To: Dravis, Samantha[dravis.samantha@epa.gov]
From: Dana O'Brien
Sent: Wed 5/17/2017 11:46:39 AM
Subject: BIO Food and Agriculture Comments to the EPA Docket
BIO Comments on EPA Evaluation of Existing Regulations.pdf

Samantha – I want to ensure you have a copy of Bio Food and Agriculture's comments to the EPA docket. Let me know if you have any questions or would like to talk more with our regulatory gurus. Dana.

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Dana M O'Brien

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Biotechnology Innovation Organization

May 15, 2017

Environmental Protection Agency
Office of Regulatory Policy and Management, Office of Policy (1803A)
1200 Pennsylvania Avenue NW
Washington, DC 20460

Submitted Electronically via Federal eRulemaking Portal (http://www.regulations.gov)

Re: Docket ID No. EPA-HQ-OA-2017-0190. Evaluation of Existing Regulations.

Dear Sir or Madam:

The Food and Agriculture Section of the Biotechnology Innovation Organization (BIO) is pleased to submit these comments in response to the U.S. Environmental Protection Agency's (EPA) request for public input to inform its "Evaluation of Existing Regulations," recently published in the Federal Register.[1] We focus our comments here on EPA regulations promulgated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) as applied to certain products of agricultural biotechnology.

BIO is the world's largest trade association representing roughly 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO represents many of the agricultural biotechnology product developers in North America, including companies developing products subject to EPA oversight and the relevant regulations referenced herein.

Under the 1986 Coordinated Framework for Regulation of Biotechnology (Coordinated Framework),[2] three U.S. federal agencies review and authorize commercial agricultural 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.

Under the Coordinated Framework, EPA's role in the oversight of products of agricultural biotechnology is to regulate pesticide-like substances produced in biotechnology-derived plants. 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. In most cases the plants involved are the so-called "Bt" crops, which produce a protein derived from a common soil bacterium, Bacillus thuringiensis, to control certain insect pests that feed on the plant. As with conventional chemical pesticides, EPA regulates PIPs under FIFRA.[3] Additionally, as with conventional pesticide residues, EPA also regulates PIP residues in food or feed crops under Section 408 of the FFDCA.[4] EPA regulations defining regulatory requirements, criteria, and procedures for PIPs under FIFRA and FFDCA are codified in 40 CFR Part 174.

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[1] 82 FR 17793 (April 13, 2017).
[2] 51 FR 23302 (June 26, 1986).
[3] 7 U.S.C. 136 et seq.
[4] 21 U.S.C. 321 et seq.

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Crop varieties containing PIPs have been in widespread use in agriculture for the last 20 years and have a long history of safe use. Since 1995, EPA has approved 36 different PIPs for commercial use in several crops.[5,6] In 2016, Bt varieties of cotton and corn accounted for 84% and 79% of total U.S. production acreage, respectively.[7] A 2016 review of 20 years of safety data prepared by the National Academies of Sciences concluded that the widespread planting of PIP crops resulted in significant decreases in the use of chemical pesticides, decreased presence of pest insects, reduced yield losses due to pest damage, and increased biodiversity on farms using Bt crops relative to farms treated with synthetic insecticides.[8] PIPs are generally considered low risk pesticides as they are biodegradable, activity is specific to target pests, they do not accumulate in the soil, and serve EPA's goal of reducing chemical usage while providing effective means of targeted pest control. In many cases, the same proteins produced in PIP crop varieties are approved for use in organic agricultural production when applied externally to the plant.

Despite these products' long history of safety and documented environmental benefits, EPA has singled out PIP products for a disproportionate level of regulatory scrutiny, resulting in a negative impact on agricultural innovation and threatening America's leadership role in this field. EPA's regulatory performance with respect to ag-biotech products has declined over the years, as regulatory requirements and costs have increased significantly. Even though Congress enacted the Pesticide Registration Improvement Act (PRIA) to impose very specific time limits for reviews of new uses and registration of new PIPs in genetically engineered (GE) plants, the EPA's Office of Pesticide Programs (OPP) often extends the legally-mandated time limits for biotech products. Delays are frequently caused by unnecessary and redundant additional external reviews and lengthy discretionary comment periods that provide no additional risk assessment value. Further, EPA routinely grants only time-limited conditional registrations for PIPs.

The economic costs associated with EPA review and registration of pesticides are significant. In addition to establishing timeframes for regulatory reviews, PRIA defines the fees that EPA may collect to support its reviews. In Fiscal Year 2016, the EPA collected more than $48 million from registrants in PRIA registration and maintenance fees.[9] Costs incurred from registration fees are multiplied by a proliferation in the number of individual actions that require separate EPA review and registration. In addition to PRIA-associated fees, developers incur costs to conduct studies in support of EPA review, as well as ongoing costs to maintain compliance with registration requirements. Significant opportunity costs also result from lengthy delays in EPA review. Ultimately, these economic burdens can stifle innovation and delay or prevent the development and marketing of environmentally beneficial products.

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[5] https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated

[6] It should be noted that, to date, EPA has granted most, if not all, PIPs "tolerance exemptions," which means the PIP is considered so safe that the EPA does not establish a maximum level at which the substance may be found in foods.

[7] https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption/

[8] National Academies of Sciences, Engineering, and Medicine (2016). Genetically Engineered Crops: Experiences and Prospects.

[9] This figure includes all PRIA categories, not just those associated with PIPs. EPA does not report fee data by PRIA category. https://www.epa.gov/sites/production/files/2017-02/documents/paying-fees-fy16.pdf, and https://www.epa.gov/sites/production/files/2017-02/documents/maintenance-fees-fy16.pdf

EPA's oversight should be based upon the best available science and narrowly focused on its statutory mandate to assess unreasonable adverse effects on the environment and reasonable certainty of no harm. As the U.S. government contemplates regulatory policy priorities for the EPA, it will be important to take into account the history of safe use and environmental benefits of biology-based agricultural solutions, the similarity of these products to those developed by conventional methods, and the impact of the agency's regulatory practices on modern agricultural innovation and farmer access to biology-based tools.

In what follows, we provide concrete examples of EPA regulations related to products of agricultural biotechnology that are either outdated, unnecessary, ineffective, or that impose costs exceeding their benefits— with suggested actions EPA could take to improve them.

Right-Sizing Regulatory Oversight

EPA should ensure that FIFRA is applied in a way that promotes agricultural innovation and reduces regulatory burdens

While it has always been EPA's stated intention to regulate the safety of the pesticidal substance itself and not the plant producing the substance, in practice this is not always the case. EPA requires separate reviews and registrations each time the PIP is added to a different plant, another registered PIP stack[10] combination, or when the PIP is deployed as a seed blend. Additionally, EPA requires separate reviews and registrations each time the active ingredient associated with a registered PIP is expressed in a different crop species, leading to a proliferation of separate reviews and registrations for what are identical pesticidal substances. This approach leads to unnecessarily redundant reviews, significantly increased registration costs, and is inconsistent with FDA's policy on food safety assessment of non-pesticidal proteins.[11] EPA should conduct its regulatory review of PIPs under FIFRA in a way that ensures that products meet the applicable safety standards, but that reduces unnecessary or duplicative data collection and submission and ensures that products reach market on an efficient and predictable timeline.

In addition, EPA should implement FIFRA's provisions, e.g., related to the registration of establishments, recordkeeping, reporting, inspection, and import-export requirements, in a manner that incentivizes the development and continued use of PIPs and other innovative agricultural technologies, recognizes the environmental benefits conferred by use of these products, and provides a regulatory environment that supports the United States' ability to compete in the global agricultural marketplace.

A companion change to the tolerance setting process under the FFDCA would also be beneficial. Specifically, by granting tolerance exemptions for all food crops, or broad crop groups, EPA would eliminate needless rulemaking proceedings where any PIP residues that might occur have already been determined to be safe by the Agency.

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[10] A "breeding stack" combines two or more PIPs into a single plant variety via conventional plant breeding. A "molecular stack" combines two or more PIPs into a single plant variety via recombinant DNA techniques.

[11] https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/biotechnology/ucm096156.htm

EPA regulations define a "PIP" as "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" (emphasis added).[12] Because the genetic material itself (DNA) is not a pesticidal substance, EPA could remove this phase from its PIP definition. This would allow the agency to focus its risk assessment on the safety of the pesticidal substance itself— independent of the plant the genetic sequence is inserted into—and thereby significantly eliminate the many redundant reviews and registrations of the same pesticidal substance. Relatedly, EPA could revise its regulations to discontinue the practice of regulating harmless marker genes as "inert ingredients."

EPA should implement expedited "reduced risk" registration requests for PIPs under FIFRA Section 3(c)(10)

This section of FIFRA requires the Administrator to consider any registration application or a registration amendment for an expedited review if the pesticide can accomplish one of four possible objectives:

i. Reduce the risks of pesticides to human health.
ii. Reduce the risks of pesticides to non-target organisms.
iii. Reduce the potential for contamination of groundwater, surface water or other valued environmental resources.
iv. Broaden adoption of integrated pest management strategies or make such strategies more available or more effective.[13]

Experience has shown that all of the commercialized PIPs accomplish more than one of the above goals, making them eligible for expedited review.

EPA should exempt familiar PIPs from registration requirements as "minimum risk pesticides"

EPA regulations include a mechanism to identify certain substances as "minimum risk pesticides" and thus exempt from certain FIFRA requirements.[14] Most of the substances on the list are relatively safe, naturally-occurring substances used as pesticides. Bt proteins that EPA has previously reviewed, has had many years of experience with, and have been found to be safe should also be included on this list of exemptions. Similarly, EPA should finalize a rule[15] it proposed in 2007 that would have excluded from FIFRA requirements certain PIPs that provide resistance to viral diseases (this class of PIPs confer viral resistance without even producing a pesticidal protein).

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[12] 40 CFR 174.3
[13] FIFRA Sec 7(c)(10)(B)(i-iv)
[14] 40 CFR 152.25(f).
[15] 72 FR 19589-19640, 19640-19660 (April 18, 2007).

EPA should publish guidance on appropriate data for assessing human health and environmental risks of PIPs

EPA can provide greater transparency and predictability for developers by publishing guidance describing the core data that are generally sufficient and necessary for assessing the risks of PIPs and how those data are used in the risk assessments. EPA should also provide guidance on additional data that may be expected if specific risks require further evaluation based on indications or uncertainties in the core data. These data expectations should be based on the EPA's 25 years of experience in evaluating PIPs for unreasonable adverse effects on the environment and reasonable certainty of no harm to human health. Such guidance should 1) recognize the long-established safety of PIP products; 2) have a clear connection to specific protection goals and risk-assessment endpoints; 3) be limited to any potential risks of the PIP itself, and not the plant; and 4) not include data already extensively reviewed by other agencies. Additionally, EPA has a number of mechanisms at its disposal to reduce unnecessary data requirements, including agency determinations that certain data requirements are not applicable, as well as agency-driven or submitter-requested data waivers.

EPA should engage with industry on best practices regarding insect resistance management (IRM)

Preventing the evolution of pests resistant to PIPs is an issue of critical importance to our industry. We appreciate that the government, including EPA, has an important role to play in delaying the evolution of resistant pests. However, EPA IRM requirements have become increasingly onerous and proscriptive, inconsistent with resistance management for non-PIP conventional chemistries, and may push the boundaries of EPA statutory authority. We encourage EPA to work with industry to identify smart, flexible IRM best practices to help maintain the continued durability of our products.

EPA should eliminate redundant oversight of field trials overseen by USDA

USDA's Animal and Plant Health Inspection Service (APHIS) oversees field trials of certain genetically engineered plants. If the GE plant is producing a PIP, EPA will often require an experimental use permit (EUP) to oversee the same field trial, imposing near-duplicate (and sometimes contradictory) regulatory requirements. In those instances of jurisdictional overlap, EPA's redundant oversight is unnecessary.

EPA should eliminate the double-standard for herbicides applied to herbicide-tolerant crops

In addition to regulation of PIPs, EPA also oversees the safety of herbicides applied to crops genetically engineered to be resistant to the particular herbicide. In practice, EPA discriminates against herbicides associated with GE crops by routinely requesting additional data and studies, extending comment periods, using scientific advisory panels, and frequently extending PRIA-mandated timeframes. We believe there is no scientific basis for treating herbicides associated with herbicide-tolerant crops, as a class, differently than any other herbicides. EPA should ensure that this double-standard is eliminated from its safety reviews.

Right-sizing Regulatory Scope

Over the last few years, EPA has made several attempts to expand the scope of its regulation by broadening its interpretation of what it considers to be a PIP. Our comments above focused on existing EPA regulations appropriate for repeal, replacement, or modification, but we also strongly discourage EPA from broadening its scope of regulation into new areas without a clear justification that the costs of expanded regulation would not outweigh the impacts on innovation of low-risk and environmentally beneficial products.

EPA should not stretch its FIFRA authority to regulate non-pesticidal biotech traits or substances

We believe that EPA should limit its regulation of PIPs to those pesticidal substances that mitigate the adverse effects of a pest through a mode of action directly toxic to a pest. FIFIRA includes in its definition of a pesticide plant regulators. The term "plant regulator" means "any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the product thereof."[16] Plant growth regulators are chemicals applied to plants in a variety of agricultural and horticultural contexts to alter the timing of certain stages of plant growth, for example, to change the timing of flowering. We strongly oppose interpreting genetic changes that alter plant growth to be a plant regulator-like pesticide as defined by FIFRA. This represents an implausible stretch of FIFRA, far beyond its original intent to regulate the safety of toxic chemical substances in the environment. Expansion of EPA oversight into new areas will only come at a cost of significant impact on innovation with little benefit to human health and the environment.[17]

EPA should not regulate products of plant breeding innovation that can be created via traditional plant breeding methods

Increasingly, breeders are developing enhanced plant varieties using the latest plant breeding methods, such as genome editing. In many (if not most) instances, these plants would not produce any pesticidal substance, and therefore should not be considered a PIP and subject to FIFRA regulation. Further, because many products of plant breeding innovation will be similar to or indistinguishable from varieties that could be produced through more conventional plant breeding techniques, there is no justification to impose additional pre-market oversight on such products. EPA recognized the safety record of plant breeding in the United States and that plant breeders have provided a safe food supply and have standards of practice to maintain this safety record. Based on this safety record, EPA exempted PIPs derived through conventional breeding from sexually compatible plants from almost all regulatory oversight, except the post market reporting of adverse effects. EPA stated that it did not want to

[16] FIFRA Sec 7(136)(v)

[17] In 2008, EPA determined that a GE cantaloupe, which had been engineered to ripen more slowly— and thus prevent food waste— contained a PIP, because it was engineered to have reduced levels of a naturally-occurring plant growth regulator (ethylene). Similarly, in 2010, EPA determined that a plum tree engineered to be resistant to plum pox virus, a devastating disease of plums and other stone fruit species, produced a PIP because it conferred resistance to a pest— despite the fact that the trees didn't produce any new substance that could be identified as pesticide-like. Following EPA's rulings, neither product was ever brought to market.

unnecessarily supplant the self-regulating aspects of plant breeding.[18] Recognizing the long safety record of plant breeding in the United States, EPA has exempted PIPs derived from conventional plant breeding from FIFRA regulation. Some PIPs developed through certain genome editing applications meet the definitions under the EPA's existing exemption for conventional breeding and EPA should explicitly confirm this interpretation.

In summary, given high regulatory costs and long history of safety and environmental benefits associated with PIPs, we strongly encourage EPA to use this opportunity to reexamine the regulatory burdens imposed on developers of plants producing PIPs and the adverse impacts those burdens have on agricultural innovation. As we have documented here, EPA has a number of methods by which the agency could right-size its regulatory system, while still achieving its important mission of protecting human health and the environment.

Thank you for the opportunity to provide comments on EPA's regulatory review process. Please feel free to contact me directly if you have any questions about our comments.

Sincerely,

Clint Nesbitt
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[18] 66 FR 33783