



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2019-0682; FRL-10013-29]

EPA Draft Proposal to Improve Lepidopteran Resistance Management; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is making available for public comment a proposal to improve current resistance management strategies for certain Lepidopteran pests of *Bacillus thuringiensis* (Bt) plant-incorporated protectants (PIPs) in corn and cotton. EPA is soliciting input from all affected stakeholders such as corn and cotton growers, crop consultants, industry, academia, non-governmental organizations and the general public.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2019-0682, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed

information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Anne Overstreet, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are a registrant or manufacturer of Bt PIPs, grow Bt corn or cotton PIPs for crop or animal production, serve as a corn agronomist, crop consultant or extension specialist, or conduct insect resistance management-related research. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

C. How can I get copies of this document and other related information?

A copy of the proposal, titled “EPA Draft Proposal to Address Resistance Risks to Lepidopteran Pests of Bt Following the July 2018 FIFRA Scientific Advisory Panel Recommendation” is available in the docket under docket identification (ID) number EPA-HQ-OPP-2019-0682.

II. What Action is the Agency Taking?

EPA is making available for public comment a proposal to improve current resistance management strategies for certain Lepidopteran pests of *Bacillus thuringiensis* (Bt) plant-incorporated protectants (PIPs) in corn and cotton. EPA’s proposal contains measures designed to delay lepidopteran development of resistance to Bt corn and cotton PIPs in response to multiple reports of Bt resistance among some pests. The proposal was informed by advice received by the Agency from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel and from unsolicited comments received from several stakeholder

groups. EPA believes that the proposed measures will prolong the effectiveness of Bt PIPs for Lepidopteran pest control. This goal has significance, given the long safety record of Bt PIPs. If used properly, Bt PIPs greatly reduce the need for conventional pesticides and the risks they may present to human health and the environment. EPA is soliciting comments from all affected stakeholders, including corn and cotton growers, crop consultants, industry, academia, and the general public.

As part of its regulation of Bt corn and cotton PIPs, EPA requires measures to delay the development of resistance among target pests. These measures include the use of non-Bt PIP refuges to provide susceptible insects (to dilute any resistance genes in the population), annual monitoring to detect resistance in pest populations, mitigation steps if resistance develops, a refuge compliance program, and grower education.

EPA is concerned about recent cases of Bt resistance among corn and/or cotton pests that have been documented by academic and industry researchers. Bt resistance has been reported for corn earworm, fall armyworm, western bean cutworm, and southwestern corn borer. In a white paper prepared for the SAP meeting, EPA identified a number of risk factors that likely contributed to these resistance cases and could lead to more widespread resistance incidents in the future. These risk factors include a lack of “high dose” toxin expression in Bt PIPs for some of the Lepidopteran target pests, cross resistance between different Bt PIPs, cross-pollination of Bt and refuge plants in Bt corn seed blend products, poor compliance with non-PIP refuge requirements, and ineffective resistance monitoring methods. Seeking guidance on these concerns, the Agency convened a FIFRA SAP meeting in July 2018. The panel was tasked with evaluating the reported cases of resistance and EPA’s identified risk factors and providing guidance on potential improvements to the current resistance management program. Meeting

materials, including EPA's white paper, the charge to the panel, and the SAP's final report, are available in docket number EPA-HQ-OPP-2017-0617.

Following the SAP meeting, EPA developed a proposal to bolster current resistance management strategies for Lepidopteran target pests of Bt corn and cotton PIPs. EPA's proposal addresses the following aspects of resistance management:

- A proposed new resistance definition for "non-high dose" Lepidopteran pests, based on unexpected injury (UXI) levels in Bt corn and cotton;
- Enhanced resistance monitoring using sentinel plots in regions at high risk of resistance and investigations of UXI cases with standardized pest damage thresholds;
- Improved resistance mitigation for cases of confirmed resistance by implementing best management practices (BMPs) once UXI has been detected;
- Increased communications among stakeholders to provide "early warnings" on potential cases of resistance to Bt PIPs;
- Industry reporting to EPA on UXI investigations and BMP implementation.

EPA believes these proposed enhancements are consistent with the SAP's guidance and will prolong the effectiveness of Bt corn and cotton PIPs by reducing selection pressure for resistance, improving resistance monitoring, and better mitigating populations that do develop resistance. The Agency's goals are to prolong the durability of Bt corn and cotton PIPs while maintaining the environmental benefits of these management tools.

In addition to the above elements, EPA has identified three further measures for public comment, but will not take a position on them until it has reviewed all stakeholder input:

- Phase down of single traits and non-functional pyramids;
- Increasing percent refuge in seed blend products; and

- Measures to improve refuge compliance.

The Agency is seeking input on the proposal from potentially affected entities and other stakeholders, including (but not limited to) registrants of Bt PIPs, corn and cotton growers, crop consultants/agronomists, commodity groups, extension entomologists, academic researchers, and the general public. Commenters are also encouraged to provide input on the specific recommendations of the SAP, including alternate approaches or counter proposals towards addressing the issues raised by the panel and the Agency's resistance management goals. During the comment period, EPA will seek to further engage affected entities and other stakeholders through webinars in late July and August to discuss the proposal and answer questions.

Authority: 7 U.S.C. 136 *et seq.*

Dated: August 19, 2020.

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