



# AGRICEN



Understanding the Complex Technology  
Landscape for Plant Biostimulants  
Current and Emerging Regulatory  
Environment in the U.S.

Dave Lanciault, Board Member

# Biostimulants: Working Definition\*

*As stated in draft for USDA*

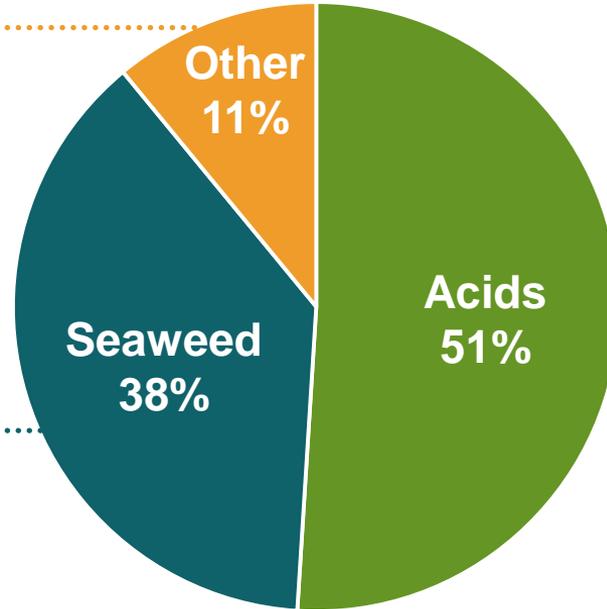
*“Substance(s), microorganism(s), or mixtures thereof, when applied to seeds, plants, the rhizosphere, soil or other growth media, act to **support a plant’s natural nutrition processes** independently of the biostimulant’s nutrient content, thereby, improving nutrient availability, uptake or use efficiency,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

\* Currently, no agreed definition exists for legal / regulatory purposes. Proposed to USDA in industry draft input for Report to Congress

# Biostimulants: Estimated at Over \$3B Globally

*Percent of Sales (2020 est)*

- Microorganisms
- Chitosan, other biopolymers
- Protein hydrolysates
- Other extracts / compounds



- Kelp / Seaweed Extracts

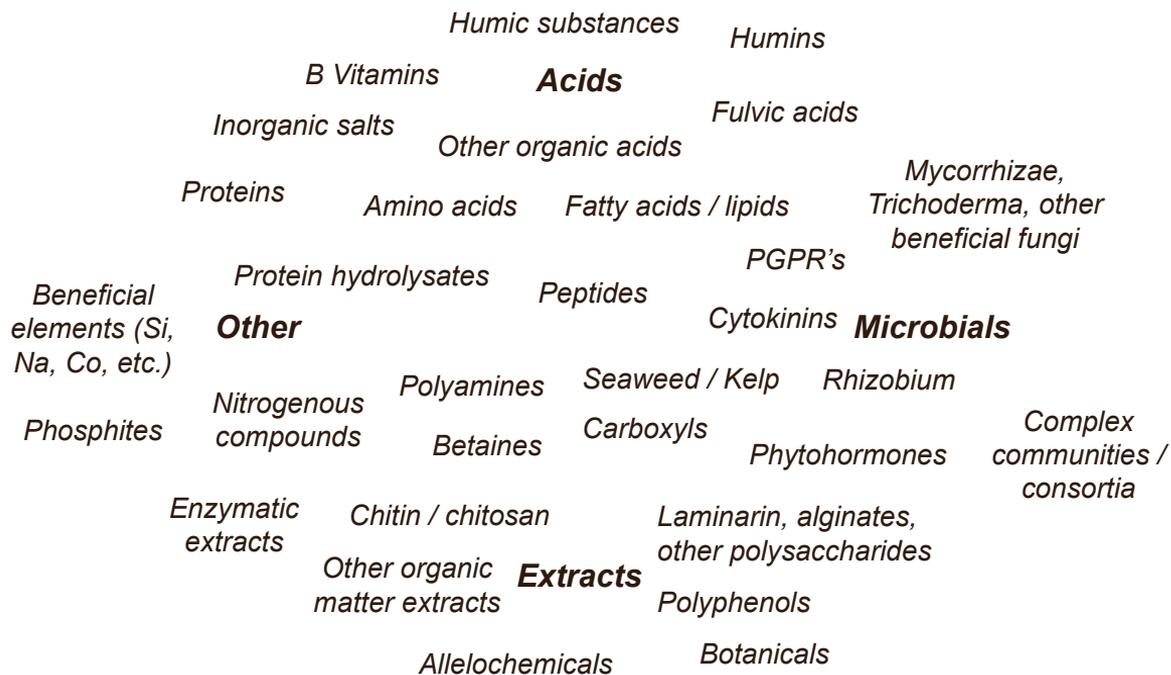
- Humic
- Fulvic
- Other organic
- Amino

■ Acids ■ Extracts ■ Other

Sources: P. du Jardin analysis of Plant Biostimulants 2015; DunhamTrimmer2019



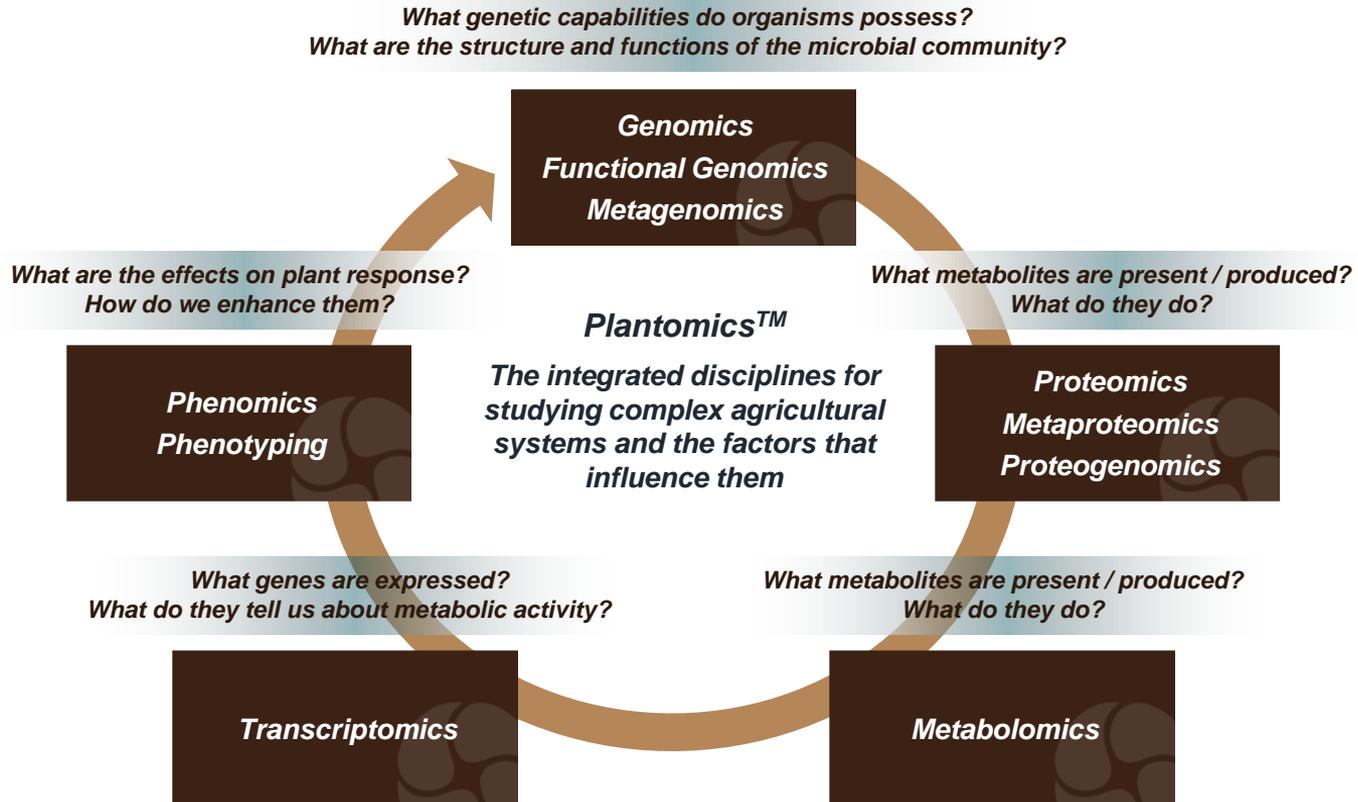
# A Complex Landscape of Substances



Sources: Agricen Sciences' analysis of market analysts, survey papers on Biostimulants



# Omic Capabilities is Opening Up R&D



# Driving Deep R&D into Novel Actives and Effects

*Historic Positioning*

*Focus  
Isolate  
Concentrate  
Refine*

*“Discovery” (R&D) Driven  
Innovation*

## Complex organic extracts

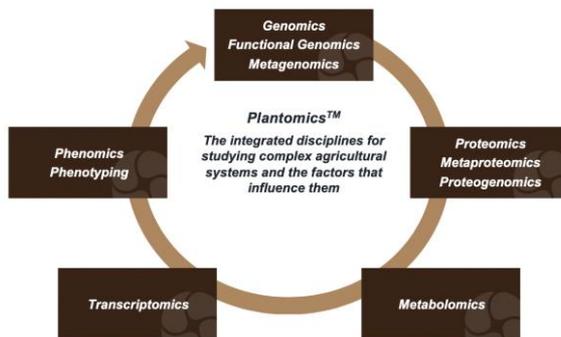
- *e.g., SWE, organic acids*

## Microbial products

- *Single strain or consortia*

## Broad generic claims:

- *Soil structure, function*
- *Nutrient processing, uptake*
- *Soil microbial activity*
- *Plant growth promotion*



## Specific compounds

## Clear, focused Modes of Action

## Optimized strains

- *Potentially improved?*

## Claims sound more like:

- *“Improved ATP hydrolysis”*
- *“Stimulate enzyme production”*
- *“Regulate stress response pathway”*
- *“Improves transpiration”*



# Regulatory Question: Where Do They Fit?



## Pesticides

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



## Plant Biostimulants



## Fertilizers

A 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

### ***What is a “plant regulator”? According to FIFRA 2(v):***

“The term ‘plant regulator’ means 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, inoculants, and soil amendments.”



# Industry's Consolidated Comments to EPA Include...

- Clarify the term “naturally occurring” – does it include synthetic analogs?
- Some PGR claims listed are also true for fertilizers, soil amendments inoculants and biostimulants
- Allow PBS to make plant growth and development promotion claims (e.g. enhanced germination, seedling vigor, root and shoot growth, yield, yield quality, etc.):
  - As logical, natural consequences of primary benefits
- Recognize and clarify “multi-function products”
- 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
  - Some items referenced are well-known, well-regulated, AAPFCO-defined fertilizers and soil amendments (e.g. seaweed extracts, humic and fulvic acids)
  - Consistent with global initiatives on PBS – specifically the EU
- Define “Nutritional Chemicals” under FIFRA as a category excluded from regulation
- Coordinate with USDA on PBS legal definition as part of Report to Congress (EPA Administrator consulted)



# Economic Impact of EPA Guidance\*

- Annualized cost of **up to \$449m**
  - Up to \$2B over the first five years
- Estimated impact includes such items as:
  - Data package development (for submission as PGR's)
  - Federal registration
  - State registration
  - Approvals for use as organic pesticides
  - Manufacturing, labeling, branding and supply chain costs
- This economic impact does **not** encompass:
  - Adverse impacts on growers (e.g., product withdrawals or delays)
  - Future requirements (e.g., new formulations with registered actives)

\* If implemented as presently drafted

Source: Compliance Services International; BPIA ? USBC analysis



# What's Next?

## EPA Guidance:

- Public comment period closes July 28, 2019
- EPA review / respond to comments - by ?
- OMB review of revised guidance - ?
- *EPA target to issue is not later than Q1 2020\**

## USDA Report to Congress - Due December 2019

- Requires extensive validation up the chain of command, and
- Requires coordination with EPA / Administrator
- Industry, other stakeholders standing by to support USDA requests for more info
- Timetable beyond 2019, including legislative action, is unclear

\* Target date per Russ Jones of EPA in May 2019 PPDA Meeting





THANK YOU

# 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
- ✓ Dual uses for active ingredients
  - ✓ Global consistency

## EPA

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

## USDA

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

*USDA-led Biostimulant Work Group*

\* As articulated by Biostimulant Industry Workgroup (BIW), a collaboration led by BPIA and US Biostimulant Coalition



# Composition of USDA Biostimulant Workgroup

*Participants in workgroup convened and facilitated by USDA-APHIS (March 2018)*

## 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



# Actions Recommended to USDA by Industry

## Proposed for the Report to Congress:

1. Enact short-term legislation to:
  - Define plant biostimulants (PBS)
  - Direct EPA Administrator to clarify PBS as excluded under FIFRA
2. USDA-facilitated initiative for more uniform approach to state-level registration of PBS
  - Common label, consistency of claims
  - Safety and efficacy certification standards and processes
3. USDA establish / facilitate Task Force to define regulatory and non-regulatory requirements for a uniform framework
4. Longer-term legislation supporting a Uniform National Framework

