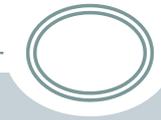


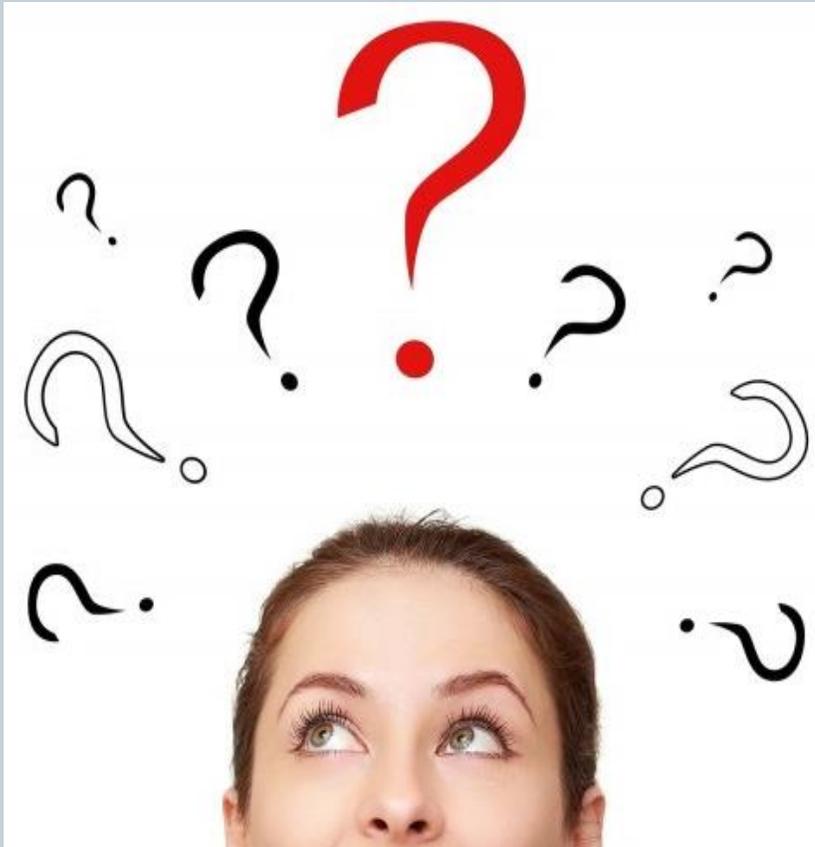
Defining, Analyzing and Characterizing Biostimulants



**AAPFCO METHODS FORUM
ALBUQUERQUE, NM**

FEBRUARY 13, 2019

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?
- Will biostimulants affect my NCAA Final 4 bracket?

Biostimulant Industry Goals

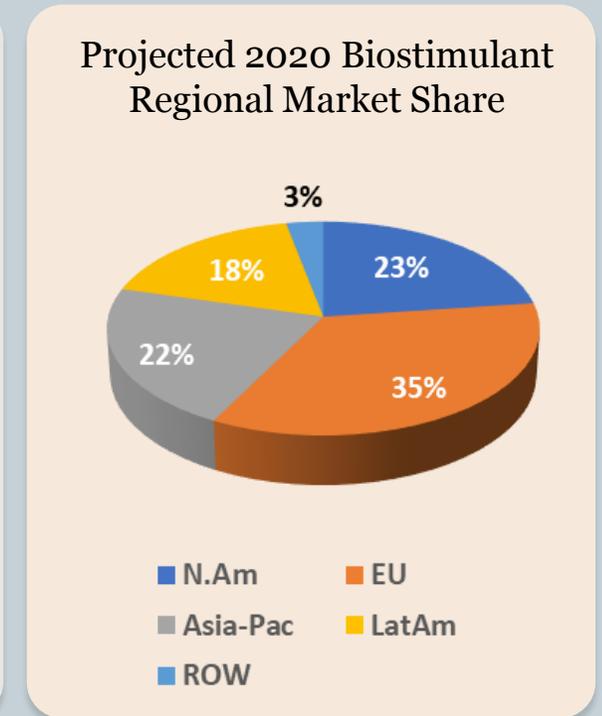
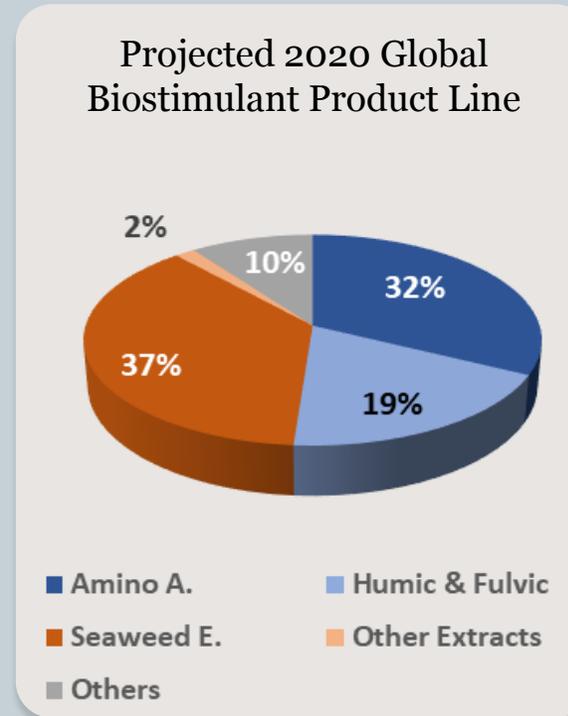
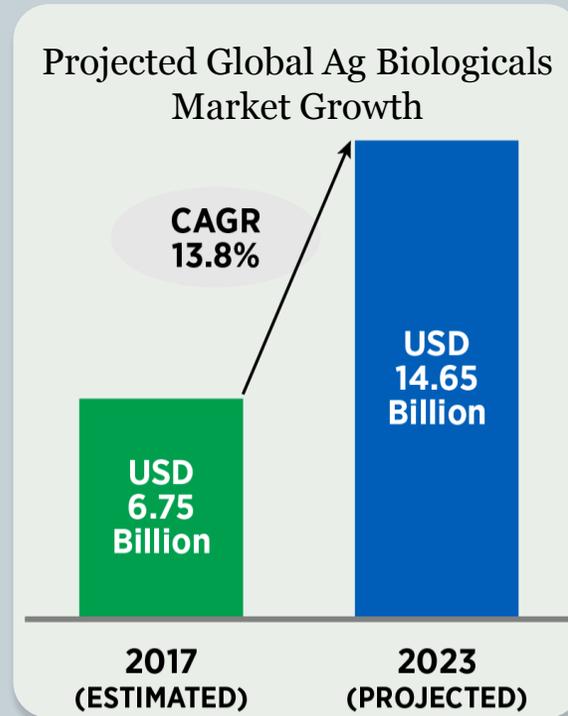


An improved regulatory process for biostimulant products that will enable an effective & efficient registration & review process to the benefit of all stakeholders.

- ✓ 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” is 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 growing media, supports or improves nutrient availability, uptake or efficiency, tolerance to abiotic stress or crop quality and yield. A plant biostimulant is neither a pesticide, fertilizer, agricultural liming material nor animal or vegetable manure

Microbial, extracts, acids, other

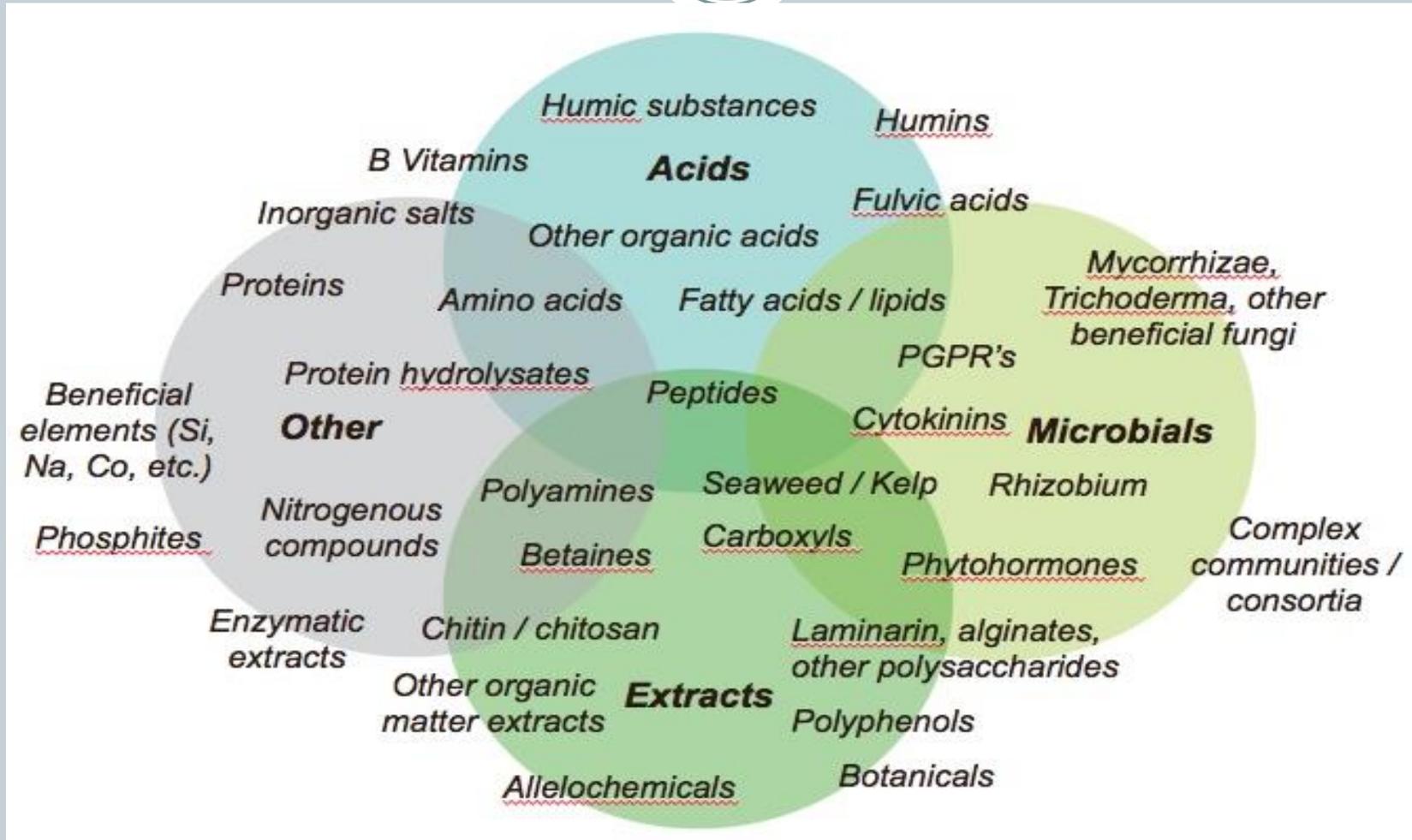


Fertilizers

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



Ongoing Federal Efforts



- EPA: Guidance Document: November 13, 2018, OMB
- Farm Bill: Became Law December 20, 2018:
 - *Authorizes USDA to draft biostimulant report to the President and Congress.*
 - *Identify 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.*
- USDA: Biostimulant Stakeholder Meetings Facilitated by APHIS:
 - July 18, 2018
 - October 17, 2018

In the absence of State or Federal Biostimulant regulation...

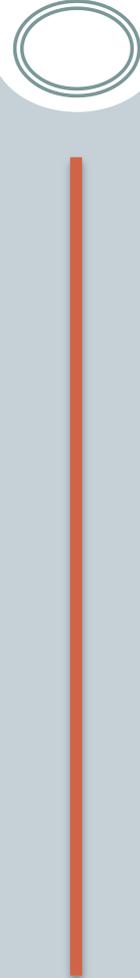


Industry can:

- Establish science-based criteria to qualify Biostimulants and product claims
- Define “Biostimulants”
- Proactively develop a Biostimulant certification program e.g. USDA AMS
- Require third party (e.g. USDA) certification of conformance with criteria
- Establish a national registry of certified Biostimulant products
- Differentiate the quality and safety of Biostimulants from non-certified products
- Enhance the credibility of the Biostimulant industry
- Achieve a level of harmonization with Biostimulant standards established ex-US

A Biostimulant Certification Program would not replace State or Federal regulation

Criteria for Biostimulant Certification



- Microbial contaminants
 - Heavy metal contaminants
 - Product composition & characterization
 - Verification of product claims
 - Human and environmental safety risk assessment
 - Product Labelling
- Methods, sampling, and appropriate data and/or documentation to be established for each criteria
 - ANSI, ISO, OECD, and/ or industry standards exist for many criteria or in development in EU and elsewhere
 - Others to be developed by Industry Workgroup

Example - Verification of Efficacy Claims



- Focus placed on ensuring the methodology employed is scientifically credible, validated and auditable.
- Credible parameters for verifying claims of efficacy to include:
 - Appropriate experimental design and statistical analysis (replication, clearly defined variables and sampling methods, positive and negative controls, appropriate statistical analysis)
 - Representative rates, crops and application methods evaluated to support labeled uses
 - If tested in the field – multiple locations
- Flexibility enables a company to determine best methodology for their product

Product composition, characterization and labelling



- Guaranteed product contents confirmed using scientifically credible, verifiable and auditable methods.
- Label reflects product contents, efficacy and other claims
- Flexibility enables company to determine best methodology for their product
- Methodology employed can be maintained as confidential but audited by qualified third party

Human and environmental safety risk assessment



- Based on the type of biostimulant
- Decision tree approach
- Qualified literature review to support history of safe use
- Data development, studies, if needed
- More specific criteria to be developed

In summary...



As the Biostimulant industry continues to work with AAPFCO, and EPA issues guidance or regulations that more clearly defines a plant regulator or Biostimulant, the development of science-based criteria to qualify Biostimulants and product claims may serve as the basis for industry certification or potential State or Federal regulations that harmonize with regulatory programs established in other countries.



Thank You

