



December 21, 2020

OPP Docket

Environmental Protection Agency Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

RE: AAPCO's Comments on EPA's Guidance for Plant Regulator Label Claims, Including Plant Biostimulants, Docket Identification (ID) Number EPA-HQ-OPP-2018-0258-0169

This letter is submitted on behalf of the members of the Association of American Pesticide Control Officials, Inc. (AAPCO). Members of AAPCO consist of the officers charged by law with the execution of the state, territorial, provincial, and federal pesticide laws in the United States, including all its territories, and in Canada. AAPCO thanks the EPA for incorporating stakeholders comments into the current draft of the Guidance for Plant Regulator Label Claims, Including Plant Biostimulants.

The updated guidance captures the current regulatory framework and focuses the registration requirement on product claims, either made on the label or any other labeling available. While this is less than ideal it does mirror other regulatory scenarios for example; Neem being used as leaf shine; and, AquaShade and AquaShadow, where they are identical products, however one is a registered aquatic weed control the other is a pond colorant. This guidance neither helps nor harms the current regulatory framework for State Lead Agencies. It does not provide the regulatory certainty that some regulators had hoped for but does codify the current landscape for regulated entities.

AAPCO very much appreciates EPA not creating another category of exempt products similar to the current 25b exemption from regulation under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Basing registration requirements on label claims will provide a clear path forward when reviewing products.

Current State Regulatory Framework

State pesticide and fertilizer laws determine if a product requires registration, and whether it needs to be registered as a pesticide, fertilizer or soil amendment. Therefore, within the current and proposed framework, biostimulants may be regulated differently in each state. Depending on the state, the fertilizer law may require registration as a fertilizer for any product making plant growth or nutrient claims. Product labels making plant growth claims are also required by states to provide a guaranteed analysis; however, with many biostimulant products there is a challenge in producing a guaranteed analysis because the mechanism or mode of action(s) may not be understood or easily quantified. In some cases, state pesticide regulatory programs would also decide if a product was acting as a plant growth regulator (PGR), and may consult with the US EPA. The current regulatory framework does not provide one program or State or Federal agency for the regulation of biostimulants.

With lack of a single Federal Agency providing oversight, states may need to seek a legislative solution for the creation of Biostimulant Registration Programs to provide the regulatory framework, consumer protection and proof for efficacy claims regarding biostimulants.

While AAPCO was hopeful that this issue would be addressed at the federal level, it is becoming increasingly obvious that biostimulant regulatory programs will need to be developed at the state level with registration funding the programs similar to other agricultural inputs.

EPA Updated Draft Guidance

AAPCO appreciate EPA's efforts to incorporate our concerns into the Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants. AAPCO had suggested an expansion of Table 4 as well as asking for more detail. While it is no longer in table format, the specific active ingredients are listed and significant detail has been provided. While we still have concern that some of the industry will either knowingly or unknowingly ignore the primary active function of their product thereby allowing the product to be unregistered as a pesticide, the guidance provides more detail and can be used a resource for states that encounter biostimulant products in the marketplace. AAPCO continues to be hopeful that as regulatory partners a streamlined system can be established for referral of unregistered biostimulant products.

According to 40 CFR, and adequately addressed in the guidance document, a product or substance requires registration as a pesticide if;

- “The person who distributes or sells the substance claims, states or implies (by labeling or otherwise): 1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or 2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide” (40 CFR 152.15(a))
- “The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.” (40 CFR 152.15(c))

- Internal guidance from EPA, A plant growth regulator, through physiological action, is intended to accelerate or retard growth, or alter plant behavior or produce of the plant... Whether a product is considered to be a plant growth regulator depends on whether the plant response or mode of action being claimed would go beyond what would be expected from simple nutrition. The composition of the product may aid in making the determination.

Currently some, but not all states, are actively reviewing biostimulant products in the market based on claims, labeling, or ingredients. Based on the three references above; and as AAPCO interprets the draft guidance, states may see an increased burden to confirm the regulatory compliance of biostimulants.

In response to the guidance provided by EPA, AAPCO is requesting the following:

- Provide details of EPA's enforcement response when products are found non-compliant in the market or through state registration or inspection processes.
- Discuss with AAPCO a mechanism **other than enforcement case review or regional referral**, for referring unregistered products to the EPA.
- Provide clarification, or additional information, that references use sites and use rates with specific active ingredients.
- Ensure that the guidance provided by EPA is able to be edited and updated without opening the rulemaking processes. This will accommodate new technologies, label concerns, and acknowledgment of new biostimulants as they continue to advance.
- Provide clarity on what products can be used on food or feed crops, and address tolerance related issues.

AAPCO takes EPA's Draft Guidance seriously and looks forward to continuing the discussion on enforcement and a referral mechanism. In addition, AAPCO looks forward to collaborating with EPA in the development a framework for biostimulant products that is congruent with current federal and state regulatory programs.

AAPCO and EPA should develop protocols for a clear and concise regulatory path for biostimulants that encompasses all the requirements of the 2018 Farm Bill language. AAPCO does not readily see an option presented that would fulfill the Farm Bill requirements for "efficient and appropriate review, approval, uniform national labeling, and availability of plant biostimulant products to agricultural producers."

Below are concerns identified by AAPCO.

- Difficulties in a state's ability to assess label claims, evaluate product safety, and determine if there is a tolerance or tolerance exemption for products used on food or feed crops.
- Microbial biostimulants have not been adequately addressed.
- Within the options, AAPCO would need specifics about what is required and what is voluntary at industry, state and federal levels.
- Within the proposed options, AAPCO would require details about the EPA enforcement response for non-compliant products. There is a strong need for a mechanism to provide adequate compliance related funding for EPA.
- AAPCO would need to have included an option that focuses on EPA registration of biostimulants under a "PRIA Lite" review framework.

AAPCO hopes that EPA is adequately staffed to provide support and guidance for State Lead Agencies, and when warranted, provide a timely enforcement response for non-compliant products. Should EPA need additional information, please do not hesitate to contact AAPCO.

Thank you for developing the Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants and the opportunity to provide additional comments

Sincerely,



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