



July 26, 2019

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RE: AAPCO's Comments on EPA's Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants, Docket Identification (ID) Number EPA-HQ-OPP-2018-0258-0003

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 AAPCO thanks the EPA for developing the Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants.

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 amendment. Therefore, within the current framework, biostimulants may be regulated differently in each state. Depending on the state, the fertilizer law may require for any product making plant growth or nutrient claims be registered as a fertilizer. 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.

FIFRA Exempt Products and Regulatory Efforts

As biostimulants gain momentum in the market, a primary concern for AAPCO members is the lack of EPA regulation for biostimulants. If biostimulants continue down this path, there is considerable potential for a breakdown in effective and consistent regulatory action at both the federal and state level.

Another complication with biostimulants is that they are not easily defined. Biostimulants may or may not be functioning as plant growth regulators, they may be promoting plant health or crop yield because they are functioning as fungicides, insecticides, nematicides, herbicides or through some other type of action. Definitions for the term biostimulant have been proposed since the

1950s. Providing and creating a concrete definition for a type of product that is not easily defined creates concern for state regulatory agencies when connected to a regulatory framework.

Creating another exempt product category, similar to FIFRA Section 25(b) minimum risk pesticide products or devices, will increase the burden on already resource exhausted state lead agencies (SLAs). Knowing the resources that are currently consumed by the 25(b) and device registration issues and the time consuming review processes at the state level, state programs will be negatively impacted by another federally exempted product class. Many states lack the resources to take on another high demand state-specific review process. Historically, there has been little regulatory oversight or support from EPA when addressing issues associated with FIFRA exempt products, which has increased the burden on states.

Currently in states, particularly in minor crop states or states that register amendments, a fertilizer specialist will refer the biostimulant product in question to the state pesticide specialist, and then the state pesticide specialist will refer the product to the Regional EPA Office, who will then refer it to EPA Headquarters. Many hours are spent dealing with these products, and issues are often not resolved.

Recent trends have shown an increase of non-compliant and adulterated exempted products in the marketplace. With the options that are being proposed for future regulatory paths, there is great concern that biostimulants will follow the same under-regulated path. Concerns exist that the current proposal for biostimulant regulation would provide another pathway for unregistered pesticides to make it to the market. There is a need for a plan to provide adequate compliance related funding for EPA.

EPA Draft Guidance

AAPCO is apprehensive that, with EPA's Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants, industry will either knowingly or unknowingly ignore the primary active function of their product, allowing the product to be unregistered as a pesticide. State regulatory programs often rely on EPA for registration decisions, toxicological and efficacy review, and appropriate label restriction of pesticide products.

According to 40 CFR, 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:

- Expand details and references in Table 4, including microbes.
- Include enforceable language with Table 4 in reference to what is, and what is not, considered a pesticide.
- Provide details on what enforcement would look like from EPA when products are found non-compliant in the market or through state registration or inspection processes.
- Provide clarification, or additional information, that references use sites and use rates with specific active ingredients.
- Ensure that reference tables provided by EPA are 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 possible tolerance related issues.

AAPCO takes EPA's Draft Guidance very seriously and strongly supports additional guidance, enforceable language and the support from EPA to help develop a federal framework for biostimulant products that is congruent with current federal and state regulatory programs.

The EPA Guidance document should provide insight on 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 for including Table 4 in the guidance.

Sincerely,



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