

SUMMARY

EPN Comments on EPA's Proposed Exemptions of Certain Genetically Modified Plant-Incorporated Protectants

December 8, 2020

On December 8, 2020, EPN submitted [comments](#) on EPA's [proposed](#) regulations that would allow certain genetically modified plant-incorporated protectants (PIPs) to be exempt from Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration and Federal Food, Drug, and Cosmetic Act (FFDCA) requirements. Plants can be genetically modified to help them produce substances that fight pests. These plant-made pesticides are called PIPs. Currently, only crops genetically modified through conventional breeding are exempt from the FIFRA and FFDCA requirements. EPA's proposed rule would extend the exemptions to include certain PIPs created through biotechnology.

EPN's comments highlighted the following concerns:

- **EPA must satisfy the demanding legal standard and consider all potential risks and benefits to promulgate an exemption under FIFRA.** EPA has not done that for the purpose of this proposed rulemaking.
- **EPN does not agree that the history of safe conventional breeding is a sufficient basis for the rule.** Instead of using a "conventional breeding" analogue 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.
- **Exempted PIP products could potentially be harmful to human health or the environment.** 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 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, which could lead to developers mistakenly believing their PIPs are exempt and introducing them into the environment.
- **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.**
- **The process for determining eligibility for the exemption is flawed.** The self-determination approach gives the developer of an exempted plant too much discretion in determining whether the plant qualifies, and the EPA confirmation approach is inadequate because it fails to specify what types of information the developer should provide to the agency for review.
- **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: the potential impacts on U.S. exports and an erroneous determination by a developer that a PIP was eligible for the exemption.
- **The applicability of an exemption is unclear.** 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.

Background

FIFRA is a federal law that sets up the basic U.S. system of pesticide regulation to protect applicators, consumers, and the environment. It is administered by EPA and the appropriate environmental agencies of the respective states. FIFRA has undergone several important amendments since its inception that have expanded EPA's present authority to oversee the sales and use of pesticides with emphasis on the preservation of human health and protection of the environment by strengthening the registration process, by shifting the burden of proving safety to the chemical manufacturer, and by enforcing compliance by users with detailed, carefully crafted instructions on the labeling of pesticide products.