

## PRE-PUBLICATION NOTICE

On Wednesday, March 20, 2019, Alexandra Dapolito Dunn, the EPA Assistant Administrator for Chemical Safety and Pollution Prevention, signed the following document:

Action: Notice.

Title: **Pesticides; Draft Guidance for Pesticide Registrants on Plant Regulator Label Claims, Including Plant Biostimulants; Notice of Availability**

FRL #: 9986-27

Docket ID #: EPA-HQ-OPP-2018-0258

EPA is submitting this document for publication in the *Federal Register* (FR). EPA is providing this document solely for the convenience of interested parties. It is not the official version of the document for purposes of public notice and comment under the Administrative Procedure Act. This document is not disseminated for purposes of EPA's Information Quality Guidelines and does not represent an Agency determination or policy. While we have taken steps to ensure the accuracy of this Internet version of the document that was signed, the official version will publish in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (<https://www.govinfo.gov/app/collection/fr>) and on Regulations.gov (<https://www.regulations.gov>) in the docket identified above.

Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at <http://www.regulations.gov>. For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

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**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2018-0258; FRL-9986-27]**

**RIN 2070-ZA21**

**Pesticides; Draft Guidance for Pesticide Registrants on Plant Regulator Label Claims, Including Plant Biostimulants; Notice of Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Agency is announcing the availability of and seeking public comment on a draft guidance document entitled “Guidance for Plant Regulator Label Claims, Including Plant Biostimulants.” 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. This draft guidance document is intended to clarify that products with label claims that are considered to be plant regulator claims are subject to regulation as a pesticide.

**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-2018-0258, 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:**

*For general information contact:* Prasad Chumble, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (703) 347-8367; email address: [chumble.prasad@epa.gov](mailto:chumble.prasad@epa.gov).

*For technical information contact:* Russell Jones, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (703)308-5071; email address: [jones.russell@epa.gov](mailto:jones.russell@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Executive Summary**

###### *A. What Action is the Agency Taking?*

EPA has developed a draft guidance document, entitled “Guidance for Plant Regulator Label Claims, Including Plant Biostimulants.” 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 draft guidance document.

###### *B. What is the Agency’s Authority for Taking This Action?*

This draft guidance document is issued under the Federal Insecticide, Fungicide, and Rodenticide Act (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. EPA also provides related non-binding guidance on its website at <https://www.epa.gov/pesticides>.

*C. Does this Action Apply to Me?*

This draft guidance may be of particular interest to those who are producers of 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.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. 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 may reduce confusion, 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 of bringing a product to market; in some situations, uncertainty could deter firms from developing products. To the extent this guidance clarifies what products must be registered and what products do not need to be registered, it will reduce the effort firms expend to determine the appropriate regulatory path. However, these impacts are likely to be small and intangible.

#### *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 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. Overview**

This draft guidance document provides guidance about plant regulator label claims, including plant biostimulant claims. Plant biostimulants (PBS) are a relatively new, but growing, category of products containing naturally-occurring substances and microbes that are used to

stimulate plant growth, enhance resistance to plant pests, and reduce 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 increasingly attractive for use in sustainable agriculture production systems and integrated pest management (IPM) programs, which in turn can reduce the use of irrigation water, as well as agrochemical supplements and fertilizers.

Statutory definitions for PBS currently do not exist in the United States or overseas and there is no applicable regulatory definition of PBS under FIFRA. The draft guidance does not address or attempt to provide a regulatory definition for “plant biostimulant.” The Agency is seeking comment on this draft guidance. The Agency is also seeking comment on whether EPA should develop a definition for plant biostimulants, noting that the development of such a definition would require rulemaking.

In developing the draft guidance, EPA considered whether a PBS product, as understood by EPA, 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) includes plant regulators, defoliant, desiccant, and nitrogen stabilizers in its definition of a pesticide, so they are subject to federal registration as pesticides under FIFRA. In addition, FIFRA section 2(v) both defines plant regulator and explains which substances are excluded from the definition. Based on the plant regulator definition contained in FIFRA section 2(v), many PBS 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. Other PBS products will not involve EPA oversight because they do not fit within the specific FIFRA definition of how a plant regulator functions. A key consideration is what claims are being made on product labels. This draft document is intended to provide guidance on identifying product label 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 both claims that are considered plant regulator claims and claims that are not considered plant regulator claims.

As guidance, this document is not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice. While EPA has made every effort to ensure the accuracy of the discussion in the draft guidance, the obligations of EPA and the regulated community are determined by statutes, regulations, or other legally binding documents. In the event of a conflict between the discussion in the draft guidance document and any statute, regulation, or other legally binding document, the draft guidance document would not be controlling.

### **III. 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 Office of Management and Budget's (OMB) has determined that this draft guidance document qualifies as a significant guidance document under OMB's Final Bulletin for Agency Good Guidance Practices (<https://www.gpo.gov/fdsys/pkg/FR-2007-01-25/pdf/E7-1066.pdf>). As such, the draft document was submitted to OMB for review under Executive Orders 12866 (58

FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes to the document made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

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

This action 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 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.

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

Dated: \_\_\_\_\_.

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**Alexandra Dapolito Dunn,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*