

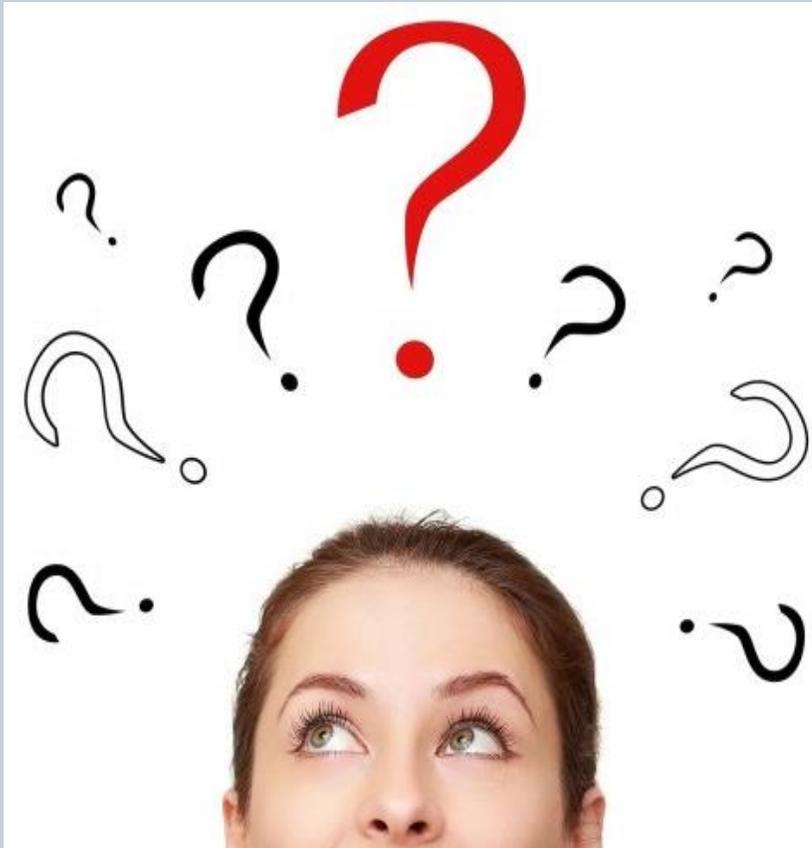
Biostimulant Overview



AAPFCO METHODS FORUM
NEW ORLEANS
FEB 20, 2020

AMY ROBERTS, LALLEMAND PLANT CARE
ON BEHALF OF
US BIOSTIMULANT COALITION
&
BPIA

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?
- What does the USDA Farm Bill report say?

Biostimulant Industry Goals

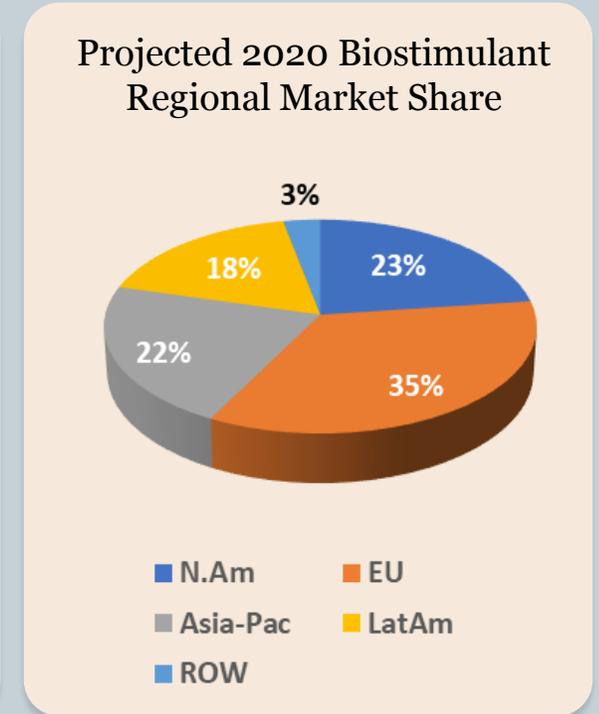
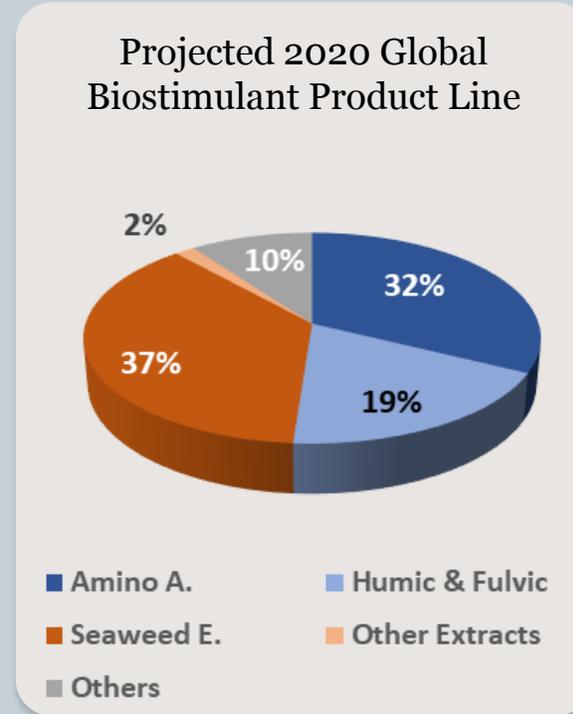
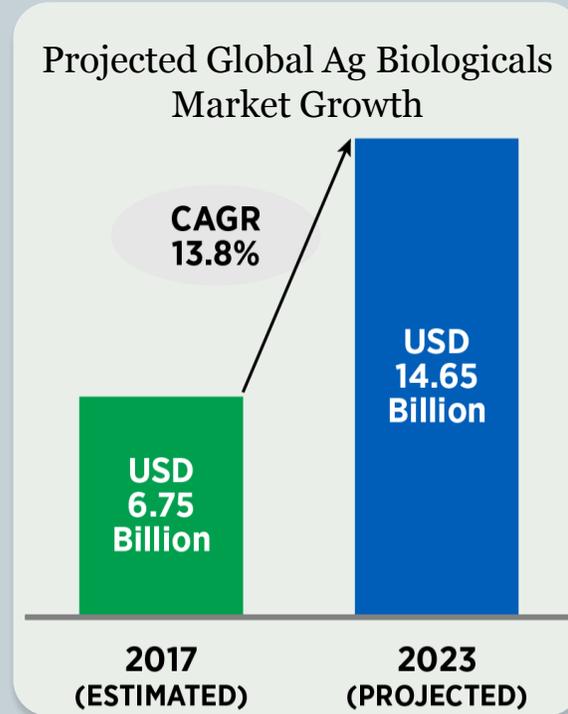


An improved regulatory process for biostimulant products that will enable an effective & efficient registration & review process to the benefit of all stakeholders.

- ✓ 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 multiple function 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

Substance(s), microorganism(s), or mixtures thereof, when applied to seeds, plants, the rhizosphere, soil or other growth media, **act to support a plant's natural nutrition processes independently of the biostimulant's nutrient content**, thereby, improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress; and consequent growth, development, quality or yield.

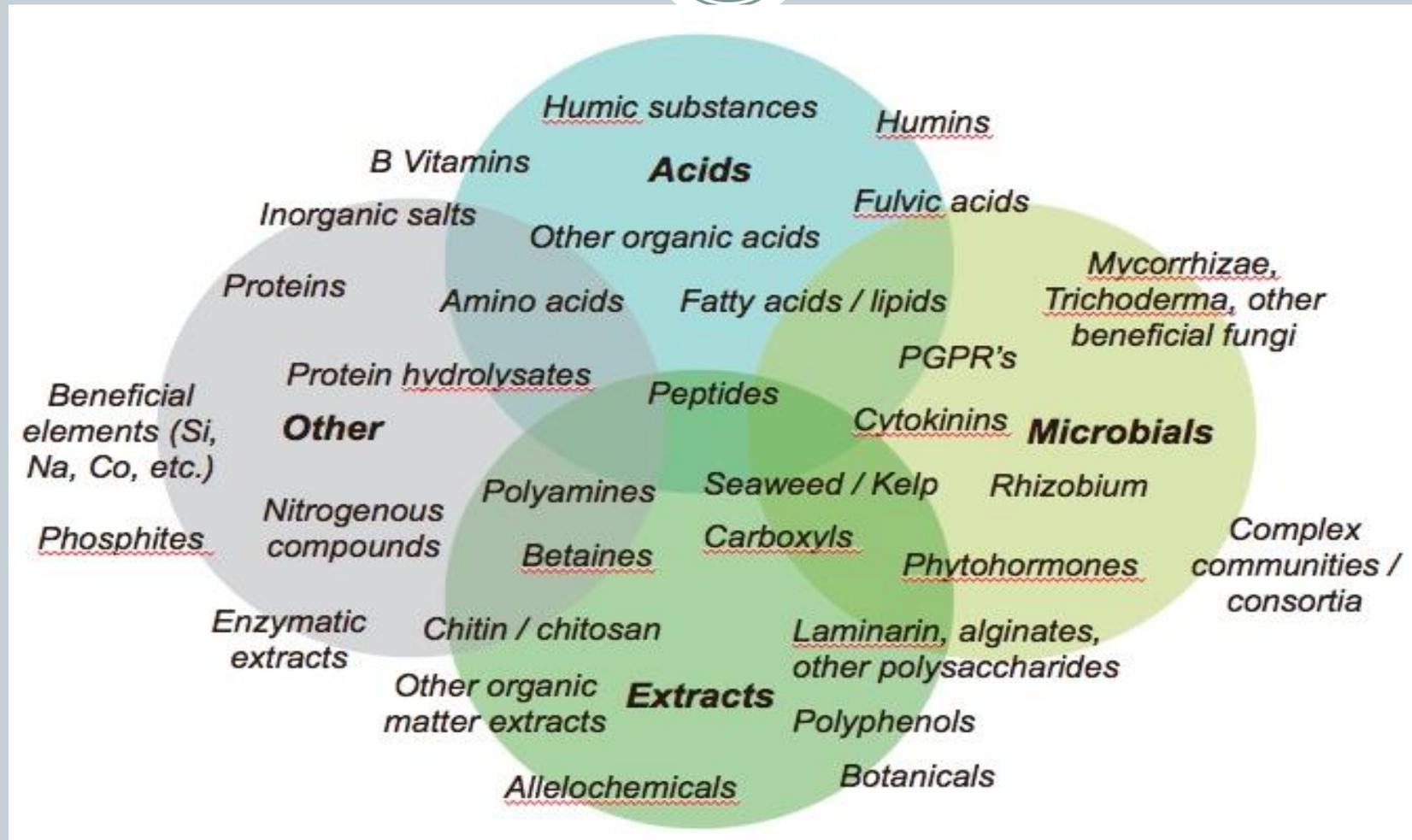


Fertilizers

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.
- 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** BPIA and USBC meet with USDA to discuss potential options for APHIS to regulate biostimulants
USBC and BPIA members agree on language for 2018 Farm Bill defining biostimulants and requesting establishment of a study 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 report.
- 2019** March: EPA publishes draft guidance. Biostimulant industry submits comments in July.
- 2020** USDA convenes stakeholder meetings and accepts stakeholder input in June of 2019. Uses that input to develop report. Report finalized Dec 2019.

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*

USDA Report to Congress



USDA Report Includes 6 Options.

- Regulatory/non-regulatory
- Federal legislation/rulemaking required
- State legislation/rulemaking required
- Defines a “plant biostimulant”
- Addresses need for uniform national labeling
- Implications, changes for FIFRA, Plant Protection Act, FFDCA
- Estimated time of completion
- Preferred by industry, States, Federal agencies

USDA Report to Congress

• Comparing the Options



Function	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
Non-regulatory option						✓
Regulatory option	✓	✓	✓	✓	✓	
Federal legislation required				✓	✓	
Federal rulemaking required				✓	✓	
State legislation required	✓ ¹	✓	✓	✓ ¹	✓	
State rulemaking required	✓	✓	✓	✓	✓	
Plant biostimulant defined		✓	✓	✓	✓	
Uniform national labeling		✓ ¹	✓	✓	✓	
FIFRA amended (EPA)				✓	✓	
Plant Protection Act amended				✓ ²	✓ ²	
Implications for FFDCA (FDA)				✓	✓	
Based on model bill for States		✓	✓			
Federally facilitated			✓	✓		✓
Facilitated by others	✓	✓			✓	
Process Verified Product		✓	✓		✓	✓
Voluntary	✓ ¹					✓

Option 3: Described



Creation of “Model Bill” with USDA Facilitation

Identical to Option 2 except that USDA (Instead of NASDA) would facilitate a working group of state regulatory officials, AAPFCO, industry.

May speed up the process.

Favored by NASDA, Federal agencies.

Function	Opt 3
Non-regulatory option	
Regulatory option	✓
Federal legislation required	
Federal rulemaking required	
State legislation required	✓
State rulemaking required	✓
Plant biostimulant defined	✓
Uniform national labeling	✓
FIFRA amended (EPA)	
Plant Protection Act amended	
Implications for FFDCA (FDA)	
Based on model bill for States	✓
Federally facilitated	✓
Facilitated by others	
Process Verified Product	✓
Voluntary	

2020 Projected Biostimulant Industry Activity



1. Review USDA report: **Complete**
2. Prepare and finalize position paper on USDA report: **In progress**
 - Position paper will focus on *hybrid* of Options 3 and 4.
 - Option 3 asks USDA to convene stakeholder meetings to work towards developing a model bill at the state level. Elements from Option 4 will need to be addressed over the longer term to resolve ongoing regulatory questions with EPA.
3. Support implementation of USDA report, after discussion with Congress, USDA and related State and industry stakeholders. **To begin soon.**

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 (Method Forum or potential new committee)
- More routine communication / more participation in AAPFCO committees related to biostimulants / beneficial substances

We're asking from AAPFCO:

- Dialogue with us
- Coordination with USDA as we work to implement report
- Suggest other mechanisms that might be helpful? Model bill and/or SUIP?
- Help us make to make improvements for both industry and state regulators
- Share your thoughts ?

Questions?

