



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2016-0310; FRL-9947-25]**

**Plant-Incorporated Protectants: Proposed Modification of Registration Procedures for Plant-Incorporated Protectants in Breeding Line Intermediates; Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA is making available for comment a White Paper describing how the Agency is proposing to modify its current approach to plant-incorporated protectants (PIPs) in breeding line intermediates (BLIs) under Section 3, Registration of Pesticides, of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). A PIP is a type of pesticide intended to be produced and used in a living plant, or the produce thereof. A BLI is an intermediate used in plant breeding to bring together, or “stack,” two or more PIPs that have each been individually engineered into different lines of a seed propagated plant. These proposed changes are intended to bring efficiencies to the Agency’s approach to PIPs in BLIs while not reducing EPA’s ability to ensure that PIPs in BLIs meet the requirements of FIFRA.

**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-2016-0310, 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](mailto: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 person or company involved with agricultural biotechnology that may develop and market plant-incorporated protectants. 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:

- Pesticide and Other Agricultural Chemical Manufacturing (NAICS code 32532) e.g., establishments primarily engaged in the formulation and preparation of agricultural and household pest control chemicals;
- Food Processing (NAICS code 311) transforming agricultural products into products for immediate or final consumption;
- Crop Production (NAICS code 111) e.g., establishments primarily engaged in growing crops, plants, vines or trees and their seeds;
- Colleges, Universities and Professional Schools (NAICS code 611310) e.g., establishments of higher learning which are engaged in development and marketing of virus-resistant plants;
- Research and Development in the Physical, Engineering and Life Sciences (NAICS code 54171) e.g., establishments primarily engaged in conducting research in the physical, engineering or life sciences, such as agriculture and biotechnology.

*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 White Paper Concerning Registration of Plant-Incorporated Protectants for Use in Breeding Line Intermediates to Produce Stacked Products is available in the docket under docket identification (ID) number EPA-HQ-OPP-2016-0310.

**II. What Action is the Agency Taking?**

EPA is making available for comment a White Paper describing a proposed modification of its approach to regulation of plant-incorporated protectants (PIPs) in breeding line intermediates (BLIs) under Section 3, Registration of Pesticides, of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This modification is proposed in light of the increasing use of BLIs to stack together several different PIPs during seed production.

A plant-incorporated protectant (PIP) is a type of pesticide defined at Title 40 of the Code of Federal Regulations as “intended to be produced and used in a living plant, or the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or the produce thereof.” BLIs are an integral part of the process used to bring together, using conventional breeding in seed production, two or more PIPs that have each been individually engineered into different lines of a seed propagated plant. EPA’s proposed

modification of its approach to regulation of PIPs in BLIs is a refocusing of the Agency's use of its authority to regulate pesticides, and maintains EPA's ability to ensure that PIPs in BLIs meet the requirements of FIFRA.

The White Paper describes how the Agency proposes to refocus its authority to regulate PIPs in BLIs. Currently, each combination of PIPs in BLIs must have a unique registration before it can be sold or distributed in commerce. Under the proposal described in the White Paper, rather than requiring a unique registration for each BLI combination, EPA would regulate PIPs in BLIs through the terms and conditions imposed on the registrations issued for each PIP to be combined through the use of BLIs in the stacked commercial PIP product. Such registrations would control which PIPs can be used in which BLIs and how the PIPs in BLIs can be used. Under the proposed approach, EPA would continue to assess PIPs in BLIs for potential risk and continue to use its FIFRA authorities to ensure safe use of PIPs in BLIs.

EPA's proposed modifications would introduce changes into its approach to PIPs in BLIs that are intended to reduce administrative costs for both the Agency and for companies using BLIs to stack several PIPs together in a single product. The proposed modification is directed solely at PIPs in BLIs used for the purpose of producing seed and is not intended to change EPA's approach to issuance of unique registrations for PIPs intended for full commercial sale and distribution. A full copy of the White Paper is available in docket EPA-HQ-OPP-2016-0310.

EPA requests comment on the proposal as a whole and on the various aspects of the proposal from both the public and industry, including seed companies, farmers, grain dealers, food processors and grocery manufacturers. EPA is specifically seeking

comment from state regulatory officials on how this proposed approach might affect their approach to pesticide regulation. EPA asks comment on the extent to which this type of approach to PIPs in BLIs relieves administrative burden and cost for the regulated community, and how frequently registrants are likely to use such an approach. EPA also requests comment on how the proposed approach would affect efficiency and cost savings, in light of the commercial seed production landscape created by the licensing of intellectual property in the form of PIPs. EPA also asks farmers, grain dealers, food processors and grocery manufacturers whether this proposed change in approach could affect their activities, including possible effects on trade, and if yes, how.

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

Dated: June 14, 2016.

Mark A. Hartman,

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

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