

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2018-0258; FRL-10015-32]

Pesticides; Updated Draft Guidance for Pesticide Registrants on Plant Regulator Products and Claims, Including Plant Biostimulants; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and seeking public comment on an updated draft guidance document entitled “Guidance for Plant Regulator Products and Claims, including Plant Biostimulants,” which was originally issued for public review and comment in March 2019. Guidance documents are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. EPA updated the original draft guidance document in response to the public comments received on the original draft guidance document. EPA is seeking an additional round of public comment on this updated draft guidance document, which is intended to provide guidance on identifying product claims that are considered to be plant regulator claims by the Agency, thereby subjecting the products to regulation as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Examples are provided of both claims that are considered plant regulator claims and claims that are not considered plant regulator claims. This draft guidance document also contains a narrative discussion regarding current and previously registered plant regulator active ingredients and their modes of action. This draft guidance does not address or attempt to provide a regulatory definition for “plant biostimulant” or for “nutritional chemical” or to change any existing regulatory definitions. After considering the comments received on this draft updated guidance, EPA intends to issue a final guidance document.

DATES: Comments must be received on or before December 30, 2020.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2018-0258, through the *Federal eRulemaking Portal*

at <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.

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:

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SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

EPA is announcing the availability of and seeking public comment on the updated draft guidance document, entitled “Guidance for Plant Regulator Label Claims, Including Plant Biostimulants,” which was originally issued for public review and comment in the *Federal Register* issue of March 27, 2019 (84 FR 11538, FRL-9986-27). This document is intended to provide guidance to EPA personnel and decisionmakers, and to pesticide registrants. EPA invites comment from prospective guidance users and other stakeholders concerning this updated draft guidance document.

B. What is the Agency’s authority for taking this action?

This updated draft guidance document is issued under FIFRA, 7 U.S.C. 136-136y. EPA regulations regarding pesticide registration and exemptions from registration are contained in 40 CFR parts 150 through 189.

C. Does this action apply to me?

This action is directed to the public in general. However, this action may be of particular interest to those persons who are producers or registrants of pesticide products making labeling claims that are considered to be plant regulator claims by the Agency, thereby subjecting the products to regulation under FIFRA as pesticides. The North American Industrial Classification

System (NAICS) codes are provided to assist you and others in determining if this action might apply to certain entities. Potentially affected entities may include, but are not limited to:

- Pesticide and Other Agricultural Chemical Manufacturing (NAICS 32532), e.g., pesticide manufacturers or formulators of pesticide products, pesticide importers or any person or company who seeks to register a pesticide.
- Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing (NAICS 325300), e.g., establishments primarily engaged in manufacturing agricultural chemicals, including nitrogenous and phosphoric fertilizer materials, mixed fertilizers, and agricultural and household pest control chemicals.

Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

D. What are the potential incremental economic impacts of taking this action?

The Agency anticipates that this guidance will reduce uncertainty, in both the regulated community and regulatory agencies, as to whether specific products are or are not subject to registration as a pesticide under FIFRA. Reducing uncertainty may reduce costs, not necessarily monetary costs, but in the effort to bring a product to market; in some situations, uncertainty could deter firms from developing products. To the extent this guidance improves the understanding as to what products must be registered and what products do not need to be registered, the effort firms expend to determine the appropriate regulatory path is reduced.

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

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.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 <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Overview

A. Intended Purpose of the Guidance

EPA intends to provide guidance to the pesticide registrant concerning plant regulator label claims, including plant biostimulant claims. Plant biostimulants (PBS) are a growing category of products containing naturally-occurring substances and microbes that are used to stimulate plant growth by enhancing water and nutrient use efficiency, and reducing abiotic stress. The increasing popularity of PBS arises from their ability to enhance agricultural productivity by stimulating natural processes in the plant and in soil using substances and microbes already present in the environment. PBS can promote greater water and nutrient use efficiency, but do not provide any nutritionally-relevant fertilizer benefit to the plant. PBS products are becoming attractive for use in sustainable agriculture production systems and integrated pest management programs, which in turn can reduce the use of irrigation water, as well as agrochemical supplements and fertilizers.

One question to consider is whether a product physiologically influences the growth and development of plants in such a way as to be considered plant regulators by the Agency and thereby triggering regulation under FIFRA as a pesticide. FIFRA section 2(u) defines plant regulators as pesticides, so they are subject to federal registration as pesticides under FIFRA, and FIFRA section 2(v) provides a definition of a plant regulator, as well as for those substances that may be excluded from the definition. Based on the plant regulator definition contained in FIFRA section 2(v), many plant biostimulant products and substances may be excluded or exempt from regulation under FIFRA depending upon their intended uses as plant nutrients (e.g., fertilizers), plant inoculants, soil amendments, and vitamin-hormone products. A key consideration is what claims are being made on product labels. This document is intended to provide guidance on identifying products and product claims that are considered to be plant regulator claims by the Agency, thereby subjecting the

products to regulation under FIFRA as pesticides. Examples are provided of claims that are considered plant regulator claims and claims that are not considered plant regulator claims.

B. The March 2019 Draft Guidance

In recognition of the growing categories of products generally known as plant biostimulants, EPA identified the need to provide guidance on identifying products and product claims that are considered to be plant regulator products and plant regulator claims by the Agency, thereby subjecting the products to regulation as pesticides under FIFRA. EPA discussed its approach with stakeholders, including the Association of American Plant Food Control Officials (AAPFCO), the Biological Products Industry Alliance (BPIA), the United States Biostimulants Coalition (USBC), and the State FIFRA Issues Research and Evaluation Group (SFIREG). In the **Federal Register** of March 27, 2019 (84 FR 11538, FRL-9986-27), EPA announced the availability of and sought public comment on a draft guidance document that was developed based on those discussions. The Agency extended the comment period twice and received 161 comments, of which 18 were requests for an extension of the comment period. The Agency has considered the public comments received and has prepared a response to comment document that is available in the docket under Docket ID No. EPA-HQ-OPP-2018-0258.

B. The Updated Draft Guidance

Given the diversity of public comments on the original draft guidance document, EPA has developed responses to comments received and updated the draft guidance accordingly. Although much of the guidance remains the same, examples of some targeted changes involve the incorporation of suggested edits to the product claims tables and the replacement of Table 4 with a narrative. EPA believes that allowing for additional public feedback will be useful in determining whether added clarification addresses the comments received on the original draft guidance document.

III. Do guidance documents contain binding requirements?

While the requirements in the statutes and Agency regulations are binding on EPA and the applicants, guidance documents are not binding on either EPA or pesticide registrants, and EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide registrants may assert that the guidance

is not appropriate generally or not applicable to a specific pesticide or situation.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

The updated draft guidance was determined to be significant due to interagency equities and interests. As such, the updated draft guidance was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This updated draft guidance document is not subject to the requirements for regulatory actions specified in Executive Order 13771 (82 FR 9339, February 3, 2017).

C. Paperwork Reduction Act (PRA)

This updated draft guidance does not create paperwork burdens that require additional approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* The information collection activities associated with pesticide registration are already approved by OMB under OMB Control No. 2070-0060. The corresponding information collection request (ICR) document is entitled "Application for New and Amended Pesticide Registration" (EPA ICR No. 0277.16). Clarifying which products are subject to pesticide regulations is not expected to have more than a de minimis impact on the number of products regulated annually and is not, therefore, expected to impact the estimated burdens. In addition, since EPA provides the language for and approves pesticide labeling, OMB has determined that pesticide labeling requirements generally qualify for the labeling exception.

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

Dated: November 19, 2020.

Alexandra Dapolito Dunn,
Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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