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Office of Pesticide Programs (OPP)
Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0001

RE: Comments of the Biotechnology Industry Organization Plant-Incorporated Protectants Potential Revisions to Current Production Regulations; U.S. Environmental Protection Agency Advance Notice of Proposed Rulemaking 72 Fed. Reg. 16312 (Apr. 4, 2007) Docket ID No. EPA-HQ-OPP-2006-1003

To whom it may concern:

The Biotechnology Industry Organization (BIO) is pleased to submit these comments in response to the Advance Notice of Proposed Rulemaking (ANPRM) for Plant-Incorporated Protectants (PIPs); Potential Revisions to Current Production Regulations, published by the U.S. Environmental Protection Agency (EPA or Agency) on April 4, 2007. 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 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

Nature and traditional plant breeders have given us many varieties of plants that are able to protect themselves from insects, viruses and other enemies. Over the past twenty-five years, using the techniques of modern biotechnology, scientists have been able to modify or "genetically engineer" commodity crops such as corn, cotton, soybeans and canola to express a pesticidal substance in the plant itself in order to protect the plant from harmful insect pests. The pesticidal substance, referred to as a "plant-incorporated protectant" or "PIP," is typically a protein which originates in nature and is harmful only to a narrow range of target pests. With the active support of BIO and its food and agriculture member companies, these innovative new products are regulated by three separate federal agencies to ensure that they are as safe to grow and as safe to eat as conventional crops. Plants with pest resistance traits are also being developed for non-food uses.

As with conventional chemical pesticides, EPA regulates PIPs under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In addition, EPA regulates PIPs expressed in food or feed crops, like conventional chemical pesticides used on food or feed crops, under Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

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

Moreover, with respect to PIPs specifically, the potential environmental and agricultural effects of the plant itself are regulated by the U.S. Department of Agriculture (USDA) under the Plant Protection Act and, for food and feed crops, the safety of the whole food produced by the plant 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.

Plants expressing pesticidal substances have been safely tested in the field under EPA and USDA permits since 1986, and have been cleared for commercial use following review by EPA, USDA and FDA since 1995. Although subjected to intensive governmental, academic and commercial monitoring and oversight, 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.

As EPA has repeatedly acknowledged, PIPs possess certain characteristics that distinguish them from traditional chemical pesticides and, as a result, EPA has developed certain regulatory requirements, criteria and procedures that are unique to PIPs. One area in which PIPs differ markedly from traditional chemical pesticides relates to the manner in which they are produced. In contrast to the production of chemical pesticides in "bricks and mortar" facilities, PIPs are produced in a unique, one-time event that takes place in a laboratory. Afterwards, seeds and other propagative materials in which the new genetic material has been successfully incorporated are produced by seed companies and others and planted by growers in the identical manner as they have always been. The PIPs are then expressed at various points in the lifecycle of the plant and in various plant parts. The concentration of the PIP varies by plant, plant tissue and plant growth stage.[1]

As a result, industry has long maintained that plants engineered to express pesticidal substances are "treated articles" for purposes of FIFRA – items such as lumber, paints, shower curtains, kitchen cutting boards, and conventional corn seed that are treated with a pesticidal substance in order to protect the article itself from harmful insects, mold or bacteria. 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.

To be clear, BIO's members have always provided EPA with all required information pertaining to PIPs, at both the experimental field test stage and following approval and commercialization. Moreover, these companies intend to continue to provide such information as long as EPA deems it necessary. What we ask is for the relevant information to be provided in a manner and format that is most appropriate for PIPs and that takes into account the differences between PIPs and conventional chemical

[1] BIO's comments cover all substances that meet the definition of a PIP and are regulated by EPA under FIFRA, including plant virus coat protein PIPs.

pesticides. Our goal is to avoid the rather serious, negative impacts that could result to researchers, growers, registrants and the regulatory process were the Agency to attempt to

fit a square peg in a round hole by applying FIFRA's recordkeeping and reporting requirements to PIPs in the same manner that they are applied to traditional chemical products. Such an approach would be tantamount to regulating plants as pesticides, a policy that has been disavowed by the U.S. government for the past 20 years.

For all of these reasons, BIO supports amendments to the existing EPA regulations to clarify the recordkeeping and reporting requirements that apply to PIPs. In particular, the rule should clearly identify requirements for recordkeeping based upon authorities under Section 3 (for registrants), Section 5 (for holders of experimental use permits), and any other appropriate sections of FIFRA such as Section 8. In addition, each PIP registrant and each PIP permit holder should be allowed to maintain the records required by EPA at a location or locations to be designated by the registrant or permit holder for that PIP, where the records would be available for inspection by EPA. The need for flexibility in the designations made by regulated parties of locations for purposes of inspection under Sections 5 and 8 is due in no small part to the tremendous variability in the commercial relationships and size and scale of operations of individual PIP researchers and registrants. Furthermore, EPA's rule needs to distinguish between records to be maintained (and accessible to EPA on request) and information to be routinely submitted to EPA, which should only be required where a need has been clearly established. Those requirements that are consistent for all PIPs should be included in the rule. Requirements that apply to individual PIPs or categories of PIPs should be imposed through the terms and conditions of individual registrations and permits.

As we discuss in more detail in the comments that follow, there are a number of legal and policy reasons why it is inappropriate to subject PIPs or PIP-related plants to the establishment registration and facility-based production reporting requirements that apply to conventional chemical pesticides. However, apart from these legal arguments, as a practical matter for PIPs, establishment registration and annual production reports are particularly ineffective tools for promoting compliance and managing potential risks. Instead, a much more valuable tool for EPA is recordkeeping designed specifically for PIPs and full EPA access to those records. For this reason, we are proposing that EPA amend its regulations to implement a streamlined set of reporting requirements which are better suited for PIPs than the conventional chemical requirements, coupled with a robust set of recordkeeping requirements that allow EPA to track the production and movement of PIP-related products. This combination of requirements will provide EPA with a more practical and a more effective regulatory mechanism for promoting compliance, enforcing the terms and conditions of PIP registrations and managing any potential risks that may be identified with PIPs.

RESPONSE TO REQUEST FOR COMMENTS[2]

1. Current Regulations Under Review

a. Registration of establishments (FIFRA Section 7 and 40 CFR 167.20)

Question: Given that PIPs by definition are intended to be produced and used in a living plant, what activities should the Agency consider to be part of PIP "production" as that term is defined in FIFRA (which includes manufacturing, preparing, compounding, propagating, or processing any pesticide or packaging, repackaging, labeling, and relabeling the container) and what establishments should be registered to help EPA manage any potential risks associated with PIPs? What other types of facilities, if any (e.g., growers involved in seed production), involved in the development of PIP-containing varieties should be subject to these requirements? Please explain the reason for your response.

Response: For a number of reasons, it is inappropriate and unnecessary to require establishment registration and production reporting for PIPs or plants that express PIPs. First, EPA has consistently taken the position that the Agency will not regulate PIP-related plants under FIFRA; indeed, under the government's Coordinated Framework for Regulation of Biotechnology, it is USDA, not EPA, that exercises primary authority over these plants and FDA that is responsible for the safety of the whole food produced by the plants. In addition, the FIFRA establishment registration and production reporting requirements were intended to address specific concerns associated with chemical pesticide production which are inapplicable to PIPs. Because PIPs are so fundamentally different from chemical pesticides, they are of a character that does not require establishment registration and production reporting in order to fulfill the purposes of the statute. Finally, plants capable of expressing registered PIPs qualify as treated articles and thus are exempt from regulation under FIFRA – including establishment registration and production reporting.

We discuss each of these points in more detail below.

i. EPA has consistently acknowledged that the Agency does not regulate plants.

Plants, seeds and other propagative materials capable of expressing a PIP are not regulated as pesticides and are not subject to FIFRA's production reporting and establishment registration requirements. To the extent that EPA ultimately deems it necessary to apply any of these requirements to PIPs, the Agency must carefully distinguish between the pesticidal substance which is regulated by EPA and may be expressed in the plant at any point in time, and the plant itself.[3] The need to make this

[2] Questions posed by EPA are shown in italics.

[3] The Plant Protection Act defines the term "plant" broadly to include seed and other propagative materials: "any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a

distinction was the basis for one of several recommendations made by the National Research Council (NRC) in its review of EPA's proposal for regulating PIPs.[4]

With the support of the biotechnology industry, EPA has actively regulated pesticidal substances expressed in biotechnology-derived plants for over 15 years and proposed regulations to address the unique characteristics of those substances in 1994. The first set of PIP regulations was finalized in 2001 and codified in Part 174 of title 40, Code of Federal Regulations.[5] At no time before, during or after the issuance of the current PIP regulations has the Agency ever expressed an interest in regulating plants engineered to express PIPs as pesticides. Indeed, in the Agency's own words, it has issued "numerous statements that EPA would not regulate the plant per se, but rather substances within the plant when these were used for pesticidal purposes."[6]

While the safety of conventional chemical pesticides and pesticidal substances expressed in biotechnology-derived plants is regulated exclusively by EPA, the safety of biotechnology-derived plants, including those intended to express PIPs, is actively regulated by USDA under the Plant Protection Act.[7] Similarly, for food and feed crops, the safety of the whole food produced by a biotechnology-derived plant is reviewed by FDA, where it is subject to regulation under Sections 301, 402, 403, and 409 of the FFDCA.[8] This division of responsibility is in keeping with the regulatory scheme set forth in 1986 by the federal government for approval of commercial biotechnology products, which designated USDA's Animal and Plant Health Inspection Service as the lead agency for genetically engineered plants and FDA as the lead agency for the safety of genetically engineered foods.[9]

ii. PIPs are of a character that does not require regulation under FIFRA's production reporting and establishment registration requirements in order to fulfill the purposes of the statute.

Under Section 25(b)(2) of FIFRA, EPA can exempt a pesticide from the requirements of the Act if the pesticide is "of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act."[10] The production reporting and

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plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, and a seed." 7 U.S.C. § 7702(13). Use of the term "plant" in these comments is based on this definition.

[4] National Research Council. 2000. Genetically Modified Pest-Protected Plants: Science and Regulation at 4 and 152. National Academy Press, Washington, DC.

[5] 66 *Fed. Reg.* 37772 (July 19, 2001).

[6] 66 *Fed. Reg.* 37781; see, also, 59 *Fed. Reg.* 60496, 60498 (Nov. 23, 1994).

[7] 7 U.S.C. §§ 7701 et seq. USDA administers a permit program that requires review of the potential agricultural and environmental effects of biotechnology-derived seed, plants and other regulated articles. *See* 7 C.F.R. pt. 340.

[8] 21 U.S.C. §§ 331, 342, 343, and 348.

[9] *See* Office of Science and Technology Policy. Coordinated Framework for Regulation of Biotechnology. 51 *Fed. Reg.* 23302, 23304 (June 26, 1986).

[10] 7 U.S.C. § 136w(b)(2).

establishment registration requirements as currently set out in EPA's regulations were intended to apply to facilities that formulate and process conventional chemical pesticides. Farms and other facilities that grow and process PIP-containing plants are fundamentally different from chemical facilities that produce conventional chemical pesticides. Moreover, as discussed below, subjecting PIPs and PIP-containing plants to the establishment registration and production reporting requirements of FIFRA is unnecessary in order to accomplish the purposes of the statute. Accordingly, EPA should exempt PIPs from these requirements under Section 25(b)(2).[11]

In order to evaluate whether or not the purposes of the statute would be furthered by subjecting PIPs to establishment registration and facility-based production reporting requirements, it is appropriate to look first to the statute itself. In particular, we look to Section 7 of FIFRA,[12] which sets out the statutory requirements pertaining to establishment registration and production reporting.

As EPA has explained, Section 7 is intended to serve a dual purpose. First, the establishment registration requirement is intended to facilitate EPA's inspection of facilities where pesticides and active ingredients are produced. This inspection authority allows EPA to more readily detect instances in which pesticide products are adulterated or otherwise contaminated.[13] According to the Agency:

> production information [under Section 7] permits EPA to trace ineffective, contaminated, or otherwise violative products to their source, and minimize any adverse environmental impact that might arise from the production or distribution of violative products.[14]

In addition, the ability to identify and inspect these establishments allows the Agency to more easily detect and respond to instances in which pesticide production activities lead to environmental contamination. As EPA explained in the context of its establishment registration regulations:

> The amendment to FIFRA requiring the registration of establishments producing active ingredients was made in response to an incident in Hopewell, Virginia, which resulted in widespread contamination of the environment with kepone, a highly toxic substance. . . . By requiring producers of active ingredients to register their establishments and keep certain books and records,

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[11] Significantly EPA has made it clear that Section 25(b) can be used not only to exempt pesticides from FIFRA regulation altogether, but also to exempt pesticides from some, but not all, of the requirements of the statute. Thus, for example, in the PIP Rule, EPA acted under Section 25(b) to exempt from the FIFRA registration requirements PIPs that are derived from conventional breeding techniques; however, EPA specifically provided that those PIPs are still subject to adverse effects reporting requirements under the Act. *See* 40 C.F.R. § 174.71.

[12] 7 U.S.C. § 136e.

[13] *See, e.g.*, 45 *Fed. Reg.* 46100 (July 9, 1980).

[14] 64 *Fed. Reg.* 499, 501 (Jan. 5, 1999).

> Congress hoped to avoid a recurrence of incidents like the one in Hopewell, Virginia.[15]

Second, the production reports received under Section 7 allow EPA to assess the scope of any problem that might be detected in a product, and to respond appropriately.[16] According to the Agency:

> Requiring such [pesticide producing] establishments to report their production would provide the Agency with data enabling it to assess and properly respond to any problem that might develop with a product.[17]

In the context of conventional chemical pesticides, the Section 7 establishment registration and production reporting requirements make sense. A conventional chemical pesticide is typically formulated in one, or a few, "bricks and mortar" facilities. At those facilities, various chemical ingredients are combined to create the formulated product, which, generally speaking, must conform to the specifications contained in the confidential statement of formula (CSF) for the product. If an inappropriate ingredient is used in the formulation process, an EPA inspector can readily detect the problem – for example, by obtaining samples of the product, examining the labels of the ingredients used to formulate the product and confirming whether those ingredients are consistent with the ingredients identified on the CSF. Similarly, if the inspector finds an adulterated or contaminated product in channels of trade, the inspector can trace the defective product back to the establishment at which it was produced, and he can ascertain, through an inspection of the facility and an examination of facility records, whether the product deficiencies are attributable to problems with the formulation process. The inspector can also review the facility's production reports to determine how much of the improperly formulated product was distributed in commerce. Finally, in instances where pesticide producing facilities utilize hazardous chemicals in the formulation process, the establishment registration requirements allow EPA to target those facilities for inspection, so as to ensure that those hazardous chemicals do not pose undue environmental risks.

However, PIPs are fundamentally different from conventional chemical pesticides. Most significantly, unlike conventional chemical pesticides, PIPs are expressed at various points in the lifecycle of living plants, rather than being produced in a controlled formulation process in chemical manufacturing facilities. Because PIPs are expressed in living plants, there are no centralized production facilities where an inspector can observe product being manufactured or formulated. Similarly, there are no ingredient labels to examine, so as to ensure that the proper ingredients are used in the right proportions in formulating the PIP. Indeed, there is no "formulation" process for an inspector to oversee at all.

The closest analogy to formulation in the PIP context arguably occurs at the initial

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[15] *Id.*
[16] *Id.*
[17] 45 *Fed. Reg.* 46100.

transformation step, when the genetic material coding for the pesticidal substance (*i.e.*, the PIP "active ingredient")[18] and the genetic material coding for any markers (*i.e.*, the PIP "inert ingredient")[19] are inserted into the genome of the recipient plant. This transformation step occurs very early on in the development process – when, typically, several experimental PIPs are undergoing research and development at the same time. Thus, as a practical matter, an inspector would never be able to observe the "formulation" of a PIP (or inspect a facility that is "formulating" a PIP) that is found in channels of trade, because by the time the product (*i.e.*, the PIP-related plant) is in channels of trade, the "formulation step" (the initial transformation) has long been completed. Consequently, one of the main purposes of Section 7 – providing EPA with information enabling the Agency to detect and correct instances where products are being improperly formulated – cannot be achieved by requiring the registration of facilities at which PIP-related plants are propagated.

Similarly, because PIPs are not formulated from hazardous chemicals in centralized facilities, any environmental risks that might be posed by PIPs (minimal as those risks might be) are not associated with specific "production" facilities. Rather any environmental risks that PIPs might present are the potential risks associated with the propagation of plants that express PIPs, wherever that propagation occurs. These risks are essentially the same, regardless of whether the propagation is by a commercial grower producing a food, feed, or fiber crop, a seed company conducting field trials, or a contract grower producing parent or commercial seed stock. Thus, there is no point in attempting to identify, through the establishment registration process, the specific locations at which PIPs are being "produced" as opposed to being "used" by a grower, since there are no unique environmental risks associated with farm fields that are devoted to "production" versus "use". This contrasts sharply with the production of conventional chemical pesticides, where the producing facilities frequently use and store large quantities of potentially hazardous chemical ingredients and, therefore, *do* present potential environmental risks that are unique and distinct from the environmental risks associated with use of the product. Consequently, another purpose of Section 7 – providing EPA with information that allows the Agency to more easily detect and respond to the unique environmental hazards associated with discrete pesticide production activities and facilities – is simply inapplicable in the context of PIPs.

Finally, if an inspector were to identify concerns regarding a PIP-related plant in channels of trade, the type of production volume and location information that would be provided under Section 7 for a conventional chemical pesticide – which is intended to allow EPA to "assess and properly respond to any problem that might develop with a product" – either would already be available to the Agency through other means or would be maintained by the PIP developer and could be required by EPA through this rulemaking under the authority of FIFRA Section 3.[20] As we discuss in more detail below, a substantial amount of detailed information pertaining to the propagation of PIP-related plants is already maintained by PIP developers and either submitted or available to EPA.

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[18] *See* 40 C.F.R. § 174.3.
[19] *Id.*
[20] 7 U.S.C. § 136a.

Consequently, the other remaining purpose of Section 7 – providing EPA with production information that allows the Agency to assess the scope of any problem that might be detected in a product, and to respond appropriately – can be fulfilled without requiring that commercial farms, seed production fields, research facilities, or other locations that grow or process PIP-related plants comply with the requirements of Section 7.

Accordingly, because establishment registration and production reporting for PIPs are not necessary to carry out the purposes of FIFRA, PIPs should be exempt from those requirements pursuant to FIFRA Section 25(b)(2). By defining a PIP as a pesticidal substance that is intended to be produced in a living plant, EPA's PIP regulations should be interpreted so as to effectuate the Administrator's exemption authority under Section 25(b)(2).

iii. Plants that contain registered PIPs are exempt from regulation as pesticides pursuant to the EPA's treated article exemption.[21]

The treated article exemption provides that the following materials are "exempt from all provisions of FIFRA" when used in the manner described:

> An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.[22]

Thus, an article will be exempt from regulation under FIFRA by virtue of the treated article exemption if the following three conditions are satisfied: (i) the article contains or is treated with a pesticide; (ii) the pesticide is intended to protect the article itself; and (iii) the pesticide is registered for this use.

When EPA registers a PIP, the PIP is registered for use in a particular plant for the purpose of protecting the plant from one or more pests.[23] This was made clear when EPA defined the term "plant incorporated protectant" to mean, in pertinent part, "a pesticidal substance that is intended to be produced and *used in a living plant*, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance."[24]

In the case of a plant capable of expressing a registered PIP, all of the criteria of the treated article exemption are satisfied: the plant (i) contains a pesticide (the PIP), (ii) for the purpose of protecting the plant itself, and (iii) the pesticide is registered for the

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[21] 40 C.F.R. § 152.25(a).
[22] *Id.*
[23] 59 *Fed. Reg.* 60510-11.
[24] 40 C.F.R. § 174.3 (emphasis added).

purpose of protecting the plant.[25] Accordingly, when plants capable of expressing registered PIPs are propagated in the field, what is being produced is a treated article, not a pesticide. Treated articles are exempt from regulation under FIFRA, including regulation under Section 7.[26] Consequently, the farms and facilities engaged in the growing and processing of plants that contain a registered PIP, because they are "producing" treated articles and not pesticide products, are exempt from the production reporting and establishment registration requirements of FIFRA.

For all of these reasons, we believe it is inappropriate and unnecessary to subject PIPs or PIP-related plants to the establishment registration requirements of FIFRA Section 7. Nevertheless, we understand that EPA may have a legitimate need to identify the specific facilities where records pertaining to the production, sale and distribution of PIP-related products are maintained so that the Agency can conduct inspections of those books and records pursuant to FIFRA Section 8.[27] In order to accomplish this important function, we propose that every PIP registrant and EUP holder should be required to designate at least one facility where required books and records pertaining to the PIP must be maintained and held available for inspection by the Agency. In short, with respect to PIPs, an establishment should not be viewed as a place where an inspector can go to observe a pesticide being manufactured or formulated. Instead, EPA should use its authority to require designation of a facility or facilities where relevant records are required to be maintained and available for inspection.

b. Production reporting (FIFRA Section 7 and 40 CFR 167.85)

Question: What production reporting, by whom and in what units (volume, weight, number of seeds, etc.) would be appropriate? Should reporting units be dependent on the reproductive methodology of the crop (e.g., seeds, bulbs, or tubers)? Given your response to Unit [1.a.], what types of production reporting would provide the Agency with information valuable for compliance assurance purposes and for managing any potential risks associated with a violation?

Response: For the reasons noted in response to 1.a. above, BIO does not believe that PIPs should be subject to "production reporting" as that term is used for conventional chemical pesticides under FIFRA. Nevertheless, we also recognize that, even if it is inappropriate to require facility-based production reporting for PIPs, EPA may nevertheless have a legitimate interest in monitoring the volume of certain PIP-related products in commerce in the United States. For that reason, BIO's members have always provided EPA with relevant information under FIFRA Section 3 for commercialized PIP

[25] The application of the treated-article exemption to PIPs was acknowledged by the NRC in its 2000 report. National Research Council. 2000. Genetically Modified Pest-Protected Plants: Science and Regulation at 152. National Academy Press, Washington, DC

[26] As noted above, articles or substances that qualify for the treated article exemption are exempt from "*all provisions* of FIFRA." 40 C.F.R. § 152.25 (emphasis added).

[27] 7 U.S.C. § 136f.

related products, as specified by the Agency under the terms and conditions of registration for individual products.[28]

To confirm this requirement, we propose that EPA amend the Part 174 regulations to specify those situations in which a need for reporting has been clearly established and, for the specified categories of PIPs, require that the registrant provide the Agency with an annual report on the quantity of each PIP-related product that the registrant sells each year. This information, coupled with the recordkeeping requirements discussed below, will provide EPA with the information it needs for compliance assurance and management of any potential risks identified with PIPs. Importantly, the proposed recordkeeping requirements would also provide EPA with access to current information, which would presumably be more useful for the Agency's purposes than traditional annual production reports, which provide information about the *previous* year's production.

c. Recordkeeping and inspection (FIFRA Sections 8 and 9 and 40 CFR 169.2 and 169.3)

What establishments or other locations are appropriate to be inspected for records and samples, and what records would be appropriate for producers of PIPs to maintain?

Response: BIO supports amendments to the existing EPA regulations to clarify the recordkeeping and reporting requirements that apply to PIPs. Specific recommendations follow, first for all PIPs, then for PIPs subject to an experimental use permit (EUP), and finally for registered PIPs. Recommendations related to inspections are also provided.

i. Recordkeeping and reporting in general – EPA's PIP regulations should:

- identify the recordkeeping and reporting requirements that apply to PIPs based upon authorities under Sections 3, 5, and any other appropriate sections of FIFRA such as Section 8, and exempt PIPs under Section 25(b) from inappropriate FIFRA requirements such as Section 7;
- carefully distinguish between the pesticidal substance that may be expressed in the plant at any point in time and the plant itself;
- require each PIP registrant and each holder of an EUP for a PIP to maintain the records required by EPA at a location or locations to be designated by the regulated party (registrant or permittee) for that PIP;

[28] The information that EPA has required from PIP registrants and EUP holders under Sections 3 and 5 of FIFRA has never been dependent upon nor even referenced the concept of a registered establishment under Section 7 of FIFRA.

- specify that all records required to be maintained for PIPs be made available for inspection by EPA upon request at a location or locations to be designated by the registrant or permittee for that PIP;
- distinguish between records to be maintained (and accessible to EPA on request) and information to be routinely submitted to EPA, which should only be required where a need has been clearly established;
- specify recordkeeping and reporting units based on the reproductive methodology of the plant (e.g., seed, bulb, tuber, bud, root, cutting, graft, or scion);
- include only those recordkeeping and reporting requirements that are consistent for all PIPs, with all other product-specific requirements addressed under the terms and conditions of individual permits and registrations;
- recognize the individual relationships that exist between PIP registrants and EUP holders on the one hand, and their licensees, dealers, contractors and cooperators on the other, and provide for appropriate phase-in periods for recordkeeping and reporting requirements; and
- recognize that much of the information contained in records to be maintained and/or reported to EPA is proprietary and subject to the protections provided by law for trade secrets and other confidential business information.

With regard to the specific types of records that might provide EPA with information valuable for compliance assurance purposes and for managing any potential risks associated with a violation, BIO suggests that the Agency give serious consideration to the following information categories:

ii. Recordkeeping for PIPs under an EUP:

- Name and address of each cooperator and participant involved in the EUP;
- Location of each site where planting took place under an EUP and, for each site, the quantity of material planted, number of acres planted and dates when plants were in the ground;
- Disposition of EUP material at each site; and
- Plot plan or other diagram indicating adjacent land use during the EUP period.

iii. Recordkeeping for registered PIPs:

- Lot numbers of commercial seed or other propagative material for each registration and a description of how lot numbers were assigned;
- Origin information identifying:
  - the source of each lot of commercial seed or other propagative material by name and address (e.g., growers, licensees, field locations, brokers, wholesalers), and
  - certification of each lot of commercial seed or other propagative material where applicable;
- Sales or distribution of each lot of commercial seed or other propagative material to distributors, retailers and/or customer representatives including quantity of material, dates, names and addresses, and delivery records;
- Treatment information by lot (e.g., seed treatment) identifying each substance used, rate of application, date of treatment, and name and address of treater; and
- A sample for each lot of commercial seed or other propagative material to be maintained for one year after final disposition of the lot.

iv. Inspections:

Section 8 of FIFRA requires PIP registrants and applicants for registration to maintain such records with respect to their operations as the EPA determines are necessary for the effective enforcement of the statute, and to make such records available for inspection and copying upon request.[29] The records and samples identified above for PIP registrants should be available for EPA inspection at a location or locations to be designated by the registrant for that PIP. For PIPs covered by an EUP, the records identified for permittees should be subject to inspection under Section 5 of FIFRA[30] at a single location to be designated by the permittee. Field test locations should remain subject to inspection by EPA under Section 5 and the regulations in Part 172, but these locations should not be subject to inspection for records as these sites are typically not well-suited to serve as records repositories. The need for flexibility in the designations made by regulated parties of locations for purposes of inspection under Sections 5 and 8 is due in no small part to the tremendous variability in the commercial relationships and size and scale of operations of individual PIP researchers and registrants.

[29] 7 U.S.C. § 136f.
[30] 7 U.S.C. § 136c.

As to the Agency's inspection authority under Section 9 of FIFRA,[31] there is some question as to the applicability of that authority to PIPs due to the unique characteristics of PIPs and the fact that PIPs per se are not sold or distributed in commerce. In addition, the Agency's authority to inspect EUP sites and records is independent of Section 9. For these reasons, any inspections conducted by the Agency beyond Section 5 or 8 should be authorized by regulation under Section 3 only to the extent necessary to effectuate the purposes of FIFRA. The one example for application of this authority that appears to make sense for PIP-related products would be a requirement for registrants to allow entry to the EPA to each facility where samples of PIP-related commercial seed or other propagative materials are maintained. This access would be provided for the express purpose of allowing the Agency to inspect such samples.

d. Labeling (FIFRA Section 2 and 40 CFR 156.10)

Please comment on current labeling practices for PIPs. Are current labeling practices sufficient? For example, do grower agreements offer sufficient information and compliance assurance to ensure registered PIPs are used in a manner that protects human health and the environment? Are there circumstances where labeling different from that currently in practice for PIPs may be appropriate?

Response: BIO supports EPA's current labeling practices and finds that, in conjunction with certain mandatory information measures, these practices are sufficient to ensure that registered PIPs are used in a manner that protects human health and the environment. For the sake of clarity, however, EPA should clearly describe the current labeling practices in its regulations. Specifically, EPA should clarify the following points:

- Seed or other propagative materials capable of expressing a registered PIP are not required to bear a FIFRA label because (i) other mandatory information measures of equal or greater utility are available and (ii) these PIP-related propagative materials are treated articles and not pesticides. The FIFRA label for a PIP is held by the registrant or the registrant's agent. [32]

- A PIP-related product (i.e., seed or other propagative material from an unregistered PIP or a registered PIP intended for an unregistered use) that is being used under an EUP must bear an EUP label, consistent with 40 CFR 172.6. However, a registered PIP being used in an EUP trial for a registered use and in a manner consistent with its registration is not required to bear an EUP label.

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[31] 7 U.S.C. § 136g.

[32] *See, e.g,,* 66 *Fed. Reg.* 37783 ("Under current procedures for plant-incorporated protectants, the pesticide label is held by the producer or the producer's agent(s) and is attached to seed sent to seed propagators. The actual pesticide label requires that informational material must be provided to the farmer with bags of seed sold to farmers. The informational material should indicate that the seed contains a registered plant-incorporated protectant and . . . also conveys any other information pertinent to the grower on the registration and use of the plant incorporated protectant.")

For registered PIPs, it is important to recognize that the Agency can mandate the use of several different information measures under FIFRA Section 3, and has not hesitated to do so, to help ensure the proper use of PIP-related products.[33] For example, for several currently registered PIPs, EPA has determined that growers should implement insect resistance management ("IRM") measures. Accordingly, as a condition of registration for these PIP-related products, EPA has required that registrants utilize multiple methods of communication to provide growers with information on IRM requirements.

A written agreement between the PIP registrant and each grower who purchases PIP seed is specifically required by EPA and is a primary example of the IRM communication tools implemented by registrants. The grower agreement must be signed by the grower and contractually obligates the grower to comply with the IRM requirements specified by EPA. Other examples of measures implemented by registrants include grower guides that provide detailed information on IRM requirements, tags placed on seed bags that identify the EPA registration number and active ingredient for the PIP and alert the purchaser to the IRM requirements, and additional forms of communication to inform and educate growers which may be made in person or in written or electronic form at key points during the planting and growing season.

The IRM requirements mandated by EPA under FIFRA Section 3 are enforced against the registrants through an EPA-approved compliance assurance program (CAP).[34] Any registrant that fails to implement the CAP would be at peril of cancellation of its registration under Section 6 of FIFRA,[35] thereby providing a compelling compliance/enforcement incentive. Growers that plant PIP seed are not applying or using a pesticide for purposes of FIFRA, therefore they are not subject to the "misuse" provisions of FIFRA.[36] As previously discussed, these growers are planting seed that is subject to regulation by USDA and, for EPA purposes, has all of the characteristics of a treated article, much like seed that has been treated externally by a conventional chemical pesticide.

These IRM information measures, EPA's ability to hold PIP registrants accountable for their implementation, and the desire of registrants to maintain the efficacy of their products, have consistently proven to be very successful in achieving grower compliance with IRM requirements. Data regarding rates of adherence to IRM requirements submitted annually to EPA by the registrants of insect-resistant corn and cotton products demonstrate that growers are very much aware of IRM requirements and there is no reason to believe their awareness would be improved by placing a large volume of mostly

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[33] The EPA's authority under FIFRA Section 3 covers full registrations as well as those that are more limited, such as "seed increase" registrations. *See, e.g.,* 60 *Fed. Reg.* 4910, 4911 (Jan. 25, 1995).

[34] In addition, the registrations mandate the inclusion of various measures in the CAP in order to promote grower compliance with IRM provisions, including mandatory in-person interviews with growers to reinforce required IRM practices and to assess grower compliance with those practices, as well as mandatory penalties for growers that do not properly implement the required IRM measures. Registrants must submit regular reports to EPA on CAP implementation.

[35] 7 U.S.C. § 136d.

[36] Growers of plants engineered to express PIPs are subject to FIFRA "enforcement" only indirectly as a consequence of any actions taken by EPA against the responsible registrant.

extraneous, FIFRA-type label information on the seed bag. This experience demonstrates that grower compliance with specific terms and conditions attached to a PIP registration is best obtained through education and other targeted communications and, where necessary, through the use of grower guides and agreements – rather than through the use of a traditional (and for PIPs, largely superfluous) FIFRA label. Moreover, this precedent shows that, if EPA believes that it is necessary to communicate special instructions or information to growers for a specific PIP or class of PIPs, EPA can require, as a condition of registration, that appropriate, targeted communications be made directly to growers in conjunction with their purchase of the PIP-related product.

EPA has previously stated that it wants to ensure that everyone involved in the use of PIP-related products is using these products correctly, while not causing undue burden on the regulated community.[37] Since PIP crops were first registered and commercialized, the first goal has been met in two ways. First, the registrant is required as a condition of the registration to provide the grower with information regarding the identity, proper use and proper stewardship of the product. As illustrated above, this has been accomplished by the use of grower guides and agreements, which are provided to the grower by the registrant, and supported by numerous additional required communications to growers. These communication measures have become an established fixture in the grower community and are one of the primary means by which (i) growers obtain relevant information concerning the required practices for use of plants engineered to express pesticidal substances and (ii) registrants secure the commitment of those growers to follow those practices.

With regard to the second goal, because most of the information on a FIFRA label is not pertinent to plants engineered to express PIPs, requiring a FIFRA label to be distributed in commerce with seed or other propagative material would cause unnecessary confusion, expense and recordkeeping throughout the commercial chain and would detract from the targeted information that has consistently helped to ensure grower compliance with PIP-specific requirements. For the reasons stated in 1.a. above, to the extent that EPA believes it is necessary to require a FIFRA label for a registered PIP, that label appropriately should reside with the registrant and there is no need for distribution of such a label in commerce.

e. Experimental use permits (FIFRA Section 5 and 40 CFR Part 172)

Are there aspects of production in association with PIP EUPs that are different from production associated with others types of pesticides used in EUPs? If there are differences, how should they be addressed for PIP EUPs?

Response: PIPs used under EUPs are fundamentally different than other types of pesticides and should be addressed independently as set forth in response to the questions above.

f. Production for export (FIFRA Section 17 and 40 CFR 168.65 – 168.85)

[37] *See, generally,* 66 *Fed. Reg* .37772.

What conditions would ensure that a PIP is intended for export only, and what would be necessary for such a PIP to meet the requirements of FIFRA?

Response: This issue pertains to the foreign purchaser acknowledgement statement (FPAS) and EPA notification requirements under Section 17(a) of FIFRA[38] and 40 CFR Part 168, Subpart D. These provisions are largely irrelevant for PIPs because, in contrast to conventional chemical pesticides, few other countries, if any, regulate PIPs as pesticides. Accordingly, for most if not all countries that might receive a notification from EPA under Section 17(a), indicating that a PIP being exported to the country is not registered as a pesticide in the U.S., this notification would be meaningless and confusing because it is inconsistent with the regulatory regime adopted by those countries. Moreover, under the Advanced Informed Agreement provisions of the Cartagena Protocol on Biosafety[39] and analogous national regulatory programs, notification to the receiving country would be required before new PIP-containing plants, seed or other propagative material could be imported into that country – wholly independent of any notification by EPA under FIFRA. Consequently, there is no legal or policy reason to impose FIFRA labeling or purchaser acknowledgment requirements on plants, seeds or other propagative materials that contain a PIP and imposing those requirements would likely cause confusion in the receiving country. We believe that no special measures are required to "ensure that a PIP is intended for export only."

2. *Are there other characteristics not described in [the ANPRM] unique to PIPs that may affect the application of the existing regulations associated with pesticide establishments and pesticide production to PIP producers?*

Response: In response to the preceding questions posed by EPA we have identified a number of characteristics not described in the ANPRM that are unique to PIPs and would be likely to affect the application of the existing pesticide establishment and production requirements to PIPs. In preparing proposed amendments to its regulations, we urge the Agency to carefully consider these characteristics and the serious adverse impact that application of these requirements to PIPs and PIP-related products would have on researchers, growers, registrants and the regulatory process.

3. *Are there additional sections of FIFRA implementing regulations related to pesticide establishment and production regulations that should be modified to more effectively address the unique characteristics of PIPs?*

Response: At this time, BIO has not identified any additional regulatory provisions related to pesticide establishment and production that should be modified to more effectively address the unique characteristics of PIPs.

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[38] 7 U.S.C. § 136o(a).

[39] The Cartagena Protocol on Biosafety and other related materials are available from The Secretariat of the Convention on Biological Diversity (http://www.biodiv.org).

We appreciate the opportunity to provide comments at this early stage of the rule-making process and look forward to working with EPA in the months ahead.

Sincerely,

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Food and Agriculture