AGRICEN

Plant Biostimulants: Current State and Future Directions

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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: A True “Niche” Market

The numbers that excite us:

- A $2.2b global market [1]
- CAGR 13.0% through 2025 [1]
  - Row crop CAGR of nearly 14% [1]
- Surge in AgTech investing [2]:
  - ~$2b invested in 2018; >$170m in plant science
  - >$6.5b invested past five years
  - Over 200 deals closed
  - Average deal size up, to $10m
  - Headline deals in hundreds of millions

But, put in perspective:

- Less than 1% of $300b crop inputs market [3]
- Over 40% of sales go to 8% of acres (fruits and vegetables) [1]
  - Estimate 20 to 25% penetration? [3]
- Row crops dramatically underserved
  - Estimate ~3% penetration? [3]
- Overall – 3 to 5% penetration (> 95% non-adoptive)
- Period of adoption is closer to 70 years than 10

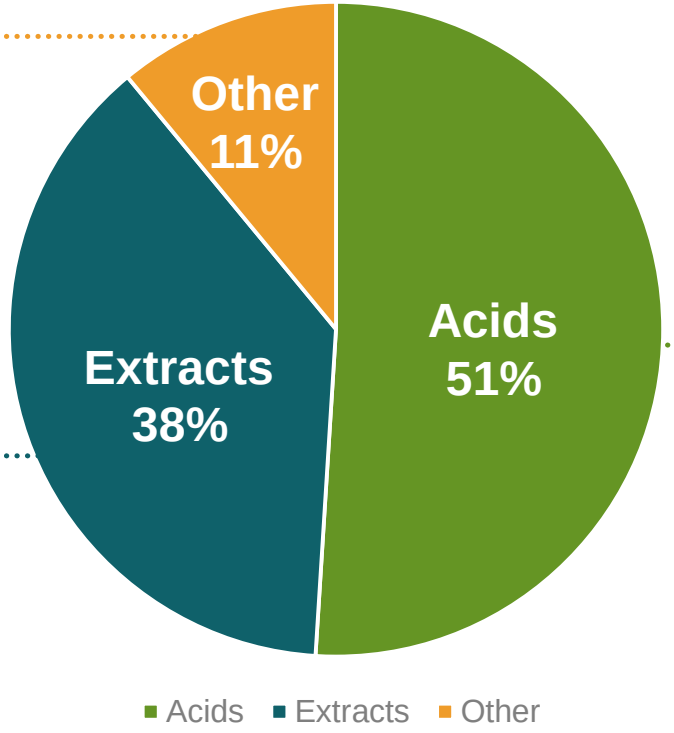
[1] *Dunham Trimmer estimates, © 2019*
[2] *Finistere Ventures, 2018 Agtech Investment Review.*
[3] *Agricen analysis of market fundamentals*

Biostimulants Market: $3B Globally?

Percent of Sales (est., 2020)

- Microorganisms
- Chitosan, other biopolymers
- Protein hydrolysates
- Other inorganic / organic compounds

- Kelp / Seaweed
- Plants (Botanicals)



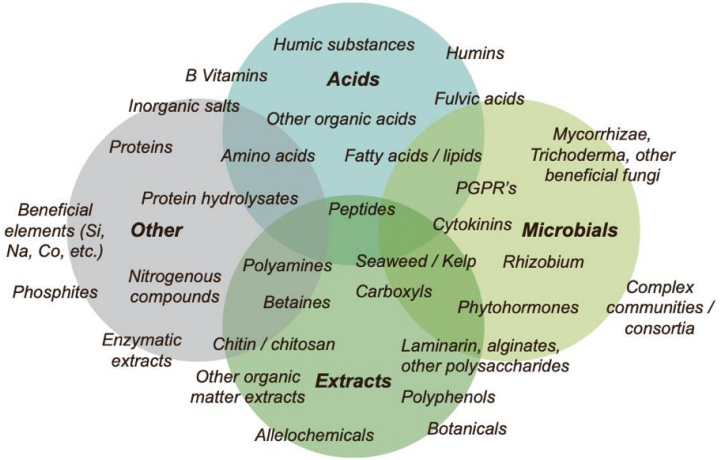
- Humic
- Fulvic
- Other organic
- Amino

Sources: Dunham Trimmer Analysis 2019; P. du Jardin analysis of Plant Biostimulants 2015

A Complex Picture for the Grower

How to move from this…

Landscape of Biostimulant Technologies[1]



…to answering grower's critical questions?

- What problem are we trying to solve?
- What are the best technologies to solve it?
- How do I fit them into my practices?
- How will I know it's working?
- How do I get full value from all my inputs?
- How does this make me money?

[1] Source: *Agricen analysis of market analysts, survey papers on Biostimulants, © 2017*

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 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

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)

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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

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

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What's Next?

EPA Guidance:

- Public comment period closed 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

The R&D Pipeline – Driven by “Natural Product Discovery”

- Aspirin, quinine, morphine, digitoxin
- Penicillin isolated in 1928, other antibiotics in 50’s
- Treatments for AIDs, breast cancer, Alzheimer’s
- 80% of people in world still rely on plant-based medicines

The “Omics Revolution” in 90’s Pharma: A Game Changer

- The arrival of high-throughput screening of potential bioactives
  - Enabled by sequencing efficiencies, computational biology / bioinformatics
  - Increased speed, dramatic reductions in processing cost
  - An explosion of information and the ability to use it to guide discovery

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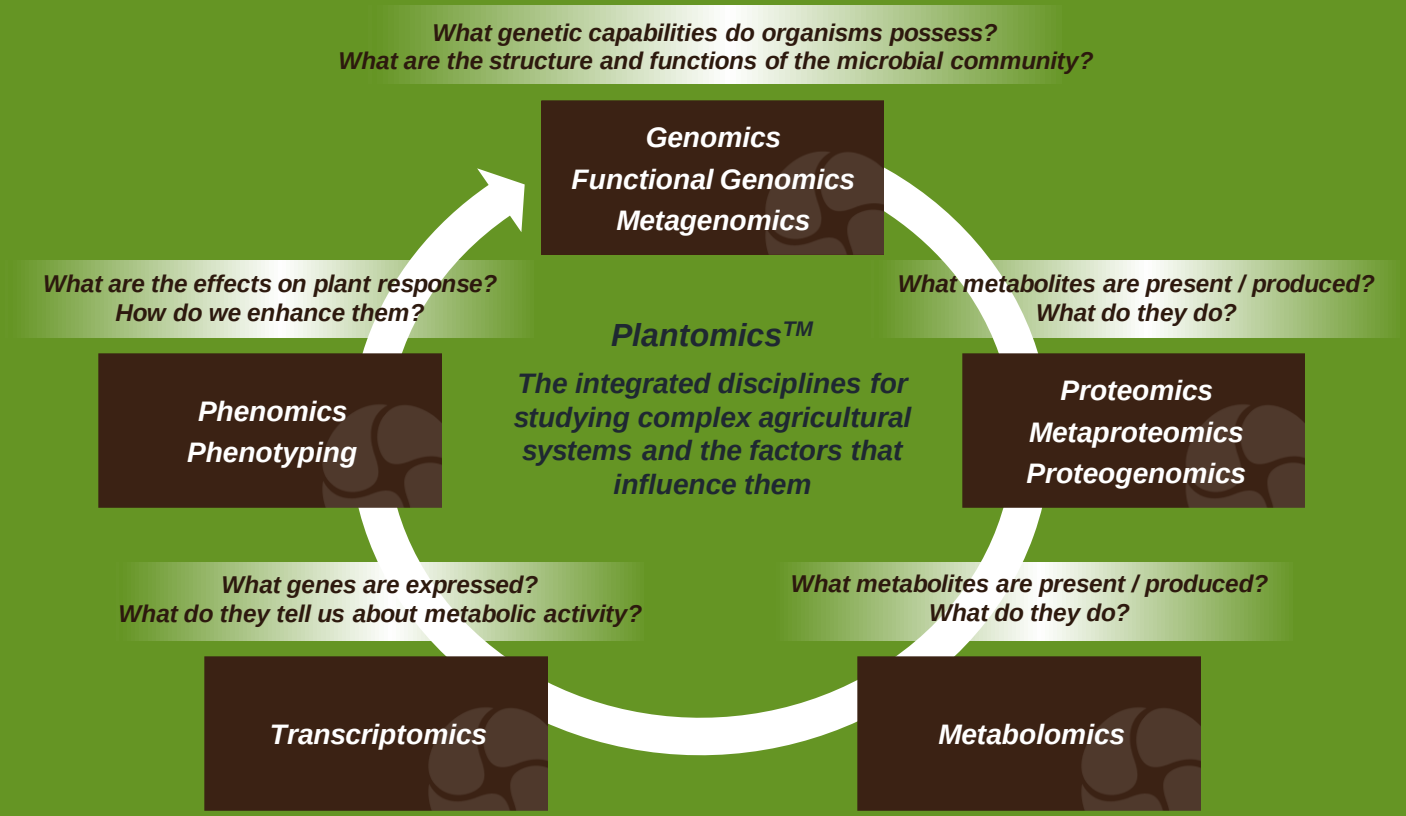
Omics Capabilities is Opening Up R&D



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Driving Deep R&D into Novel Actives and Effects

Historic Positioning

Focus
Isolate
Concentrate
Refine

"Discovery" (R&D) Driven Innovation

Complex organic extracts

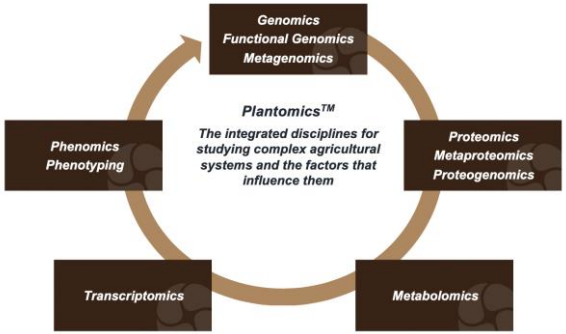
- *e.g., SWE, organic acids*

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

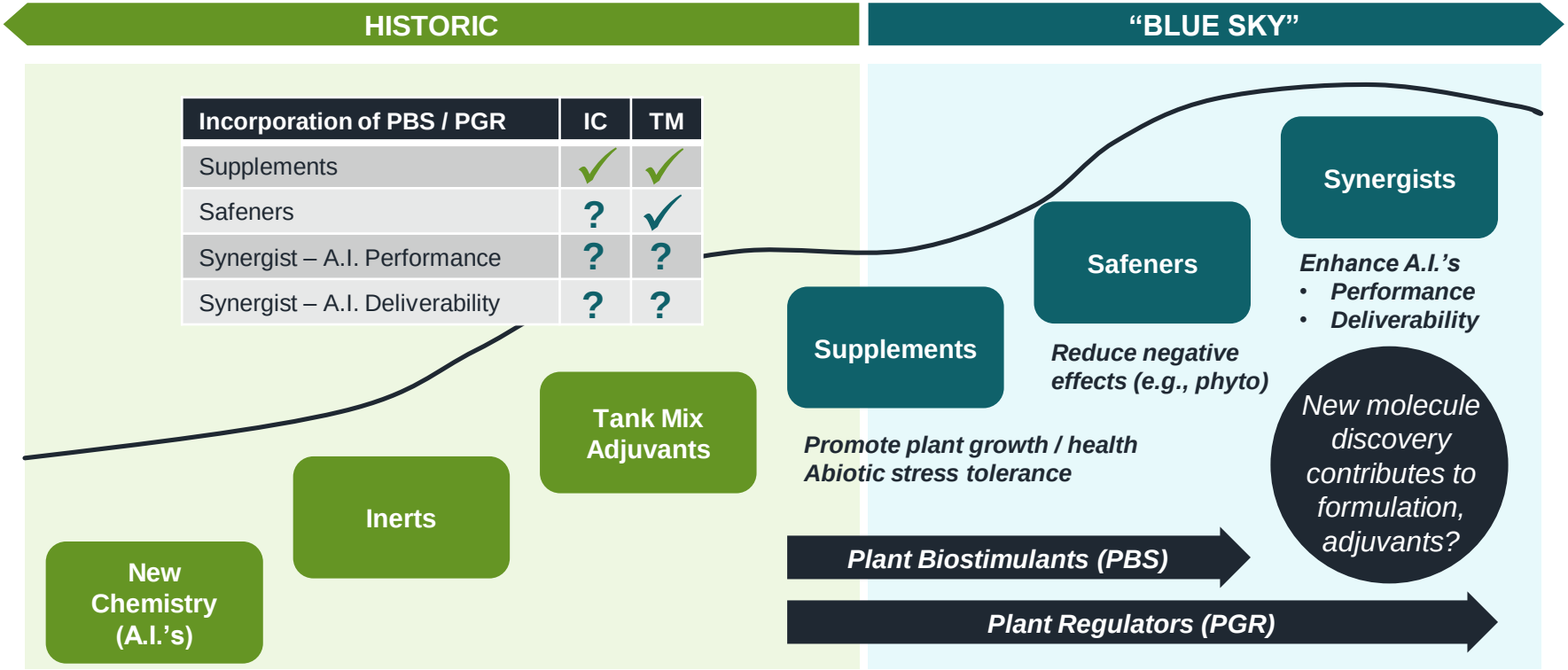
- *Potentially improved?*

Claims sound more like:

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

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

How Might PBS / PGR Technologies Impact Adjuvants?



What is Needed to Grow Adoption?

Market penetration of 3% - ~ the size of KY

- Prove the value to growers
- Demonstrate technology reliability
  - 80% success rate?
- Educate for informed choice
- Win over the influencers
- Price for ubiquitous adoption
- Improve overall farm economics
- Make it seamless to use
- Make it “sticky”

Need to overcome the stigma of a “luxury” technology

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Growing the Market Calls for New Forms of Collaboration

"Open Innovation"[1] means:

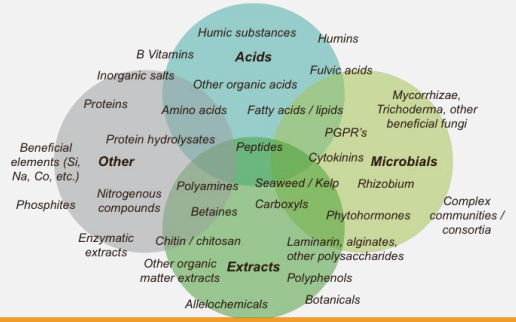
- Tapping the best knowledge and skills – wherever they reside
- Creating value from internal and *external* R&D
- *Monetizing* innovation (not just "papering" it)
- Effective, repeatable innovation business models
- Efficiently translating concepts to practice

[1] *Source: Chesborough, Henry, "Open Innovation: The New Imperative for Creating and Profiting from Technology", HBS Press, © 2003*

Collaboration Opportunities Exist Across the Value Chain

TECHNOLOGY

Sourcing the best content to meet solutions needs



VALUE CHAIN COMPETENCIES

Leveraging capabilities and know-how

MARKET FOCUS

Segment-specific focus, expertise and resources

A New Business Model for Disruptive Innovation?

Summing Up: Key Messages

- **The plant biostimulant market is attractive and growing**
- **The supply side may be growing faster still**
  - Is a shakeout, rationalization inevitable?
- **Winning strategies will require:**
  - Growing the breadth, pace of adoption (mainstream relevance)
  - Fully leveraging finite resources
- **Solutions innovation excellence is cradle-to-grave**
  - Selecting targets – developing innovations – delivering the value
- **New models for collaboration are inevitable**
  - With partners equitably sharing the value they jointly create

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THANK YOU