

# Developing Collaborative Strategies to Enhance Credibility of the Plant Biostimulant Industry

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# Biostimulants raise a lot of questions

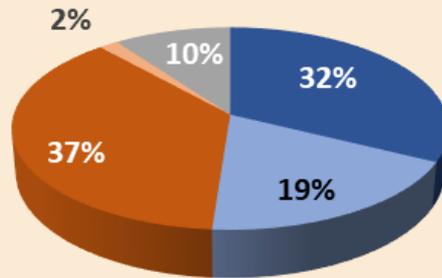


- What are they, is everything included in their definition?
- Aren't they covered by existing fertilizer regulations?
- Aren't they really just “beneficial substances”?
- Isn't “biostimulant” just a marketing term?
- Are companies trying to avoid regulation as pesticides?
- How do we know they really work?
- What data do they have to justify their claims?
- Where is EPA in regulating them?

# “Biostimulant” is not just a marketing term

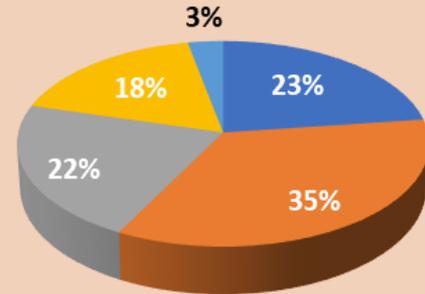
**Biostimulant sales estimated at over \$3B globally by 2020**

Projected 2020 Global Biostimulant Product Line



■ Amino A.      ■ Humic & Fulvic  
■ Seaweed E.    ■ Other Extracts  
■ Others

Projected 2020 Biostimulant Regional Market Share



■ N.Am      ■ EU  
■ Asia-Pac    ■ LatAm  
■ ROW

# Biostimulants – A Unique Category of Agricultural Input



## Pesticides

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

\*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



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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

# Industry Focus Has Been on Two Initiatives

## Industry Goals\*:

Ability to use the term “biostimulant”

Make biostimulant claims

Credibility for the industry

Clear, consistent, and predictable  
process to market

One label for all states

Safety assessment

Multiple functions for active ingredients

Global consistency

## USDA

*Report to Congress on Plant Biostimulants  
(required by 2018 Farm Bill)*

*USDA-led Biostimulant Work Group*

## EPA

*“Draft Guidance for Plant Regulator Label  
Claims, Including Plant Biostimulants”*

*\* As articulated by Biostimulant Industry Workgroup (BIW), a collaboration led by the  
Biological Products Industry Alliance and the US Biostimulant Coalition*

# Composition of USDA Biostimulant Workgroup

## Federal:

USDA Animal Plant Health Inspection Service  
USDA Agricultural Marketing Service  
EPA Biopesticides and Pollution Prevention  
Division  
FDA Consumer Safety

## State:

National Association of State Departments of  
Agriculture  
Association of American Plant Food Control  
Officials  
Association of American Pesticide Control Officials

## Industry:

American Seed Trade Association  
Biotechnology Innovation  
Organization  
Biological Products Industry Alliance  
Humic Products Trade Association  
The Fertilizer Institute  
United States Biostimulant Coalition



# USDA Biostimulant Timeline



May '18:  
Industry  
Solicits USDA  
Participants

Jul '18: USDA  
WG Kickoff  
Meeting

Dec '18: Farm  
Bill Signed by  
President

- Sep '18 –  
May'19: WG  
Meetings and  
Weekly  
Subgroup Calls

Jun '19:  
Industry  
Recommends  
Framework for  
USDA Report  
to Congress

# U.S. Congress: Passage of 2018 Farm Bill - Signed into law by President Trump on December 20, 2018

## SEC. 10111. Report on Plant Biostimulants

- Governs various facets of U.S. farm policy for 5 years
- First U.S. law to address biostimulants
- Requires USDA to provide a report to Congress addressing:
  - Regulatory, non-regulatory, and legislative recommendations for biostimulants
  - Biostimulant definition
  - Uniform national label



# Industry Recommendations to USDA on Report to Congress



## 1. Enact short-term legislation to:

- Define plant biostimulants (PBS).
- Direct EPA to amend current pesticide regulations (40 CFR Part 152) to:
  - (i) incorporate the same uniform national definition of “plant biostimulant” and
  - (ii) exclude PBS from regulation as plant regulators (or pesticides).
- Authorize and direct USDA to develop a uniform national framework for plant biostimulant products in consultation with the States, appropriate state organizations, industry and other stakeholders.

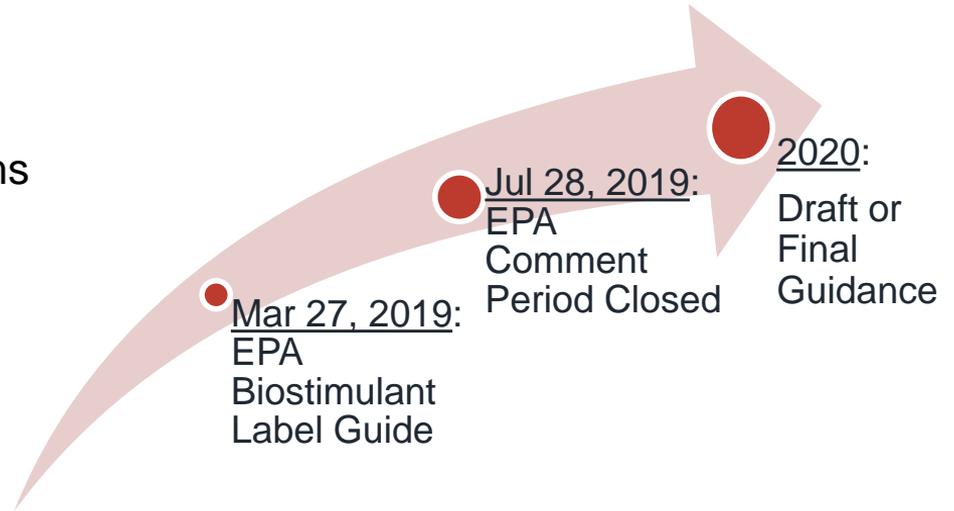
## 2. USDA to establish and facilitate a stakeholder Task Force to establish regulatory and non-regulatory requirements for a uniform National PBS Framework.

- Develop a more uniform approach to the state regulation of PBS.
- Establish an accepted common label and consistency in product claims.
- Establish safety and efficacy certification standards and processes.



# U.S. EPA: Guidance on Plant Biostimulants

- Provides guidance on when products are considered “plant growth regulators” and subject to EPA pesticide registration
- Provides guidance on what types of claims can be made for EPA registered biostimulant/plant growth regulator products





# Industry's Comments to EPA on Draft PBS Guidance

- Recognize Plant biostimulants (PBS) support natural plant nutrition processes and optimal plant health.
- Allow product claims reflecting natural consequence of these benefits, e.g. enhanced: germination, seedling vigor, root/ shoot growth, yield, quality and abiotic stress tolerance.
- Recognize PBS may have multiple functions depending on formulation, rate and application.
- Eliminate Table 4 (list of “plant regulator active ingredients”) from the Guidance, as FIFRA is a *claims, knowledge and intent* based approach...not substance-based
- Coordinate with USDA on a legal PBS definition consistent with 2018 Farm Bill.
- Define “Nutritional Chemicals” under FIFRA as a category already excluded from regulation.
- Expand current vitamin-hormone exemption to allow use of such products on food crops.

# Potential Roadmap to a Uniform PBS National Framework

## Congress Passes “Biostimulant Act”

- Define plant biostimulant (PBS)
- Direct EPA to amend CFR:
  - incorporate definition of “plant biostimulant”
  - exclude PBS from regulation as plant regulators/ pesticides.
- Authorize/ direct USDA to develop a uniform national framework for PBS products.

## USDA Develops National Framework

- USDA in consultation with States, state organizations, industry & other stakeholders establishes a PBS Task Force to:
  - Develop uniform approach to state regulation of PBS
  - Establish accepted common label & product claims
  - Establish criteria & processes to certify safety and efficacy

## State Fertilizer Programs Implement Framework

- Amend State Fertilizer Law to incorporate national framework;
- Develop state regulations incorporating framework by reference;
- If necessary, develop additional requirements

# A few suggestions for navigating a complex regulatory landscape...

- Have the science & data to credibly demonstrate how & why your product works
- Document & confirm product safety
- Understand the regulations & regulatory landscape
- Respect the role of regulators
- Develop relationships
- Participate in industry groups
- Judiciously use consultants
- Incorporate regulatory in business strategy & product development from the get-go
- Recognize regulatory does not end with registration
- Don't get me started on organic certification
- Plan for the worst & hope for the best

“Integrity is doing  
the right thing,  
even when no one  
is watching.”

C. S. Lewis

**THANK YOU**

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