

ALERT

U.S. Environmental Protection Agency Releases Draft Guidance on Acceptable Label Claims for Plant Biostimulants

Keith A. Matthews

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On March 27, 2019, the U.S. Environmental Protection Agency (EPA) published in the *Federal Register* a Notice announcing the availability of a draft guidance on acceptable label claims for “plant biostimulants” (Pesticides; Draft Guidance for Pesticide Registrants on Plant Regulator Claims, Including Plant Biostimulants; Notice of Availability, 84 Fed. Reg. 11538).[1] The publication of EPA’s announcement commenced a 60-day public comment period that will end on May 28. EPA’s draft Plant Biostimulants guidance, if completed and issued by the Agency, would provide useful direction to producers and distributors of plant biostimulant products on the types of label claims that EPA has determined will not render such products subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Agricultural inputs producers, growers, and individuals and entities interested in the production and use of biostimulant products should take advantage of the opportunity to submit substantive informative comments on EPA’s draft biostimulants guidance.

Plant biostimulants are substances (biochemical, microbial, or chemical) that enhance crop yields by physiologically “stimulating” the plant. (Plant biostimulants are different from fertilizers because, rather than simply providing nutrients to plants, they alter the way plants respond to nutrients.) Advances in plant molecular biology are leading to better understanding of the physiological processes that influence and control crop plant productivity. There is substantial interest in developing and marketing plant biostimulant products that

Authors

Keith A. Matthews
Of Counsel
202.719.4462
kmatthews@wiley.law

Practice Areas

Environment & Product Regulation
Pesticides and FIFRA

take advantage of the increased understanding of the physiology of crop plants. Presently, however, the scope of regulatory coverage of plant biostimulants is unclear, which leads to uncertainty.

Due to a quirk in U.S. pesticide law, the definition of “pesticide” includes not only substances that are intended to ‘prevent, destroy, repel, or mitigate’ pests, but also substances that alter the physiological behavior of a plant or “the produce thereof.” Such substances are called “plant regulators” and can be regulated as pesticides. If a substance is classified as a plant regulator subject to FIFRA regulation, this could significantly increase the cost of developing the product, and cause substantial delay in bringing it to market.

For years there has been uncertainty as to what claims can be made for biostimulant products that would not subject them to regulation as plant regulators, i.e., as pesticides. EPA’s draft guidance provides useful clarification as to label claims that can be made for plant biostimulant products that will not render them subject to regulation as pesticides. The draft guidance lists specific label claims that EPA has determined are acceptable plant biostimulant claims that will not subject these products to regulation as pesticides.

Examples of such acceptable non-pesticidal claims include:

- Alleviates/avoids/corrects/prevents nutrition-based/nutrient deficiency-based plant disorders
- Enhances/aids/supports/helps/improves abiotic stress tolerance
- Enhances/aids/supports/helps microbial populations
- Improves/aids/supports/helps/enhances conversion of applied nutrients to plant available forms
- Improves efficiency of applied fertilizers
- Improves nutrient uptake via natural chelating/complexing agents
- Improves/aids/supports/helps/enhances conditions for better plant establishment
- Improves overall plant nutrition
- Increases plant nutrient assimilation efficiency
- Aids/supports/helps/enhances/optimizes soil conditions for greater root mass
- Aids/supports/helps/enhances/improves tolerance of and/or resistance to abiotic stress
- Increased tolerance to sodium (Na)
- Optimizes nutrient use efficiency
- Protects plants/leaves from burning with over-application of foliar nutrients (and burning effects of salt)
- Recovers crops affected by stress due to inefficient management
- Reduces lodging
- Supports nutrient uptake
- Supports/aids/helps nutrient uptake to prevent, mitigate, or correct a specific plant nutrient disorder

EPA's draft guidance also includes a list of label claims that would subject a product to regulation as a plant regulator. The list of pesticidal claims includes:

- Enhances/promotes/stimulates fruit growth & development
- Enhances/promotes/stimulates plant growth & development
- Enhance/inhibit development
- Promote stem elongation
- Root/shoot stimulator
- Stimulates cell division, cell differentiation & cell enlargement
- Accelerates/controls/delays abscission/development/ripening/senescence
- Induce/promote/retard/suppress flowering
- Induce/promote/retard/suppress bud break
- Induce/promote/retard/suppress seed germination
- Alters/improves plant/tree shape/structure
- Controls suckering
- Inhibits/promotes sprouting
- Enhances/promotes crop/fruit/produce color/development/quality/shape
- Enhances/promotes fruit growth & development
- Fruit and nut thinner/sizer

The list of label claims that would subject a product to regulation as a plant regulator is not surprising as these claims clearly indicate an effect on the rate of growth of plants or plant tissues.

In addition, a separate administrative action could have significant impacts on the regulatory status of biostimulants. The 2018 Farm Bill requires that the U.S. Department of Agriculture (USDA) draft a report to the President and the Congress that provides recommendations as to regulatory and non-regulatory actions that will "ensure the efficient and appropriate review, approval, uniform national labeling, and availability of plant biostimulants products to agricultural producers." USDA is required to submit this report to the President and the Congress by December 20, 2019. USDA has indicated that it intends to meet this statutory deadline. In drafting the report, USDA is to consult with EPA and "the several States, industry stakeholders, and such other stakeholders" as USDA determines necessary. The consultation requirement provides an excellent opportunity for industry and other interested stakeholders to engage substantively in the development of USDA's biostimulants report.

Depending on the recommendations crafted by USDA, the biostimulants report mandated by the 2018 Farm Bill could be the next step in a critically needed clarification and re-set of the approach to regulating biostimulants in the United States. It will be incumbent on stakeholders that either are producing or that may produce biostimulants, or that use or may use biostimulants, to be involved substantively in both the EPA and

USDA processes. By allowing USDA only one year to organize, draft, and complete the plant biostimulants report, Congress has established a very ambitious deadline for the Department. Interested industry stakeholders should take steps immediately to ensure their participation in this process.

Wiley Rein 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 Plant Biostimulants guidance, and in engaging in USDA's process for developing the biostimulants report. Should you have any questions on either of these processes, or any other issues concerning biostimulants, please contact Keith at Keith A. Matthews (kmatthews@wiley.law).

[1]The draft guidance is available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2018-0258-0002>.