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December 8, 2020

By Electronic Submission
(Docket #: EPA-HQ-OPP-2019-0508)

Re: Comments on EPA's Proposed Exemption for Plant-Incorporated Protectants Created Through Biotechnology

The Center for Science in the Public Interest (CSPI)[1], Environmental Defense Fund (EDF)[2], Consumer Federation of America (CFA)[3], and National Wildlife Federation(NWF)[4] appreciate the opportunity to comment on EPA's Proposed Rule (85 FR 64308-64344, October 9, 2020) that would provide an exemption from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration requirements and the Federal Food, Drug, and Cosmetic Act (FFDAC) pesticide residue requirements for certain plant-incorporated protectants (PIPs) created in plants through biotechnology. A PIP is "a pesticidal substance that is intended to be produced and used in a living plant." (40 CFR 174.3) EPA issued regulations in 2001 that set forth how PIPs would be regulated under FIFRA and FFDCA, including the requirement that those PIPs be registered before commercial use. Those regulations exempted PIPs produced through conventional breeding between sexually compatible species, finding that they did not pose any risks that required oversight. However, the exemption did not apply to PIPs from sexually compatible species that were created through biotechnology. With the advent of new biotechnology techniques such as gene editing that allow developers to create PIPs using genetic material from sexually compatible species, EPA is now proposing to exempt certain of those PIPs if they meet scientific criteria ensuring those PIPs are similar to PIPs created through conventional breeding and do not present unreasonable adverse effects to humans or the environment.

[1] CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by the over 400,000 member-subscribers to its *Nutrition Action Healthletter* and by foundation grants. CSPI receives no funding from industry or the federal government.

[2] EDF, with over 2.5 million members, is a leading international, non-partisan, nonprofit organization dedicated to protecting human health and the environment by effectively applying science, economics, law, and innovative private-sector partnerships.

[3] Consumer Federation of America (CFA) is an association of over 250 non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and food safety organizations.

[4] The National Wildlife Federation (NWF) is America's oldest and largest conservation organization, made up of 52 state and territorial affiliates and representing more than 6 million members and supporters across the nation. NWF's mission is to unite all Americans to ensure wildlife thrive in a rapidly changing world.

One of the reasons EPA is proposing this rule is to implement Executive Order 13874 on "Modernizing the Regulatory Framework for Agricultural Biotechnology Products" (June 11, 2019), which directed EPA and other regulatory agencies to "use existing statutory authority, as appropriate, to exempt low-risk products of agricultural biotechnology from undue regulation." We agree with the Executive Order that regulations should be "science-based, timely, efficient, and transparent." However, EPA's current proposal does not adequately limit the proposed exemption to a category of PIPs that one can confidently conclude, based on current scientific evidence, will not pose unreasonable adverse effects to humans or the environment. Therefore, we recommend the following significant changes to the Proposed Rule to ensure that PIPs meet exemption criteria that are consistent with the FIFRA and FFDCA requirements.

I. EPA (Not Developers) Should Determine Whether to Exempt PIPs Developed Through Biotechnology.

EPA should not allow developers to self-determine if their products are exempt because developers, who have clear conflicts of interest, could make incorrect determinations leading to the release of PIPs that adversely impact humans and/or the environment. Instead, EPA should require each developer to apply to EPA for a PIP exemption and EPA should confirm whether the PIP satisfies the exemption requirements. If EPA does allow for self-determination, developers should be required to provide EPA with the scientific evidence supporting that determination. Finally, EPA should establish a publicly available list of all exempt PIPs on its website.

A. EPA Should Conduct Mandatory Confirmation of Exempt Status for All Exempt PIPs.

The Proposed Rule exempts a small subset of PIPs from FIFRA oversight, if they meet detailed scientific criteria. EPA argues that these PIPs should be exempt because they use new technologies to develop pesticidal substances that are virtually identical to substances that naturally exist in that plant and which have no history of adversely impacting humans or the environment. The criteria EPA proposes for this category of PIPs include, but are not limited to, the pesticidal substance must come from a sexually compatible plant, the pesticidal substance must be identical to the substance from the source plant or native allele of the gene, and the pesticidal substance must not be expressed at higher levels, in different tissues, or at different developmental stages than in the sexually compatible plant. Meeting these criteria may be difficult to do, often involving sophisticated analysis and careful interpretation of data. While some developers might make scientific and objective determinations that their products are exempt, others might feel pressure to interpret data to meet their business objectives and incorrectly self-determine products as exempt. An incorrect determination could result in unreasonable adverse harms to humans (e.g., increased exposure to an oral toxin) and/or the environment (e.g., production of a PIP that harms a beneficial insect).

To prevent incorrect determinations of exemption (either accidental or intentional), EPA should require that developers submit to EPA evidence that a PIP meets the exemption criteria,

and exemptions should not become effective until EPA has reviewed the evidence and reached a decision. Such a regulatory procedure would not be burdensome to EPA or to developers. Under the Proposed Rule, the developer needs to certify to EPA that its product meets the exemption criteria by sending a letter to EPA and maintaining records supporting its certification for five years. The developer must develop, collect, and analyze data to support an exemption determination, so submitting that information to EPA will result only a de minimis increase in costs. Furthermore, EPA has proposed that it would review and approve exemptions submitted voluntarily within 120 days. If EPA makes mandatory confirmation that a product meets an exemption and responds to developers within 120 days, developers would still be able to quickly market their products. Therefore, making the confirmation process mandatory would not have an adverse financial impact. However, if industry incorrectly determines an exemption for even just one product, there could be a significant and costly impact on humans and/or to the environment. To prevent harms caused by incorrect self-exemptions, EPA should require mandatory confirmation in its final rule. The information EPA proposed for documenting an exemption in Section 174.95 (a)-(c) of this Proposed Rule, relating to the biology of the plant, description of the pesticidal trait and how the trait was engineered into the plant, and molecular characterization of the PIP, should be the information submitted to EPA for its mandatory exemption confirmation.[5]

B. If EPA Permits Self-Determining an Exemption, EPA Should Retain the Requirement for Submission of a Self-Determination Letter but Also Require Submission of the Evidence Supporting the Exemption.

If EPA chooses to allow PIP developers to self-determine exemptions, then it should retain the proposed requirement that each developer submit a letter certifying that its PIP meets the exemption criteria. However, the letter submitted to EPA should include additional information supporting the determination. The Proposed Rule only requires that the letter state the "name of the plant-incorporated protectant." However, the name of the PIP may or may not be descriptive of what it does. There is also no requirement that the developer state where in the plant the PIP will be expressed. At a minimum, the letter should be required to identify the plant species, briefly describe the pesticidal trait, and provide a short summary of how the pesticidal trait was introduced into the plant variety (*i.e.,* where it came from and how it was scientifically manipulated to produce the PIP). In addition, the developer should be required to attach to the letter the information documenting how it reached the decision that the PIP is

[5] While Section 174.95 (a)-(c) generally discusses the categories of information needed by the developer and EPA to assess applicability of the exemption to a PIP, details about what information will satisfy each of the criteria is lacking. Whether in the Proposed Rule or in implementing guidance, EPA should establish its expectations on what information is sufficient to satisfy each exemption criteria. For example, to determine sexual compatibility between donor and recipient plants, EPA should require evidence that a cross between conventional plants of the donor and recipient result in a viable plant. To verify that the pesticidal substance is found in levels similar to that in sexually compatible plants, EPA should require evidence of the levels found in both the donor and recipient plant in each tissue and growth stage. If the plant has known toxic or allergenic compounds, evidence should be provided that those levels in the recipient plant do not exceed those founds in varieties of the plant currently eaten by humans.

exempt (the same information spelled out in Section 174.95 (a)-(c)). The Proposed Rule requires the developer to generate that information and retain it in its records, so providing it to EPA would not be burdensome. This additional information will make it much easier to EPA to carry out its compliance functions under the Proposed Rule and FIFRA.

We do not support any final rule that fails to require PIP developers to submit information to EPA about exempted products (i.e., makes self-determination letter submission voluntary). Without receiving a letter identifying an exempt PIP, EPA (and the public) will have no way of knowing with certainty what PIPs are being sold to farmers. EPA will have no way to determine if the developer is meeting their recordkeeping obligation under 40 CFR 174.73 because, without the knowledge that a developer has an exempt PIP, EPA would not know there are records it has the right to review. More importantly, exempt PIP developers are not exempt from Section 174.71, which requires submission to EPA of any information regarding adverse effects. Without records describing the product, EPA will be hindered in its ability to conduct a timely investigation of the adverse effects and impose any necessary risk management measures.

Not receiving a self-determination letter with substantive information about why the PIP is exempt also will make it difficult for EPA to act if EPA learns about information that puts into question whether a PIP qualifies for exemption. How will EPA be able to properly consider the information it receives and determine whether an exemption is proper without knowing what information the developer relied upon when it made its self-determination? Assessing information about a PIP's exemption status will be much more difficult and take more time if EPA has no previous knowledge of the PIP. If the information EPA receives is an adverse effect with immediate impacts on humans or the environment, the extra time taken to research the PIP and its developer due to the lack of a self-determination letter in EPA's files could result in unnecessary additional adverse impacts.

C. EPA Should Publish a List of Exempt PIPs

EPA has been transparent about the current PIPs produced using biotechnology that are being utilized in agriculture. The Agency has provided the public with the scientific data supporting its registration of each PIP produced with biotechnology, and the EPA website includes a list of currently and previously registered PIPs with information about the active ingredient, the crop, the year it was registered, its status (active or cancelled), as well as a link to the safety analysis in EPA's regulatory documents. EPA should provide a similar list of all PIPs produced through biotechnology that would be exempt from oversight under the Proposed Rule. Making a list of exempt PIPs available would inform consumers about products in the marketplace and improve consumer trust about biotechnology. A list would also be invaluable to the food industry, farmers, and our trading partners who with that information can ensure that those substances do not unnecessarily impede markets, trade, or farmer and consumer choice. At a minimum, the public should be provided with the following information: the crop, the pesticidal trait or active ingredient, and a link to the self-determination letter/EPA

confirmation determination with at least a summary of the information required by Section 174.95 (a)-(c).

II. The Criteria for Exemption Could Result in Exempted PIP Products that are Harmful to Human Health or the Environment

The Proposed Rule would exempt PIPs created through biotechnology under certain conditions from the requirement of registration under FIFRA and the need for a tolerance under the FFDCA. EPA interprets the standard for an exemption under FIFRA Section 25(b) to be that the pesticide "(1) poses a low probability of risk to the environment and (2) is not likely to cause unreasonable adverse effects to the environment in the absence of regulatory oversight under FIFRA." (85 FR at 64313). The safety standard under FFDCA Section 408 is that "there is a reasonable certainty that no harm will result from aggregate exposure to the chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." (21 USC 346(c)(2)(A)(ii)). While it is likely that many PIPs created in accordance with the proposed exemption would be free from risks to humans or the environment and meet these two statutory safety standards, there also may be some PIPs that could qualify for the proposed exemptions and present potential risks to humans or the environment. Therefore, EPA should consider those instances and add additional exemption eligibility criteria to its Proposed Rule to ensure that any PIPs that might pose unreasonable adverse impacts do not qualify for the exemption.

A. There Could Be Risks to Human Health if the PIP Substance is Unfamiliar in the Diet of Americans or It Is Present in Higher Levels Than Previously Found in the Diet.

The Proposed Rule requires that the substance in the PIP is limited to the same tissue at the same developmental stage of the sexually compatible plant and that levels cannot exceed those in the sexually compatible plant. This is meant to ensure that production of the substance in the donor and recipient plants is similar and does not result in any new or increased risk to humans through dietary exposure. The Agency states that "… any variations in the levels of PIPs based on sexually compatible plants created through biotechnology is not expected to exceed the levels of these substances currently in the food supply." The Agency then concludes that if humans have been exposed to the active PIP substance in sexually compatible plants in the past and it has not caused problems, moving that substance into a new variety is safe. However, there are at least two potential scenarios that could qualify for the exemption but would not be consistent with EPA's analysis regarding potential risks. In one scenario, a PIP substance could come from a sexually compatible plant that is not eaten by humans. In the other scenario, the PIP substance could be eaten but in significantly lower amounts than would be found in the PIP created with biotechnology, resulting in higher levels of dietary exposure and possible differences in cumulative exposure.

The Proposed Rule allows developers to create a PIP with any substance from a sexually compatible species, independent of whether that species is used for agricultural purposes or is currently eaten by humans. In fact, the Proposed Rule mentions several times that it

anticipates that some developers will use non-agricultural plants to develop the exempt PIPs. Many crops have land races, wild relatives, and even weedy relatives that could be sexually compatible and some of those plants may not be consumed by humans.[6] A developer could transfer a pesticidal substance from one of those plants to an agricultural crop and ensure that the substance is present at the same levels, in the same tissues, and in the same developmental stage as the donor plant, thereby qualifying the plant for the exemption. However, if that the source plant was not part of the food supply, the pesticidal substance would be new to humans and could be toxic, allergenic, or pose some other food consumption risk.[7] Therefore, EPA should limit its exemption to sexually compatible species that have been safely consumed by humans and not assume that all sexually compatible plants that could act as donor plant only have substances that humans have safely consumed.

Additionally, even for PIPs that come from donor plants consumed by humans, the pesticidal substance in exempt PIP may be expressed at a much higher level than in the donor plants. The goal of the PIP developer using biotechnology is to get the recipient plant to produce a substance at the higher levels found in the donor plant (often a non-agricultural plant). The resultant plant likely will subject humans to higher levels of the pesticidal substance, which could have acute or cumulative impacts on humans. Even if the donor plant is an agricultural product, but one that comes from outside the United States, there could be adverse impacts or increased sensitivity among Americans that have not been exposed to it through consumption for many years. Conventional crop breeders historically have not tried to introduce pesticidal substances so they are less familiar with these substances and what levels will be safe for human consumption.

EPA states in its proposal that most substances in plants used for food are not toxic and that any of those used in PIPs would not present any toxic effects. However, EPA does point out that plants consumed by humans also contain substances that may pose a dietary risk. The example cited is glycoalkaloid solanine, a substance that is biosynthesized in potatoes. While solanine poisoning is rare, it can, in high doses, cause effects such as gastrointestinal tract irritation and drowsiness. Some land races of potatoes in Peru can have higher levels of

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[6] EPA states that "Plant breeders have for many years followed established practices to ensure safety when moving genes into agricultural varieties from nonagricultural relatives, particularly from inedible relatives, with no indication that substances resulting from these genes present higher levels of risk than those from genes moved only amongst agricultural varieties as long as those established practices are followed (Ref. 13, 14, 15, 16). Therefore, the likelihood that the inclusion of nonagricultural varieties as potential source plants would lead to unsafe dietary exposures from residues of PIPs based on sexually compatible plants created through biotechnology is low." (85 FR at 64327) However, while it is "low" for the whole category of PIPs, individual PIPs still could pose an unsafe dietary exposure.

[7] EPA States in its Proposal that "Given that PIPs based on sexually compatible plants created through biotechnology are intended to represent a subset of substances present in plants that breeders are familiar with and that in many instances have been safely consumed by humans, EPA does not expect that these substances, or residues of these substances, would result in novel dietary exposures." (85 FR at 64327) EPA admits that in not all cases will the PIP substance have been safely consumed by humans.

solanine than would be found in commercial potato varieties. Potato breeders are familiar with solanine and make sure that exposure levels remain low but that may not be the case for other crops and substances that could be toxic. A toxic substance in a crop could be moved from a donor plant to a recipient plant resulting in increased exposure leading to a human dietary risk. Thus, EPA should consider the actual levels of exposure to a substance rather than just its presence and whether similar levels are found in the donor plant.

Consumers could be exposed to higher quantities of a pesticidal substance by consuming a product containing a PIP exempted under the Proposed Rule than by consuming an agricultural product already on the market that contains the same substance at lower levels. Therefore, EPA needs to exclude from the exemption PIPs developed from sexually compatible species where the level of the pesticidal substance is greater than what has been historically consumed by Americans.

B. The Exempted PIPS Could Pose Risks to the Environment, Including Non-target Species.

As with dietary exposure, EPA contends that there will be no environmental impact from PIPs that qualify for the exemption because they would not be new to the environment of the recipient plant. For example, EPA contends that exempted PIPs will not pose risks to nontarget wildlife because non-target organisms living within the range of the wild donor plants would have already adapted to exposure to these wild plants. The Agency goes on to contend that the non-target organisms would experience no greater exposure when the PIP is moved into a commercial agricultural crop. However, a pesticidal substance that does not have adverse impacts in the mountains of South America could have adverse impacts on a farm in California or Iowa.

Given that many agricultural crops are cultivated on vast acreage across the country, it is likely that the source of a pesticidal substance (a wild relative, weedy species, and/or land race) would have a more limited range than the commercial crops into which the PIP is introduced. Thus, agricultural crops containing exempted PIPs are likely to be grown in different geographic areas from the range of wild donor plants. Consequently, non-target organisms in geographical areas where the new plant would be grown may not be adapted to exposure to the substance in the PIP and could be adversely impacted. If the PIP is expressed at higher concentrations in the genetically engineered product than in wild plants, gene flow to wild relatives could further increase exposure rates. This would result in potential risk to non-target organisms, including endangered species. It also could result in adverse impacts on other parts of the environment, such as the accumulation of the PIP substance in soils, groundwater, or surface water. To prevent such adverse impacts, EPA should limit the exemption to PIPs whose exposure levels have been the same in the geographic region and environment where the recipient plant will be grown.

III. The Eligibility Criteria for the Proposed Exemption Needs Clarification and Refinement.

In the Proposed Rule, EPA has attempted to limit the exemption to substances that already exist in a plant and have not had unreasonable impacts on humans or the environment. While, EPA has done a decent job identifying and defining the criteria used to determine if a PIP created using biotechnology with sexually compatible species is exempt, further clarifications and refinements are needed for some of the terms/criteria in the Proposed Rule to ensure that the exemption only applies to those PIPs that have a low probability of risk.

A. EPA Should Define "Biotechnology"

In this Proposed Rule, EPA is creating an exemption for PIPs "based on a sexually compatible plant created through biotechnology" yet provides no definition of "biotechnology." When EPA created an exemption for PIPS created from a sexually compatible plant through conventional breeding, it defined "conventional breeding." The conventional breeding definition specifically excludes "Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion." (40 CFR 174.3) The Federal Register notice for the Proposed Rule specifically states that the exemption for "conventional breeding" was meant to "specifically exclude plants developed through biotechnology." Therefore, is "biotechnology" meant to encompass the use of "recombinant DNA and other techniques wherein genetic material is extracted from an organism and introduced into the genome of the recipient plant…"? Such a definition might not include many gene editing techniques, some of which use proteins or RNA instead of DNA to make precise genomic changes. Clarity around what products will be included is critical to understanding the scope of the exemption.

A second problem with not defining "biotechnology" is that the rule may be interpreted to suggest that PIPs produced with different existing techniques, or new techniques not yet discovered, all qualify for the exemption. Different techniques have different levels of precision and efficiency, and how they are designed and implemented can impact the likelihood of "off-target" effects (unintended genetic changes that may occur in addition to changes to the intended trait). While many existing techniques can be designed to produce safe PIPs while limiting off-target effects, other techniques are less precise, and it is impossible to predict what off-targets and unintended impacts might arise for yet undiscovered genome altering techniques. EPA should consider limiting the exemption to highly precise and efficient gene modifying techniques, such as CRISPR, and provide the opportunity to amend the definition in the future to add or subtract techniques depending on their precision, efficiency, and ability to limit off-targets to changes that plant breeders can eliminate. Alternatively, EPA could establish criteria that gene modifying techniques must meet to qualify for exemption and then determine which techniques qualify now and in the future.

B. EPA Should Modify the Definition of "Sexually Compatible."

The Proposed Rule defines in Section 174.3 that plants are "sexually compatible" if "a viable zygote can be formed through the union of two gametes through conventional breeding." (85 FR at 64342). However, a better definition would require that the viable zygote survive to maturity, which would ensure that the offspring of the two gametes survive to produce a whole plant and can reproduce. Therefore, we propose that EPA include in this definition a requirement that the PIP developer have evidence that the union of the donor plant and the recipient plant have been successfully bred using conventional breeding techniques and produces a whole mature plant.

C. EPA Should Clarify How to Apply the Exemption Criteria that Require that the Pesticidal Substance in the Recipient Plant Be Expressed in the Same Levels, Tissues, and Developmental Stage of the Donor Plant

The Proposed Rule provides that the exemption is available only when the PIP substance from the donor plant is expressed in the recipient plant at the same levels, at the same developmental stages, and in the same tissues as in the donor plant. However, the Proposed Rule is not clear on whether all three criteria apply simultaneously or independently. Would a recipient plant qualify only if it expressed a PIP substance at the same level as found in the same tissue and same growth stage of the donor plant? Or would a recipient plant qualify if the PIP substance from the donor plant was expressed at a higher level in the corresponding tissue or growth stage, so long as the level of the PIP in the recipient plant did not exceed a level seen in the donor plant, albeit in a different tissue or growth stage? We recommend that EPA clarify that the criteria should be met separately for each tissue and growth stage.

IV. EPA Makes Assumptions About the Product Development Process but Does Not Mandate Requirements to Ensure Those Actions Are Carried Out by Product Developers

In proposing the exemption, EPA makes numerous assumptions about conventional breeding between sexually compatible plants and the role of plant breeders in ensuring plant varieties that will not adversely impact humans or the environment. For example, EPA states that:

> Given that PIPs based on sexually compatible plants created through biotechnology are intended to represent a subset of substances present in plants that breeders are familiar with and that in many instances have been safely consumed by humans, EPA does not expect that these substances, or residues of these substances, would result in novel dietary exposures. (85 FR at 64320)

This statement assumes that plant breeders are familiar with all potential substances present in sexually compatible plants. However, scientists could identify or discover a land race or sexually compatible relative of a known plant with a substance with which some or all plant

breeders are not familiar. If the substance is from a sexually compatible relative that is not consumable by humans or has not been consumed by humans recently, there may be no information for the breeder about its safety for human consumption. In addition, breeders are a diverse group of scientists and one breeder working on a PIP may or may not be an expert on all the sexually compatible plants for a given crop nor all the potential substances those sexually compatible plants make.

EPA also assumes that an exempt PIP made with biotechnology will not be marketed until it undergoes many generations of conventional breeding and selection to eliminate any detrimental effects that could adversely impact humans or the environment. As EPA states:

> The screening and selection practices result in the selection of plants intended for commercialization that display desirable behavior, including desired levels of expression of various traits. Historically, these practices have proven to be reliable for ensuring safety, and plants containing PIPs based on sexually compatible plants created through biotechnology are expected to also pass through these same screening and selection processes. (85 FR at 64321)

While it may be true that the process of multiple back-crossing of plants to achieve a desired trait has successfully eliminated undesirable or harmful traits to date, there is no guarantee that these procedures will be used for PIPs produced with biotechnology. One of the advantages of using biotechnology with sexually compatible species is its speed over conventional methods of moving alleles between sexually compatible plants. Therefore, it is possible that developers of exempt PIPs might forgo the long breeding process that EPA assumes will happen.

Rather than assuming that the development of exempt PIPs will be overseen by plant breeders with expert knowledge about sexually compatible plants and the substances made by those plants, and that the development process will involve an elaborate screening and selection process, EPA should impose those conditions as necessary obligations for a PIP to qualify as exempt.

V. EPA Should Add Additional Requirements for Exempt PIPs

In the Proposed Rule, EPA mandates only two requirements for developers that are exempt: (1) to report to EPA any adverse incident reports (40 CFR 174.71), and (2) to maintain records and provide those records to EPA upon request (40 CFR 174.73). To carry out its responsibilities under FIFRA, EPA should require the following for all PIPs that qualify for the new exemption:

- EPA should retain the right to inspect any facility where the records are held, or the exempted plant is grown and to obtain copies of required records. The inspection authority is an essential component of any enforcement program that aims to ensure compliance with the requirements of the exemption.

- EPA should require the PIP (e.g., the seeds) be clearly labeled to identify that they contain a plant-incorporated pesticide that has been found exempt from most FIFRA requirements. The purchaser needs to be made aware that they are buying a pesticide so that they can identify any adverse impacts from using that product.

- The producer of the exempt PIP should be required to conduct monitoring and surveillance to ensure that there are no unreasonable adverse impacts to humans or the environment. EPA should set forth the required monitoring to capture any potential short-term or long-term impacts.

- EPA has determined that these exempt PIPs are low risk and EPA's registration program has found that low risk PIPs are "public goods" that provide safer alternatives to more risky conventional pesticides. EPA should consider development of "pest resistance" to be an adverse effect and require developers to report all incidents of pest resistance. In addition, EPA should be able to require that, as a condition of exemption, the developer needs to agree to establish a pest resistance management plan to delay resistance development. EPA could set forth in guidance the parameters for such a plan.

CSPI, EDF, CFA, NWF appreciate the opportunity to provide these comments to the EPA and would welcome the opportunity to meet with the staff at EPA to discuss the issues addressed here in more detail.

Sincerely,

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