

ALERT

EPA Releases Draft Final Plant Regulator Guidance

December 1, 2020

On November 30, 2020, the U.S. Environmental Protection Agency (EPA) published a Federal Register notice announcing the availability of the draft final guidance on label claims for plant regulators, including plant biostimulants (Pesticides; Updated Draft Guidance for Pesticide Registrants on Plant Regulator Products and Claims, Including Plant Biostimulants; Notice of Availability and Request for Comment, 85 Fed. Reg. 76562). The draft guidance is available [here](#). EPA is requesting comment on the draft final Plant Regulator guidance until December 30, 2020. EPA has stated that it “anticipates finalizing this guidance in January 2021.” EPA’s stated accelerated time frame for producing the final Plant Regulator guidance places a premium on effective participation in the public comment period that will end December 30.

EPA initially released a draft Plant Regulator guidance for comment in March 2019. I discussed the initial EPA draft Plant Regulator guidance in a March 28, 2019 Wiley Alert, “EPA Releases Draft Guidance on Acceptable Label Claims for Plant Biostimulants.” This previous Alert explained the regulatory conundrum that results in some biostimulants potentially being regulated as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), while other biostimulants can be marketed without being subject to onerous regulation as pesticides. EPA’s 2019 draft Plant Regulator guidance was intended to provide clarity to product developers as to the types of claims that would make a product subject to regulation as a pesticide.

For the most part, three of the tables included in the 2019 draft Plant Regulator guidance were useful in describing specific label and marketing claims that would render products either subject to

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regulation as plant regulator biostimulants or not subject to regulation as plant regulators. A fourth table, however, purported to identify substances that, if included in a biostimulant product, would categorically render that product subject to regulation as a plant regulator ("Table 4. Plant Regulator Active Ingredients Contained in EPA-Registered Products Having Modes of Action that Trigger Regulation Under FIFRA as a Pesticide," EPA 2019 draft Plant Regulator guidance at pages 10-11). EPA's Table 4 included a number of substances that, while they are active ingredients in some EPA-registered products, are also currently contained in biostimulant products for which plant regulator claims are not made and that are not currently regulated or registered under FIFRA as plant regulators. A fair reading of EPA's draft guidance is that EPA could take the position that it would consider any product containing one of these substances to be regulable as a plant regulator notwithstanding the claims that are made for the product.

Inclusion of Table 4 engendered substantial comment on the draft Plant Regulator guidance (see docket EPA-HQ-OPP-2018-0258 at www.regulations.gov). In the draft final Plant Regulator guidance, EPA removes Table 4 and replaces it with discussions of (1) "Substances that have no other use than as plant regulators or pesticides;" (2) "Substances that may have plant regulator and non-plant regulator activity;" and (3) "Regulatory approaches for substances and products that have multiple plant regulator and non-plant regulator modes of action." (Draft Final Plant Regulator Guidance at pages 11-15.)

Given the very shortened timeline that EPA has indicated regarding its intent to issue the final Plant Regulator guidance, agricultural inputs producers, growers, and individuals and entities interested in the production and use of biostimulant products must not fail to provide input on the draft guidance. In particular, EPA's discussions of substances that it concludes have no uses other than as plant regulators and that may have both plant regulator and non-plant regulator uses, and its discussion of its intended regulatory approaches to such substances likely will be of significant concern to many biostimulants producers. While it is always important to submit concise, substantive, and well-supported comments to administrative dockets, given the fact that EPA has indicated that it will issue the final guidance within three weeks of the December 30 close of the comment period, the necessity to do so here is even more important. Preparation of comments that adequately convey the substance of the comment and preserve the commenter's procedural rights will be of the utmost importance.

Wiley attorney Keith A. Matthews (former Director of EPA's Biopesticides and Pollution Prevention Division) is particularly well positioned to assist stakeholders in developing comments on EPA's draft final Plant Regulators and biostimulants guidance. Should you have any questions on the history and/or legal bases for EPA's action, or any other issues concerning biostimulants, please contact Keith at kmatthews@wiley.law.