulated status and any conditions placed on plants granted an exemption from permit requirements must be imposed pursuant to the authority granted the Agency under the PPA. As such, any conditions imposed must be only to reduce plant pest and noxious weed risks and for no other purposes.

- APHIS already undertakes a substantive review of the human, environmental and agronomic safety of plants subject to Part 340. For example, a determination of non-regulated status under the current rule involves the Agency's review of data submitted on not only plant pest risk characteristics, but also:

> disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organisms [including humans], indirect plant pest effects on other

[4] Importantly, even under the existing plant pest provisions of the Part 340 regulations, "APHIS does not determine nonregulated status for GE organisms … based on economic or marketing factors." 74 Fed. Reg. at 26833.

> agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information which the Administrator believes to be relevant to a determination...

7 C.F.R. § 340.6(c)(4). Given the breadth of data already required, there is no need for substantive changes to that evaluation process to address APHIS' noxious weed authority.

- BIO agrees that the public may be unaware of the breadth of data on which APHIS makes its regulatory decisions under Part 340 and encourages APHIS to better inform the public of how it will apply its PPA noxious weed authority in conformance with its application of this authority to other types of plants.

**3) Elimination of the notification procedure – a streamlined procedure for authorizing the importation, interstate movement or environmental release of certain GE organisms – including specific suggestions for protecting against the introduction of plant pests or noxious weeds while minimizing any additional burden or delay for applicants**

In the issue paper APHIS shared on this topic at the Public Meeting, APHIS described its goals of more flexible, risk-appropriate oversight, better regulatory enforcement, and improved transparency. APHIS-2008-0023-5409.1. BIO applauds those goals. BIO also supports the Agency's acknowledgement that "the proposed regulations need a clearer description regarding categories, permit conditions, and any other requirements associated with a category. *Id.* at 2. BIO appreciates APHIS's recognition of the importance of timeliness to the regulatory system, and strongly encourages the Agency to codify the timeframes outlined ("familiar crops/traits will be reviewed in a similar timeframe as current notifications and other crops/traits will be reviewed in a similar timeframe as current permits" *id.*) in the final rule.

In response to the Agency's question as to how APHIS can clarify in the regulations which GE organisms fall into each category and revise them to make them more closely risk-based, in BIO's original comments we provided an in-depth discussion regarding how a science-based permitting system could operate. BIO provided extensive comments to the Agency indicating that the permit system described in the proposed rule was not grounded in science and instead created a one-size-fits-all approach to regulation. In addition, the proposal included new and burdensome requirements for data and recordkeeping, both at the application stage and once the permit is granted. In the preamble to the proposed rule, the Agency did not justify a clear need for all this information – it does not assist in Agency decisionmaking nor does it reduce a plant pest or noxious weed risk.

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.[5] That table made it relatively clear how individual species-trait

[5] APHIS, "Introduction of Genetically Engineered Organisms: Draft Programmatic Environmental Impact Statement – July 2007" (Draft EIS) at 140. *See* 72 Fed. Reg. 39021 (July 17, 2007) (announcing availability of Draft EIS and

combinations would be categorized, 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 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. A draft of such guidance should be made available for comment at the same time a new proposed rule is published to allow stakeholders to properly consider the manner in which APHIS proposes to handle this important process. 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.

- Any new system of permit categories must be science based and must reflect Agency experience and familiarity with GE plants, such as the system described in Table 4.2 in the draft EIS.

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

- Any information requirements imposed on an applicant for a particular permit category must accommodate information already submitted to the Agency by the applicant, as well as information in the public domain, and be appropriate to the potential risk posed by the release of organisms permitted under that category.

- The permit categories in the new regulations must contain a category functionally equivalent to existing notifications. This category should provide a simplified application process, expedited Agency review, and reduced regulatory burdens for applicants and the Agency, while still ensuring safety.

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requesting comments). A link to the Draft EIS is available at http://www.aphis.usda.gov/brs/pdf/complete_eis.pdf (last viewed June 23, 2009).

- Recordkeeping requirements should not demand the production and preservation of arbitrary pieces of paper, but should instead allow the responsible party to create an appropriate system of records that demonstrate regulatory compliance.

- Recordkeeping and reporting requirements must recognize the demands of biological timetables and other practical realities of agricultural research and production.

**4) Regulation of GE crops that produce pharmaceutical and industrial compounds, including specific suggestions on how to provide appropriate protection based upon risk.**

Consistent with international scientific standards, APHIS has set forth assessment methodologies for all proteins or newly produced compounds regardless of their intended use.[6] Genetic engineering of plants to produce substances having pharmaceutical or industrial applications 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. There is no scientific reason that, under appropriate conditions, food crops should not be used for the production of a wide variety of substances, or that either food or non-food crops used for these purposes should not be grown outdoors, under permit conditions appropriate for the risk posed by that crop and the pharmaceutical or industrial compound produced.

The preamble to the proposed rule implies that APHIS will continue to impose strict permit conditions on plants that produce pharmaceutical and industrial compounds. However, imposing inappropriately stringent confinement measures or placing entire broad categories of products in risk tiers prior to an evaluation of specific risks posed by any plant producing a new substance would be arbitrary and restrictive to a degree not supported by the available science or the law. By the same token, arbitrarily assigning crops to ill-defined classes such as "Plant Made Pharmaceutical" or "Plant Made Industrial" provides neither transparency nor predictability to the regulatory system and is not justified by the science.

- If APHIS adopts a multi-category permitting system, the assignment of a particular GE plant to a permit category, including a plant producing an industrial or pharmaceutical compound, must be done according to science-based criteria and must reflect Agency familiarity with the particular plant.

- Descriptive categories (e.g., PMP, PMI) cannot be the basis for determining which permit category is appropriate. The assignment of all GE plants to a particular permit category must be based on the identified risks posed by the plant itself.

- Any organism posing little or no risk must move through the permitting process in an expedited way.

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[6] *See* Draft EIS, Appendix F-5.

In the issue paper APHIS shared at the Public Meeting, the Agency rightly noted that marketing and public perception concerns are not an appropriate basis for regulation under the PPA. APHIS-2008-0023-5409.3 at 3. Like other potential plant pests and noxious weeds, these plants should be regulated on the basis of a science-based risk analysis.

**5) A regulatory policy for the determination of remediation in low-level presence (LLP) instances.**

BIO appreciates the safety-based approach APHIS describes in the issue document distributed at the Public Meeting on this topic and the Agency's expressed intent to incorporate its 2007 LLP policy into the regulatory text of the Part 340 rule, with appropriate modifications to incorporate noxious weed authority. APHIS-2008-0023-5409. BIO recognizes that APHIS has the discretion to decide whether or not to order corrective or remedial actions in any given LLP situation in order to protect the public and the environment. BIO supports a pragmatic approach to LLP, coordinated between APHIS, the United States Food and Drug Administration, and the United States Environmental Protection Agency.

BIO appreciates the opportunity to provide supplemental 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