



BIOSTIMULANTS

An Evolving
Regulatory Arena

HISTORICAL PERSPECTIVE ON THE REGULATORY APPROACH IN THE US

- ▶ There has been no recognized regulatory definition for “biostimulant” and regulators have not allowed it to be used on product labels or in marketing.
- ▶ So how have biostimulant products come into the US market in the past?

▶ State regulation as fertilizers

- ▶ Products with significant levels of recognized plant nutrients

▶ State regulation as soil and plant amendments

- ▶ States regulate this category of products in a variety of different ways with differing requirements which makes achieving a single product label for national distribution challenging.
- ▶ Limited claims can be made
- ▶ Difficult to identify/isolate the active ingredients (especially since many products are a complex mixture where interactions between components may play a significant role in product's effectiveness)
- ▶ Product mode of action is often not well understood
- ▶ Methods for analyzing and quantifying active ingredients may not be available

▶ State regulation as beneficial substances

- ▶ There are only a small number of materials that have been added to this category thus far.
- ▶ Ingredients must go through the AAPFCO definition process.
- ▶ Many of the same difficulties identified above come into play as part of the definition process.

▶ State regulation as plant growth regulators (PGRs)

- ▶ Many states have concerns that the products are actually Plant Growth Regulators.
- ▶ State regulators have referred products to state pesticide colleagues or to EPA.

▶ EPA regulation

- ▶ Under FIFRA, a plant regulator is any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments.
- ▶ Biostimulant products often do not cleanly fall under plant regulator definition, but may also not be clearly exempt from FIFRA.
- ▶ No good way for companies to determine if product was considered a plant regulator without attempting an EPA registration – which is a complex, time consuming and expensive process.



CURRENT REGULATORY INITIATIVES: US FARM BILL

- ▶ Provides the first regulatory definition of a biostimulant in the US
 - ▶ A substance or micro-organism that, when applied to seeds, plants, or the rhizosphere, stimulates natural processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality and yield.
 - ▶ The goal is to have a definition that will be accepted by federal and state regulators
 - ▶ This is currently only a *proposed, not accepted or final*, definition which may change.
- ▶ Stakeholders involved – USDA, US EPA, states, industry

▶ Mandate and goals

- ▶ Became law December 20, 2018: Authorizes USDA to draft a biostimulant report for the President and Congress.
- ▶ Authorizes USDA to make potential regulatory, non-regulatory, and legislative recommendations to ensure the efficient and appropriate review, approval, uniform national labeling, and availability of plant biostimulant products to agricultural producers.



- ▶ Industry goals:
 - ▶ Create/establish a regulatory framework for biostimulants that will allow for a single nationwide label
 - ▶ Establish registration requirements for dual use products that are driven by claims and intent
 - ▶ Provide clarity on acceptable claims for biostimulant products
 - ▶ Provide a clear and predictable path to market
 - ▶ Harmonize with global biostimulant regulation

▶ Current status

- ▶ USDA is currently reviewing a draft report put together by the various committees with the goal of presenting to Congress and President by December 2019.
- ▶ First step in a potentially lengthy process. The recommended approach must go through the federal legislative process to establish a legal framework.
- ▶ Necessary to get buy-in from all stakeholders, especially states. State laws would need to be updated to reflect any new federal framework.
- ▶ Differences exist among stakeholders regarding the best path forward.

CURRENT REGULATORY INITIATIVES: EPA GUIDANCE DOCUMENT

- ▶ “Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants” submitted for public comment on March 21, 2019.
 - ▶ Purpose
 - ▶ Provide insight into how and where EPA sees biostimulants fitting into the current regulatory framework
 - ▶ EPA perspective
 - ▶ Many new biological products are entering the marketplace – with uncertain regulatory status
 - ▶ Provide greater clarity to industry and states on the types of products and claims that would be considered plant regulators and those that are clearly outside of the definition

- ▶ Industry concerns

- ▶ Assessment of products should be based on intent and claims, not strictly on active ingredients

- ▶ Is there room for a dual use approach?

- ▶ Has the agency considered:

- ▶ The implications of the guidance on producers?

- ▶ On products already in the marketplace?

- ▶ On the EPA itself?

- ▶ Table 2 – Non-Pesticidal Claims

- ▶ Are these the only claims that would be allowed for a biostimulant product?

- ▶ States may limit the claims to those on this list, which stifles claim development and innovation.



- ▶ Table 3 – Plant Growth Regulator (PGR) Claims
 - ▶ Would any product making these claims be considered a PGR?
 - ▶ Are these the only claims that would require registration under FIFRA?
- ▶ Table 4 – Plant Growth Regulator Active Ingredients
 - ▶ Would any product containing these ingredients be considered a PGR requiring registration under FIFRA?
 - ▶ What happens to the products already on the market as fertilizers or soil amendments that contain some of these ingredients, such as seaweed or humic acid products?



▶ Current status

- ▶ Comments from all interested parties were due July 28, 2019.
- ▶ Multiple stakeholder groups, including BPIA, the Biostimulant Coalition, CropLife and others prepared responses based on member comments.
- ▶ Companies were encouraged to submit their own comments as well.

CURRENT REGULATORY INITIATIVES: PRIA IV

- ▶ PRIA IV - Regulatory determination option (M0009 action)
 - ▶ Establishes a framework to determine whether a product requires registration under FIFRA
 - ▶ Has a defined timeline for EPA review (4 months) and a formal process, including fees
 - ▶ Companies must be prepared to accept that EPA's determination may not be the answer they want

FUTURE OUTLOOK

- ▶ Consequences of current initiatives
 - ▶ Some states are already using the draft EPA guidance in making product registration decisions
 - ▶ Some states are interpreting the tables presented in the guidance as checklists for assessing product claims and ingredients
 - ▶ Other states are granting “provisional” registrations, which could be revoked based on the final EPA Guidance
 - ▶ Companies are eager to start using the term biostimulant – which is still only a proposed definition. States still do not accept use of the term.
 - ▶ EPA and USDA initiatives are happening in parallel but are not in alignment. This needs to be resolved or there will be continued uncertainty for producers and states.



Biostimulant certification program under USDA – similar to the USDA NOP program



A federal registration requirement housed under USDA



FIFRA legislation revisions to clarify PGR definition and include biostimulant definition as excluded category

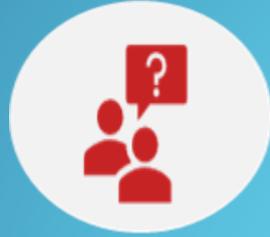


Fleshing out the definition of “nutritional chemicals” as an excluded category under FIFRA to include biostimulants



EPA requires product registration as pesticides for many types of biostimulants as described in the current guidance. This approach would be at odds with other global efforts, such as recent EU legislation on biostimulants. The cost and timeframes for such registration could put US producers at a competitive disadvantage and hamper innovation.

POSSIBLE OUTCOMES



Whatever happens at the federal level, if anything, will also have to be accepted at the state level. State laws may need to be changed to reflect new approaches, as many states currently include substances such as humic acid in their laws as non-pesticidal products.



States may start requiring companies to obtain a M0009 determination from EPA before registering products they are unsure about



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