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INDUSTRY ORGANIZATION

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Improving Regulations Docket
Environmental Protection Agency
EPA Docket Center, Mailcode: 2822T
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Washington, D.C. 20460-0001

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RE: Docket ID No. EPA-HQ-OA-2011-0157 (Improving Regulations: Pesticides) and EPA-HQ-OA-2011-0156 (Improving Regulations: General), 76 Fed.Reg. 9988 (February 23, 2011);

To whom it may concern:

The Biotechnology Industry Organization (BIO) is pleased to submit these comments in response to the U.S. Environmental Protection Agency's (EPA) request for public input on the Agency's regulatory review, which will be carried out in response to President Obama's January 18, 2011, Executive Order (EO) 13563, "Improving Regulation and Regulatory Review."

BIO is a not-for-profit trade association that represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States (U.S.) and in 30 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

The process of natural selection has provided many plants with endogenous substances that protect the plant from pests, such as insects and viruses. Plant breeders have long used a wide variety of methods, including genetic crosses with wild relatives, mutagenesis and selection, to provide crops with pest protection. Thirty years ago, breeders incorporated the tools of modern biotechnology to insert genes into crops which will lead to the production of substances that confer pest resistance. These substances, referred to as "plant-incorporated protectants" or "PIPs," are typically naturally occurring proteins that are harmful only to a narrow range of crop pests. PIPs are biodegradable, do not accumulate in the soil[1], and serve EPA's goal of reducing chemical usage while providing effective means of targeted pest control.

Under the 1986 Coordinated Framework for Regulation of Biotechnology (Coordinated Framework), three U.S. federal agencies review and authorize commercial biotechnology-derived products: EPA, the U.S. Department of Agriculture (USDA), and the U.S. Food and Drug Administration (FDA). Through the Coordinated Framework, biotechnology-derived plants have produced multiple benefits, including decreased production costs, increased crop yields due to reduced insect damage, and improved food safety.

In the case of PIPs, EPA regulates the pesticidal substance in biotechnology-derived plants.[2] As with conventional chemical pesticides, EPA regulates PIPs under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As with conventional pesticide residues, under Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA also regulates PIP residues in food or feed crops.

[1] Mendelsohn, M., J. Kough, Z. Vaituzis and K. Matthews. 2003. *Nature Biotechnology* 21:1003-109.
[2] *See* Office of Science and Technology Policy. Coordinated Framework for Regulation of Biotechnology. 51 *Fed. Reg*. 23302, 23304 (June 26, 1986).

Together these statutes address any potential adverse effects on health, safety or the environment that might be presented by any pesticidal substance.

The safety of biotechnology-derived plants, including those that express PIPs, is regulated by the U.S. Department of Agriculture (USDA) under the Plant Protection Act.[3] USDA administers a permit program that requires review of the potential agricultural effects of biotechnology-derived seed, plants and other regulated articles from the earliest field test or other movement.[4] The potential environmental impacts of USDA's decisions and determinations of non-regulated status are also subject to the National Environmental Policy Act (NEPA).[5] Similarly, for food and feed crops, the safety is reviewed by the U.S. Food and Drug Administration (FDA), where it is subject to regulation under Sections 301, 402, 403, and 409 of the FFDCA.[6] These divisions of responsibilities are clearly established in the Coordinated Framework.[7]

Issue: Integration and Innovation

The division of regulatory responsibility established by the Coordinated Framework has functioned well for 25 years. Millions of plants expressing pesticidal substances have been safely field tested under EPA and USDA permits since 1986, and to date 39 PIP products[8] have been cleared for commercial use following review by EPA, FDA and USDA. During that time not a single instance of actual harm to health, safety or the environment has ever been confirmed for any biotechnology-derived crop that has satisfactorily completed the U.S. regulatory process.

Therefore, in keeping with EO 13563 and the March 11, 2011, White House memo, *Principles for Regulation and Oversight of Emerging Technologies,* to date, the three agencies responsible for regulating the various aspects of PIPs - EPA; FDA; and USDA- have exhibited "coordination across agencies"… "in an effort to craft a coherent approach"… with "clear recognition of the statutory limitations of each Federal agency."

One way in which PIPs have decreased production costs is by lowering input costs due to less insecticide use. From 1997 – 2008, the number of pounds of active ingredient per planted acre decreased from .275 to .05 for corn and from 2 pounds to .6 pounds for cotton.[9] There is a strong correlation between the decrease in pesticide use and rising percentage of corn and cotton PIP acres. The use of PIPs has also increased yields. For example, use of cotton and corn PIPs increased yields a total of 7.7 billion pounds for both crops in 2006. When combined with the decrease of 9.6 million pounds of active ingredient applied to corn and cotton acres, the net benefit to U.S. corn and cotton growers was $685.6 million in 2006, alone.[10] Interestingly, a recent study showed that the greatest beneficiaries of corn PIPs are growers who opt to grow conventional corn varieties.[11] The researchers estimate that farmers in five Midwestern states received cumulative economic benefits of nearly $7 billion between 1996-2009 from growing corn PIPs, with benefits of more than $4 billion accruing to conventional corn growers. The scientists found

[3] 7 U.S.C. §§ 7701 et seq.
[4] *See* 7 C.F.R. pt. 340.
[5] 42 U.S.C. §§ 4321 et seq.
[6] 21 U.S.C. §§ 331, 342, 343, and 348.
[7] *See* Office of Science and Technology Policy. Coordinated Framework for Regulation of Biotechnology. 51 *Fed. Reg*. 23302, 23304 (June 26, 1986).
[8] http://www.epa.gov/oppbppd1/biopesticides/pips/pip_list.htm
[9] National Research Council. 2010. *Impact of Genetically Engineered Crops on Farm Sustainability in the United States.*
[10] National Council for Food and Agricultural Policy.2008. *Quantification of the Impacts on US Agriculture of Biotechnology-Derived Crops Planted in 2006.*
[11] Hutchinson, et.al., 2010. *Areawide Suppression of European Corn Borer with Bt Maize Reaps Savings to Non-Bt Maize Growers.* Science 330:222-226

that, in conventional corn fields adjacent to PIP corn fields, populations of the European borer, one of the targeted pests of corn PIPs, declined by 28 to 73 percent.

Additionally, because of the improved pest control provided by PIPs, these crops are infected less often by fungal pathogens. This, in turn leads to lower levels of mycotoxins, such as aflatoxin and fumonisin, that can be harmful to both animals and humans.[12] Additionally, limiting chemical applications mitigates environmental and human health exposure and potential risks.

To ensure that the environmental and food safety benefits of biotechnology–derived PIPs continue to accrue, it is essential that the three agencies continue to respect the division of regulatory responsibilities established by the Coordinated Framework.

BIO has long maintained that plants engineered to express pesticidal substances are "treated articles" for purposes of FIFRA. Moreover, regardless of the status of PIP-related plants as treated articles, PIPs themselves are of a character that does not require regulation under certain of the recordkeeping and reporting provisions that apply to conventional chemical pesticides in order to carry out the purposes of FIFRA.

In EPA's 2007 Advanced Notice of Proposed Rulemaking,[13] the Agency implied that it may subject PIPs to the establishment registration and facility-based production reporting requirements that were developed to address specific concerns associated with chemical pesticide production in brick-and-mortar facilities rather than plants growing in farmers' fields. In other words, EPA may begin to regulate plants like chemical pesticides, subject to all FIFRA requirements, irrespective of the potential risk of the PIP or the applicability of the regulations to plants. Not only will this reverse EPAs longstanding position that the Agency will not regulate plants, this shift would create a duplicative regulatory system for low risk products having substantial environmental benefits. A decision by EPA to regulate PIP-containing seeds and plants as pesticides would discourage innovation and could cause significant disruption in U.S. agriculture by restricting or limiting (or threatening to restrict or limit) the distribution, packaging or repackaging, and labeling or relabeling of seeds and plants that contain PIPs.

In addition, BIO opposes EPA regulating all biotechnology-derived crops, not just PIPs, using FIFRA's plant growth regulator authorities. Any attempt to regulate these products will not only be "redundant, inconsistent and overlapping," it will also run counter to other principles outlined in Executive Order 13563 and the March 11, 2011 memo on regulation of emerging technologies. For example, broadening of EPA's oversight of biotechnology-derived crops would "unjustifiably inhibit innovation and stigmatize new technologies."

Issue: Regulatory Predictability

Section 1. *General Principles of Regulation* of EO 13563 lists promoting predictability and reducing uncertainty as key elements of a functional regulatory system. In the past few years, the predictability of EPA's regulation of PIPs has decreased significantly. Uncertainty in both the timeline for decision-making, as well as data requirements for PIPs has increased.

The Pesticide Registration Improvement Act (PRIA), enacted in 2004 and reauthorized in 2007, requires applicants to pay service fees to EPA for processing their applications. The intent of the law is to provide additional resources for EPA's registration activities so that applicants can be assured registration

[12] Munkvold, G.P., R.L. Hellmich, and W.B. Showers. 1997. Phytopathology 87: 1071-1077; Munkvold, G.P., R.L. Hellmich, and L.G. Rice. 1999. Plant Disease. 83:130-138.
[13] 72 Fed.Reg 16312 (Apr. 4, 2007)

decisions are made in the mandated time frames established by PRIA. As PRIA fees have increased for PIPs, EPA's adherence to the mandated time frames has lessened. This uncoupling of increased resources from certainty of the timing of decision-making has been most noticeable for PIPs. According to data provided by EPA's Office of Pesticide Programs at a December 17, 2011, meeting of the PRIA Renegotiation Analysis Teams, for FY 2009 and the first two quarters of 2010, the percent of renegotiated timelines for all new products was 23 percent; for PIPs, the percentage of renegotiated timelines for new products was 100 percent. For those new PIP products, the timeline for decision-making increased by 50 percent.

A 50 percent increase in the predicted timeline for product approval is disruptive for any business and significantly increases uncertainty. Moreover, it is essential that EPA understand that extending timelines is especially detrimental to seed companies. A 30-day delay in a decision for product approval can easily become a one-year delay for a seed company, depending on the time of year the delay occurs. Unlike chemical manufacturing, seed production is restricted to certain times of the year, and growers across the country select the seed varieties they will plant during a 2-3 month timeframe. If a seed company's business plan is predicated on a decision being made by a certain time and that window of opportunity passes them by, they will not have another opportunity to sell their product for a year.

Issues: Benefits and Costs/Science and Obsolete Regulations

The National Academy of Sciences recommended that EPA's regulation of PIPs be flexible and open to change so that the Agency could readily adapt to new information and improved understanding of the science that underlies PIP regulatory decisions.[14] The EO 13563 and White House memo, *Principles for Regulation and Oversight of Emerging Technologies,* stress flexibility and adaptability as essential components of any regulatory system. Flexibility and adaptability are of particular importance for regulatory systems governing emerging technologies, which can have a profound effect on innovation and job creation.

The pesticidal substances expressed in the PIPs developed to date are protein molecules derived from various strains of the naturally-occurring soil bacterium, *Bacillus thuringiensis*, or Bt. Organic and conventional farmers have used Bt sprays for nearly 50 years. As stated above, no documented harm to human health or the environment has been confirmed for any of the Bt crop varieties. In a 2003 article published in *Nature Biotechnology*,[15] EPA staff reassessed detailed information on the many potential risks that they evaluate in their assessments of PIPs. From this comprehensive reassessment they determined that Bt crops "do not pose unreasonable risks to human health or the environment." Years of experience growing Bt crops have confirmed the Agency's determination of safety.

Studies have shown that the regulatory compliance costs[16] for Bt corn varieties in 2005 ranged from $7 – 15.4 million.[17] Some studies estimate significantly higher costs for regulatory compliance.[18] The high cost of the regulatory approval process is a barrier to the development and commercialization of any Bt crop variety, but is prohibitive for the small acreage, minor use crops typically developed at public

[14] National Research Council. 2000. Genetically Modified Pest-Protected Plants: Science and Regulation at 153. National Academy Press, Washington, DC.
[15] Mendelsohn, Mike, John Kough, Keith Matthews Nature Biotechnology 21: 1003 – 1009. September 2003.
[16] The figures cited are limited to the direct costs of regulatory compliance, which is only a portion of the regulatory burden imposed on these crops. For example, the indirect costs from 1) unexpected regulatory delay, such as expenses for seed inventories that are carried over and opportunity costs of foregone profits, and 2) segregation costs while awaiting approvals in certain markets are not included.
[17] Kalaitzandonakes, N., J.M. Alston and K.J. Bradford, 2007. Nature Biotechnology. 25:509-511.
[18] Just, R., Alston, J.M., D. Zilberman (eds.) *Regulating Agricultural Biotechnology: Economics and Policy*. 2006. Springer. New York; Belsie, L. August, 2001. *Christian Science Monitor.*

institutions for the benefit of small farmers.[19] A number of studies attribute the paucity of biotechnology-derived specialty crops (e.g., fruits and vegetables), to the high costs of regulatory compliance.[20]

Given the high regulatory costs, low risks and proven environmental benefits of these crops, perhaps it is time to reconsider the risk:benefit ratio of EPA's regulation of plant-incorporated Bt pesticides.

EPA's mission is protection of human health and the environment. Scientific studies of Bt crops, including those conducted by EPA, and years of real world experience growing Bt crops on millions of acres have shown that these products provide EPA with new, safe tools for meeting its mission.

We appreciate the opportunity to provide comments on EPA's regulatory review process and look forward to working with EPA in the months ahead.

Sincerely,

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Managing Director, Science and Regulatory Affairs

[19] McElroy, D. 2004. Nature Biotechnology. 2004. 22:817-822; Pew Initiative on Food and Biotechnology. June, 2004. Conference Proceedings: *Impacts of Biotech Regulation on Small Business and University Research: Possible Barriers and Potential Solutions.* www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg?Summaries_-_reports_pubs/proceedings.pdf

[20] Miller, J.M. and K,J, Bradford. 2010. Nature Biotechnology. 28:1012-1014; Graff, G.D., D. Zilberman and A.B. Bennett. 2009. Nature Biotechnology. 27:702-704; Bradford, K., A. Van Deynze, N.Gutterson, W.Parrott and S.Strauss. 2005. Nature Biotechnology. 23:439-444.