

PLANTRESPONSE

STRONGER BY NATURE

Biologicals: Emerging technologies for growers

November 2019



Overview

- Company overview
- Biologicals -
 - Market Opportunities
 - Definition & Market Drivers
 - Fit with Best Management Practices
 - Expected Regulatory Framework
- Common Questions
- Case Study: PRB110
- Questions & Answers

Thank-you

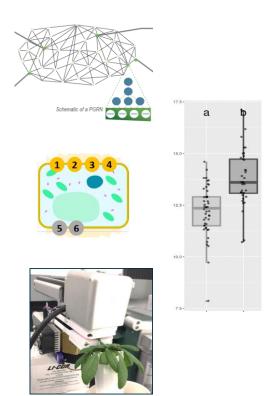
Dr. Rempel, Ms. Hoskins & conference organizers for opportunity to be here today.





PlantResponse Biotech

- Born from the laboratory of Dr. Antonio Molina (UPM).
- Complementary technology platforms fused to create a robust screening capability.
 - ☐Genetic-level response Transcription factor response
 - ☐Cellular-level response particularly in the area of plant innate immunity
 - □Whole-plant response gas and water exchange, photosynthetic efficiency, etc.
- Portfolio of near- and medium-term products with known MOA.



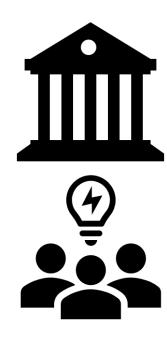




PlantResponse Biotech

PRB R&D technology scouting strategy

Total funding allocated to PRB R&D from on-going collaborations = **€1.01M**









Biologicals – an emerging opportunity for growers



Market Drivers

The global agricultural biologicals market is currently valued at \$6.75 billion in 2018 and is projected to ... grow from \$4.5B in 2014 to \$14.65B by 2023, at a CAGR of 13.8%.

Consumers

Sales of organic food and non-food products in the US alone hit a record \$39.1 billion in 2014, up 11.3% from the previous year, according to the Organic Trade Association. Organic sales now near a 5% share of the total food market.

Pressure on agricultural industry to reduce inputs like CPCs and fertilizers.

Growers

Today, companies developing biologicals that are complimentary to conventional products are at a vast advantage to those working in isolation.

Biologicals provide safer alternatives and allow growers to apply reduced loads of conventional CPCs.

Retailers

For retailers and distributors, biological products provide opportunities for product line extensions, science driven portfolio expansion, and differentiation in the market.



On the other hand...

- The current crop input market is ~\$300B.²
- Biologicals represent less than 1%²
- Over 40% of biologicals are sold into the fruits and vegetables market, which represent about 8% of crop acres¹
- Agricen estimates that less than 3% of row crops use biologicals²
- 1. Dunham Trimmer estimates, © 2019
- 2. Agricen analysis of market fundamentals





A **few** industry participants

















Agrinos°









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Some biological technologies*

- Humic acids
- Proteins
- Amino acids
- Fatty acids/lipids
- Peptides
- Protein hydrolysates
- Polyphenols

- Enzymatic extracts
- Chitin/chitosan
- Betaines
- Polyamines
- Seaweed/kelp extracts
- Cytokinins
- Carboxyls





What are Biologicals?

Biologicals are naturally-derived products that elicit a beneficial effect in a plant or protective effect against abiotic & biotic stress

- > They represent a more environmentally friendly alternative to chemical agents
- > Regulatory process is accelerated relative to conventional chemical products

Typical Product Types Fall Into 3 Classes:

Microbe

Living organism that colonizes the plant/soil



Extract

Mixture of small/large molecules, cell fragments, etc.



Single agent

Compound purified from an extract/microbe





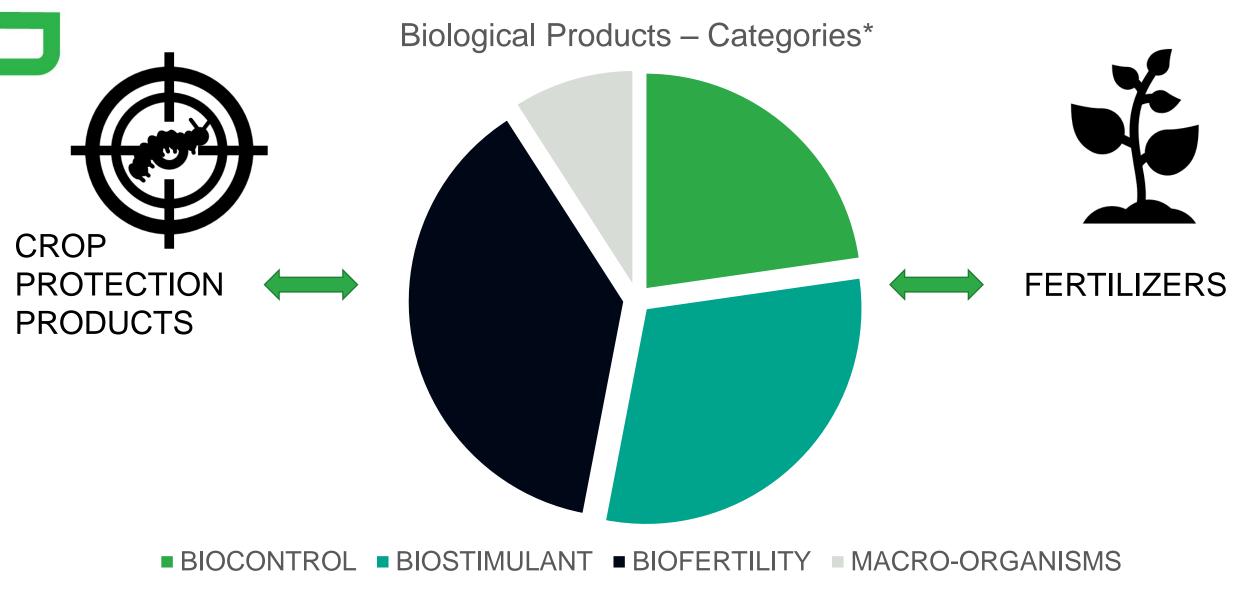
Current Best Management Practices

- Seed selection (genetic potential... hybrid vigor)
- Fertility (optimal use rates, timing, source and application method)
- Crop Protection Products (weeds, insects, disease, etc.) as part of an IPM program.
- <u>Digital Agriculture</u> (precision planting, GPS, variable rate













Types of Biological Products

• **Biocontrol** – act on a weed, pest or disease



• **Biostimulant** – improve crop performance



Biofertilizers – microbial supplement to improve nutrient use efficiency



Macro-organisms – beneficial insects







Types of Biological Products

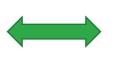
- **Biocontrol** can be an extract, biosimilar chemical, organic acid, etc.
- Biostimulant seaweed extracts and humic acids, some microbials, and other extracts
- **Biofertilizers** microbials that improve nutrient use efficiency or fix nitrogen.
- Macro-organisms beneficial insects, mites and nematodes



The Regulatory Challenge

Biological Products – Categories

CROP PROTECTION PRODUCTS







FERTILIZERS

- BIOCONTROL
- BIOSTIMULANT
- BIOFERTILITY
- MACRO-ORGANISMS

PESTICIDE REGISTRATION

?????

FERTILIZER REGISTRATION





The Regulatory Challenge

*EU:

- New Fertilizer Directive approved and published. Went into effect July 15, 2019.
- Many biologicals & plant biostimulants excluded from scope of EU 1107/2009, however many gray areas.
- Staged over time: New regulation becomes fully applicable on July 16, 2022.

*USA:

- Biostimulant description included in Farm Bill along with request for stakeholders to report to Congress on potential regulatory and legislative recommendations.
- In parallel, EPA released draft guidance document in Q1, 2019. Public comment period extended until July 28, 2019. Slightly different definitions relative to USDA Farm Bill.
- Considerable uncertainty remains on regulatory oversight, timelines and regulatory approval costs for biostimulant products.

Canada:

- CFIA Regulations very well established with standardized and product-specific requirements governed by very clear timelines. Best to confirm product-specific data requirements prior to submission.
- Most biological products regulated as Microbial or Plant Supplements. Classification depends on product viability (live organism or product) and claims / mode of action related to improvement of plant growth, crop yield, claimed interaction with plants, soil, etc.





Practical Regulatory Challenges

US Regulatory: FIFRA or state registration as a fertilizer or soil amendment, etc.

- New product is not biocidal or even biostatic
- Stimulates plant growth, development, increases yield
- Works best when crops are under abiotic stress (heat, drought)
- Is it a PGR? If not, how do you register it with a common label?
- What about a seaweed extract or amino acid combined with micronutrients?





BIOLOGICALS: SOME QUESTIONS TO ASK





Discernment: Products that create value

- What does it do, specifically (what is the effect)?
- Does that solve one of my problems/challenges?
- What is the mode of action, specifically (how does it work)?
- How do you know (how did you learn the MOA)?
- What are the circumstances under which it works?
- When does it not work as well?
- Is there a yield penalty under certain circumstances?
- In your trial data, what percent of the time did you get a positive result?
- What is my expected ROI?
- How is it registered? Why?
- Are field-trial results ever statistically significant?





Discernment: Products that create value

Handling:

- How do I apply it (liquid or solid, etc.)?
- How many times do I apply it?
- At what rate?
- Is it tank-compatible with CPCs and fertilizers, etc.?
- Any "watch-outs?"





Case study (what to look for)

PRB110



Example: PRB110

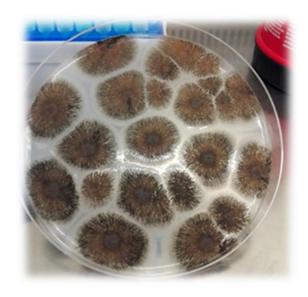
- Technology in pipeline, not a finished product
- Fungal endophyte isolated from wild-growing Arabidopsis in Spain

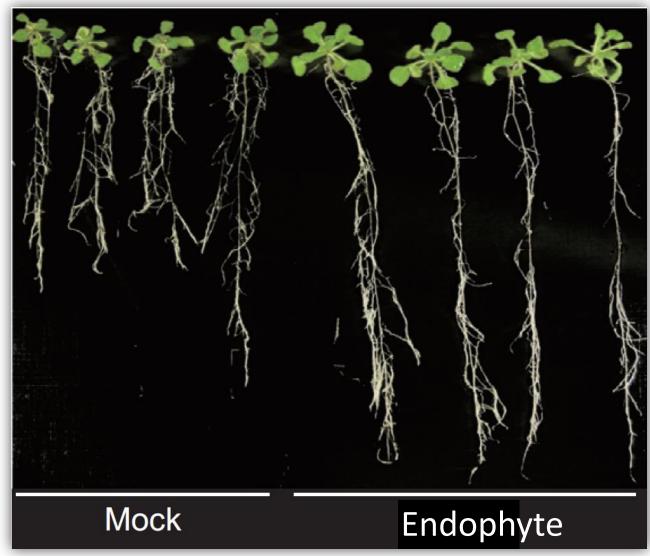




Mode of action

 Arabidopsis plants grown in low phosphate (Pi) conditions with and without the endophyte. Seven-dayold plants were inoculated with the endophyte or water and grown in low Pi MS medium for 18 days.

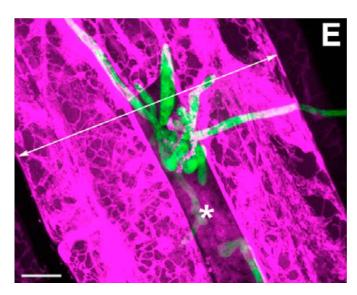






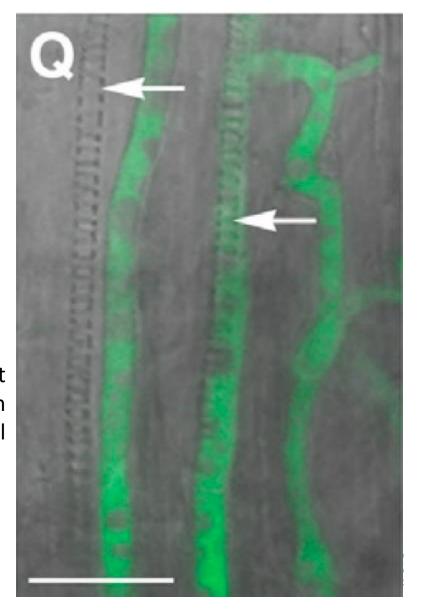
Mode of action: phosphate transfer

• Using a green fluorescent protein (GFP)- expressing strain, it was successfully demonstrated that the fungal endophyte colonized the plant root and then grew hyphae through the stele, or root central cylinder to colonize the shoot. P uptake measured with isotope-labeled P.



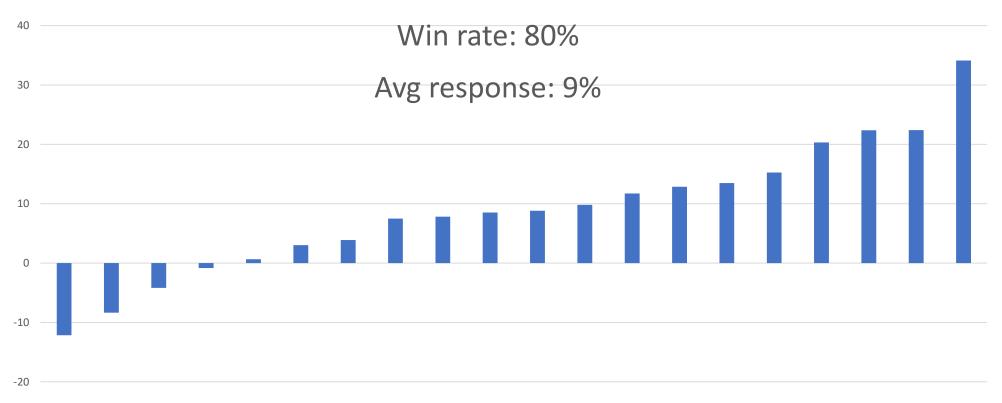
(E) Successful colonization 2 dpi

(Q) Hyphae inside the root central cylinder, with xylem tracheids in the same focal plane (arrows) 8 dpi. Scale bar = $20 \mu m$.



PRB110: Overall performance in row crops

PRB110 normalized yield response compared to the Control (%)







Discernment: Products that create value

- What does it do, specifically (what is the effect)? Increases P-use uptake and efficiency
- Does that solve one of my problems/challenges? Are your soils alkaline/calcareous or acidic, historically low P?
- What is the mode of action, specifically (how does it work)? Elicited P-starvation response, translocated P into shoots and leaves. Grew external hyphae for greater soil exploitation
- How do you know (how did you learn the MOA)? GFP, isotope labeled P
- What are the circumstances under which it works? Alkaline soils, P-deficient soils
- When does it not work as well? Did not answer
- Is there a yield penalty under certain circumstances? A few negative results Northern Europe
- In your trial data, what percent of the time did you get a positive result? 80%
- What is my expected ROI? Did not answer (COGs)
- How is it registered? Why? Microbial supplement in Canada
- Are field-trial results ever statistically significant? Did not answer (Yes!)



Conclusions and Outlook

- Biologicals are emerging as critical components of Best Management Practices
- Biologicals are becoming more science-based and specific in what they do
- Biologicals can be integrated into existing IPM/fertility plans, or offer alternatives
- The distributor selling the product and the grower need to ask some basic questions to verify that the product
 - Has a good fit
 - Is science-based
 - Has a clear mode-of-action
 - Reasonable ROI







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