Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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Docket No. APHIS-2007-0044
Regulatory Analysis and Development
Plant Protection Division
Animal and Plant Health Inspection Service
United States Department of Agriculture
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Re: Draft Environmental Impact Statement; Determination of Regulated Status of Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate

To whom it may concern:

These comments are submitted by the Biotechnology Industry Organization (BIO) in response to the January 12, 2010 announcement (the Notice) by the United States Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS or the Agency) of APHIS's preparation of a draft environmental impact statement (DEIS) in connection with making a determination on the status of the Monsanto Company and Forage Genetics International alfalfa lines designated as events J101 and J163, collectively, glyphosate-tolerant (GT) alfalfa, as regulated articles under the Plant Protection Act (PPA) and implementing APHIS regulations at 7 C.F.R. Part 340.[1] BIO appreciates the opportunity to provide these comments.

**Background**

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's member companies engaged in the development of biotechnology-derived[2] commodity crops and other plants and organisms have acted under the regulatory oversight of APHIS, along with the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), since well before the first products were commercialized over ten years ago. Since that time, these products have yielded significant economic and environmental benefits, lowering both the

[1] 75 Fed. Reg. 1585.

[2] The Part 340 regulations and various reports of the National Research Council (NRC) and other scientific bodies use such terms as "genetic engineering," "genetically engineered," "transgenic" or "genetically modified."

costs and environmental impact of food, feed and fiber production in the United States and 21 other nations. This success has been grounded on the work that APHIS and the other federal agencies overseeing this technology have conducted to ensure the safety of these products for the environment, as well as for the consuming public. BIO applauds the work that APHIS has undertaken in past years to develop and enforce a robust, science-based approach to the regulation and development of these products.

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 of biotechnology-derived crops already on the market, and about the promise shown by GE plants and plant products still in development. BIO and its members are proud of this record of safety and of benefit to growers and the environment.

BIO applauds the work APHIS has done in preparing the DEIS. The document illustrates the careful analysis APHIS undertakes in reviewing the safety of biotechnology crops, and recognizes the leadership role that APHIS plays in protecting American agriculture:

> "Protecting American agriculture" is the basic charge of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS provides leadership in ensuring the health and care of plants and animals. By ensuring plant and animal health, the agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health.[3]

While this DEIS was prepared pursuant to a court order,[4] BIO strongly supports the science-based position that an environmental impact statement is not required for every determination of nonregulated status made under the Part 340 regulations.[5]

**Coexistence**

As part of APHIS's mission of protecting American agriculture, the DEIS includes an important assertion of USDA's position on the coexistence of various types of agricultural production: "USDA asserts that all methods of agricultural production (conventional, organic, and the use of genetically engineered varieties) can provide benefits to the environment, consumers, and farm income."[6] This policy guides, as it must, the purpose and need of the DEIS and the conclusions APHIS reaches in the document. As the DEIS documents, the science and realities of agricultural practice fully support these conclusions. While the use of modern biotechnology may be an appropriate regulatory trigger under the PPA, for purposes of an analysis conducted under the National Environmental Policy Act (NEPA), it is important for APHIS to make clear that the process of genetic engineering does not raise unique or independent risks. This

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[3] DEIS at xiii and 1.
[4] *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).
[5] *See* 42 U.S.C. § 4332(C) (requiring an EIS only for "major Federal actions significantly affecting the quality of the human environment").
[6] DEIS at xiii and 1.

determination has been made on several occasions by the National Academy of Sciences:

> Based on a detailed evaluation of the intended and unintended traits produced by the two approaches to crop improvement, *the committee finds that the transgenic process presents no new categories of risk compared to conventional methods of crop improvement but that specific traits introduced by both approaches can pose unique risks.*[7]

This distinction between the PPA regulatory trigger and the potential risk posed by GE plants as compared to plants developed through traditional breeding is particularly important in the context of the NEPA process. While the regulators within APHIS may be familiar with the types of genotypic and phenotypic review appropriate for a particular regulated article, the broader involvement of the public in the NEPA review process requires a more complete discussion of the nature of the risks assessed in the NEPA review, and a full discussion of the context in which the risk assessment for these plants occurs.

Traditional Breeding Causes Genetic Changes

Plant evolution is based on the interplay and unique combinations of genes among plants. This biological certainty has existed since the dawn of time. It was the ability to harness this activity that allowed humans to cultivate crops and develop agriculture millennia ago. Public understanding of this aspect of plant biology would benefit from a broader discussion in the final EIS of pollination and gene flow among conventionally bred plants.

For example, there has been some significant public concern regarding the novelty of the very operation of genetic engineering – the insertion of a gene into other genetic material by means of the techniques of modern biotechnology. While the technology by which this takes place is, indeed, revolutionary in its application, the resulting movement of genetic material from plant to plant is a universal occurrence. Humans' manipulation of this event has been going on for thousands of years, and has intensified with every generation since Mendel. FDA has commented in various policy and guidance documents on the similarity in issues raised across various breeding methods (narrow-crosses, wide-crosses, mutagenesis, recombinant DNA techniques), and stated that all of these techniques "require extensive back crossing with the parent line to eliminate mutations unlinked to that responsible for the desired phenotype and undesirable traits in extraneous genetic material introduced along with that encoding the desired trait."[8]

The techniques of modern biotechnology allow us for the first time to directly observe and record the genetic contents of plants around us and to manipulate them with greater specificity and certainty than ever before. Because we can trace those changes for the first time, however, does not mean that this is the first time that significant genetic changes in plants have occurred. Such changes occur naturally and constantly. Humans are entirely unaware of the vast majority

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[7] NRC, Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation (National Academy Press, 2002) at 5 (emphasis in the original). *See also* NRC, Genetically Modified Pest-protected Plants: Science and Regulation (National Academy Press, 2000) at 5-6 and 42-45; National Academy of Sciences, Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues (1987) at 22.

[8] FDA, Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, 22986 (May 29, 1992).

of genetic changes taking place in plants all around them. In modern agriculture, plant scientists are actively attempting to promote and direct these changes and to improve plant health, sustainability and nutrition.

Minor genetic changes do not create safety concerns in modern commercial breeding programs. Phenotypic variations resulting from conventional breeding are typically far broader than those possible through genetic engineering but pose no known risks in the vast majority of cases. For example, sexually crossing wild varieties of tomatoes into cultivated varieties has resulted in the transfer of chromosomal segments of variable sizes, encoding dozens to hundreds of unknown genes.[9] However, despite these variations in the specific molecular environments in which the transferred genes were present, the commercial varieties all exhibited the desired phenotype – they all looked, grew and tasted as expected.[10]

This was not an isolated incident. Recent genome mapping and sequencing results support the argument that slight genomic alterations have no meaningful effect on the way humans interact with plants – through the plant's phenotypic properties. Total DNA content, the number of genes, and gene order can vary considerably even among varieties of the same species.[11] Studies have shown that different varieties of maize (corn), chili pepper and soybean can differ by as much as 42%, 25% and 12%, respectively, in their DNA contents.[12] For soybeans, this means that different soybean varieties can differ by over 100 million base pairs of DNA.[13] (By comparison, transgenes add only a few thousand base pairs to genomes, reflecting the greater precision associated with modern biotechnology.) Among corn plants, even individual plants within a defined population have different numbers of genes.[14] Transposable elements move into and out of genes, where they can alter gene expression or serve as sites of chromosome breakage or rearrangement. Parts of DNA continuously insert themselves between genes and are likely to have resulted in improvements in plant adaptation through both evolution and breeding.[15]

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[9] Bradford, K. *et al.*, *Regulating Transgenic Crops Sensibly: Lessons from Plant Breeding, Biotechnology and Genomics*, 23 Nature Biotechnology 439, 441 (2005) (citing Ho, J.Y. *et al.*, *The Root-knot Nematode Resistance Gene (Mi) in Tomato: Construction of a Molecular Linkage Map and Identification of Dominant cDNA Markers in Resistant Genotypes*, 2 Plant J. 971 (1992); Young, N.D. & Tanksley, S.D., *RFLP Analysis of the Size of Chromosomal Segments Retained Around the Tm-2 Locus of Tomato during Backcross Breeding,* 77 Theor. Appl. Genet. 353 (1989)).

[10] *Id.*

[11] *Id.* at 442 (citing Arumuganathan, K. & Earle, E.D., *Nuclear DNA Content of Some Important Plant Species*, 9 Plant Mol. Biol. Rep. 208 (1991); Fu, H.H. & Dooner, H.K., *Intraspecific Violation of Genetic Colinearity and its Implications in Maize*, 99 Proc. Nat'l Acad. Sci. USA 9573 (2002); Song, R. & Messing, J., *Gene Expression of a Gene Family in Maize Based on Noncolinear Haplotypes*, 99 Proc. Nat'l Acad. Sci. USA 9055-9060 (2003)).

[12] *Id.* (citing Graham, M.J., Nickell, C.D. & Rayburn, A.L., *Relationship Between Genome Size and Maturity Group in Soybean*, 88 Theor. Appl. Genet. 429 (1994); Mukherjee, S. & Sharma, A.K., *Intraspecific Variation of Nuclear DNA in* Capsicum annuum *L.*, 100 Proc. Indian Acad. Sci. USA 1 (1990); Rayburn, A.L., Auger, J.A., Benzinger, E.A. & Hepburn, A.G., *Detection of Intraspecific DNA Content Variation in* Zea mays *L. by Flow Cytometry,* 40 J. Exp. Bot. 1179 (1989)).

[13] *Id.* at 442 (citing Fu, H.H. & Dooner, H.K. *Intraspecific Violation of Genetic Colinearity and its Implications in Maize*, 99 Proc. Nat'l Acad. Sci. USA 9573 (2002); Ilic, K., San Miguel, P.J. & Bennetzen, J.L., *A Complex History of Rearrangement in an Orthologous Region of the Maize, Sorghum, and Rice Genomes*, 100 Proc. Nat'l. Acad. Sci. USA 12265 (2003)).

[14] *Id.* (citing Fu & Donner (2002); Song & Messing (2003)).

[15] *Id.* (citing San Miguel, P., *et al.*, *Nested Retrotransposons in the Intergenic Regions of the Maize Genome*, 274 Science 765 (1996); Ceccarelli, M., Giordani, T., Natali, L., Cavallini, A. & Cionini P.G., *Genome Placticity During*

Although traditional cross-breeding is not without some degree of risk, that potential risk is quite small, carefully managed and widely accepted. Some conventional breeding techniques include intervarietal hybrids, wide interspecies crosses, inbreeding, ploidy modification and tissue culture.[16] Conventional breeding also includes mutation breeding, in which random genetic changes are induced throughout the plant's genome. These breeding methods, routinely used in conventional agriculture, can and do produce collateral (*i.e.,* pleiotropic) effects.

In all these cases, the selection of plants to take forward to further breeding and commercialization is based almost entirely on the basis of phenotypic characteristics (observable traits, *i.e.,* how the plant looks, thrives and produces).[17] Genetic analysis of the unique genetic makeup of plants was impossible until quite recently and remains expensive and time-consuming. It is also largely unnecessary for the vast majority of plant breeding. While some potential risks to human health or the environment may be associated with any cross-breeding, traditional agronomic practices have developed reliable and well-accepted methods for addressing and minimizing these risks.

For example, over 2,200 crop varieties have been commercialized that have had an irradiation-induced mutation step in their pedigrees.[18] Only in extremely rare instances were increases in a potentially harmful constituent found in varieties developed through either irradiation or chemical mutagenesis.[19] Even in the few cases where such constituents were found at unexpectedly high levels in these conventionally bred cultivars, they were substances already known to be present in those species (*e.g.* solanine in potato or psoralens in celery) rather than entirely novel compounds.[20] Accordingly, they would be detected using standard phenotypic screens. For over a century of conventional plant breeding, developers have safely monitored and controlled variations in trait expression within a plant population during the course of these phenotypic screens – the multi-generational process of selection for desired traits.

It is in the context of these genetically significant, yet phenotypically invisible variations that genetic engineering should be considered. For NEPA purposes, the mere application of genetic engineering or the mere presence or absence of a particular gene should not, in and of itself, be relevant to the Agency's NEPA assessment of a PPA decision regarding an individual plant or other organism. The Agency can and should be able to draw certain conclusions regarding the safety of the breeding technique of genetic engineering based on the broad scientific consensus regarding the relative safety of this breeding technique compared to conventional breeding, which has an excellent safety record. While specific phenotypical effects can and should be analyzed on a case-by-case basis, this EIS is also the appropriate document in which to draw the line under a number of questions that some have raised regarding the technology as a whole.

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*Seed Germination in* Festuca arundinacea, 94 Theor. Appl. Genet. 309 (1997); Shirasu, K., Schulman, A.H., Lahaye, T. & Shulze-Lefert, P., *A Contiguous 66-kb Barley DNA Sequence Provides Evidence for Reversible Genome Expansion*, 10 Genome Res. 908 (2000)).

[16] *Id.* at 441.

[17] *Id.*

[18] *Id.* (citing van Harten, A.M., Mutation Breeding. Theory and Practical Applications (Cambridge University Press 1998).

[19] *Id.* (citing Haslberger, A.G., *Codex Guidelines for GM Foods Include the Analysis of Unintended Effects,* 21 Nat. Biotechnol. 739 (2003); Kuiper, H.A., Kleter, G.A., Noteborn, H.P.J.M. & Kok, E.J., *Assessment of the Food Safety Issues Related to Genetically Modified Foods,* 27 Plant J. 503 (2001)).

[20] *Id.*

Among the most important of these issues is the environmental irrelevance of the movement of a specific gene from one plant to another *absent any phenotypic change.*

The Agency should also acknowledge that its PPA review includes an assessment of the stability of the introduced trait. Such analysis provides the scientific basis that allows the Agency to conclude that, based on the multi-generational stability of the introduced genetic material and the subsequent confirmation of the stability of the introduced trait, the PPA assessment conducted on one (or several) generations is applicable to all derived progeny. The process of breeding and selection of commercial varieties derived from the initial genetically engineered lines confirms the overall agronomic properties of the derived progeny, including an assessment that the introduced trait is in fact performing as expected. Thus, the breeding and selection process itself serves as an additional mechanism to ensure that the assessment made by APHIS on a particular introduced trait is relevant to the subsequent progeny.

There are other reasonable conclusions that the Agency should reach related to the application of genetic engineering in and of itself including that: (a) gene flow from transgenic to non-transgenic plants is no more likely than between other plants simply because the plant is transgenic;[21] (b) transgenic plants are no more likely as a group to persist in the environment than conventionally bred plants;[22] (c) no evidence suggests that horizontal gene transfer poses any significant potential risk for the transfer of traits from genetically engineered plants simply because the plant is produced through biotechnology.[23]

Marketing Standards Address Economic, Not Environmental Issues

The draft EIS does not include an extensive discussion of an alternative under which no cross-pollination would be allowed. Some members of the public advocated for this approach in the comments to the APHIS scoping document, and some commenters to the draft EIS have expressed concern about the absence of such an approach.

Under some situations, limited in terms of time, geography and acreage, the absence of movement of genetic material may potentially be assured. As a practical matter, when operating in a farmer's field or any other biological system, it is not realistic to discuss such an option and no legal or scientific basis supports such a "zero tolerance" standard.[24] This is true regardless of

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[21] *See, e.g.,* discussion in APHIS DEIS for proposed amendments to Part 340 at 73-74 (http://www.regulations.gov/search/Regs/home.html#documentDetail?R=090000648026695b).

[22] *See, e.g., id.* at 76-79.

[23] *See, e.g., id.* at 83-86

[24] Indeed, acting under the auspices of the Office of Science and Technology Policy (OSTP), APHIS, FDA and EPA have each adopted a policy that recognizes the likelihood that commercial products may contain the low-level presence of genetic material from products that have not yet completed the regulatory review process. 67 Fed. Reg. 50578 (Aug. 2, 2002) (OSTP); 72 Fed. Reg. 14649 (Mar. 29, 2007) (APHIS); 71 Fed. Reg. 35688 (June 21, 2006) (FDA); 72 Fed. Reg. 25303 (May 4, 2007) (EPA). *See also* Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, Annex 3: Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food, CAC/GL 45-2003, Codex Alimentarius Commission, http://www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf. (Codex was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work

whether the plants being grown are conventional, organic or GE. Instead, calls for a "zero tolerance" appear to be based on a lack of trust in government safety assessments, disapproval of private rights to the intellectual property associated with new seed traits, or simple unhappiness over a newly-recognized but age-old lack of control over the genetic content of food. While a discussion of marketing standards and consumer preferences may have its place in an EIS under certain circumstances, the inclusion of a fully developed alternative to address these issues would appear to be inconsistent with the policy objectives of APHIS' Part 340 program and the proposed determination of non-regulated status for an herbicide-tolerant crop that triggers this NEPA review.

The Federal Seed Act and state laws govern seed purity standards in this country. All recognize the realities of growing crops in a biological system and none are based on a "zero tolerance" standard. Long-standing seed certification programs administered at the state level address the production of certified seed throughout the U.S.[25] Private seed certification programs and individual grower choice may impose more stringent seed purity standards, but the decision to market seed, food or other agricultural products according to a more stringent standard is a purely economic choice. While certain seed producers may choose to implement a more stringent standard with regard to the presence of an herbicide-tolerant crop, this is a private economic, market-based choice, not one required by statute. Those growers who believe it will be in their economic interests to maintain a more stringent standard will take the necessary steps to meet the demands of their alternate markets. This is purely an economic and market-based decision, not an environmental impact. Once a GE plant such as GT alfalfa has satisfactorily completed the federal review process, there is no health, safety or environmental basis for restricting the movement of genetic material from those GE plants.

One marketing standard followed by a small but growing minority of farmers was codified in the Organic Food Production Act of 1990 (OFPA). Although the OFPA itself is silent regarding the use of genetic engineering in crop production, the regulations implementing the OFPA, known as the National Organic Program (NOP) prohibit the use of genetic engineering in organic production.[26] This would prohibit a grower from, for example, planting a GE crop that has been engineered to produce its own pesticide, and selling it as organic because the grower does not have to use chemical pesticides on it. In implementing the NOP, however, USDA has *specifically recognized* that some level of genetic material from GE plants may be present in organic crops *without affecting the organic nature of the crop or the farm*:

> This regulation prohibits the use of excluded methods [genetic engineering] in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the

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undertaken by international governmental and non-governmental organizations. http://www.codexalimentarius.net/web/index_en.jsp).

[25] *See generally* Association of Official Seed Certifying Agencies, http://www.aosca.org/.

[26] 7 C.F.R. §§ 205.105(e); 205.2.

> products of excluded methods should not affect the status of an organic product or operation.[27]

In short, the NOP provides no guarantee of "zero tolerance" for the presence of genetic material from GE plants.

Although not directly at issue here, it should also be noted that GT alfalfa and all other herbicide-tolerant plants deregulated by APHIS have successfully cleared food and feed safety review with the FDA. FDA recognizes the uniformity and ubiquity of genetic material (nucleic acids) and the fact that genetic material does not raise a safety concern as a component of food.[28] Under FDA policy, the safety of GE crops is established through a showing that the GE crop is as safe for food and animal feed as conventionally bred crops. This showing was made for the GE alfalfa at issue here. FDA policy also does not require labeling of any food derived from GE plants or other new plant varieties unless material differences exist regarding nutrition, allergenicity, or basic use of the food or feed. From a food safety standpoint, GT alfalfa is indistinguishable from conventional alfalfa.

Food products produced from GE crops are universally consumed today and have been on the market for over a decade, with no instances of harm to human health or the environment in any crop that has completed the deregulation process. The environmental impact of any gene flow from those crops to any others has been negligible. It is unlikely that many people in the United States today can accurately claim that their diets are completely free from food produced from GE crops.

There do exist consumers who desire food with an absolute absence of genetic material from GE crops, despite the fact that this material can neither be seen, smelled, touched, nor tasted, and despite the fact that it has been found to be safe for humans and the environment by hundreds of scientists and dozens of regulatory authorities around the world. "Zero tolerance" food and consumer markets have been established for these consumers, based on this preference. These markets may suffer if consumers had a better understanding that "zero tolerance" cannot be guaranteed.

This market impact is not so closely related to the physical impacts caused by deregulation that it should be the subject of NEPA review. The physical impacts of the use of an herbicide-tolerant crop relate to the fact that a particular herbicide can now be safely sprayed on it; other pesticides will be used less often on the crop and the herbicide to which the crop is tolerant will be used more. The fact that the crop contains genetic material that makes the use of an alternate herbicide possible is irrelevant to the physical environment in all other respects. There are no phenotypical or safety differences between the GE products on the market today and their conventional counterparts. For this reason, the vast majority of markets in the United States and an expanding number of overseas markets are indifferent to the presence of genetic material from deregulated GE plants that may be present in crops or food at any level. The mere presence of this genetic material does not have a direct social or economic impact.

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[27] 65 Fed. Reg. 80548, 80556 (Dec. 21, 2000) (finalizing NOP).

[28] FDA, Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, 22990 (May 29, 1992) (declaring genetic material to be safe).

This is not to deny that social or economic impacts exist. However, these impacts are grounded in personal presumptions and preferences about these products and, in some cases, the companies that produce them, that are unrelated to the physical presence of specific genetic material. These impacts are so attenuated from the direct physical impact of the genetic transfer as to be beyond the scope of NEPA analysis. The simple dislike of the products of genetic engineering as a personal preference does not give rise to a potential environmental impact that is appropriate for NEPA review. The preference that some have for crops produced without GE technology may arise from perceived unrealized risks to human health or the environment. Such risks are, by definition, wholly speculative and unrealized in the physical world. The fact that a market exists to cater to a fear of those risks or to matters of personal choice, and some perceive this action to threaten that market, do not bring those risks or personal preferences within the realm of the physical environment NEPA was intended to address.[29]

A "zero tolerance" guarantee is neither logical, reasonable nor consistent with the purpose and scope of this decision-making. As stated in the draft EIS, the mission of the decision maker here, APHIS, "is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of genetically engineered organisms."[30] It is impossible to use GE crops in any meaningful way in commodity agriculture while guaranteeing the "zero tolerance" called for by some. The enormous costs and dislocations that would be involved in segregating fields, equipment, transportation, storage and packaging in an attempt, potentially futile, to guarantee a "zero tolerance" standard are unwarranted in light of the absence of meaningful differences between these and other commodity crops, including in terms of potential health, safety or environmental impacts. Satisfaction of the preference of a minority of consumers and the producers who service them cannot justify the costs that "zero tolerance" would impose on the vast majority of producers and consumers who are satisfied with safe, wholesome, affordable food. Accordingly, while the DEIS discussed gene flow and relevant mitigation measures in detail, it is appropriate that APHIS did not include a fully developed "zero tolerance" alternative. Even if such an alternative were to be included, it would not merit adoption for the reasons discussed above.

**Regulation of Pesticides**

Congress saw the need for a separate statute regulating herbicides and other pesticides when it passed the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in 1947. Through subsequent major revisions to FIFRA in 1972, 1975, 1978 and 1988, and the passage of the Food Quality Protection Act in 1996, Congress has provided for an increasingly comprehensive pesticide regulatory system that is protective of health, safety and the environment.

EPA is the federal agency charged with the responsibility for regulating pesticides. Under FIFRA, every herbicide and other pesticide sold or distributed in the United States must be granted a registration. The regulations and policies that implement FIFRA are revised and updated as necessary to address new needs and the latest science and technologies. EPA's responsibilities include ensuring the correct use instructions are available to growers through the

[29] 40 C.F.R. § 1500.2(b) (directing federal agencies "to emphasize real environmental issues and alternatives" in implementing NEPA).
[30] DEIS at 2.

evaluation of supporting health, safety and environmental data and approval of the herbicide label. A pesticide product can only be used legally according to the directions for use on the label.

Herbicide Safety

Nearly 900 scientists and program officials in EPA's Office of Pesticide Programs ensure that products are properly registered and comply with federal law. These experts are responsible for ensuring that pesticides cause no unreasonable adverse effects on the environment and human health. EPA's initial registration and subsequent reregistration and registration review processes include the evaluation of potential health effects on humans and environmental effects on wildlife and other non-target organisms - birds, amphibians, mammals, beneficial insects, including bees, and plants. These processes include scientific, legal, and administrative elements through which EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, method and timing of application, and other conditions of its use; and storage and disposal practices.

Under FIFRA's strict provisions, the process of bringing pesticides to market by securing an EPA registration is complex and demanding, based on strong scientific principles and undertaken according to stringent government review and regulation. EPA requires over 100 separate scientific safety tests to ensure that a product, when used properly, does not present an unreasonable risk to health or the environment, as required by law.[31] On average, only one in 139,000 chemicals makes it from the chemist's laboratory to the farmer's field; pesticide development, testing and EPA approval takes 8 to 10 years and costs manufacturers between $152-184 million for each product.[32]

The data required by EPA are used to evaluate whether a pesticide has the potential to cause adverse effects on humans, wildlife, fish, and plants (including endangered species and other "non-target" organisms – organisms that the pesticide is not intended to act against). The registration applicant must also supply data addressing the pesticide's potential impact on surface water or ground water (which might result from leaching or runoff, for example). Potential human health and safety risks range from short-term toxicity to long-term effects such as cancer and reproductive system disorders.

A pesticide's registration is not the only opportunity EPA has to evaluate that product's safety. For example, EPA recently completed a program to review older pesticides (those initially registered before November 1984) ensure that they meet current scientific and regulatory standards. This process, called reregistration, considers the human health and ecological effects of pesticides and results in any actions necessary to reduce risks that are of concern. Glyphosate and many other herbicides satisfactorily completed the EPA's reregistration process. EPA concluded its reregistration evaluation of glyphosate in 1993. At that time, the Agency produced a 291-page Reregistration Eligibility Decision document (RED) on glyphosate, setting forth the data on which it made a decision to reregister all then-existing uses of the pesticide, based on the pesticide having met the no unreasonable adverse effects standard found in FIFRA.

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[31] http://www.epa.gov/pesticides/regulating/index.htm#eval.
[32] http://www.pestfacts.org/use/responsible_use.htm.

Where pesticides may be used on food or feed crops, EPA also sets tolerances (maximum pesticide residue levels) for the amount of the pesticide that can legally remain in or on foods. EPA undertakes this analysis under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). Under the FFDCA, EPA must find that such tolerances will be safe, meaning that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. This finding must be made and the appropriate tolerance established before a pesticide can be registered for use on the particular food or feed crop in question. Several factors must be addressed each time that a tolerance is established or modified, including a tolerance to allow the use of an herbicide over-the-top of an herbicide-tolerant crop. Those factors include:

- the aggregate, non-occupational exposure from the pesticide (exposure through diet, from using pesticides in and around the home, and from drinking water);
- the cumulative effects from exposure to different pesticides that produce similar effects in the human body;
- whether there is increased susceptibility to infants and children, or other sensitive subpopulations, from exposure to the pesticide; and
- whether the pesticide produces an effect in humans similar to an effect produced by a naturally-occurring estrogen or produces other endocrine-disruption effects. [33]

EPA's registration, reregistration and tolerance decisions for glyphosate and other pesticides provide a formal and authoritative record of federal agency action that should be adopted by APHIS and incorporated by reference as a matter of course in NEPA assessments prepared for any actions proposed under Part 340 that involve a pesticide.[34]

Weed Resistance

Herbicides kill weeds by disrupting normal plant functions. Pesticides may be classified by their "mode of action," that is, the initial enzyme, protein or biochemical step affected by the herbicide's application. Herbicide resistance occurs when the herbicide's mode of action is no longer effective at killing a target weed. Through evolutionary selection, plants susceptible to the herbicide die, while those few having some type of natural resistance survive and reproduce without competition from the susceptible plants. Through repetition of this process across generations of plants, resistance of a significant portion of a weed population can survive and spread. Herbicide-resistant weeds are not a new phenomenon. Farmers and others in this country have been confronted with the challenge of herbicide resistance in hundreds of weed species for decades. As a result, the agricultural community has developed and implemented a variety of well-known and tested measures to address the potential development of herbicide resistance in weeds.

[33] Based on determinations of safety made under the FFDCA, EPA has granted food and feed safety tolerances allowing for the post-emergence use of glyphosate and other herbicides on every commercialized herbicide-tolerant crop. *See generally* 40 C.F.R. pt. 180.
[34] *See* 40 C.F.R. § 1502.21.

EPA has addressed the issue of pesticide resistance in a guidance document to pesticide registrants. That guidance document, Pesticide Registration (PR) Notice 2001-5: "Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling," provides labeling guidelines by which a pesticide registrant can alert users to steps they can take to delay pesticide resistance, including the development of the herbicide resistance trait in weeds.[35] The EPA's PR Notice includes recommended pesticide label statements to remind growers of various herbicide resistance management practices, including recommendations for the use of tank mixes of herbicides with different modes of action and weed monitoring.[36]

Despite claims by some commenters that pesticide resistance amounts to the creation of "superweeds," the occurrence of pesticide resistance is a simple fact of biological evolution that is well-understood by the farming community, addressed by EPA, and managed by well-established agricultural practices. It is not caused by, nor is it unique to, GE cropping systems.

BIO appreciates the opportunity to provide these comments in response to the Agency's Notice.

Sincerely,

Sharon Bomer Lauritsen
Executive Vice President
Food and Agriculture

[35] http://www.epa.gov/PR_Notices/pr2001-5.pdf.
[36] *Id.* at 6.