

Biostimulant Overview



AAPCO MEETING ALEXANDRIA

MARCH 4, 2019

Biostimulant Industry Goals

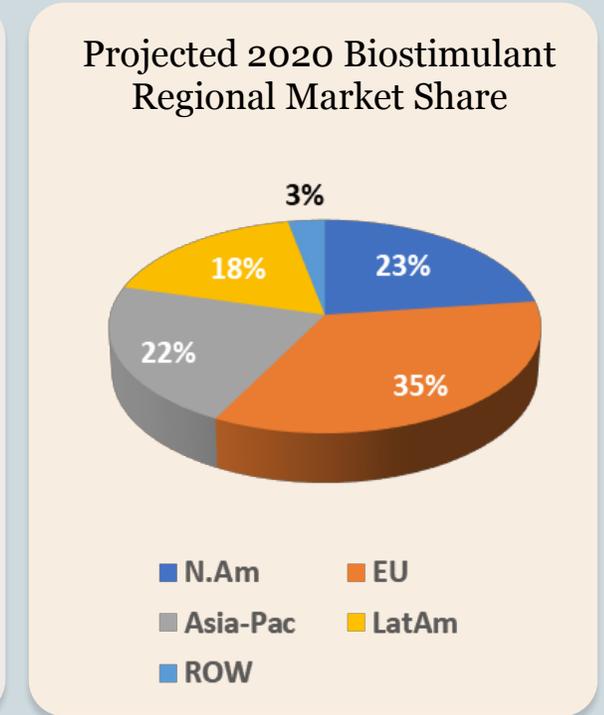
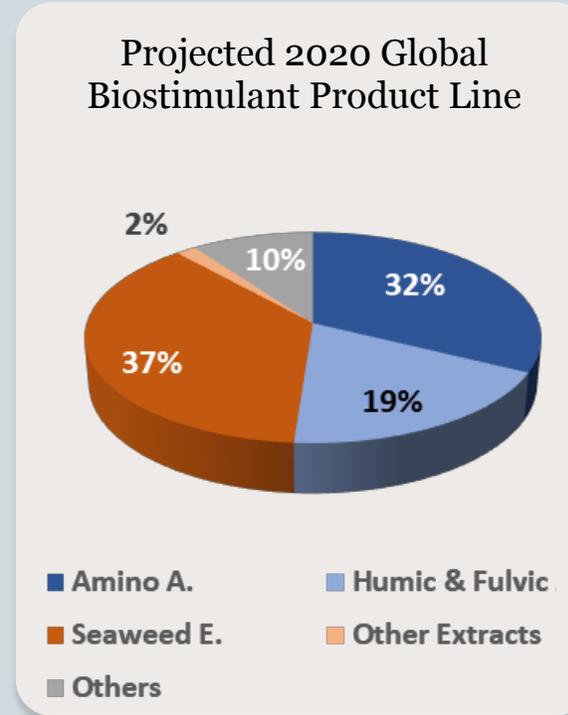
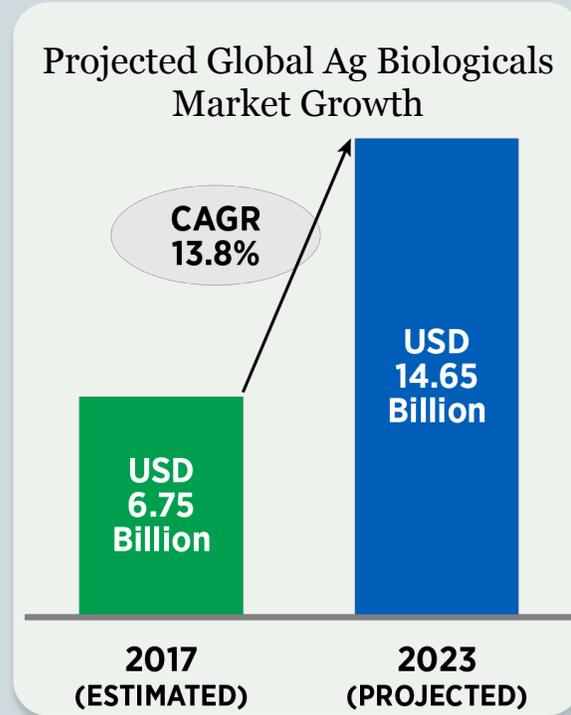


An improved regulatory process for biostimulant products that will enable an effective & efficient registration & review process to the benefit of all stakeholders.

- ✓ Ability to use the term “biostimulant”
- ✓ Make biostimulant claims
- ✓ Credibility for the industry
- ✓ Clear, consistent, predictable process to market
- ✓ One label for all states
- ✓ Safety assessment
- ✓ Dual uses for active ingredients
- ✓ Global consistency

“Biostimulant” not just a marketing term

**Biologicals market
projected to be
evenly split between
biopesticides &
biostimulants**



Biostimulants – A Unique Category of Agricultural Input



Pesticides

Prevent, destroy, repel or mitigate a pest or intended as a plant regulator, defoliant, or desiccant

Insecticide, fungicide, herbicide, plant regulator, defoliant, desiccant

Insecticides: carbamates, neonicotinoids, pyrethroids, microbials, etc.



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Biostimulants

A substance or micro-organism, when applied to seeds, plants, or soil, supports or improves nutrient availability, uptake & efficiency, tolerance to abiotic stress or crop quality and yield. A plant biostimulant is neither a pesticide, plant regulator, fertilizer, agricultural liming material nor animal & vegetable manure

Microbial, extracts, acids, other

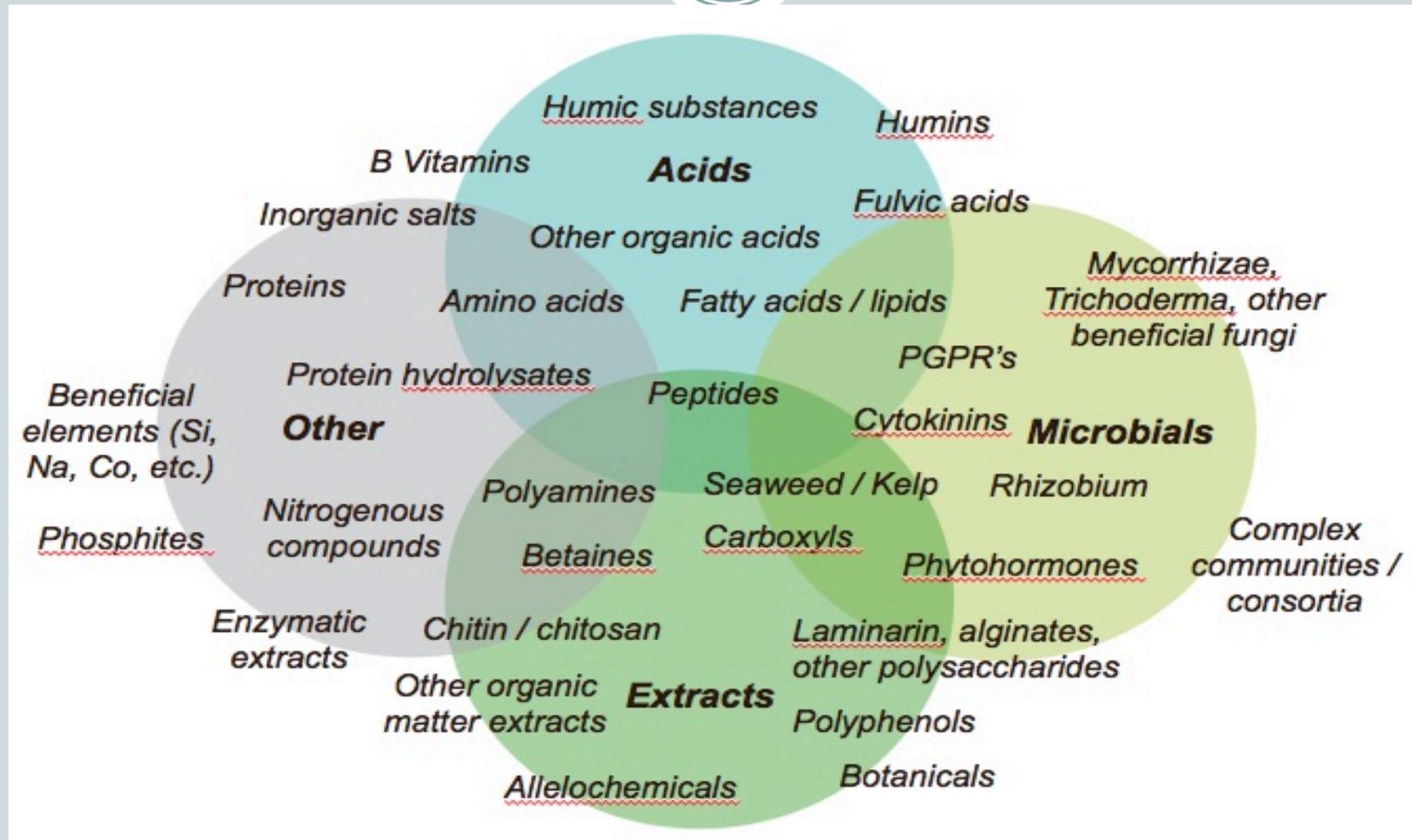


Fertilizers

Substance containing one or more recognized plant nutrient(s) used for its plant nutrient content and designed for use or claimed to have value in promoting plant growth, except unmanipulated animal and vegetable manures, marl, lime, limestone, wood ashes and other products exempted by regulation

Macro and micro nutrients

The Emerging Landscape of Biostimulant Products



Biostimulant Industry & Agency Timeline

- 2013 – 2015** – US Biostimulant Coalition works with AAPFCO to define biostimulants. AAPFCO does not define biostimulants. Established “Beneficial Substance” category
- 2015** – USBC turns attention to EPA. Meets to discuss how products are not plant regulators in traditional sense and requests regulatory clarity. USBC suggests EPA define “nutritional chemicals” – a category along with plant inoculants, soil amendments, nutrients and trace minerals currently excluded from FIFRA
- 2016** – USBC/ BPIA collaborate and meet with EPA on how biostimulants are distinct from pesticides/ plant regulators. USBC gives EPA several documents clarifying excluded category claims and describes nutritional chemicals. EPA clarifies guidance will cover claims but needs more time to define nutritional chemicals. Guidance document expected to publish in 2017 but Trump is elected, all regulatory actions require further review.
- 2017** – USBC and BPIA meet with EPA in May, guidance is on-track for publication before end of year. BPIA and USBC meet with USDA to discuss potential options for APHIS to regulate biostimulants. EPA informs industry in October that guidance is delayed due to required OMB review. USBC and BPIA members agree on language for 2018 Farm Bill defining biostimulants and requesting establishment of workgroup to develop regulatory framework for biostimulants
- 2018** – House and Senate Ag Committees support biostimulant language in Farm Bill. December: Farm Bill signed into law. EPA confirms guidance document is unlikely to be published in 2018 and does not have bandwidth for additional effort on defining nutritional chemicals and biostimulants. USDA agrees to coordinate a multi-stakeholder workgroup to develop framework

Ongoing Federal Efforts



- EPA: Guidance Document: November 13, 2018, OMB: OIRA
- Farm Bill: Became Law December 20, 2018: authorizes USDA to draft biostimulant report to Congress. Includes description of plant biostimulant.
- USDA: Previous Biostimulant Stakeholder Meetings Facilitated by APHIS:
 - July 18, 2018
 - October 17, 2018

OMB/EPA



- Guidance for Plant Biostimulant Products sent to OMB on November 13, 2018
- Currently undergoing OMB Review
- Biostimulant Industry met with OMB on Feb. 4, 2019 to get status update. They are still working on it.

The screenshot displays the Reginfo.gov website interface. At the top, the header includes the seal of the Executive Office of the President, the text "OFFICE of INFORMATION and REGULATORY AFFAIRS", "OFFICE of MANAGEMENT and BUDGET", and "EXECUTIVE OFFICE OF THE PRESIDENT". The "Reginfo.gov" logo is prominently displayed. To the right, it identifies the "U.S. General Services Administration" and "GSA". A search bar is present with radio buttons for "Agenda", "Reg Review" (which is selected), and "ICR". A navigation menu below the header lists: Home, Unified Agenda, Regulatory Review, Information Collection Review, FAQs / Resources, and Contact Us. The main content area is titled "Pending EO 12866 Regulatory Review" and contains the following details for a specific entry:

RIN: 2070-ZA21 View EO 12866 Meetings	Received Date: 11/13/2018
Title: Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims	Stage: Proposed Rule
Agency/Subagency: EPA / OCSPP	Economically Significant: No
Legal Deadline: None	Affordable Care Act [Pub. L. 111-148 & 111-152]: No
International Impacts: No	Dodd-Frank Wall Street Reform and Consumer Protection Act, [Pub. L. 111-203]: No

Farm Bill Language



- *“(a) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit a report to the President and Congress that identifies any potential regulatory, non-regulatory, and legislative recommendations, including the appropriateness of any definitions for plant biostimulant, to ensure the efficient and appropriate review, approval, uniform national labeling, and availability of plant biostimulant products to agricultural producers.*
- *(b) CONSULTATION.—The Secretary shall prepare the report required by subsection (a) in consultation with the Administrator of the Environmental Protection Agency, the several States, industry stakeholders, and such other stakeholders as the Secretary determines necessary.*
- *(c) PLANT BIOSTIMULANT.—For the purposes of the report under subsection (a), the Secretary—*
- *(1) shall consider “plant biostimulant” to be 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; and*
- *(2) may modify the description of plant biostimulant, as appropriate.”*
- Clarifying Report Language, included in the Farm Bill states:
- *"The Managers recognize the importance of plant biostimulants as an emerging technology for production agriculture. The Managers intend for the Secretary of Agriculture, in consultation with Administrator of the EPA, States, and relevant stakeholders, to provide a report to Congress that identifies any potential regulatory, non-regulatory, and legislative recommendations, including the appropriateness of any definitions for plant biostimulants. The Managers intend for this report to facilitate the regulatory framework for plant biostimulant products and ensure the efficient and appropriate review, approval, uniform national labeling, and availability of these products to agricultural producers*

Overview of Sacramento Workshop



- Biostimulant Stakeholder Workgroup (BSW) discussed the current regulatory environment for plant biostimulant products, with the input of biostimulant manufacturers, distributors, relevant industry associations, and Federal and State regulatory authorities, and propose recommendations for improvement.
- BSW will develop list of recommendations to assist USDA in drafting Farm Bill authorized report.

What are we suggesting? / What are we asking for ?



We're suggesting:

- More regular dialogue on this topic
- Working partner in AAPFCO committees
 - ✦ Uniform label
 - ✦ Efficacy data (potential new committee)
- More routine communication / more participation in AAPFCO committees related to biostimulants / beneficial substances

We're asking from AAPFCO:

- Dialogue with us
- Input into USDA report
- Explain how uniform bills and model documents work?
- Suggest other mechanisms that might be helpful? SUIP?
- Help us make to make improvements for both industry and state regulators
- Share your thoughts ?

Biostimulants raise a lot of questions



- What are they, is everything included in their definition?
- Aren't they covered by existing fertilizer regulations?
- Isn't "biostimulant" just a marketing term?
- Aren't they really just "beneficial substances"?
- Are companies trying to avoid regulation as pesticides?
- How do we know they really work?
- How can they be fertilizers when their nutrient content doesn't support the benefits claimed?
- What data do they have to justify their claims?
- Where is EPA in regulating them?

Questions?

