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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2014-0805; FRL-9920-16]

EPA Proposal to Improve Corn Rootworm Resistance Management; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is making available for public comment a proposal to improve the corn rootworm insect resistance management program currently in place for registrations of plant-incorporated protectants (PIP) derived from *Bacillus thuringiensis* (Bt) in corn.

EPA is also soliciting input from all affected stakeholders including corn growers, industry, academia, and the general public.

DATES: Comments must be received on or before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2014-0805, 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>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Robert McNally, 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 PIPs for control of corn rootworm, grow corn rootworm-protected corn 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>.

II. What Action is the Agency Taking?

EPA is making available for public comment a proposal to improve the corn rootworm insect resistance management program currently in place for registrations of plant-incorporated protectants (PIP) derived from *Bacillus thuringiensis* (Bt) in corn. EPA's proposal contains measures designed to delay corn rootworms' development of resistance to Bt microbial pesticides genetically engineered into corn. This proposal responds to reports of widespread corn rootworm resistance to two Bt corn traits and reflects advice received by the Agency from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP). EPA believes that the proposed enhancements would prolong the effectiveness of Bt PIPs for

corn rootworm control significantly – which is important because of the long safety record of these PIPs. If used properly, PIPs greatly reduce the need for conventional pesticides and the risks they may present to human health and the environment. EPA is soliciting input from all affected stakeholders including corn growers, industry, academia, and the general public.

A copy of the proposal, entitled “EPA Framework for PIP Registrants: Proposal to Address Key SAP Recommendations for Corn Rootworm (CRW) IRM,” is available in the docket.

As part of its regulation of insect resistance management for Bt PIPs, EPA requires a resistance monitoring program for the major target pests of corn and cotton. The primary objective of resistance monitoring is to detect shifts in susceptibility before the onset of resistance leads to widespread field failure. Specific resistance monitoring strategies have consisted of two main components:

1. Investigation of unexpected field damage reports from growers, extension agents, consultants, or company agronomists, and
2. Monitoring for changes in susceptibility through targeted population sampling and testing.

For both objectives, bioassays are used to determine the susceptibility of each sampled population. If resistance is detected in the assays, a remedial action plan is triggered with the goal of containing the resistant population to maintain trait durability.

CRW presents a number of challenges for resistance monitoring. The insect has one generation per year, undergoes obligate diapause, and feeds subterraneanly -- factors that limit the ability to conduct susceptibility bioassays. CRW are generally less sensitive to Bt toxins than other target pests of Bt PIPs (e.g., lepidoptera). To illustrate, all of the Bt toxins registered for

CRW control (Cry3Bb1, Cry34/35, mCry3A, and eCry3.1Ab) are not considered “high dose” (as defined by EPA’s 1998 FIFRA SAP), meaning that some susceptible CRW individuals will likely survive exposure to Bt. These factors can complicate both field scouting and interpretation of bioassays. Timing is also a concern; because of obligate diapause, a sampled population may not be tested (and determined to be resistant) until the following season.

EPA is concerned about the ability of CRW to develop resistance to Bt corn PIPs. Recent reports have documented CRW resistance to two Bt traits, Cry3Bb1 and mCry3A, in parts of Iowa and Illinois. Seeking guidance in regards to these concerns, the Agency convened a FIFRA SAP meeting in December 2013. The panel was tasked with evaluating EPA’s current resistance monitoring strategy for CRW and providing recommendations for improvement. Meeting materials, including a white paper detailing EPA’s concerns with CRW resistance monitoring, the charge to the SAP, and the SAP’s final report, are available in docket number EPA-HQ-OPP-2013-0490.

Following the SAP meeting, EPA developed the mitigation proposal to enhance CRW resistance management. EPA’s proposed enhancements address the following five aspects of CRW resistance management:

- Integrated Pest Management (IPM) as a component of corn rootworm resistance management.
- Responses to unexpected damage in Bt corn fields.
- Elimination of the requirement for annual random sampling of corn rootworm from the Corn Belt.
- Use of on-plant assays for resistance determinations.

- Enhancements to current remedial action plans.

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

The Agency is seeking input on the proposal from potentially affected entities and other stakeholders, including (but not limited to) registrants of pesticides and PIPs for corn, corn growers, crop consultants/agronomists, commodity groups, extension entomologists, independent researchers, and the general public. Commenters are also encouraged to provide input on the specific recommendations provided by the SAP, including alternate approaches or counter proposals towards addressing the CRW resistance management issues raised by the panel.

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

Dated: December 31, 2014.

Robert McNally,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

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