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EPN Comments on EPA's Proposed Rule to Exempt Certain Plant-Incorporated Protectants from FIFRA and FFDCA Requirements
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The Environmental Protection Network (EPN) is an organization comprised of almost 550 U.S. Environmental Protection Agency (EPA or Agency) alumni volunteering their time to protect the integrity of EPA, human health, and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide insights into regulations and policies proposed by the current administration that have a serious impact on public health and environmental protections.

EPN appreciates the opportunity to comment on EPA's Proposed Rule to exempt certain plant-incorporated protectants (PIPs) from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA) requirements.

I. EPA Must Satisfy the Demanding Legal Standard to Promulgate an Exemption under FIFRA sec. 25(b).

As recognized in the Proposed Rule, EPA's authority to exempt PIPs or any other pesticides from the registration requirements of FIFRA comes from section 25(b) of FIFRA. That section allows EPA to exempt pesticides from the otherwise-applicable requirements of FIFRA, if the Agency determines the pesticide is either "adequately regulated by another Federal Agency, or ... of a character which is unnecessary to be subject to [FIFRA] in order to carry out the purposes of [FIFRA]." The Proposed Rule makes clear that EPA is issuing the Proposal because it believes the exempted pesticides meet the second leg of the statutory provision: that the exempted products are of a character unnecessary to be subject to FIFRA. In applying this standard, EPA declared: "EPA interprets FIFRA section 25(b)(2) to authorize EPA to exempt a pesticide or category of pesticides that EPA determines (1) poses a low probability of risk to the environment and (2) is not likely to cause unreasonable adverse effects to the environment even in the absence of regulatory oversight under FIFRA."

EPA also added the following:

> In evaluating whether use of the pesticide poses a low probability of risk to the environment, EPA considers the extent of the potential risks caused by use of the pesticide to the environment, including humans, animals, plants, water, air, and land. Potential risks to humans include dietary risks (which are assessed under the safety standard of the FFDCA section 408) and non-dietary risks, such as those resulting from occupational or residential exposure to the pesticide. EPA will not exempt pesticides under FIFRA section 25(b)(2) that fail to meet the required low probability of risk.
>
> In evaluating whether the use of a pesticide is likely to cause unreasonable adverse effects on the environment even in the absence of regulatory oversight under FIFRA, EPA balances

> potential risks to human health and the environment from use of the pesticide against the potential benefits associated with its use. In balancing risks and benefits, EPA considers the economic, social, and environmental costs and benefits of the use of the pesticide.
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> 85 Fed. Reg. 64313.

EPN does not have significant disagreement with EPA's view about what legal standard should be applied to this action. EPN strongly believes, and assumes EPA agrees, that EPA cannot authorize an exemption under section 25(b)(2) unless the Agency has a high degree of confidence that every pesticide product potentially covered by the exemption poses no meaningful risk to human health or the environment from any reasonably likely pathway or source of risk. (In that regard, EPN has identified in section III of these comments certain potential sources of risk that it believes EPA must analyze carefully before it can determine that every potentially exempted product is very unlikely to pose any meaningful risk to human health or the environment.)

While determining that there are not likely to be any meaningful risks to human health or the environment is a critical step towards granting an exemption under section 25(b)(2), EPN submits that this necessary risk determination is insufficient, on its own, to justify an exemption under section 25(b)(2). EPA must also satisfy the requirement that the proposed exemption not cause "unreasonable adverse effects on the environment" as that term is defined in section 2(bb) of FIFRA. In determining whether a pesticide causes unreasonable adverse effects on the environment, EPA must consider social and economic costs and benefits as well as risk issues. (In that regard, EPN has identified in section VII of these comments certain potential social and economic impacts that it believes EPA must analyze carefully before it can determine that issuing a final rule will not cause "unreasonable adverse effects on the environment.") Further, when EPA exercises its registration responsibilities with respect to pesticide products, EPA must consider whether any special terms and conditions of registration, including terms and conditions related to social and economic concerns, are necessary in order to satisfy FIFRA's mandates. EPN submits the same considerations and logic must be applied to an exemption rule under section 25(b)(2).

Finally, EPN agrees that EPA has the authority to issue partial exemptions under section 25(b)(2) as it is proposing to do here (by requiring the continued submission of adverse effects information), but EPN is not convinced EPA has struck the appropriate balance in the proposal. In order to exempt the products identified in the Proposed Rule, EPA must not only make the appropriate risk determination, but also determine with high confidence that there are no additional non-risk-related terms and conditions, including labeling statements or mandating that information be provided to purchasers of the exempted products, that should be applied to the exempted products in order to minimize the possibility of unreasonable adverse effects on the environment now or in the future. Put another way, EPN does not believe that EPA may exempt products under section 25(b)(2) unless the Agency is confident that, if the products were not exempt from registration, EPA would not require additional terms and conditions of registration now, and would very likely not do so in the future. As we set out elsewhere in these comments, EPN believes that economic and social considerations dictate that additional conditions should be added to any exemption rule before it is finalized.

In sum, one standard for granting an exemption is that the exempted product is of a character not requiring regulation. This means that EPA must have a strong basis for concluding that none of the potentially exempt products will cause "unreasonable adverse effects on the environment," a term

defined in FIFRA sec. 2(bb). As the Ninth Circuit in the dicamba case recently noted, the term is very expansive, and EPA must consider all of the potential risks and benefits of the proposed exemption. EPA has not done that for the purpose of this proposed rulemaking.

II. The Basic Premise of EPA's Rationale for the Proposed Exemption is Questionable.

This rulemaking rests on a debatable proposition that the proposed exemption would essentially do nothing more than accelerate the pace at which new PIPs, which could be created by conventional breeding, can be introduced into commercial agriculture, without changing the existing scope of the kinds of new PIPs that could be introduced without regulatory oversight. **The Proposed Rule contains criteria that would exempt new PIPs so long as they were introduced into a recipient plant using "biotechnology" by transferring genetic material from a "sexually compatible" plant. The justification for the exemption is based on the notions that: (1) any PIP that can be produced by conventional breeding techniques will be safe, and (2) any transfer of genetic material from a sexually compatible plant to a recipient plant effectuated using biotechnology simply emulates what could also be achieved, although more slowly, by conventional breeding.** Given the long history that food and feed items produced through conventional breeding techniques have been almost always free from risks to human health, EPA concludes no (or only very limited) government regulation would therefore be necessary.

EPN does not agree that the history of safe conventional breeding is a sufficient basis for the rule. Our position is based on a recognition that foods can contain toxic substances and that there are potentially significant differences between the kinds of changes that would be allowed under the proposal and the kinds of changes that have been produced through conventional breeding. The National Academy of Sciences has identified a long list of many naturally occurring substances in food that are harmful to human health. If, as would be permitted by the proposal, those levels were increased in common food products, they could pose a risk to human health. Fortunately, plant breeders are well aware of most of these toxicants and have worked to ensure that the new varieties produced do not include them. Plant breeders, however, are less familiar with wild plants that could be sexually compatible with commercial crops. **Thus, EPN asserts that plant breeders may be more likely to fail to surveil for the presence of a new toxicant introduced from a wild relative. In addition, the technology developers who will use biotechnology to create new PIPs may not have the same knowledge of the range of toxicants that could be in food as their counterparts who rely on conventional breeding techniques.** Thus, it is inappropriate to rely on plant breeders' historical track records to justify exempting PIP products produced using biotechnology.

Instead of using a "conventional breeding" analog to define the scope of the exemption, EPA should establish a risk-based set of criteria to determine whether a plant qualifies for the exemption. These criteria should consider, at a minimum, the presence of potential new allergens in human food and the presence of unsafe levels of compounds that are toxic to humans or non-target species that would likely be exposed. As explained in section III, the proposed criteria determining eligibility for the exemption do not adequately address all potential types of risks.

III. Exempted PIP Products Could Potentially be Harmful to Human Health or the Environment.

EPA's proposal would exempt PIPs, created through biotechnology under certain conditions, from the requirement of registration under FIFRA and the need for tolerances under the FFDCA. As explained in section I, the standard for an exemption under FIFRA is that there will be no unreasonable adverse effects on the environment. This standard requires the finding that there will be a reasonable certainty of no harm when considering human dietary risk from residues resulting on food (as required under FFDCA section 408) and that considering any benefits resulting from use, there would be acceptable occupational and environmental risks. The Agency maintains it is unlikely that, so long as the conditions in the proposal are met, the PIPs proposed for exemption will cause unreasonable adverse effects and that there would be harm from aggregate/cumulative exposure to residues from these PIPs.

The main basis for this determination is the Agency's belief that the exemption criteria will ensure the PIPs would not result in exposures that are significantly different from what humans are currently exposed to in the food supply. The proposed exemption would limit both the location and developmental stage within the plant where the new PIP substances may occur (i.e., they can only be present in the same plant tissues and during the same developmental stages as a sexually compatible donor plant). Additionally, the levels of the substance produced in the PIP would not exceed levels found in the sexually compatible plant. These levels may not be injurious or deleterious to human health. (See, however, the comment in section IV concerning whether these criteria operate together or separately.) Interestingly, although the Agency doesn't believe adverse effects are likely, it does propose an adverse effects reporting requirement.

By definition, pesticides, including PIPs, are biologically active, and thus potentially toxic substances. While it is likely that most products created in accordance with the proposed exemption would be free from risks, theoretically the exemption's criteria do allow for the creation of potentially dangerous products. The following discusses the types of risks potentially posed from the proposed exemption and some issues with the rationale in addressing safety.

A. There could be risks to human health:

1. Through the diet, when the PIP substance is present in higher levels than previously seen in the food commodity, either solely from the commodity or as a result of increased aggregate exposure and/or cumulative exposure.

The proposal requires that the substance in the PIP be 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 would ensure that production of the substance in the donor and recipient plants is similar. The Agency further notes that since the substances in the PIPs are already subsets of substances in related food plants, they are not expected to pose any risk that differs from what people already are exposed to in the food supply. 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." It is unclear how this determination was made. If levels of a substance in a PIP were the same as those found in its counterpart non-PIP agricultural crop, there would be no need to create a PIP. The goal is to get the

recipient plant to produce a substance (the PIP) at levels found in the donor plant, (a non-agricultural plant).

EPN finds this argument unconvincing. Although people may be exposed to the same substances to which they have historically been exposed, the levels of these substances could and probably would be higher, and consequently consumers would be more exposed to these substances in food. As in all risk assessments that the EPA performs to determine the safety of pesticides, the substance's level of exposure is a critical consideration, not merely its presence.

While the Agency argues that potential risks to infants and children and other subpopulations have been considered, the argument was again that these subgroups have historically been exposed to these substances since they are subsets of the substances in sexually compatible plants. The Agency does not acknowledge, however, that the levels of these substances could be greater in their diets. The Agency addresses dietary consumption patterns in making the case that there would be no differences in exposure patterns to consumers based on the proposed exemption. This proposal would make no difference in what is consumed and that the foods that are addressed here are part of a normal diet. However, the Agency again fails to acknowledge that the levels of the PIPs could be different (i.e., higher) from what people are now consuming.

In order to demonstrate the safety of this proposal, the Agency states that hundreds of new plant varieties have entered the market, mostly via conventional breeding, each year over the last 70 years with very few of them causing safety problems. However, the majority of these new varieties were not designed to elicit pesticidal effects as is the case of PIPs. Also, the number of new plant varieties containing PIPs that would be exempt under this proposal would be expected to increase, given the ease and reduced time of development using new genetic modifying tools versus conventional breeding. The Agency states that by limiting the expression level of PIPs based on sexually compatible plants created through biotechnology, it believes that breeders will be able to ensure that exposures fall within the normal historical range of exposures that have proved to be safe through conventional breeding. Again, while history may have shown few instances, albeit not zero, where human health was impacted, it is important to keep in mind that breeders have not overwhelmingly developed plants through breeding to produce substances that serve as pesticides. It could be argued that safety based on this history has not been well tested. This exemption will provide an easier and quicker means to produce many more new plants incorporating PIPs.

The Agency states that the vast majority of substances in plants used for food are not toxic and that any of these used in PIPs would not present any toxic effects. There are, however, as the Agency itself points out, instances where a substance may pose a dietary risk. The example cited was the glycoalkaloid, solanine. This substance is biosynthesized in potatoes. While solanine poisoning is rare, it can, in high doses, cause effects such as gastrointestinal tract irritation and drowsiness. This example emphasizes the importance of considering the actual levels of exposure to a substance rather than just its presence. Consumers could be exposed to higher quantities of a substance (a substance that is acting as a pesticide) under this proposed exemption than they would be in an agricultural crop that contains the PIP at lower levels.

2. To agricultural workers and to workers in food processing facilities, floral facilities, or grocery stores who may come in contact with the PIP.

The PIPS covered by the proposed exemption could expose agricultural workers (e.g., people working with crops containing exempted PIPs) to higher levels of the substance than they are currently exposed. People engaged in activities within a field could be exposed through inhalation of pollen containing the substance and/or through dermal exposure to the plant's sap, oil, or other fluids, etc. Similarly, people employed in the floral industry, in grocery stores, or in food processing facilities could receive higher exposures. Each of these instances serves as an example of how workers may be occupationally exposed under the Agency's proposal.

The Agency again makes the argument that, because the recipient plant already has a subset of the substances, there wouldn't be any novel exposures. However, EPA fails to address, as it did for dietary exposures, whether the levels would be higher compared to the original crop. Consequently, while exposure to an exempted PIP substance itself may not be novel, the levels which people experience may well be novel.

The possibility of risks to agricultural workers and workers in food processing facilities, floral facilities, and grocery stores raises important environmental justice considerations. The potential for these types of adverse effects deserves particular attention because the population subgroups put at risk have disproportionately higher percentages of low-income and minority workers than the country as a whole. Consistent with Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," EPA should examine not only the magnitude of these occupational risks but also whether these risks would fall more heavily on minority and low-income workers, and if so, EPA should take appropriate action to address those risks.

B. There could also be risks to non-target species:

EPA contends that exempted PIPs will not pose risks to non-target wildlife because non-target organisms living within the range of the wild donor plants would have adapted to exposures from these wild plants. Therefore, EPA believes non-target organisms would experience no greater exposure when the PIP is moved into a commercial agricultural crop. Given, however, that many agricultural crops are cultivated on vast acreage across the country, it is obvious that wild plants—the likely source from which new genes will be taken—could have a more limited range than the commercial crops into which the new PIPs are introduced. Thus, agricultural crops containing exempted PIPs almost certainly could be grown in geographic areas different from the range of the donor (wild) plants. Consequently, those non-target organisms in different geographical areas where the new PIP would be grown would not have had an opportunity to adapt to the exposures to the PIP in the recipient plant and could be adversely impacted. This potential risk could be of concern to non-target organisms and may be particularly important for threatened and endangered species. This potential risk has not been adequately addressed in the proposal. It's noted that EPA's Proposed Rule also fails to address whether the proposal "may affect" listed species under the Endangered Species Act.

IV. The Criteria Governing Eligibility for the Exemption are Inadequately Specified.

The Proposed Rule does not define, with sufficient clarity and precision, the key terms in the criteria that define the scope of the proposed exemption. Because the Proposed Rule is somewhat unclear, developers may misapply the criteria and reach conclusions about the status of their PIPs that EPA would not have anticipated or intended. Developers making such mistakes might think their PIPs were exempt and begin to introduce the PIPs into the environment. To avoid such mistakes, EPN recommends that EPA clarify aspects of several key terms and criteria.

A. EPA Should Define "Biotechnology."

One needed clarification would be to add to the Proposed Rule a definition of "biotechnology." 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." 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 of the current "gene editing techniques, some of which use proteins or RNA instead of DNA to make precise genomic changes. Clarity around what is included is critical to understanding the scope of the exemption.

A second problem with not defining "biotechnology" (or establishing an overly broad definition) is that PIPs produced with all existing and future genome altering techniques would qualify for the exemption. Some methods of modifying genetic material may affect not only the intended trait, but also other traits of the plant (these changes are often called "off-targets"). Different techniques have different levels of precision and efficiency, and how they are designed and implemented can impact the likelihood of off-targets. Although many existing techniques can be designed to produce safe PIPs while limiting off-target impacts to traits that can be eliminated by plant breeders, that may not be the case for all existing techniques. And clearly one does not know what off-targets and unintended impacts might arise from the use of yet undiscovered genome altering techniques. EPA should consider limiting the exemption to PIPs created by the use of highly precise and efficient gene modifying techniques such as CRISPR. The Agency could amend the definition of biotechnology 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 scientific criteria for the gene modifying techniques that qualify for the exemption and then determine which techniques qualify now and in the future.

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

While the Proposed Rule relies on the existing definition of "sexually compatible" in 40 CFR section 174.3 , that definition should be modified so that it only captures organisms whose sexual union can result in an organism that can reach maturity and reproduce. Therefore, EPN

recommends that the Agency include as one component of the definition of the term, "sexually compatible," that the developer of a PIP must have evidence showing that a donor plant and a recipient plant have been successfully bred using conventional breeding techniques, and that the offspring is viable to maturity.

C. EPA Should Clarify How to Apply the Exemption Criteria that Require the PIP in a Recipient Plant Not Be Expressed in a New Tissue or in a New Development Stage, Compared to the Donor Plant, or at a Higher Level in the Recipient Plant than in the Donor Plant.

The proposal provides that the exemption is available only when the PIP substance from the donor plant is expressed in the recipient plant at levels, at stages, and in tissues that are consistent with those occurring in the donor plant. The proposal does not state clearly, however, whether all three criteria apply simultaneously or independently. In other words, 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? Conversely, 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? EPN recommends that all three criteria should be met for each tissue and growth stage.

D. EPA's Claim that the Proposed Exemption Would Authorize Only PIPs that Were "as Safe as Previously Approved PIPs" Is Unsupported.

In the course of a webinar explaining the Proposed Rule and answering questions from the public, EPA staff suggested that the proposed criteria defining the scope of the exemption would effectively assure that all exempted PIPs were "as safe as previously approved PIPs." As presented, this possible criterion would not be meaningful. While the criterion initially seems sound, it would not establish a clear benchmark of safety unless EPA has a) identified the previously exempted PIPs, b) described how the Agency determined the safety of the previously approved PIPs, and c) described a method for showing how a product proposed for exemption compares to a previously approved PIP. In the absence of such information, such a possible criterion would leave too much discretion to EPA and developers to apply the criterion meaningfully.

In sum, the lack of clarity about these terms and criteria means that the developer, at least initially, has discretion to determine the meaning of the terms and thus, perhaps unintentionally broad discretion to determine whether a plant qualifies for the exemption. This lack of clarity also means that there is a greater likelihood that EPA may decline to confirm the conclusion of a developer that a particular PIP qualifies for the exemption. Experience with unapproved PIPs in the food supply—including incidents involving accidental experimental releases such as with StarLink—have shown how costly it is to demonstrate that the unapproved product has been successfully removed from the food supply.

V. The Proposal Would Not Give EPA Adequate Authority to Ensure Exempted PIP Products Are Subject to Appropriate Controls to Address Risks and Other Important Factors.

EPN recognizes that most PIPs qualifying under the terms of the proposed exemption would not be likely to pose any significant risks to human health or the environment, but we also think in some circumstances PIPs qualifying for the exemption may pose significant risks. See section III of these comments. If those risks did occur, EPN thinks EPA would not, according to the proposal, have retained adequate authority under FIFRA or the FFDCA to ensure it would become aware of and could act to address such risks in a timely and effective manner.

A. EPA Should Revise the Adverse Effects Reporting Requirement.

Contrary to the claims of the preamble of the Proposed Rule, EPA probably would not learn of most significant risks caused by exempted pesticides. The preamble incorrectly describes the requirement to report adverse effects as an important safeguard—beyond the criteria defining the scope of the exemption— because required reports would alert EPA to any problems caused by an exempted product. There are, however, several flaws in EPA's analysis. As proposed, the adverse effects reporting requirement would not be legally binding, and even if it were, most adverse effects would go unrecognized.

EPN thinks that the proposal fails to make the existing adverse effects reporting requirement applicable to PIPs that would qualify for the exemption. The statutory adverse effects reporting requirement in FIFRA sec. 6(a)(2) applies only to a "registrant" of a pesticide product. Because the current proposal would exempt products from FIFRA's registration requirement, there would be no registrant of an exempted product, and FIFRA sec. 6(a)(2) would not apply. FIFRA sec. 3(a) gives EPA the authority to impose requirements on unregistered pesticides. EPA cited FIFRA sec. 3(a) as its authority to impose the existing adverse effects reporting requirement in 40 CFR 174.71. The preamble to this proposal incorrectly states that 40 CFR 174.71 would apply to PIPs exempted under the proposal. EPN thinks the reporting requirement in 40 CFR 174.71, however, may apply only to the universe of PIP products covered by the exemption in 40 CFR 174.25 created by the rulemaking that promulgated the reporting requirement. Since the current proposal contains no rule text that would expressly make the provisions in 40 CFR 174.71 applicable to the newly exempted category of PIPs and the preamble and legal authority section do not cite FIFRA sec. 3(a) as authority for the Proposed Rule, it appears that EPA has failed to extend the requirement of 40 CFR 174.71 to PIPs qualifying for the exemption.

EPN thinks that EPA can easily correct the flaw described in the prior paragraph. Since the preamble clearly indicates EPA's intention to make the adverse effects reporting requirement apply to PIPs exempted by the proposal, the public has adequate notice of EPA's intent, and there is no need to re-propose the regulation. Instead, EPA simply needs to cite FIFRA sec. 3(a) as an additional basis for its final rule and include in the text of the final rule language that clearly extends the adverse effects reporting requirement to all types of exempted PIPs.

Unfortunately, correcting a legal technicality to make the adverse effects reporting requirement applicable will not overcome its practical shortcoming: most significant types of harm will not be looked for or recognized and thus will go unreported. The producer of an exempt PIP is not required to monitor reports or conduct any surveillance. Even if there were such a requirement,

surveillance is likely to identify only acute effects that affect a large percentage of the population that has contact with a raw agricultural commodity. For example, allergenic effects are likely not to be recognized. Allergies typically develop only after repeated exposures, affect only a small fraction of the population, and only manifest hours after exposure of a sensitized individual. In the case of food allergies caused by an exempted PIP, it could be even harder to identify the causative agent because isolating a food allergen becomes particularly challenging when people eat varied diets. To the extent exempted PIPs caused low-level, chronic effects only after long-term exposure, it would be virtually impossible to discern a relationship between the PIP and the harm. Even though long-term exposure to certain conventional pesticides is known to cause adverse effects, epidemiological research, often very costly, can take years of work to compile sufficient data and is generally unable to reliably measure changes affecting small fractions of the population. In sum, adverse effects that manifest over time, affect only a small percentage of the population, or result from contact with a commodity that is most commonly part of a processed food will be very hard to identify.

Moreover, in the absence of a clear definition of "adverse effect," it appears reporting would not extend to an important category of information— incidents of pest resistance. EPA's registration program has taken the view that low-risk PIPs provide safer alternatives to more risky conventional pesticides and are a "public good." Therefore, EPA has decided the efficacy of such products should be preserved. Given this view, EPA has been willing to impose mandatory requirements on the registration of PIPs to delay the emergence of pest resistance. EPA expects the PIPs exempted under this Proposed Rule would be as safe, or safer, than pesticide products registered for similar uses. Exempted PIPs, therefore, should represent an even greater public good, and knowing about potential pest resistance should be especially important. EPN thinks the Agency's final rule should make incidents involving pest resistance a reportable event.

B. EPA Needs Stronger Authorities to Address Potential Adverse Effects Caused by Exempted PIPs.

EPN also thinks that, in any final rule, the EPA should retain the authority to address quickly and effectively any risks that are identified for products that qualify for the exemption. The proposal seems to indicate that no FIFRA requirements, except the record-keeping and adverse effects reporting duties, apply to exempted PIPs. This retained FIFRA authority is completely inadequate.

If the exemption rule is finalized as proposed,and EPA discovered that an exempted product was causing serious risks, there would be almost nothing the government could do quickly in response. The Agency would need to undertake rulemaking to modify or remove the exemption and thereby reinstate its authority to act under FIFRA against the dangerous PIP. As EPA's long experience with rulemaking under FIFRA shows, it often takes two years or more to draft a proposal, hold a public comment period, review and prepare responses to comments, and draft and publish a final rule. Under the terms of the proposal, any exempted but risky PIP product could remain in the environment until the final rule became effective— an unacceptably long time during which significant harm could occur.

There are two main reasons why the authority under the FFDCA is also inadequate to address all of the potential types of harms that could be caused by exempted products. First, by exempting PIPs from the requirement of a tolerance under FFDCA section 408, the only bases for action would be: 1) a rulemaking to revoke the exemption or 2) a determination under FFDCA sec. 406 that the PIP

was a "poisonous or deleterious added substance." Neither option offers an effective way to address dietary risks.

Revoking a tolerance exemption involves rulemaking, and rulemaking can be quite slow. Although FFDCA rulemakings can move more quickly than FIFRA rules, they are still subject to the same kinds of notice-and-comment requirements. Thus, revoking the exemption for a PIP would likely not take effect for one or more years after a problem became apparent.

Using the authority in FFDCA section 406 also would present problems. First, its use against any kind of PIP could be subject to challenge: whether an exempted PIP— a pesticidal substance produced by a genetic alteration which is intrinsic to the plant— is an "added" substance. Further, the agency invoking this authority would bear the burden of proof. (The Food and Drug Administration, not EPA, would need to invoke the authority, which also would require successful interagency coordination.) Second, the FFDCA authority only extends to risks to people from consuming food. As noted in section III of these comments, there are ways in which exempted PIPs could cause risks to workers and the environment. No agency could address such risks using the authority of the FFDCA.

Because amending the FIFRA and FFDCA rules creating the exemptions would be an inadequate way of quickly and effectively addressing harms, EPA should provide in any final rule that it retains additional controls beyond the requirement to report adverse effects. Although EPN expects that EPA would seldom, if ever, need to exercise the retained authorities, collectively the following retained authorities should provide the Agency with the ability to identify where exempted PIPs are being planted and to take steps to prevent further harm from occurring:

- First, the final rule should require any company claiming to have produced an exempted plant to maintain records showing that the plant meets each condition of the exemption. This provision of a final rule would be especially important if the final rule allows the developer of a PIP to determine, without EPA concurrence, that the PIP qualifies for the exemption. In the event there is a question about the eligibility of a PIP for the exemption, EPA should have the authority to require that the developer of the PIP have kept documentation to support the claim of an exemption.
- Second, the final rule should provide that the Agency retains 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.
- Third, EPA should require seeds, when sold, be clearly labeled to identify, at a minimum, that the seeds are exempt from most FIFRA requirements because they have been genetically engineered to express a PIP, and should identify the specific transformation that has been deemed exempt. EPA could set other requirements (as it has done for other types of exempted products) regarding the labeling of these products. For example, the label might inform the grower of the status of the product under USDA's National Organic Program.
- Fourth, EPA should make it clear that a PIP is not exempt if seed containing the PIP lacks the required labeling.

- Fifth, EPA should make it clear that failure to comply with the retained requirements and submission of false information would be unlawful under FIFRA and subject the violator to potential penalties.
- Sixth, EPA should retain the ability to issue Stop Sale, Use, and Removal Orders for any exempted products that pose significant risks. This is the most critical type of authority because it would allow the Agency to act quickly to address any risks caused by an exempted PIP.

VI. The Process for Determining Eligibility for the Exemption Is Flawed.

Neither the self-determination approach nor the EPA confirmation approach is adequate. The self-determination approach gives the developer of an exempted plant too much discretion in determining whether the plant qualifies. Even the EPA confirmation approach, which involves review of materials submitted by a developer, is inadequate because it fails to specify what types of information the developer should provide.

A. EPA Should Require that All Exempt PIPs Be Submitted to EPA to Confirm That They Satisfy the Exemption Criteria.

The Proposed Rule would exempt certain PIPs from EPA oversight under FIFRA if they meet detailed scientific criteria. If those criteria are met, EPA states that those PIPs are "low-risk" and will have minimal impact on humans and the environment. However, if any one of the criteria is not satisfied, EPA believes the PIP may no longer be "low risk," and EPA oversight is needed to ensure safety. Therefore, to ensure that the complex scientific criteria for an exemption are properly applied and only PIPs that satisfy all the criteria are exempt, EPA should require developers to submit information to EPA to confirm that the PIP meets the exemption criteria, and only after EPA's decision should an exemption become effective.

The Proposed Rule sets forth an exemption from FIFRA requirements for a small subset of PIPs developed by humans using new technologies that are virtually identical to natural substances that already exist in that plant and have a history of not adversely impacting humans or the environment. These criteria include, but are not limited to, making sure 1) that the pesticidal substance comes from a sexually compatible organism, 2) that the pesticidal substance is identical to the substance from the source plant or native allele of the gene, and 3) that the pesticidal substance is not expressed at higher levels, in different tissues, or at different developmental stages than identified in the plant that is sexually compatible with the recipient plant. Meeting all these criteria will be difficult to do, and determining if a PIP meets them will involve a sophisticated analysis and careful interpretation of data. While some developers might make a scientific and objective determination that their product is exempt, others might feel pressure to interpret data to meet their business objectives and incorrectly self-determine a product is exempt. If a PIP that is not low risk is commercialized without EPA oversight, it could result in unreasonable adverse harms to humans and/or the environment.

To prevent an incorrect exemption determination (either accidental or intentional), EPA should review and approve all exemptions. Such a regulatory procedure would not be burdensome to EPA or the developers. Under the Proposed Rule, the developer still needs to certify to EPA that its

product meets the exemption criteria and keep records supporting its certification for five years. Thus, the developer must develop, collect, and analyze data to support an exemption determination, so submitting that information to EPA will result only in a *de minimis* increase in costs. Second, EPA has proposed that it would review and decide whether to approve exemptions voluntarily submitted to it within 120 days. If EPA made confirmation mandatory and responded to the developer within 120 days, that would not cause any hardship on developers wishing to quickly market their products. Therefore, there would be little or no financial impact on product development by making the confirmation process mandatory. In contrast, however, if industry incorrectly determines an exemption for one or more products, there could be enormous costs: a significant impact on humans (e.g., increased exposure to a toxin) or to the environment (e.g., production of a PIP that harms beneficial insects), and the significant expense of ensuring that the unapproved PIP had been removed from the food supply and environment. Therefore, EPA should require mandatory confirmation in its final rule. The information EPA proposed for documenting an exemption proposed in section 174.95(a)-(c) should be the information submitted to EPA for its mandatory exemption confirmation.[1]

B. If Exemption Confirmations Are Not Mandatory, EPA Should Retain the Requirement for Mandatory Submission of a Self-Determination Letter and Require That the Submission Include Additional Information.

If EPA chooses not to mandate the exemption confirmation process, then it should retain the proposed requirement that each PIP developer submit a letter certifying its PIP meets the exemption criteria. However, the letter submitted to EPA needs additional information for it to be valuable to EPA. It is not sufficient for the letter to solely state the "name of the plant-incorporated protectant." The name of the PIP may or may not be descriptive of what it does, and there is no requirement to state the plant where it will be found. At a minimum, the letter should 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 (where it came from and how it was scientifically manipulated to produce the PIP). In addition, we would propose that the developer be required to attach to the letter the information documenting how the developer reached its decision that the PIP is exempt found in section 174.95(a)-(c). The Proposed Rule would require the developer to generate that information and retain it in its records, so providing it to EPA would not be significantly more burdensome. This additional information will make it much easier for EPA to carry out its compliance functions under any final rule and FIFRA.

While we do not support any final rule that would allow PIP developers to self-determine the eligibility of a PIP for an exemption, we even more strongly oppose a final rule that would make any notification to EPA about an exempt PIP voluntary. Without at least receiving a letter identifying

[1] While proposed 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 criterion 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 criterion. 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 sexually compatible plants, EPA should require evidence of the levels found in both the donor and recipient plant in each tissue and growth stage should be provided. If the plant has known toxic or allergenic compounds, evidence should be provided that those levels in the recipient plant do not exceed those found in varieties of the plant currently eaten by humans.

the PIP claimed to be exempt, EPA (and the public) will have no knowledge about PIPs being sold to farmers. EPA will have no way to determine if the developer is meeting its recordkeeping obligation under proposed 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, should exempt PIP developers submit to EPA information regarding adverse effects, this information will be of limited value if EPA knows little or nothing about the PIP, hindering any timely investigation of the allegations and the imposition of any necessary risk management measures.

Not receiving a self-determination letter with substantive information about why the PIP purports to be exempt also will make it difficult for EPA to act when it learns about information that puts into question whether that PIP qualifies for exemption. How will EPA be able to properly consider the information it receives and determine whether an exemption is justified without knowing what information the developer relied upon for its self-determination? That process will be much more difficult and take more time if EPA has no previous knowledge of the PIP. If the information EPA receives is a report of an adverse effect with immediate impacts on humans or the environment, the extra time taken to research the PIP and its developer because the Agency does not have a self-determination letter on file 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. EPA 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 regulatory documents. EPA should provide a similar list of all PIPs produced through biotechnology that would be exempt from oversight under any final version of the Proposed Rule. At a minimum, the public should be made aware of the crop, the pesticidal trait or active ingredient, and a link to the self-determination letter/EPA confirmation determination with the accompanying information required by proposed section 174.95(a)-(c).

VII. The Proposed Rule Does Not Adequately Assess the Potential Impacts of the Proposed Exemption.

In reaching the conclusion that the proposal is justified, EPA failed to consider potential impacts of the rule that should be weighed against the benefits of the rulemaking. As explained in section I, the legal standard for exempting additional PIPs from FIFRA requirements is that the potential benefits of the rule outweigh the potential costs. EPA has asserted that the proposed exemption would offer benefits in the form of reduced regulatory burden on developers of certain types of genetically engineered plants. At the same time, EPA asserts that the proposal would have little or no cost because the exempted products would pose at most only very low risks. As discussed in section III of these comments, the proposal fails to address several theoretically possible scenarios in which exempted products could pose significant risks to human health or the environment. But in applying the "unreasonable adverse effects on the environment" standard, EPA must also consider other types of costs, beyond those risks potentially posed by properly exempted PIPs.

The proposal is deficient because it ignores two types of potentially significant costs, the possibilities that: 1) U.S. exporters of agricultural commodities will lose access to foreign markets because the U.S.-produced commodities may contain genetically engineered materials that have not been approved by the importing country, and 2) a developer will erroneously conclude that a PIP in a food crop is exempt, leading to the expense of removing the product from the food supply and the larger environment. The costs of these impacts must be weighed against the benefits of the rulemaking.

The most glaring omission of the Proposed Rule's assessment is the absence of any discussion of the potential impacts on U.S. exports. For the overall U.S. agricultural sector and for many crops, exports comprise a very significant portion of production. One practical consequence of this rule is that other countries may refuse to allow importation of U.S. agricultural commodities for which some portion may be derived from plants containing PIPs that would be exempted by this rule. Specifically, the European Union and many Asian countries have long maintained a general prohibition on the importation of food and feed commodities derived from genetically engineered plants. (These countries probably would have even less willingness to accept commodities containing products of biotechnology that have not undergone any safety review by the government of the exporting country.) Unless the scope of the final exemption created by this rule matches the scope of exemptions in other countries, it is possible that other countries could refuse to admit a food or feed item exported from the U.S. if some portion might contain an exempted PIP. That kind of trade barrier would have far-reaching economic consequences, not only for the developer of the exempted PIP, but also for all exporters of any commodity containing the PIP. EPA should analyze how PIPs covered by its proposed exemption would be treated under the regulatory frameworks of countries that are major importers of U.S .agricultural or horticultural products.

EPA's analysis also fails to address the impact of an erroneous determination by a developer that a PIP was eligible for the exemption. At the very least, once discovered, EPA would probably conclude that the product was not allowed to be sold, and that food derived from the plant containing the PIP was adulterated. Both would lead to substantial costs to remove the plant and products derived from it from the food supply—costs that would fall heavily on food processors and food retailers—and from the environment—costs that would impact farmers and possibly the entire society. Publicity given to erroneous claims to be exempted would also be even more likely to affect foreign acceptance of U.S. exports of the commodity.

VIII. The Applicability of an Exemption Is Unclear.

Finally, EPN recommends that the final rule, or the preamble to the final rule, should plainly state that the exemption from FIFRA does not automatically constitute an exemption from Tribal, State, or local requirements. EPN expects that many who develop PIPs, which they think are exempt under the rule, may not appreciate that their products continue to be subject to regulatory requirements issued by Tribal governments, State governments, or in some cases by local governments. Including such a statement would alert developers to the possibility of additional regulatory responsibilities.

Thank you for taking EPN's comments under consideration.