February 3, 2023

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Re: Request for Information re Section 8 of Executive Order 14081: Identifying Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology (87 Fed. Reg. 77900 (Dec. 20, 2022)), APHIS-2022-0076.

The Biological Products Industry Alliance (BPIA) is the premier organization dedicated to fostering the use of biological technology including biopesticides, biofertilizers, and biostimulants in North America. Biological products are reduced-risk products based on biological or naturally derived chemistry. BPIA is a rapidly growing association with now over 160 member companies ranging from small, innovative sole proprietors to large, international companies. Our member companies have developed dependable, pioneering products for commercial agriculture, forestry, home gardens, horticulture, ornamentals, public health, and turf. Our members provide solutions that benefit growers, consumers, and the environment.

A Plant Biostimulant Listening Session was organized by BPIA with assistance from the White House Office of Science and Technology Policy (OSTP). The listening session was held on January 31, 2023, via a virtual platform. The following report summarizes the content of the listing session and includes recommendations for the future.

Executive Summary

A Plant Biostimulant Listening Session was organized by the Biological Products Industry Alliance with assistance from the White House Office of Science and Technology Policy. The listening session was held on January 31, 2023, via a virtual platform. The listening session was in support of the National Biotechnology and Biomanufacturing Initiative, which was launched through Executive Order 14081.

The topics discussed during the listing session were:

- Biostimulants: Their Function and Effective use in Modern Agriculture, US Regulatory Process and responses to EPA Consultative Questions
- The Executive Order on Advancing Biotechnology and Biomanufacturing Innovation: What is the biostimulant market today and tomorrow?
- Challenges Facing The Plant Biostimulant Industry in the United States
- Overview of Industry-Government Efforts to Date
- Coordinated Framework for Biotechnology and Biostimulants
- Plant Biostimulants and the Executive Order On Advancing Biotechnology and
- Biomanufacturing Innovation: Industry Recommendations

During the listening session the following seven priorities were identified

1. A formal recognition of the Plant Biostimulant Category
2. An established national definition of a Plant Biostimulant
3. Clarity on allowed and prohibited claims for plant biostimulants
4. A clear and defined pathway to market across all fifty states and territories
5. Appropriate regulation of composition, safety, and efficacy
6. Protection of the principle of multi-use based on product function
7. Alignment with regulatory frameworks in other regions to ensure global harmonization

Listening Session Speakers

1. Dr. Patrick Brown, Professor of Plant Nutrition at the University of California, Davis and has served as President of the International Plant Nutrition Council 2005-2009 and as a council member since 1998. In 2017 and 2021, he chaired the Biostimulants World Congress.

2. Dr. Mark Trimmer, Managing Partner, DunhamTrimmer LLC, Board Chair, BPIA

3. David Hiltz is the Director of Global Regulatory Affairs at Acadian Plant Health, a global manufacturer of seaweed-based plant biostimulants. With over 25 years' experience in the biostimulant industry, he currently serves as cochair of BPIA's Biostimulant Innovation Committee, is an executive member of The Fertilizer Institute's Biostimulant Council, and also serves on the Board of Directors of the European Biostimulant Industry Council (EBIC).

4. David Beaudreau, Jr., Senior Vice President, DC Legislative and Regulatory Services (DCLRS). His over 15 years of legislative affairs and policy experience, managing agriculture, alternative and renewable energy, biofuels, and sustainability issues, includes his role as the Director of the Biostimulant Council, a part of the Fertilizer Institute – a coalition comprised of 40 companies involved with biostimulants, which promotes regulatory consensus between state and federal regulatory agencies and is working to develop standards for biostimulants products.

5. Stan Abramson, Esq. is an attorney with ArentFox Schiff, where he specializes in regulating biotech products by USDA, EPA, and FDA. He was one of the principal drafters of the Coordinated Framework during his time at EPA. He later served as a member of the National Academy of Sciences Committee on Genetically Modified Pest-Protected Plants.

6. Keith Pitts is SVP-Sustainability and Regulatory Strategy, Bioceres Crop Solutions (NASDAQ: BIOX). Keith Pitts is the Chief Sustainability Officer for Bioceres Crop Solutions, where he manages the company's regulatory and government affairs portfolio and oversees sustainability strategies and initiatives for MBI. He joined MBI in 2008 after serving as a sub-cabinet member at the U.S. Department of Agriculture as special assistant for domestic policy to Secretary Dan Glickman, where he was responsible for overseeing the environmental, research, food safety and marketing and regulatory program mission areas, including issues related to implementation of the Coordinated Framework for Biotechnology and the consolidation and modernization of USDA plant quarantine authorities under the Plant Protection Act. Keith also served as Director of Public Policy for the Pew Initiative on Food and Biotechnology from 2001-2007, and as a subcommittee staff director for the U.S. House of Representatives Committee on Agriculture from 1991-1997.

Summary of Listening Session

Keith Jones, Executive Director of BPIA, introduced and moderated the event, stating that biostimulants can be used in agriculture and non-agriculture settings to improve natural plant processes, resulting in improved plant tolerance to abiotic and other environmental stresses. The White House Office OSTP encouraged BPIA to host this virtual listening session in support of the National Biotechnology and Biomanufacturing Initiative, which was launched through Executive Order 14081. In addition, a related request for information was released on December 20th, 2022, soliciting public comment on the topics outlined.

During the session, listeners were encouraged to submit questions at any time into the chat feature of the virtual platform or via email. The speakers planned to answer questions or address any comments from the audience as the session progressed and saved time at the end to address any remaining questions or comments.

Mr. Jones introduced guest speaker Dr. Patrick Brown, a distinguished Professor of Plant Nutrition at the University of California, Davis, who is among the highest-cited scientists globally for plant nutrition and biostimulants. Dr. Brown has received numerous National and International awards for his contributions to science and agriculture over his 32 years at the University. His contributions across all areas guide industry decision-making, innovation, capacity building, and the development of State, National, and International regulatory frameworks.

Presentation: Biostimulants: Their Function and Effective use in Modern Agriculture, US Regulatory Process and responses to EPA Consultative Questions

Presenter: Dr. Patrick Brown

Dr. Brown's presentation began with a description of the functions and role of biostimulants and their associated regulatory challenges. Biostimulants fall within the larger realm of biological products, including biological controls which can broadly be divided into microbial products, which are either living organisms produced through fermentation of the non-living byproduct of their fermentation or non-microbes that are often extracted from living materials or organic compounds. These two groups offer a variety of functions to plants in the cropping system. In the context of climate change, biostimulants will have their greatest impact on cropping systems. Climate change adds to plant stresses' frequency, intensity, and uncertainty which biostimulants can help to alleviate.

As the scope of climate change and climate uncertainty becomes more significant, so do the yields and sustainability that biostimulants and biocontrol products help produce. In the context of increasing the availability of and utilization of biological products by

manufacturers in agriculture, they are replacing a more explicitly chemical-based agricultural treatment. In particular, the European Union has pushed heavily into biological materials as sources of agricultural production chemicals instead of strictly chemical compounds. In both cases, the prevention and the optimization of the commercial framework, there is a need for clarity and evidence-based product development. There's tremendous consumer interest, biological farming practices, and a possibility or opportunity for biostimulants.

Products in this realm contribute to the overarching concept that farming systems can become more biologically sensitive to the environment. However, this premise faces considerable regulatory uncertainty. The overall reason for this Listening Session is to consider the possible need for a framework for regulating biostimulants in a commercial context. The underlying rules are important for biostimulant regulations.

Under FIFRA, EPA regulates all products used to regulate plant growth to control pest and disease incidents. They are all considered pesticides and regulated as pesticides unless they have received an explicit exemption under the 152.6 Federal Register. Currently, there are seven exempt categories from this regulation which allows a product to be registered and regulated in the U. S. as a pesticide by EPA.

Under FIFRA, Category G products are intended to aid the growth of desirable plants. A product of any of the following types intended to help the growth of a desirable plant is not a regulator under Section 2; different and is therefore not a pesticide. Other logical products excluded from the list are not treated as pesticides.

Consequently, the question is, where do biostimulants fit in this context of regulations as they currently exist in the US?

Biostimulants are a global product category, and most legislations have developed frameworks for regulating all biostimulants in their economies. For example, in 2022, the European Union formalized this definition outlining important context, “*plant biostimulant shall be an EU fertilizing product, the function of which is to stimulate plant nutrition processes, independent of nutrient content with the sole aim of improving nutrient use efficiency, stress, tolerance, product, quality abbreviated that a little bit just for clarity*.”

The European Union has placed biostimulants under its fertilizer law.

The EU has overarching pesticide regulations which they have amended to exclude plant biostimulants by amending their Plant Protection Products law to clarify that plant biostimulants are not pesticides. A plant regulator is a substance that functionally alters the life processes of plants, other than nutrients and plant biostimulants. Therefore, nutrients and plant biostimulants are explicitly included as exempt categories within their regulations while continuing to work on developing methodologies and standards for claim validations.

The U.S. is in the process of defining language relating to biostimulants, similar to the EU specifying a substance or a microorganism that, when applied to plants or the soil

stimulates natural processes.

Similarly, to the EU, the U.S. emphasizes nutrition and the processes to enhance nutrient uptake, neutral efficiency, tolerance to stress, quality, and yield. A version of 'what is a biostimulant' was introduced in H.R. 7752 of the *Plant Biostimulant Act,* which was mostly the same, but with some critical word changes.

2019 USDA Report to Congress, Alternative Definition 2:
"Plant biostimulant is a substance (s), microorganism (s), or mixtures thereof, that when applied to seeds, plants, the rhizosphere, soil or other growth media, act to support a plant's natural nutrition processes independently of the biostimulants nutrient content. The plant biostimulant thereby improves nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality or yield."

H.R. 7752 Definition:
"Plant biostimulant means a substance, micro-organism, or mixture thereof, that, when applied to seeds, plants, the rhizosphere, soil, or other growth media, act to support a plant's natural processes independently of the biostimulants nutrient content, including by improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield."

These natural processes allow biostimulants in this context to have a more significant role than simply nutrient processes. Also, this definition recognizes that these materials can affect plant growth. Explanations of the biology and biostimulant function will ultimately provide the framework for industry regulations, which producers, manufacturers, state regulators, and other stakeholders hope are developed.

Biostimulants are derived from microbial inoculations and extracting living microbes. The oldest biostimulant is derived from seaweeds.

An important fact is that the origin of many of these materials is highly diverse, including living molecules, living organisms, and non-living organisms. The nature of the existing complex mixtures of these, along with simple molecules, is that their functions need to be understood or understood to the point of this particular context in the realm of biostimulants.

A reasonably regulated function can be an effect, not a composition; the complexity of composition amongst these products and product mixes would make a compositional-based regulatory framework impossible. As the European Union did, the emphasis on regulations should talk about the effects and safety of the product, as opposed to the functional molecule of the functional chemical.

The most prominent biological rationale for biostimulants is the stress hypothesis. In all environments, biotic stress occurs due to damage done to an organism by other living organisms, for example, pathogens or parasites. Consequently, yield rarely reaches its full potential by biotic stress because of nutrient deficiencies, drought, temperature,

frost, solemnity, toxicity, etc. Biostimulants then influence how the cropping system responds to these stresses and assess how resilient, or strong the system is under duress. The plant's outcome is favorably altered by enabling plants to tolerate stress by utilizing nutrients and water more effectively.

The term plant microbiome represents all the microorganisms that live in the soil, on the plant, or in the atmosphere that affect plants. Scientists are gaining knowledge and evidence on the essential effects that microbiome function and biostimulants have on plants. As mitigated efficiencies have been improved, biostimulants' perceived role influences how the plant responds to environmental stress. Thus, a greater yield is produced than had those stresses not been mitigated. Analysis of yield gap losses has been performed for several years and shows the influence of how an applicant responds to its environment and a biostimulant.

On a theoretical yield level, many cropping systems estimate how a particular environment performs compared to a region's best-forming and best-performing crop. The aim of maximum yield, which is unachievable, would only occur with perfect conditions every day of the year. The best growers often achieve 80% of a crop's yield potential in any particular year. For example, corn's maximum yield potential is in the 400-bushel range, and most grow in the 250-bushel range. The average grower may frequently yield between 50 and 70% of the full potential, the difference being between the average farmer and the maximum.

Credible yield is called the yield gap, and it exists in all cropping systems to different degrees in different years. The primary driver of the drop is attributed to the biotic systems, and a biostimulant's role is to mitigate the biotic portion of that decline. Scientists and growers question how stressed our plant systems are now, and on occasions such as the heat spell in early 2019, corn plant leaves curled and folded over from extreme heat stress.

Part of agriculture deals with unexpected environmental events, from the germination of corn through harvest; there are many events that agronomists know are soft or weak points in the growing system. Another example could be an emergence during an overly cold waterlogged period compromising plant growth due to a persistent late frost. On the other hand, some events are predictable, such as drought, heat, and wind, when flowering and vegetative growth are particularly critical and susceptible to nutrient deficiencies. Agronomists know the plant is hypersensitive to that particular growth phase and can use evidential biostimulant literature, including thousands of examples of scientifically demonstrated effects on these stages of growth and stress events, to aid crop yield. The premise of an overall concept is that biostimulants can mitigate, interact, and interrupt the plant's response to an environmental downturn.

A common question raised during presentations is about cropping and production systems with wonderful genetic material, soils and pest controls. Many growers understand irrigation, fertilization, and disease control well.

California has excellent agriculture and triple cropping systems from lettuce to broccoli to a salad green. Under this system, with all the fertilizer, irrigation, and pest control, you get 10 to 15 tons of carbon fixed through photosynthesis. However, if you go to a natural system, for example, a Midwest prairie soil, the carbon fixation is twice to three times as high, bearing in mind it is not a fertilized system. Surprisingly, these systems can achieve fixed carbon yields twice as high as our best agricultural system. So, the question then becomes, “how does that happen, and what can we learn from this dynamic?”

While it’s true that the most resilient plant systems on earth with the highest productivity rate are natural plant systems such as midwestern prairies and not agricultural. When contemplating the resilience of these systems with multiple crops growing, every resource is used efficiently in time and spaces more favorable to biotic stressors.

Every environmental change is an opportunity and a threat to the species present. But most importantly, partnerships are occurring here between the animals present. The animals are present, and most importantly, the microbial community is present in this system. So, this hybrid system offers resilience and the ability to adapt that classic cropping systems do not. If agronomists are to manage stress events optimally, relevant information and language need to be crafted to develop the regulatory framework. Cropping systems that are resilient and tolerant to the environment have exquisite environmental monitoring capabilities. They can sense the temperature, degree of salinity, and the presence of pests and diseases.

The plant uses the sensed information to interact with its metabolism to determine where the carbon fixed in photosynthesis will be allocated. Depending upon what plants perceive in the environment at any given time, this balance exists naturally and responds to abiotic stress by altering these pathways as an interactive metabolic event. But there is one fundamental consideration: plants are overly conservative, and you might ask, why would they be conservative?

Fundamentally this decision-making is not agronomic but rather an evolutionary process where the plant attempts to produce and reproduce to ensure the next generation of plants will thrive. Agricultural productivity would benefit if we could mitigate or optimize plant response to these stresses. Simultaneously ideal agricultural outcomes come to fruition through inputs, nutrients, or inputted water. Plants perceive stress and differentiate between heat or cold stress, drought, or wind stress by triggering molecular processes called signal transduction. Through this process, plant hormones cascade down to the production of stress tolerance or stress resistance characteristics in the plant.

So, you have from the presence of stress the perception of the suppression, the alteration of the genetic metabolism of the plant to the formation of the resistance of the stress tolerance event. The foundational constraint biostimulants face in the US

regulatory framework is their potential inclusion in the definition of pesticides; which unless exempted, currently include those that act to influence mechanisms that contribute to plant growth. Consequently, existing regulations contradict any plant breeding event or watering or fertilizing action through the plant growth pathways. This ultimately creates conflict for biostimulants. EPA is aware of this conflict and has been given the explanation or definition of a plant regulator as any substance or mixture of substances intended through physiological action to accelerate or retard the rate of growth of a plant, the rate of maturity, or otherwise alter the behavior of the plants and projects.

In terms of regulating herbicides and pesticides, these definitions make clear sense; however, if reference to any substance or mixture of substances intended to accelerate the rate of plant growth is included then the development of new plant varieties through traditional breeding that optimize agronomic performance would be considered pesticides.

From an academic perspective, the EPA questioned how we interpret their pesticide regulation; in other words, what types of substances would not be considered pesticides. All plant pathways are activated when the environmental stress is perceived, and fundamentally influence plant growth and development when we do anything agronomic, such as, applying fertilizer or water or when we turn on the lights in a growth chamber.

Dr. Norman Borlaug won the Nobel Peace Prize. By extensively increasing agricultural production, Dr. Borlaug is credited with saving over a billion people worldwide from starvation. In addition, Dr. Borlaug is the only individual to have won a Nobel prize for agriculture. Many people consider this Nobel prize as the most impactful of all. The outcome drove the development of yield and European corn productivity from less than 1,000 pounds an acre to more than 5,000 pounds per acre over 50 years. The 500% increase in yield was crucial to feed the world's population and was subsequently exported to Asia and Africa, where it had a tremendous effect, perhaps saving 2 billion lives.

Dr. Borlaug's accomplishment is relevant because, though he did not know it then, these improvements, like biostimulants, were built upon breeding for changes in plant response to the environment. Had his efforts been regarded as a pesticide and therefore constrained, the industry's response to a foundational piece of agricultural technology built on manipulating plant growth and development would have been framed in a potentially unfavorable context.

In the context of a natural ecosystem, the presence of biostimulants on microbials significantly affects crops' health, tolerance, and resistance. A plant's cropping system and its root system, in particular, interact with the soil around it, called the rhizosphere (emphasis around the root). Over the last couple of decades, we have increasingly found that the soil surrounding a root is rich in microbial populations. These are not

random microbial populations, but plants facilitated on farms.

Hormones are produced in response to microbes that exist immediately around a plant's rooting system. The complex interactions between the plant in the soil and its microbes fundamentally results in the resilience of cropping systems and influences bacteria in the context of soil health. Soil health is the development of a microbial population on the plant and/or soil that is favorable for growth. Microbes contribute greatly to the ability of the plant to adapt to the environment. Microbial abundance is a fundamental measure of soil health and contribute to plant development, and regulate and control their response to stresses.

A number of biostimulants are soil applied microbes. Microbial function and its interaction with the cropping system impact climate change directly through soil health, resilience, and productivity. In recent major natural publications and journals, there is a profound focus on learning about plant biology and how plant hormones are critical for plant response to stress.

As the EPA currently regulates or considers plant regulators fundamentally, as a floor, our founding regulatory processes were developed when we could synthesize plant regulators but only use them as herbicides.

2, 4-D and other herbicides used over many generations are hormone-based fertilizers applied at such high rates that they can kill plants selectively. It is, however, now established that hormones are not simply pesticides; they are the foundational mechanism by which the plant grows and responds to the environment. So, whether it's plant or microbially derived, there's a conflict between an assumption that all hormones are harmful. This would be contrary to the fact that hormones are fundamental to the growth and development of all plants on earth coupled with stress interactions. Therefore, if we can manipulate and optimize plant response to the environment, we can tolerate climate change's effects much more effectively.

A question has been raised about how should biostimulant products be regulated given that we have this overarching statement about the pesticide nature of regulators?" Whether they are produced by plants or microbes, hormones are universally fundamental for all plant life production and growth. All the foods we eat including that bowl of salad we might choose to have for lunch, they all contain plant growth regulators in them at some levels. The EPA interprets biostimulants as beneficial to every plant, and while containing hormones, they pose no threat to human health or the environment. The biostimulant product is the naturally occurring product, the same information for a second class of compounds. So fundamentally, yes, any biologically derived biostimulant animal plant microbial will have some hormones in it.

The EPA has asked, what is the line between a compound or an event that influences a hormonal state and a plant response?" In reality, there is no clear line. Anything that affects plant growth and development will cause changes in plant growth regulation.

Plant hormone growth and development are fundamental to plant growth. The diagram I showed suggested an overlap between what a plant biostimulant does and what plant regulators do, and in the context of the existing EPA regulations say, therefore, they are both pesticides. The overlap cascades from an event in the environment to a response in the plant, passing through these regulatory networks. At this point, a natural plant hormone would have a role in that network, whereas biostimulants also have a role.

In EPA regulation, the conclusion is that hormone plant growth regulators are classified as pesticides; however, agronomists sincerely question whether they should qualify. We manipulate the soil and microbial populations every time a plant is bred for a different characteristic, traditional or molecular breeding. The next reasonable question is, does applying a biostimulant to achieve growth goals make it a plant regulator or a fertilizing product? This question is of great importance today and in the future.

Presenter's recommendations: Fitting squarely in the President's initiative on biotechnology products and manufacturing, the goal of biostimulants is to displace some of the more traditional chemical products. When biostimulants are used to optimize cropping systems, the ability of plants to tolerate climate change and stress is inherently improved while efficiency is increased.

The current definition of EPA plant regulators needs to recognize modern biological knowledge and is a significant constraint to the industry. Cultural productivity and future notability could be improved as most of our colleagues worldwide, including China, Brazil, the European Union, many Latin countries, and Canada, already recognize this differentiation. They place biofertilizer products with stimulant products.

Under fertilizer laws, recognizing that biostimulants are not pesticides is essential. It is vital to emphasize that any genetic molecular or bio-similar approach addresses climate change, nutrient use efficiency, or water use efficiency.

Legislative constraints could be resolved if there were an amendment or an exemption under the plant regulator definition's excluded categories, expanding the list from plant nutrients and soil amendments to include plant biostimulants.

Question from the Audience: "Does the stress response induction occur at a genetic or an epigenetic level?"

Response from the Presenter: There are specific stress responses that very clearly act upon the expression of the gene, particularly the gene expression as controlled by the gene regulators. That's without question. There are also epigenetics. How does the environment alter the specific function of the gene itself without changing the gene that's also been recognized as important? So, there is an environment influencing the expression of genes through the perception mechanism and the environment affecting the gene expression.

Through direct interaction of the environment with the gene itself, it does not perceive that it will change that gene and therefore be inherited by its offspring.

The Executive Order on Advancing Biotechnology and Biomanufacturing Innovation: What is the biostimulant market today and tomorrow?

Presenter: Dr. Mark Trimmer, Managing Partner, DunhamTrimmer LLC, Board Chair, BPIA. Dr. Trimmer co-founded DunhamTrimmer LLC with William Dunham and has worked in the agricultural industry for many years.

This presentation will primarily focus on how large the biostimulant market is today globally and particularly in the U.S. and North America, and how all the microbial and non-microbial products combine into this world. Therefore, figures for a market segment in this presentation include both products unless labeled as them microbial or non-microbial.

Products such as the legume inoculants have been used for 75 years at this point, in a broad sector, and brand-new microbial products have been on the market for a year or two, offering new solutions. And many non-microbial products have a long market history. In analyzing the global biostimulant market, all the figures referenced are based on sales for several years.

At the manufacturer level, not at the grower level, it encompasses the total value of the global market over the last five years. Looking forward approximately five years, in 2015, it was approximately valued at $2 Billion. U. S. dollars. We've seen that number grow to more than $3 billion by 2020, but by 2025, we are projecting that the market will exceed $5.5 billion.

One of the interesting things in the 2015 and 2020 trade is that virtually every other region in terms of the size of the market has grown except the U.S. and Canada, North America. So, in 2025, we are projecting a dramatic growth spurt for the North American market driven by microbial products, particularly microbes targeting nutrient use efficiency in new crops and broad row crop acreage.

The dramatic increase in the size of the microbial versus the non-microbial portion of the market is if we look at Europe or Asia, we'll notice that consistently the non-microbial share of the market is significantly larger. The size discrepancy is due to non-microbial typically representing about two-thirds of their market with a small portion of microbials and for different reasons. One of the main reasons for the small size of the microbial market is the regulatory system, as it creates difficulty for companies to introduce new and novel products.

In Europe, the current microbial species legislation creates a positive list that only includes a very small group of microbes that can be placed on the market at the EU

level today and is, therefore, quite restrictive to introducing new products.

Product age plays a small part in the reasoning, but the big difference is the long history of use of non-microbial products, especially plant extracts, seaweed and other products. The tradition of using those products leads to microbes becoming more important yet capturing a different market share.

Globally the types of crops will have a higher frequency of use in fruits and vegetables by 2025. Already we see an almost 50/50 split between fruits and vegetables in row crops. In direct relation to these products helping to mitigate cropping symptom stress, all plants are subject to biotic stresses for growers of any type to produce and use these products effectively to minimize stresses. Now, if I were to create the same chart and show it to you for biopesticides, it would be very different. Especially for here in the U. S. in the U. S. biotech.

Current use is much more concentrated in fruits and vegetables, about 70 to 80% of the market, and is focused on those crops with little penetration into row crops. Part of this reasoning is because of some of the consumer benefits the biocontrol products bring them. Market data shows that biostimulant products have a broader footprint and potential benefit to agriculture. Based on our projections, the non-microbial sector of the market is growing. But the growth rate is much lower than what we're projecting for the microbial aspect. The split in the North American market is also different from how we see the global market because of the growth of those microbial products, which are predominantly focused on row crops. So, we see a much higher share of row crops occurring by the time we reach 2025.

A predicted transition from being fairly balanced between fruits and vegetables and row crops to almost a two-to-one ratio, or a little more than two-to-one balance between row crops and fruits and vegetables in this North American market.

The use of biostimulants originated in Europe, and many of the companies that are leading the industry today are based in the European marketplace. Additionally, there are a couple in Canada and one in Argentina. Within the U. S. presently, there is a lot of microbial innovation domestically, and by 2025 we could predominate this space. The spearheading leadership in this initiative is coming from outside the U. S.
The driving force behind this initiative is growers facing several challenges as they try to achieve optimal crop yields as climate change persists. As climate change increases market stress, we’re witnessing rising production costs, and the price of fertilizer skyrocketed and are still well above historical averages in some parts of the world, including the U. S. An additional limiting factor is the increased lack of availability of quality resources.

To an extent, these factors can be mitigated through the use of biostimulants by allowing those crops to perform closer to their full genetic potential and supporting the sustainable use of resources by making the crops able to do more with less while tolerating stress events that are occurring on a more frequent basis. An ultimate consumer goal is that growers can meet consumers' better and society's demands for sustainable production practices. As consumers learn more about sustainability, they note that more than 400 consumer-facing sustainability labels are applied to many of the food crops and products we purchase under hundreds of labels from governments, non-government organizations, and industry and grower associations.

Some products are available globally, while others originate regionally or specific to individual countries and crops, but all of them have the same effect. They create, within the consumer's mind, a growing expectation, and a demand that food producers and marketers utilize sustainable practices. A direct benefit of using biostimulants is that they fit exceptionally well within sustainable production. In summary, the biostimulant market is growing and has significant opportunities for further growth. Several things within the marketplace dynamics are promoting change; we see the consumer sustainability demands and the consumer's willingness to pay for high-quality produce increase. Not only domestically but in many parts of the world, government policies also realize the value of supporting sustainable production practices.

There are growers seeking technologies because they are experiencing more frequent abiotic stress events impacting their yield and profitability. There's a very diverse industry, with hundreds of companies developing technology to address these challenges today. Fifty individual registrations stated that they want to market their product across the entire United States, which creates some challenges with the cost of market entry. In addition, it creates some challenges with logistics when, in many cases, certain states require a slightly different label. So, it means that the manufacturer has to manage their logistics and warehousing to ensure that the right product goes to the proper state with the correct label.

The economy faces a potential impact of commodity pricing based on the growers' ability to pay for any product. That is also a barrier to entry at some point, particularly in today's market. The barrier we see has the most effective potential for making it impossible to achieve those microbial growth numbers we're projecting is the U. S. regulation system. If the regulation system does not permit those products to end the market at a reasonable and affordable cost, the projections we're showing here will only occur.

Challenges Facing The Plant Biostimulant Industry in the United States

Presenter: David Hiltz is the Director of Global Regulatory Affairs at Acadian Plant Health, a global manufacturer of seaweed-based plant biostimulants. With over 25 years' experience in the biostimulant industry, he currently serves as cochair of BPIA's Biostimulant Innovation Committee, is an executive member of The Fertilizer Institute's

Biostimulant Council, and also serves on the Board of Directors of the European Biostimulant Industry Council (EBIC).

Biostimulants are being adopted globally, and an excellent example of an early adopter is my home country of Canada. It was not a true fertilizer, nutrient source, or pesticide or plant regulator type of product. For many years Canada has been able to register products as plant supplements and fertilizer supplements. A similar situation existed in Brazil, where some of the early biostimulants were regulated and called biofertilizers. In 2019 we saw the first large global recognition of the plant biostimulant category with the modernized fertilizer product regulation 1009, formally published in 2019 and into effect in July 2022.

Over the last few years and finally, in 2021, a formal definition of the plant biostimulant at the EU agency level and the creation of a new category of fertilizing materials for plant biostimulants had continued for years to come.

For example, China published an updated fertilizer regulation that defined plant biostimulants. India also took the lead and modernized their fertilizer regulation in 2021 with a new act. But again, it created a new category of fertilizing material for plant biostimulants. Notice the trend that all of these follow fertilizing materials in 2022 as continued success persisted when the fertilizer group in ISO TC-134 published a formal definition of plant biostimulant. Chile also published a new resolution that defined and regulated plant biostimulants moving forward. Other regions continue to express interest in these emerging regulations. For example, the European biostimulant industry council gets questioned on exactly how the regulation works in Europe and how Australia and South Africa could adopt similar regulations.

For a long-time biostimulant manufacturers have been asking questions in the U. S. We have been lobbying USDA, EPA, FCO, and anyone that will listen for a definition and an appropriate path to market for the last decade.

Although we are making some progress, it's challenging for companies that need a clear path to market these products. Some companies have been able to work them into existing regulatory pathways in the U. S., but the process must be clearer. In some cases, it needs to be clarified for both the market and the company regarding how products must be registered and what they can say about what they do.

As an industry, we seek seven major points that we, as manufacturers, are looking for in the US:

1. A formal recognition of the Plant Biostimulant Category
2. An established national definition of a Plant Biostimulant
3. Clarity on allowed and prohibited claims for plant biostimulants

4. A clear and defined pathway to market across all fifty states
5. Appropriate regulation of composition, safety, and efficacy
6. Protection of the principle of multi-use based on product function
7. Alignment with exiting global regulations for harmonization

Our first industry goal is to gain recognition of the actionable category of plant biostimulants. “Biostimulant” is not a marketing term but rather a product category designed to complement the advances made in other areas of commercial agriculture. Complementary categories are plant breeding, genetics, the advancements in fertility, and the advancements that we've seen in crop protection. Often, plant biostimulants are referred to as the fourth leg of agriculture, whereas historically, there have been three legs of agriculture enabling increased prop yields and productivity.

But this plant biostimulants category needs to be recognized as the 4th leg of agriculture has a lot of upcoming commercial agricultural challenges are activities that plant biostimulants can help with. So formally recognizing biostimulants as the fourth leg of agriculture and the category of fertilizing materials is critical to help with the future challenges for commercial agricultural activities.

To achieve our first goal, the industry needs a formal national definition of the term plant biostimulant. To highlight the suggested definition in the 2019 USDA report to the President on plant biostimulants again and subsequently in the Plant Biostimulant Act, introduced into Congress last year (2022). The formal definition of plant biostimulant sought is as follows, “Plant biostimulant is a substance, a microorganism or mixture thereof that when applied to seeds plants, the rhizosphere soil or other growth media has to support a plant’s natural processes, independent of its nutrient content and including by improving nutrient availability uptake, use efficiency, tolerance, abiotic, stress and consequential growth development, quality or yield.”

The third industry goal is to seek clarity on allowed plant biostimulant claims. Claim language often triggers challenges from various regulators because they are basically what is claimed for a plant regulator under FIFRA regulation, and there's no exemption in place for them; this creates a considerable challenge for companies trying to market products.

The EPA has been crafting proposed draft guidance on plant regulator claims for several years, including plant biostimulants. However, this document remains in draft form and unpublished as the industry seeks a formal clarification of the plant regulator claims as well as those deemed outside of and the globally associated claims that we discuss with fertilizing materials, including those claims that should fall into claims outside of regulation.

Another industry goal we're aiming for is an appropriate safety and efficacy assessment for plant biostimulants. Manufacturers should be able to demonstrate their products' composition, safety, and efficacy. Many plant biostimulants are derived from natural products and have been safely and effectively used in agriculture for decades. Creating a standard assessment would not impose unreasonable burdens that could stifle biostimulant use and innovation.

The next goal the industry hopes to achieve is defending the multi-use principle of fertilizing materials. When used at significantly different rates, some fertilizers and plant biostimulants can exhibit growth regulators or crop protection activities. For example, copper is a necessary micronutrient for plant growth, but if you use it at a certain level or a certain use pattern, it can also be used as a fungicide. However, we allow those products and avenues for registration for products like micronutrients. So, we seek a regulation that defends the principle of multiple uses, so they are defined by what they do and not what they contain.

Finally, our industry aims to secure a regulation that allows global harmonization as much as possible for manufacturers. Many manufacturers operate globally, so any possibility for regulatory alignment reduces the workload for the regulator as they start to draft the regulation and the manufacturers as they adhere to them. This synergy would allow companies to position their products similarly in different markets. In addition, many countries already have defined plant biostimulants, enabling clear pathways to market achieved by amending their existing fertilizer regulations. So, the regulation considered in the U.S. should draw upon these current definitions, the regulatory language, and the permitted claims already allowed.

After ten years of discussions with various agencies in the U. S., the time to finalize this is now. These products are becoming a critical part of agricultural practices and essential to overcome some effects of climate change. We want growers in the US to have access to these products in the same way that growers globally do under regulations in their country.

Question from the Audience: "If you could only have one of your asks would it be exclusion from FIFRA?"

Response from the Presenter: Industry would agree that language in FIFRA to exclude plant biostimulant would be our first ask because it would allow for a pathway to regulation at the state level as a beneficial substance.

Overview of Industry-Government Efforts to Date

Presenter: Mr. David Beaudreau, Jr., Senior Vice President, DC Legislative and Regulatory Services (DCLRS). His over 15 years of legislative affairs and policy experience, managing agriculture, alternative and renewable energy, biofuels, and sustainability issues, includes his role as the Director of the Biostimulant Council, a part

of the Fertilizer Institute – a coalition comprised of 40 companies involved with biostimulants, which promotes regulatory consensus between state and federal regulatory agencies and is working to develop standards for biostimulants products.

Over the past decade, the biostimulant industry has been trying to resolve some of the regulatory and legislative challenges in the U.S. Firstly, I would like to thank the state and federal partners on this call. We've been working with some folks on this call, going back to 2010 or ‘11, on biostimulant issues, specifically at EPA. In over a decade, we have made some good progress and appreciate the efforts and attention folks have put into this, both from the federal and state sides and our industry partners.

We are taking the lead on advocacy efforts, coordination efforts around the state, state-level involvement, and the federal work we've done to date. In addition, we’ve developed an informal coalition of other trade associations shown here, from American Seed Trade Association to some of the user groups, golf course superintendents, landscape professionals, among others, and other associations with member companies that manufacture or distribute biostimulant and biological products. Also, Bio CropLife America, RISE, and Humic Products Trade Association are a few other examples.

We started meeting with EPA in 2013 to discuss a guidance document around the biostimulant topic. After several conversations with them, recurring questions came from the state regulator side, primarily where the state regulators were asking the EPA: Where are you on some of these products? Should they be registered at the state level or federal level?

Through those questions and answers, we developed a concept for a clarifying document. We started asking the EPA whether they would create a guidance document that would help answer what's in and what's out in terms of what's a plant regulator. We wanted to know ‘what's outside of the regular definition’ and ‘what falls in scope, and what doesn’t. The first draft of that document was met with a good bit of opposition. A specific table was included for certain substances that the agency deemed to be regulators regardless of what claims they were making on their labels.

There was a public comment period during 2015 in which we commented and several other industry and state groups. The result was a revised document and has since gone through several different comment periods. Although the latest version came out toward the end of 2020, it's still yet to be finalized. The much-improved document and the concerning table listing specific materials were removed. Instead, there was more narrative explaining some of the other operations around a few substances mentioned earlier in that table, which was ultimately recognized as a unique category that some products could fall under different excluded categories. These unique products do not have to go through registration as plant regulators through EPA.

Some existing categories are plant nutrients or fertilizers, which was a useful recognition. It also recognized that products could have multiple functions. The multi-function concept has been a point we've tried to communicate as an industry with certain products for various soil purposes.

As we move forward with the broader dialogue around biostimulants, this was an important recognition. Now we're waiting for finalization that will provide clarity for our industry and the state regulators who have been asking for clarifying guidance for some time. This progress will also help educate other end users and groups who are curious about what's in and out of the EPA scope.

USDA has been involved with this topic since 2015 - 2016, when we met with them to explain what we were trying to achieve with EPA. USDA became more involved after the 2018 Farm Bill passed. Included in the 2018 Farm Bill was a report to Congress that the USDA wrote, and we were able to help coordinate some industry input before it was submitted at the end of December 2019. Ultimately, the report provided six options for the agency and other stakeholders to consider resolving ongoing questions about how these products are labeled and brought to market.

In summer 2020, the USDA held a roundtable discussion where they invited a lot of the folks that are on this call and some of the broader federal agency stakeholders to keep the conversation going about not only what was included in the report but what the next steps could be.

The change of Administration began a somewhat quiet period, but now USDA was more engaged coming into the beginning of last year (2022). The USDA outlook forum highlighted innovative technologies and other products, which was an opportunity for the industry to present our ongoing regulatory challenges and the opportunities that these products can provide in terms of climate change, smart agriculture, and sustainable and regenerative agriculture.

The benefits of these products that farmers care about are not solely yield improvement but the new opportunities that these products can provide in terms of climate, smart agriculture, sustainable, and regenerative agriculture. Use efficiency improvement is attractive to farmers as less fertilizer runs off into watersheds and the plant absorbs more; it's a win-win for the farmer. In addition, they’re spending a little bit less on fertilizer because they're getting a better return on it by adding a biostimulant to their operation. The environmental benefit is multi-faceted, while they're reducing nutrient runoff into soil water.

We’re hopeful that in a couple of weeks that this language could be voted to official status, which means that it's incorporated in the book and the manual. Then the state regulators can refer to that ultimately, and individual states can then adopt it. The biostimulant guidelines that the industry has developed are the standards around

products being brought to market by the industry outline: How do we know the applications work? How do we know what they're made of? What's in these products, and ultimately, are they safe for the people applying them to the plants?

The industry took it upon itself to develop a team of volunteers that, in early 2020, formed work groups to look at how we would establish some guidelines around this that we could use as an educational tool that would be useful not only for the industry itself but state and federal regulators following this topic. Two years later, we got to a point where they published it in the Journal of Regulatory Science. It looked at developing guidelines on advocacy, whether these products work, how they work, what they are, if there's seaweed extract plant extract, if they have microbial components or if there are other materials in them essentially, what's in the product, and whether they're safe or not. The document has been well received by academia and others in the industry. It serves as a framework to build off and a great tool for educating those less familiar with biostimulants. In the report, we included an explanation of how to use it and the benefits of using these guidelines.

Coordinated Framework for Biotechnology and Biostimulants

Presenter: Stan Abramson is an attorney with Arent Fox Schiff where he specializes in regulating biotech products by USDA, EPA, and FDA. He was one of the principal drafters of the Coordinated Framework during his time at EPA. He later served as a member of the National Academy of Sciences Committee on Genetically Modified Pest-Protected Plants.

It might be helpful to take a brief look at the origin of the coordinated framework which is dramatically different and leaves us in a much-improved position today than we were in 1986. Due to the hard work of folks at the agencies who have implemented the framework and seen it through all these years, we are farther ahead.

Once the world was introduced to DNA and the double helix, it's been nearly 70 years now, laboratory research with genetically engineered microbes began in earnest by the 1970's residents in Cambridge, Massachusetts, and other communities with significant R & D facilities, the concern became that these microbes might be inadvertently released from the lab with serious adverse health and environmental consequences. In addition, the concerns about lack of oversight were also expressed by some researchers and positions, state and local officials, and members of Congress expressed the concerns with lack of oversight.

These concerns were based on uncertainty and lack of experience since no biotech products were on the market yet. Any risk associated with such products was purely speculative and hypothetical. This mindset sharply contrasted to products regulated only if they were on the market with well recognized potential risks. Food, drugs, cosmetics, pesticides, and automobiles, to name just a few, were the products that gave rise to many of our health safety and environmental regulatory programs.

In the 20th century, biotech came along, and there were no products on the market then. The Federal Government's initial response and concerns with biotechnology research came in 1976 with the issuance of the guidelines for research involving recombinant DNA molecules.

The guidelines rapidly became the de facto standard for biotech research in the public and private sectors. Meanwhile, research with potential agricultural applications was increasing in labs and greenhouses and would soon reach the point where it was ready for small-scale field testing.

Although the primary focus of the guidelines was on laboratory research, and I approved the first field test of a microbe in the open environment in 1983, a scientist at the University of California modified a naturally occurring microbe that would allow strawberries to resist frost-damage. The approval was immediately challenged on environmental grounds when the Court issued an injunction against the experiment and any future field tests until NIH complied with the procedural requirements of the National Environmental Policy act. An environmental review process was also sharply criticized by a congressional sub-committee.

The experiment was subsequently approved by EPA and conducted without incident after a second lawsuit was dismissed. They were based on a comprehensive environmental review record; nevertheless, the criticism on the hill and the concern with the litigation resulted in an erosion of confidence in the process that was irreversible publicly. Private researchers were concerned that their work could be tied up in court for years and that the technology could be stifled.

The legislation would freeze the advance of science to what was known at the exact moment as laws were enacted and pressure mounted on the Reagan Administration to develop a scientific and risk-appropriate regulatory framework based on existing statutory authority.

Amended by agencies' experience in documenting and defending their risk assessments and responses initiated a public process, developing what we now know as the coordinator framework for the regulation of biotechnology. The issue was controversial, to say the least.

Some argued that no regulation was warranted, while others argued that research and product approvals should be frozen until all questions were satisfied and answered to ensure that the technology was safe. Something that ultimately came to be known as the precautionary principle.

The Administration showed a middle course and captured all biotech products but subjected them to the same statutes as their conventional counterparts. So that, for example, the GI corn plant would be as safe to grow. And the corn is as safe as conventionally bred corn. Agency oversight would be commensurate with the risk posed

by the introduction of the biotechnology product and not based on the fact that the product was created or altered by a particular process or technique then as now the framework and its updates. As well, the reports of the National Academy of Sciences all recognize that regulations should be flexible and open to change. So that agencies can adapt readily to new information and improve their understanding of the science as recognized by the Executive Order. 1408 1. We are at such a point today.

So, what we have learned in over 36 years, operating under the coordinated framework, researchers in the public and private sectors developing foods, and other agricultural products have carried out many thousands of laboratory and greenhouse experiments and thousands of more regulated field trials without any evidence of harm to health safety, or the environment from the plants or microbes involved.

New biotech products have completed market reviews and are in widespread use again. Without any evidence of adverse effects, and at last count, crops have been safely grown and consumed globally on over 7 billion acres in 29 countries.
Of course, now that we know about gene editing, it is even more precise and expeditious than recombinant techniques. So, with all of this in mind, we have a fair question as to how many other new technologies can point to such an enviable track record as those of genetic engineering. Yes. Skeptics remain, and court challenges persist. However, I have to tell you that no court has ever found a biotechnology product harmful.

For most biotech products, including plant biostimulants, the closer genetically engineered product comes to their conventionally bred counterpart, the stronger that argument becomes if the conventional product is regulated and slowly post-marketed. The same should apply to a group of products that meets the set criteria; products should be treated the same under the law. This is particularly relevant for gene editing applications where the products are typically similar or indistinguishable from conventional counterparts. It’s time to identify appropriate risk and science space opportunities to improve operations under their framework and create a flexible environment that reflects our extensive regulatory experience and supports equity and opportunity for small and medium-sized public and private entities.

We look forward to continuing to engage with you and finding meaningful ways to enhance the regulatory framework.

Plant Biostimulants and the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation: Industry Recommendations

Presenter: Keith Pitts, SVP-Sustainability and Regulatory Strategy, Bioceres Crop Solutions. I want to thank the federal agencies for the opportunity, just like my colleagues who helped prepare for this listening session. Everything's been said, I see my role as providing some color commentary and context around this initiative.

In terms of key initiatives, I want to recognize that the industry has always seen the importance of the leadership and involvement of federal agencies.

Over the past decade, while engaging federal and state regulatory agencies to define a clear path to market for biostimulants in the United States, we regularly hit a brick wall attempting to with state and their fertilizer authorities and the appropriateness of applying fertilizer regulations to biostimulants. It wasn't until EPA and USDA-APHIS engaged with the industry, other federal agencies and state agencies that focus and credibility was brought to the discussion. Particularly, we found the convening power, under the aegis of the Secretary of Agriculture and with the active involvement of USDA-APHIS leadership, extremely powerful and useful in helping the industry, state regulators and policymakers and federal agencies make some tangible progress over the past seven years—progress that otherwise, likely would not have occurred. So, even though we still have a lot of work to do, the industry would like to acknowledge how important your active involvement has been for the biostimulant, and larger biological products, industry. We have high hopes and expectations that the President's Initiative on Advanced Biotechnology and Biomanufacturing will breathe new life into this now decade-long challenge.

Several of my colleagues have reviewed the key objectives of the industry, which are as follows, securing: (1) a National, legal definition for plant biostimulants, either via law or regulation, (2) the ability to use the term "biostimulant" on product labels and marketing materials, (3) the ability to make demonstrated biostimulant claims on product labels, (4) a clear, consistent, predictable process to market, (5) a single, harmonized label format for all 50 states, (6) credible, science-based safety assessments for biostimulant products, (7) as in the European Union, have the ability for an active ingredient (A.I.) to have dual uses in the market, for example being able to register an A.I. as a FIFRA-pesticide when used at higher rate than the same A.I. at a lower rate, or different use pattern and when supported by data , (8) global consistency and harmonization for biostimulants. We believe these steps will establish credibility for the industry and for biostimulant product and will allow the industry, agriculture, in general, and US rural economies to enjoy the benefits the rest of the world is experiencing with the introduction of biostimulants into farming practices.

As mentioned by Mark earlier, biostimulants are now, globally, the single largest input

sector for agriculture. Isn't it time for the United States to establish a path to market for biostimulants and enjoy these benefits?

The definition of biostimulants. The reason why a definition is important is, whether we work with federal agencies via the coordinated framework, or solely with state agencies under a more expansive scope of their existing fertilizer or beneficial substances regulations, or some hybrid of both—absent agreement regarding an agreed upon, national definition for biostimulants, we essentially still are lost.

For example, the challenge we have with biostimulant regulations is that if you're not defined somewhere in law or regulation, you don't exist. And that's where we find ourselves right now, at least in the United States, if we cannot make biostimulant claims and call our products biostimulants. We cannot sell our products if there is no legal recognition of them. There needs to be a path for the industry to walk biostimulants through an approval process.

Currently, in the United States, the industry only has two paths to market, either via state fertilizer regulations, making claims only allowed within the context of fertilizer regulations, which, in almost all instances, currently do not include provision for either biostimulants or biostimulant claims. (Some states, like California do have statutes that allow latitude for assessing a broad range of non-pesticidal claims for products (but still not allowing the term "biostimulant" to be used, but this is generally the exception and not the norm).). Conversely, EPA is very reluctant to allow products to make non-pesticidal "plant health" claims on their label under FIFRA. In many instances, biostimulant companies are compelled to add non-essential (to their intended mode of action) nutrients to their products in order to shoe-horn the products into a particular state's fertilizer approval process.

Our necessary first step is to get a uniform, national definition for biostimulants in place, via law or regulation, in place as quickly as possible.

Next, the industry will need to 'find a home' for biostimulants. Will that be within a state model law approach, with a more expansive reach for existing fertilizer regulations? Or is there some role for the other authorities, such as those within the Federal Coordinated Framework for biotechnology to help shape the path to market? However, building a regulatory path to market for biostimulants with a state model law process can be a multi-year endeavor—perhaps decades before we have full alignment across at 50 states and can overcome the patchwork of state fertilizer regulations that currently do not accommodate biostimultants.

Certainly, there is a critical role for the federal government even within the context of working with the states and the current state model law discussion that is now underway, USDA, EPA, and FDA have deep relationships with state regulators. We need to build on those relationships and keep progressing, without active involvement by all parties, it is likely that ongoing efforts will stall once again.

As David mentioned, absent full engagement by government regulators, the industry has worked very hard to develop industry-recommended guidelines around assessment and demonstrating both the efficacy and safety of biostimulants, as well as criteria regarding standards for product composition and quality. These US industry guidelines have been developed with an intent to be harmonized with similar standard setting efforts in Europe and other jurisdictions where regulatory paths to market for biostimulants exist, like Canada and the EU, or are under active development. Even if the state model law effort was surprisingly effective and all 50 states immediately implemented the state model law for biostimulants, the involved state regulatory agencies have been very clear that they do not have the capacity or interest in being responsible for safety assessments for biostimulants,

Ultimately, the ability for active ingredients to have dual uses requires clarity around when and where a product falls under the jurisdiction of FIFRA and where it is regulated once it meets the legal definition of a biostimulant. So, even in this one instance, Federal involvement is unavoidable and necessary. In most instances, the Federal government has already taken steps to review genetically engineered microbes that have nutrient use efficiency properties, as well as all wild-type microbes of foreign origin—typically under APHIS's Plant Protection Act, or other quarantine authorities—therefore it seems within reason and legal scope to do the same for non-pesticidal microbes and other biologically-based biostimulants under those same authorities,

Also, ensuring global harmonization for both biostimulants, as well as crops, feed and foods produced using biosimulants falls within the responsibility of Federal agencies. Lacking this harmonization, technical barriers to trade for US made biostimulants and American crops produced with biostimulants could be a risk—a risk that can only be mitigated with active Federal engagement and leadership.

When we look at other sections of the President's Initiative, we also see opportunities for the biostimulant industry,

Climate Change Research. As Dr, Brown mentioned, a robust debate has developed, and continues to develop, demonstrating that biostimulants can and do play a critical role in crop resilience against abiotic stresses tied directly to climate change, like heat stress and drought conditions. Biostimulants are regularly used to improve nutrient availability, uptake and use efficacy, reducing the application rates of synthetic fertilizers and helping to mitigate the air and water quality—and soil microbiome health and diversity--associated with many traditional NPK fertilizers. USDA-led research on establishing clear BMPs for how biostimulants, and quite frankly other biological products, like biopesticides, can be used, particularly within the scope of assessment, valuation and validation for the purpose of USDA climate-smart incentives for growers, and for participation in voluntary, private-sector led carbon, biodiversity and ecosystem service markets would be of great value to both farmers and the biostimulant industry,

Supply Chain Issues with Fertilizer. Ongoing Administration efforts to repatriate fertilizer production to the US particularly in response to Russian invasion of Ukraine should consider the role that biostimulants can play in de-risking these supply chain challenges for US agriculture, as well as the important role that greater adoption of biostimulants can play in the reduction of fertilizer application rates.

Biopreferred Purchasing Programs. The biological products industry applauds US government efforts to source more biologically based products in its purchasing programs. A challenge for the industry has been that the broad diversity of existing active ingredients makes broad-based definitions and standards difficult to establish, establishing an industry-government group to develop meaningful, reasonable and adequate criteria that can cover as broadly as possible would be appreciated by the industry,

Manufacturing Capacity. Since many companies developing biological products, including biostimulants, are small companies and may not have the resources to build their own manufacturing facilities, toll manufacturing is often the norm, at least until companies get adequate sales to support construction of their own manufacturing facilities. Fermentation capacity, even in the toll manufacturing market is extremely limited in the United States. This can be a make or break proposition for small companies—programs to incentivize greater fermentation capacity in the United States, e.g. loan guarantees, grants to companies or local government or LGU/HBCU university incubators, could be valuable ways to build US manufacturing capacity and help re-establish our position as a world leader in the development and commercialization of biologicals, From my own experience, working for a company with a fermentation plant in rural southwest Michigan, jobs in biological manufacturing plants can be high-paying jobs in rural communities, and while these jobs do not require college degrees, they do require technical skills and training—educational and job training programs at high schools, community colleges or technical schools could be valuable economic growth drivers in rural communities, as biologicals continue to capture a greater share of global agricultural inputs.

In closing, I cannot over-emphasize the critical role that creating an efficient, clear, science-based regulatory framework is for the biostimulant industry. Without it, the United States will continue to fall behind the rest of the world and lose its preeminent role in the development and commercialization of biostimulants. More than 25 years ago, the United States government chose to develop a bespoke regulatory framework for biopesticides, not by waiting for the US Congress to pass new authorizing legislation, but by U.S, EPA exercising its existing authorities under FIFRA and establishing the BPPD via regulation and supporting guidance documents. Today, the U.S. has both a biopesticide industry and a biopesticide regulatory program that are considered gold standards and engines of innovation. We are the global leader in this space. Similarly, having been involved in the negotiations with Congress and the public to finalize the implementing regulations for the Plant Protection Act, when I worked for

USDA Secretary Dan Glickman more than two decades ago, I know both the law and the subsequent regulations were intentionally written to give the Secretary great latitude in accommodating new technologies, especially for new technologies like biostimulants that show the potential to be of great benefit to growers, to public health, to the environment and to the U.S. economy, [Note: In fact, I specifically remember Secretary Glickman being asked to commit, in writing, from several Members of the House Committee on Agriculture that the PPA would not be used to designate cattle grazing on Federal lands as 'plant pests'.]

The good news is that the USDA Secretary's 2019 Report to the President and to the U.S. Congress is a very thorough and respected analysis of biostimulants and their role in promoting U.S. agriculture, protecting the environment and supporting the U.S. economy. It also offers a complete and accurate assessment of all the regulatory, standard-setting, marketing and policy tools available to industry/private sector, state government and Federal government to bring biostimulants to market in the United States, including the pros and cons of each. Our primary recommendation and need from OSTP, USDA, EPA and FDA is that, under the aegis of President Biden's E.O, 14081, the new Initiative to Advance the Bioeconomy, the Administration convene a multi-stakeholder task force and go about the business of picking the best and most effective options available to us to establish a path to market in the United States for biostimulants.

Conclusion

BPIA would like to thank OSTP for the opportunity to host the Biostimulant Listening Session. BPIA looks forward to working with OSTP, USDA, EPA, FDA, and other stakeholders to achieve formal recognition of the plant biostimulant product category; establish a national definition of the term plant biostimulant; clarify allowed and prohibited claims for plant biostimulants; create a clear and defined pathway to market for plant biostimulants in all fifty states; achieve appropriate regulation of composition, safety, and efficacy for such products; while protecting the principle of multi-use based on product function; and reaching alignment with exiting regulatory frameworks in other regions for global harmonization of plant biostimulants.

Sincerely,

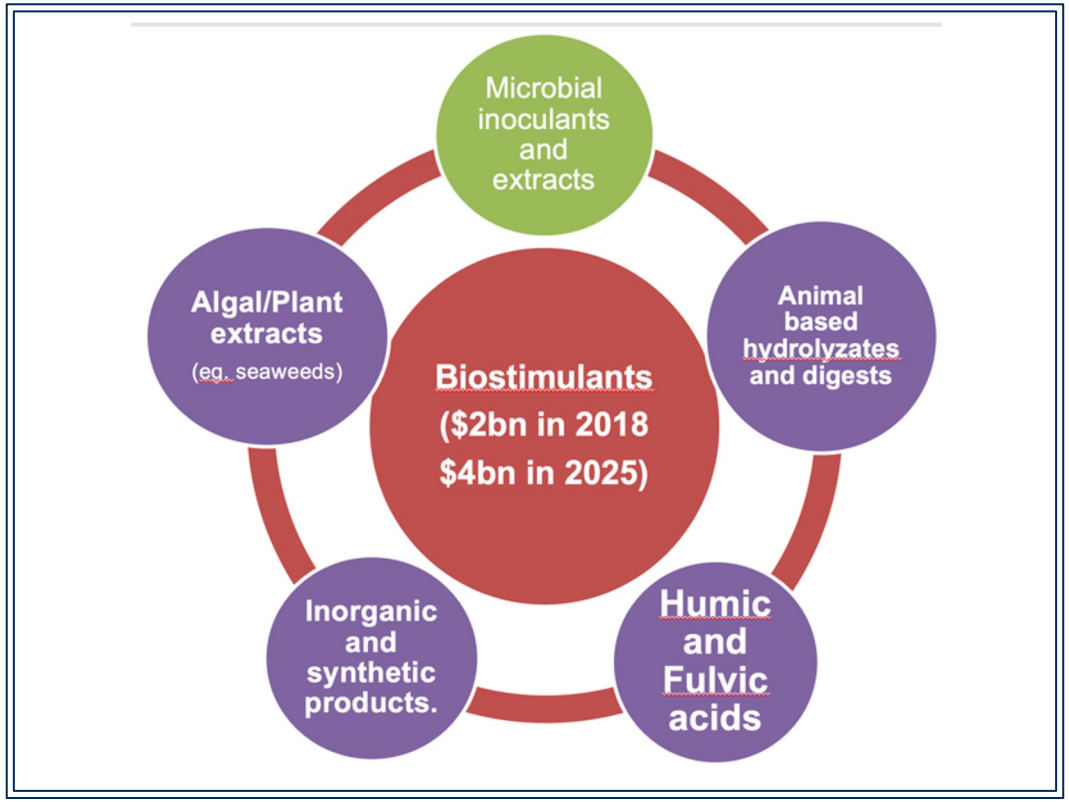
BIOLOGICAL PRODUCTS INDUSTRY ALLIANCE

Keith J. Jones
Executive Director

Biostimulants: Their Function and Effective use in Modern Agriculture, US Regulatory Process and responses to EPA Consultative Questions (7/26/2022).

Questions presented were written by EPA representatives.

Responses are the opinion of Dr. Patrick Brown and not of the EPA.



BIOLOGICAL PRODUCTS

Source: DunhamTrimmer® LLC

BIOSTIMULANTS[1]

MICROBIALS

- NUTRIENT USE EFFICIENCY (NUE) (BIOFERTILIZERS)[2]
- PLANT GROWTH PROMOTION (PGP)

NON-MICROBIAL

- PLANT & SEAWEED EXTRACTS
- AMINO ACIDS
- ORGANIC ACIDS
- INORGANIC COMPOUNDS

[1] Biostimulants are products which elicit one or more of the following effects: 1) mitigate abiotic stress; 2) enhance crop quality; 3) improve nutrient assimilation. Their functions are typically classified as NUE (Nutrient Use Efficiency) or PGP (Plant Growth Promotion).

[2] Biofertilizers are Microbials used to enhance plant nutrient uptake from soil (NUE).

- N-fixing bacteria make up the largest segment.
- N-fixing bacteria for non leguminous crops make up the fastest growing segment.
- Other NUE microbials include mobilizers and solubilizers or chelators of specific nutrients such as P, K, S, Zn, Fe.

PGP Microbials target other biostimulant properties beyond NUE.

Non-microbial biostimulants may target either NUE or other PGP effects.

- Amino Acids and Seaweed Extracts are the fastest growing segments.
- Seaweed Extracts are a complex mixture of components including plant hormones, phenolic compounds, and other active substances.
- Amino Acid products include peptide fractions.
- Organic acids are mainly humic and fulvic acids used as soil amendments.

BIOCONTROLS

BIOPESTICIDES[3]

BIOCHEMICALS[4]

- PLANT EXTRACTS
- ORGANIC ACIDS
- PGRs
- SEMIOCHEMICALS

MICROBIALS[5]

- BACTERIA
- FUNGI
- PROTOZOA
- VIRUSES
- YEASTS
- OTHERS

[3] Biopesticides are derived from natural materials such as plants, bacteria and certain minerals. Biopesticides target specific pests and are inherently less toxic than synthetic pesticides.

[4] Biochemicals include Plant Extracts (largest by sales volume), Organic Acids, PGRs (plant hormones e.g. cytokinins, auxins, etc), and Semiochemicals (allelochemicals and pheromones).

MACROORGANISMS[6]

- INSECTS
- MITES
- NEMATODES

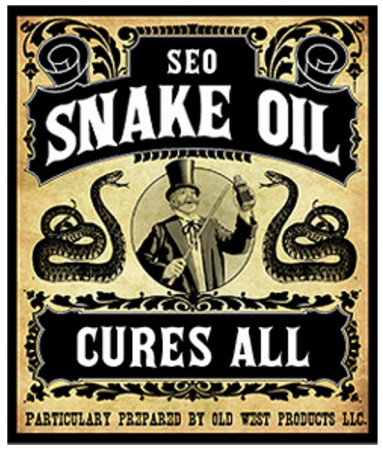
[5] Microbials refer to products based on bacteria, fungi, viruses, and protozoans. Microbials comprise the largest market of biopesticides.

- Bacteria, followed by fungi, make up the largest groups commercially (>90%).
- Biggest challenges relate to product formulation with regard to shelf-life, stability, and performance enhancement.

[6] Macroorganisms include insects, mites, and nematodes. Insects & mites are the largest groups.

- Unique in that the live organism is used in the form of eggs, larvae, pupae, or adults.
- The most important challenge in this category is logistics — shipping live organisms that require special care to survive.
- Normally not classified as Biopesticides but rather Biocontrols.

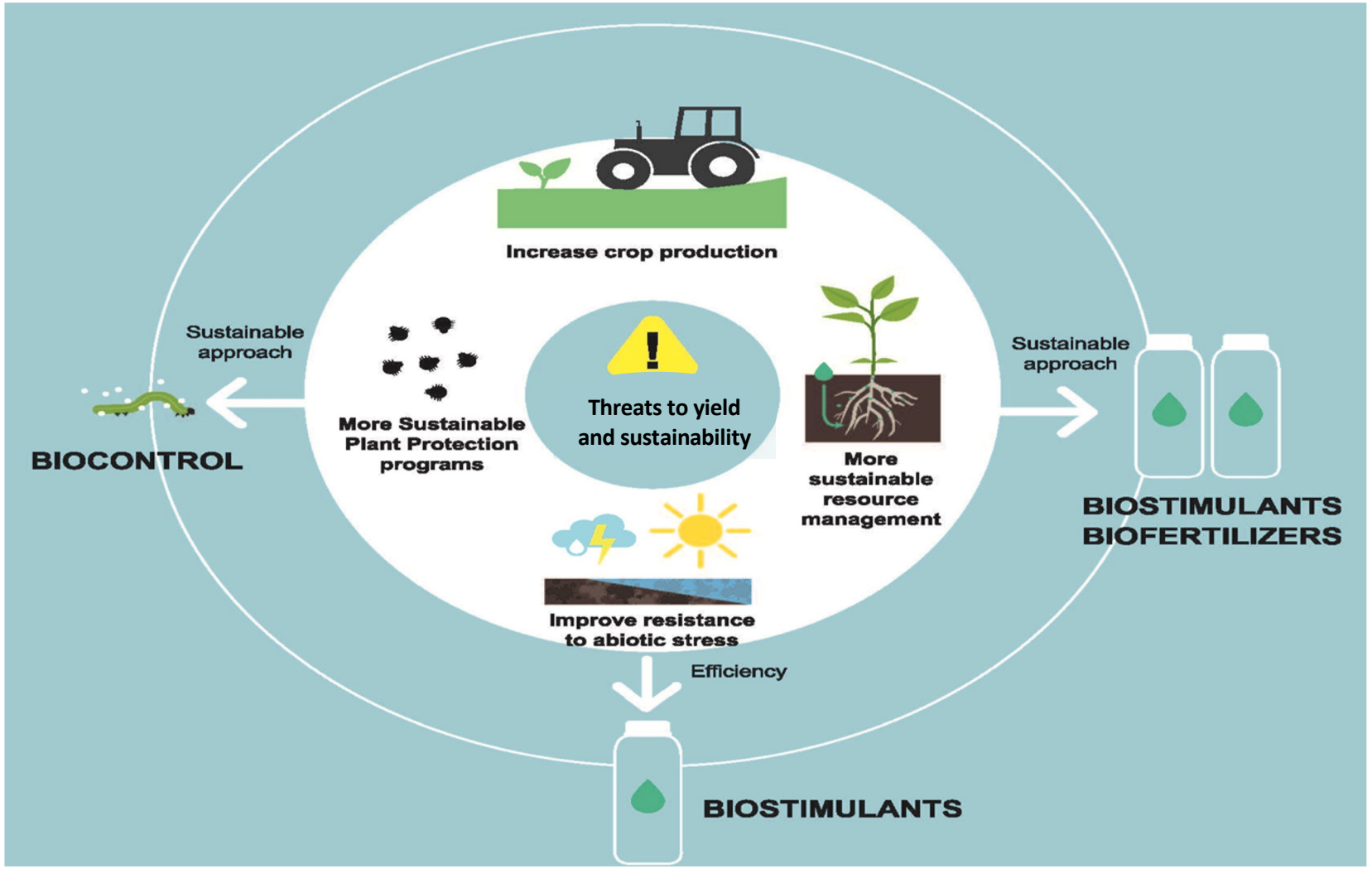
Snake Oils and Jungle Juices or Critical Benefits to Modern Biologically Sensitive Agriculture? BOTH!



or

&

There is a need for clarity and evidence based product development



There is tremendous consumer interest in biological farming practices = Opportunity

Biostimulants Face Regulatory Uncertainty.

FIFRA: The EPA considers all products that regulate plant growth or pest and disease incidence (including all plant hormones) as pesticides unless exempted under 40CFR 152.6 (there are 7 current exempt categories)

The EPA excludes from FIFRA (7 categories a-g):

(g) Products intended to aid the growth of desirable plants. A product of any of the following types, intended only to aid the growth of desirable plants, is not a "plant regulator" under section 2(v) of FIFRA, and therefore is not a pesticide:

(1) A plant nutrient product, consisting of one or more macronutrients or micronutrient trace elements necessary to normal growth of plants and in a form readily usable by plants.

(2) A plant inoculant product consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system.

(3) A soil amendment product containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth.

The European Definition of a Biostimulant

‘A plant biostimulant shall be an EU fertilizing product the function of which is to stimulate plant nutrition processes independently of the product’s nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere …(NUE, Stress, Quality, availability)…’

- In the EU the overarching pesticide regulation (PPP) was also amended to add…. ‘a pesticide is a substances the function of which is to alter life processes of plans, other than nutrients or plant biostimulants’

- EU is currently working on methodology and standards for claims validation.

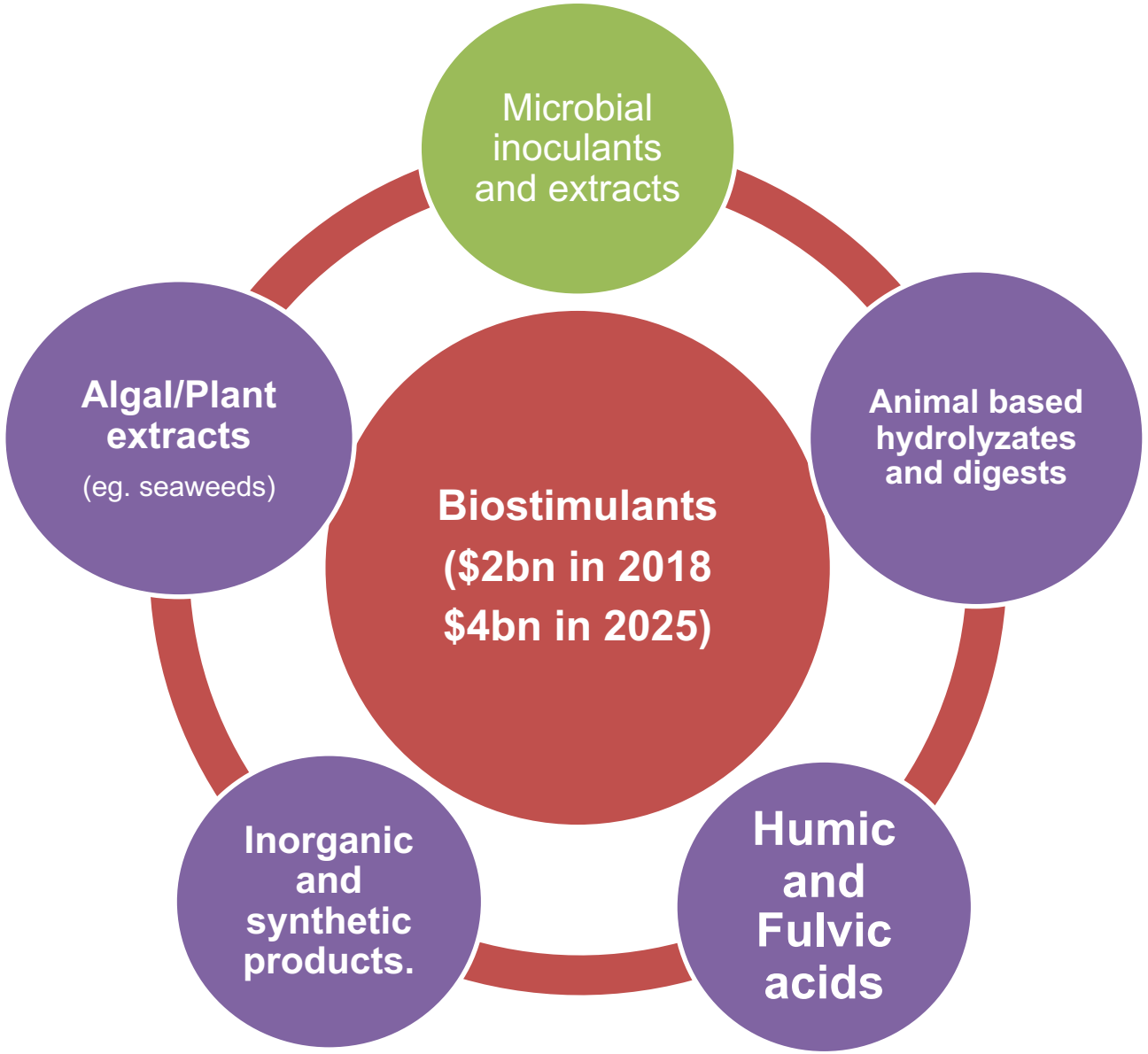
Proposed US Regulatory Definitions

Language submitted to EPA /USDA 2019: "a substance or micro-organism that, when applied to seeds, plants, soil or the rhizosphere, stimulates natural nutritional processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and crop quality and yield."

US Regulatory Definitions: Plant Biostimulant Act

Language introduced in May, 2022 HR 7752 : “a substance, micro-organism, when applied to seeds, plants, the rhizosphere, soil or other growth media, act to support a plant’s natural processes independently of the biostimulant’s nutrient content, including by improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield.”

So, what exactly do biostimulants do?



Calvo and Kloepper, 2014

Incredibly Diverse Origins:

Biological/Living: Algae/ plant/ animal/ microbial

Non living: Humates, synthetics, elements.

Complex mixes: Seaweeds, Humic, microbial fermentations

Simple molecules: Synthetic chemicals, elements, biochemicals

Understood/Not Understood.

Function not composition defines the category.

Physiological Rationale for Biostimulants

Stress Hypothesis (includes nutrient stress/nutrient efficiency)

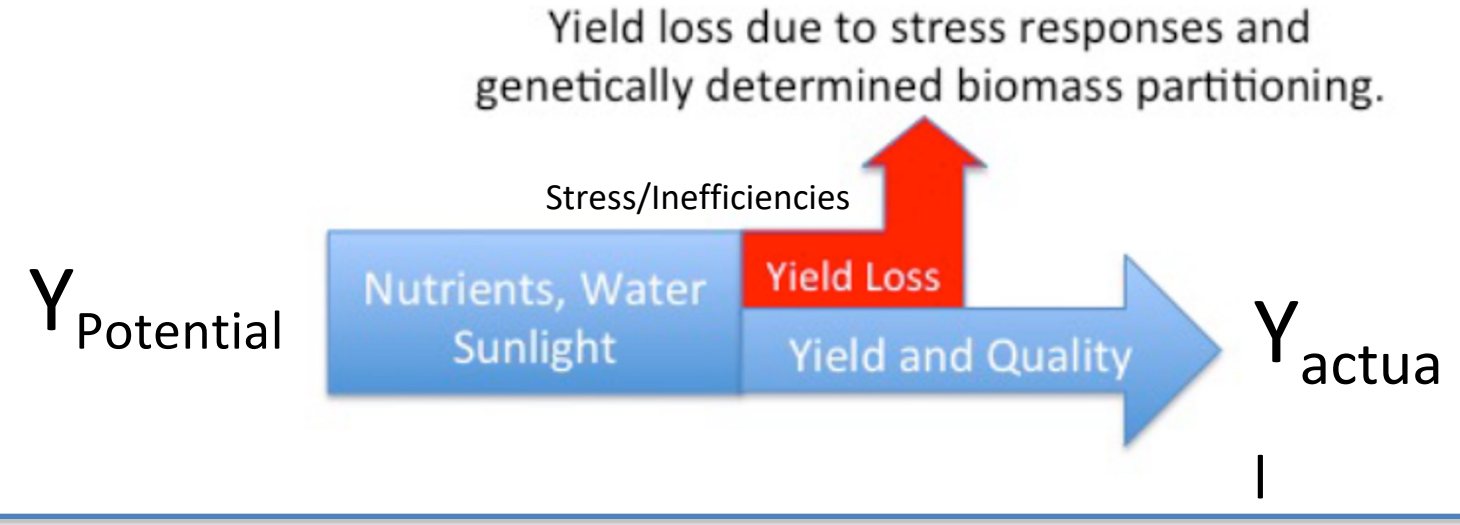
Abiotic 'stress' occurs in all environments and as a consequence yield rarely reaches full potential (abiotic stress = nutrients, drought, temperature, frost, deficiency, salinity, toxicity….)

<u>Biostimulants influence cropping system response to stress</u>

- Biostimulants enable plants to more effectively tolerate stress
- Biostimulants help plants access and utilize nutrients and water efficiently
- Biostimulants favorably alter the plant microbiome which in turn is essential for crop stress tolerance and nutrient uptake.

Brown and Saa, 2015 Frontiers Plant Sciences

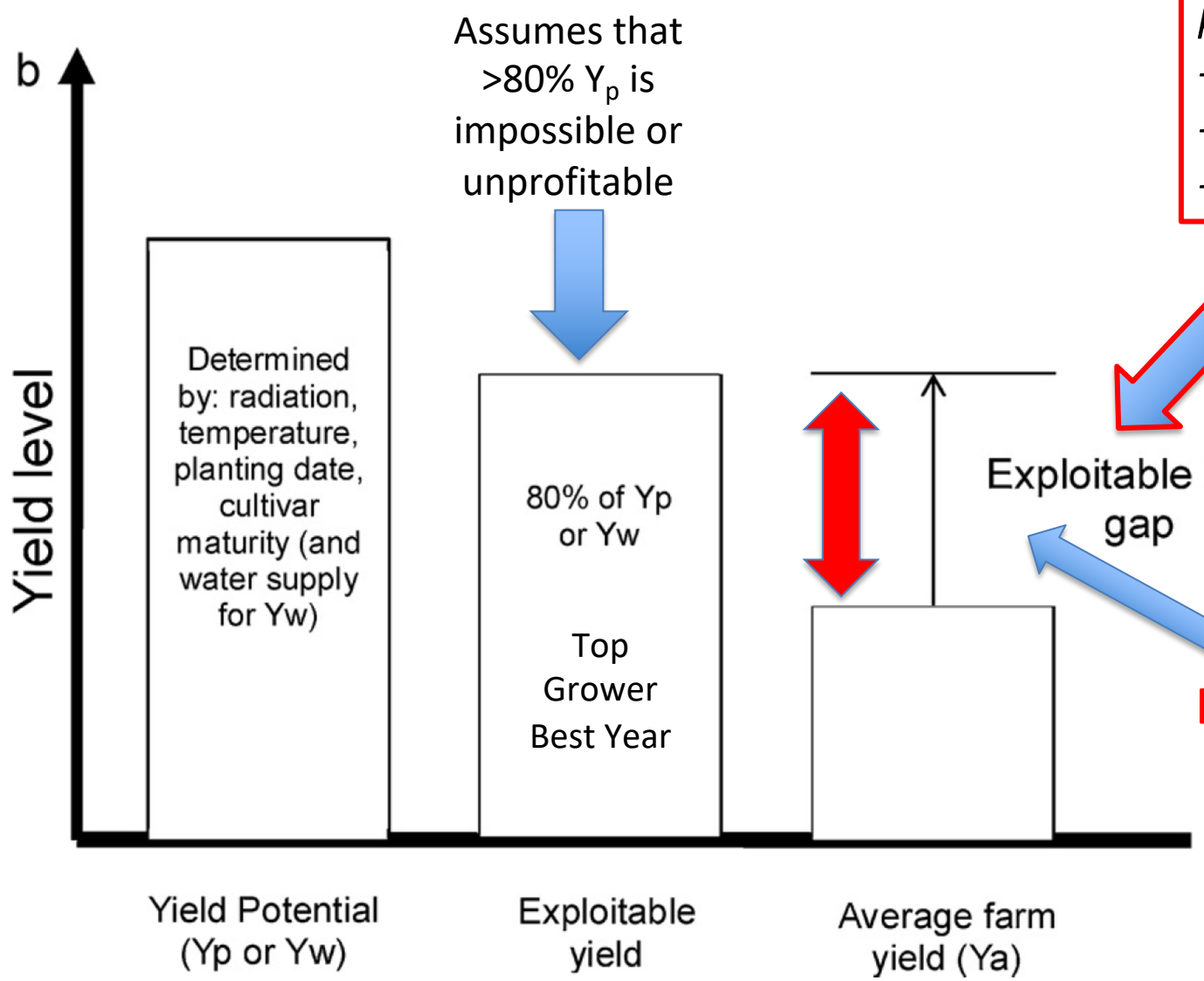
Stressed System



Yield Gap Analysis

Y_p = Maximum theoretical yield (ideal sunlight, temp, nutrient, CO_2)

Y_w =Maximum theoretical yield with water limitation



Assumes that >80% Y_p is impossible or unprofitable

Climate change is predicted to dramatically increase plant stress events.
-frequency
-intensity
-uncertainty

Exploitable yield gap

Biotic and Abiotic Stress

Biostimulants

M.K. van Ittersum et al. / Field Crops Research 143 (2013) 4–17

Are our Farming Systems Resilient?
Do they experience stress that compromises yield?

Challenge: How to prevent plant stress and deliver cost effective solutions.

Drought, Heat, Frost

Critical moisture requirement

Heat, Drought, Wind,
N-P-K-Ca-Zn-B

Rapid Vegetative Growth

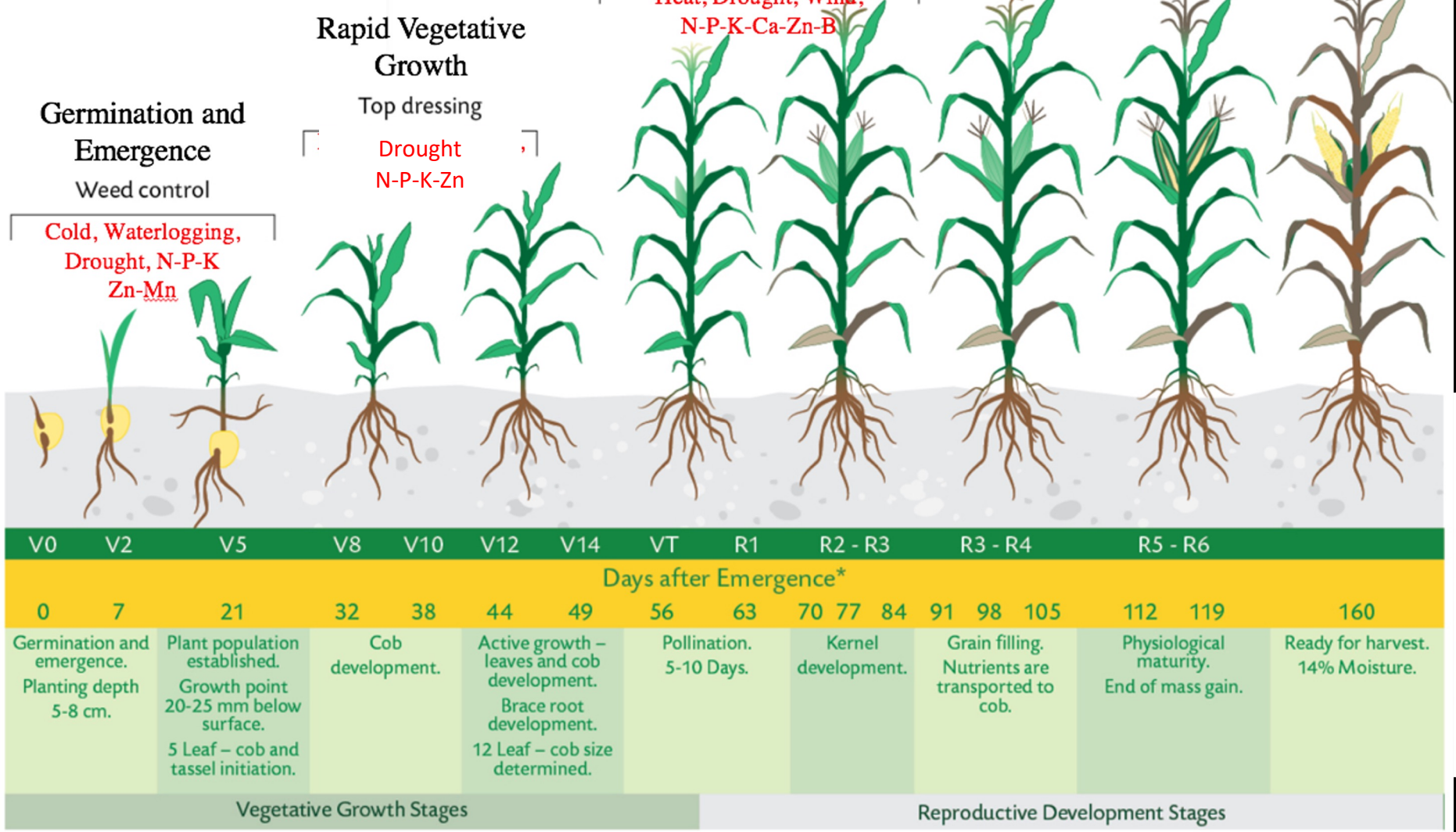
Top dressing

Drought
N-P-K-Zn

Germination and Emergence

Weed control

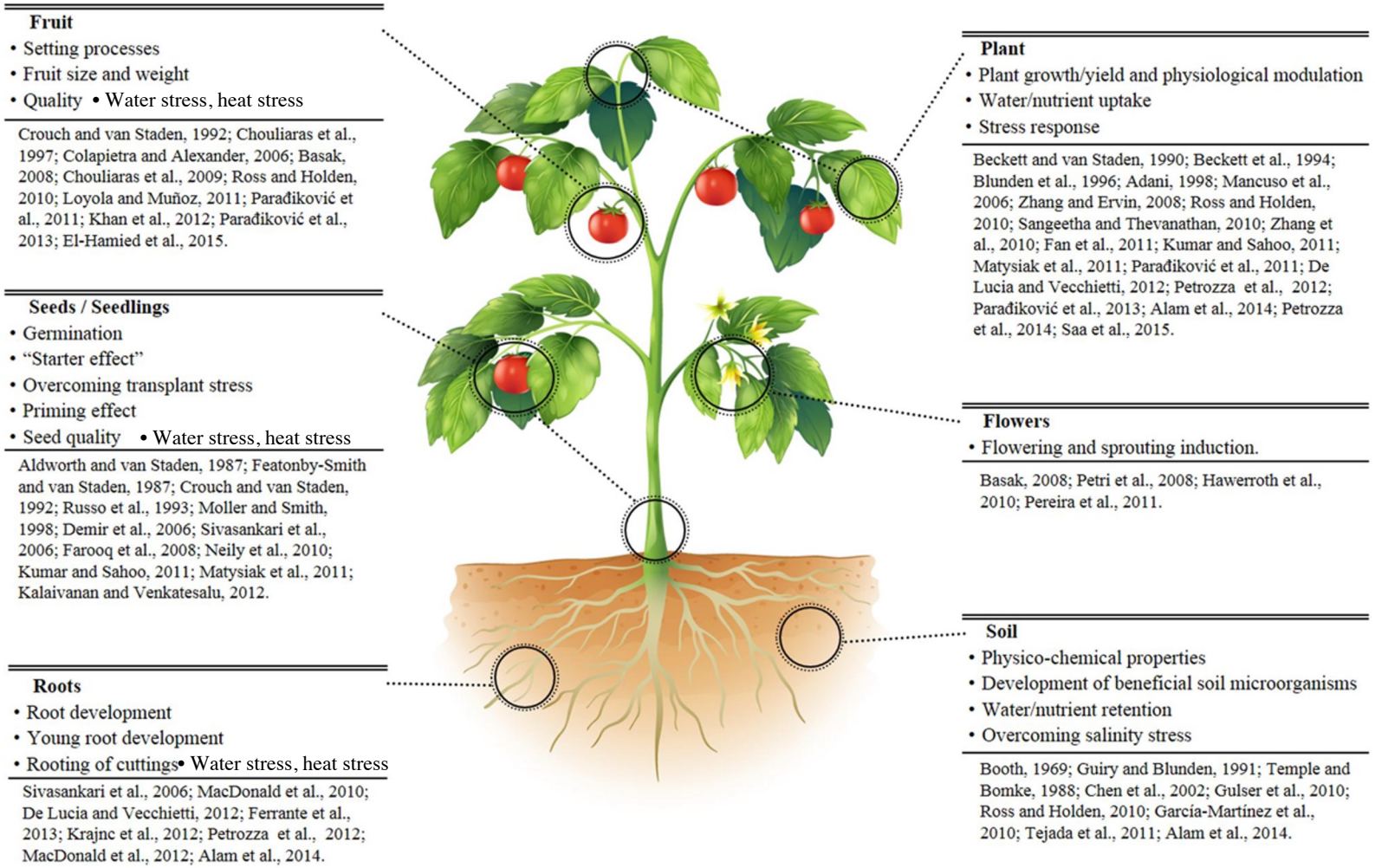
Cold, Waterlogging, Drought, N-P-K Zn-Mn



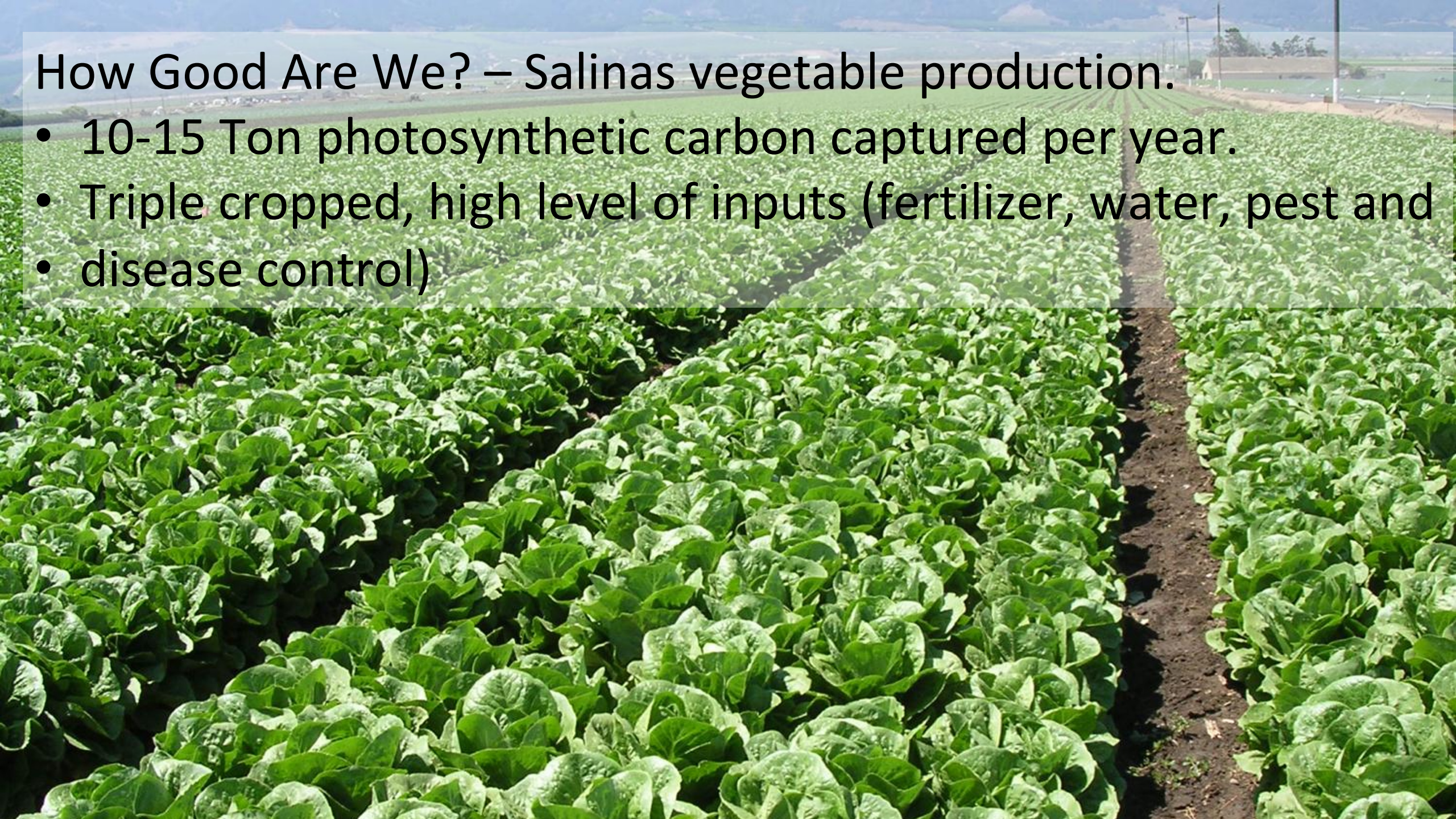
* The number of days varies between different growth classes and environments.

Figure 1. (Left) Lightly frosted corn plant with watersoaking and necrosis. (Right): A corn plant with more severe frost injury with protected growing point.

There are now hundreds of papers demonstrating positive responses of biostimulants on plant stress and yield. Only a few have a clear biological explanation, most do not.



Povero et al FIPS 2016



How Good Are We? – Salinas vegetable production.

- 10-15 Ton photosynthetic carbon captured per year.
- Triple cropped, high level of inputs (fertilizer, water, pest and
- disease control)

Mid West pasture
20-45 Ton photosynthetic C – with no inputs.

The highest productivity, most resilient plant systems on earth are not agricultural crops, they are natural ecosystems.

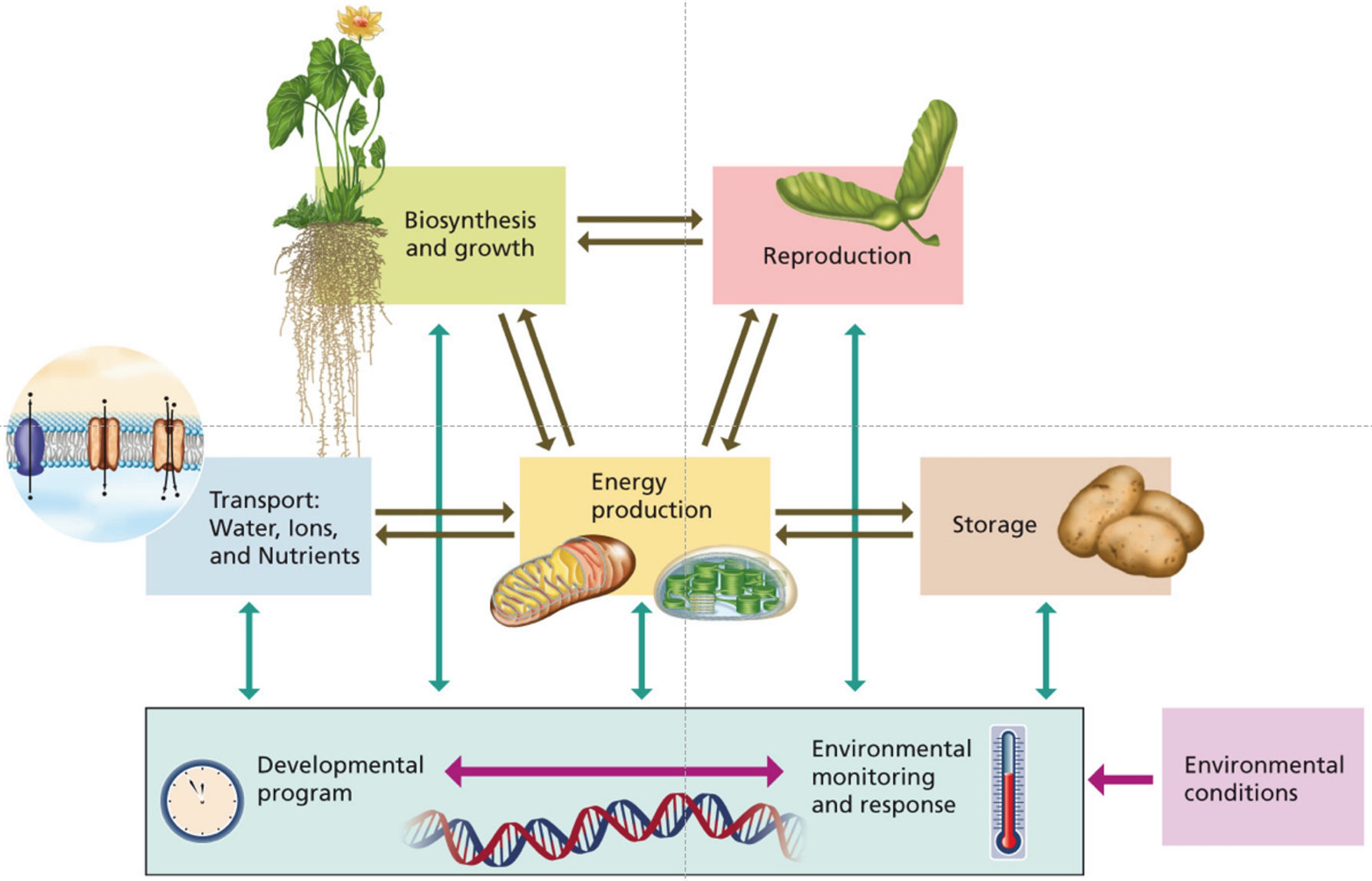
How?:

- Every resource is used efficiently in time and space
- Every change in the environment, opportunity or threat, has a species that can respond
- Partnerships (plant-microbe-animal) are formed for mutual benefit

PHOTOGRAPH BY JIM RICHARDSON, NATIONAL GEOGRAPHIC CREATIVE

What is actually happening during a stress event and how can we mitigate that?

Interactions between environmental conditions and plant development, growth, energy production, and ion and nutrient balance and storage



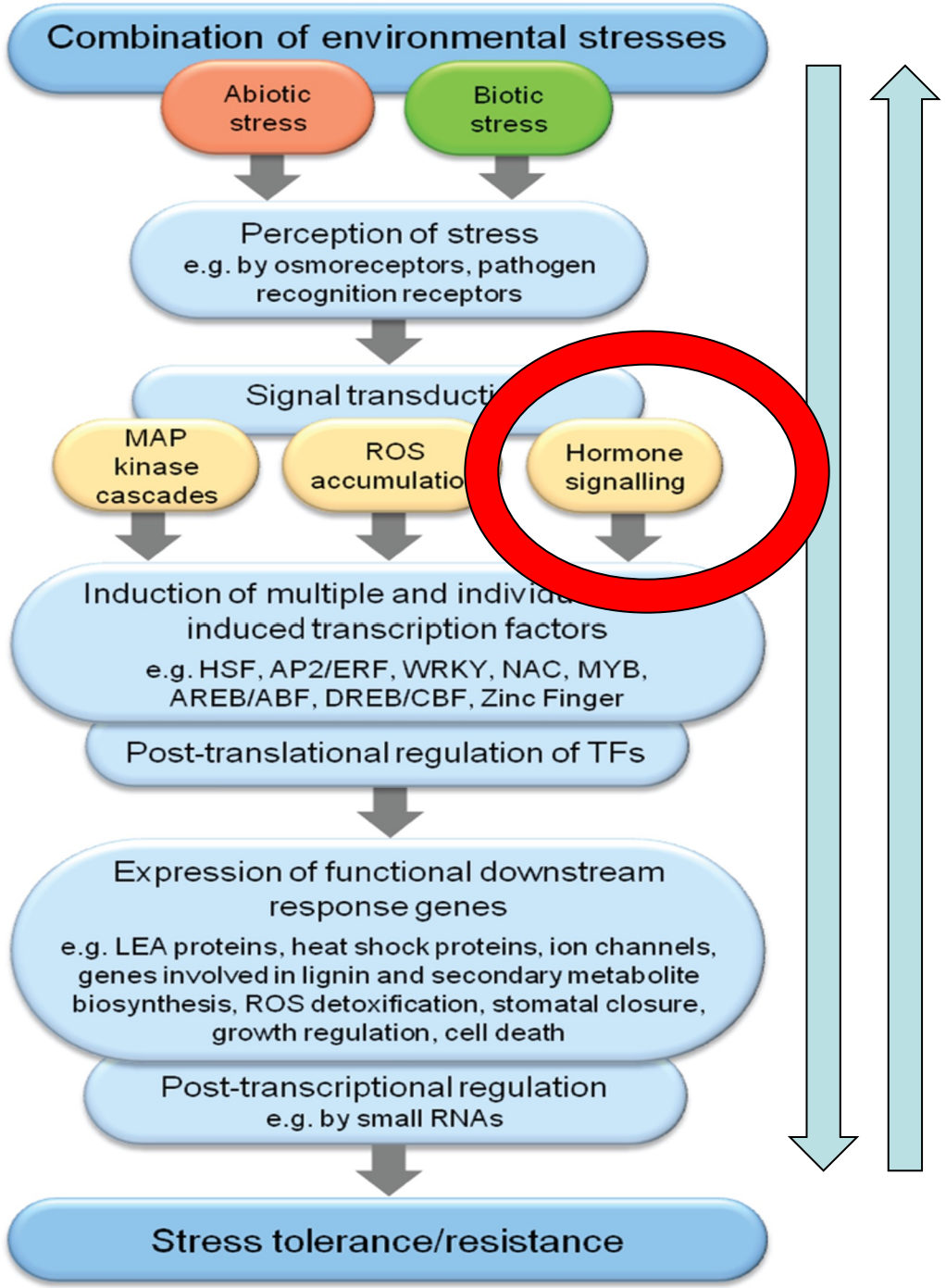
***PLANT PHYSIOLOGY AND DEVELOPMENT 6e*, Figure 24.1**

- Plants respond to the environmental stress by altering these pathways
- Plants are overly 'conservative' ensuring that at least a few seed are produced.
- Agricultural productivity would benefit if stress or stress response was modulated.
- Can we manipulate these responses with biostimulants?

Plant Perception and Response to Stress occurs through Signaling and Plant Growth Regulation

Many biostimulants have been shown to affect plant stress signaling and regulatory pathways.

Currently identified modes of action of biostimulants



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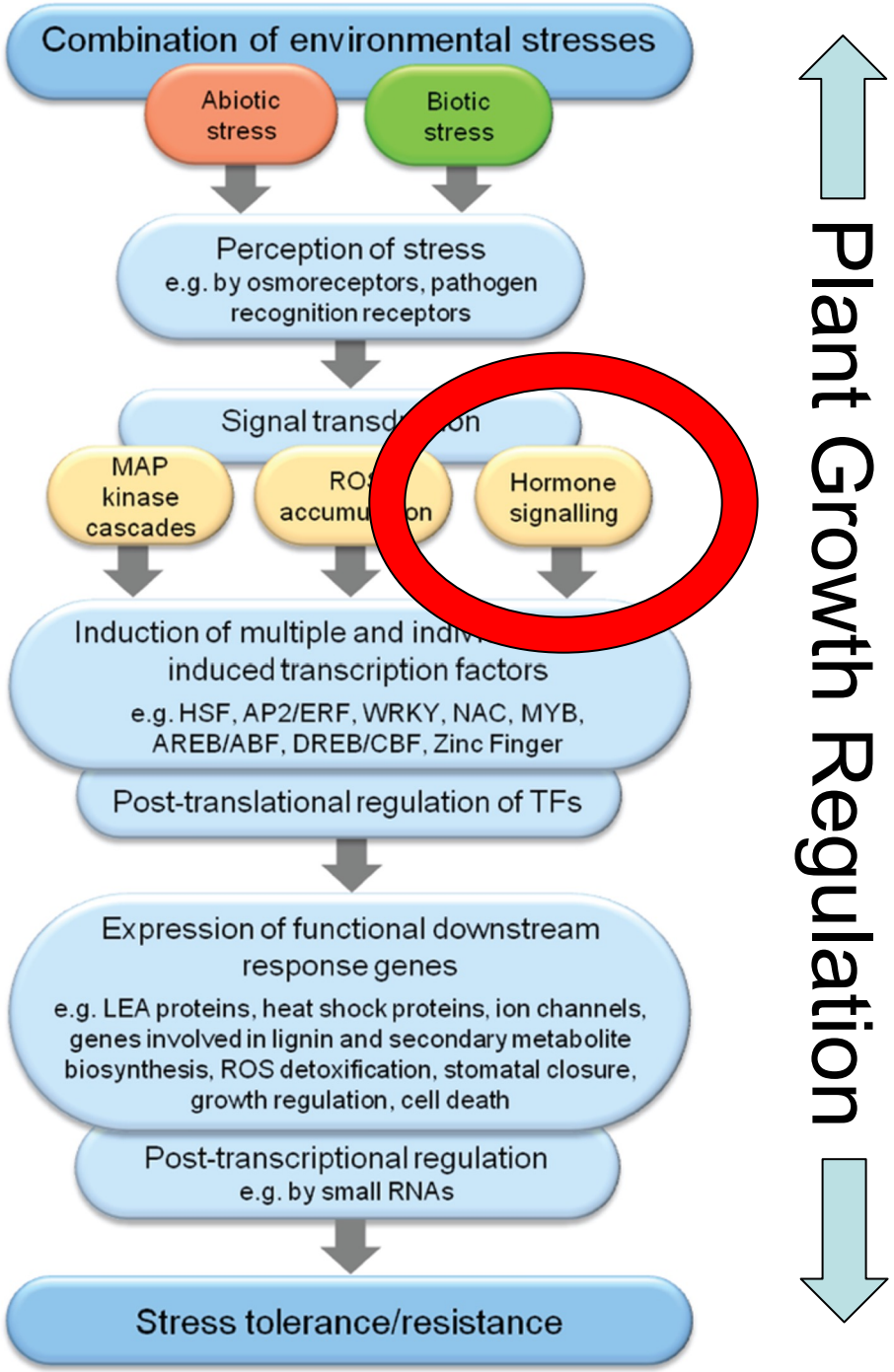
If a biostimulant, agronomic practice, molecular or conventional breeding event, soil microbiome treatment alters plant growth and stress response, is it therefore a plant regulator?



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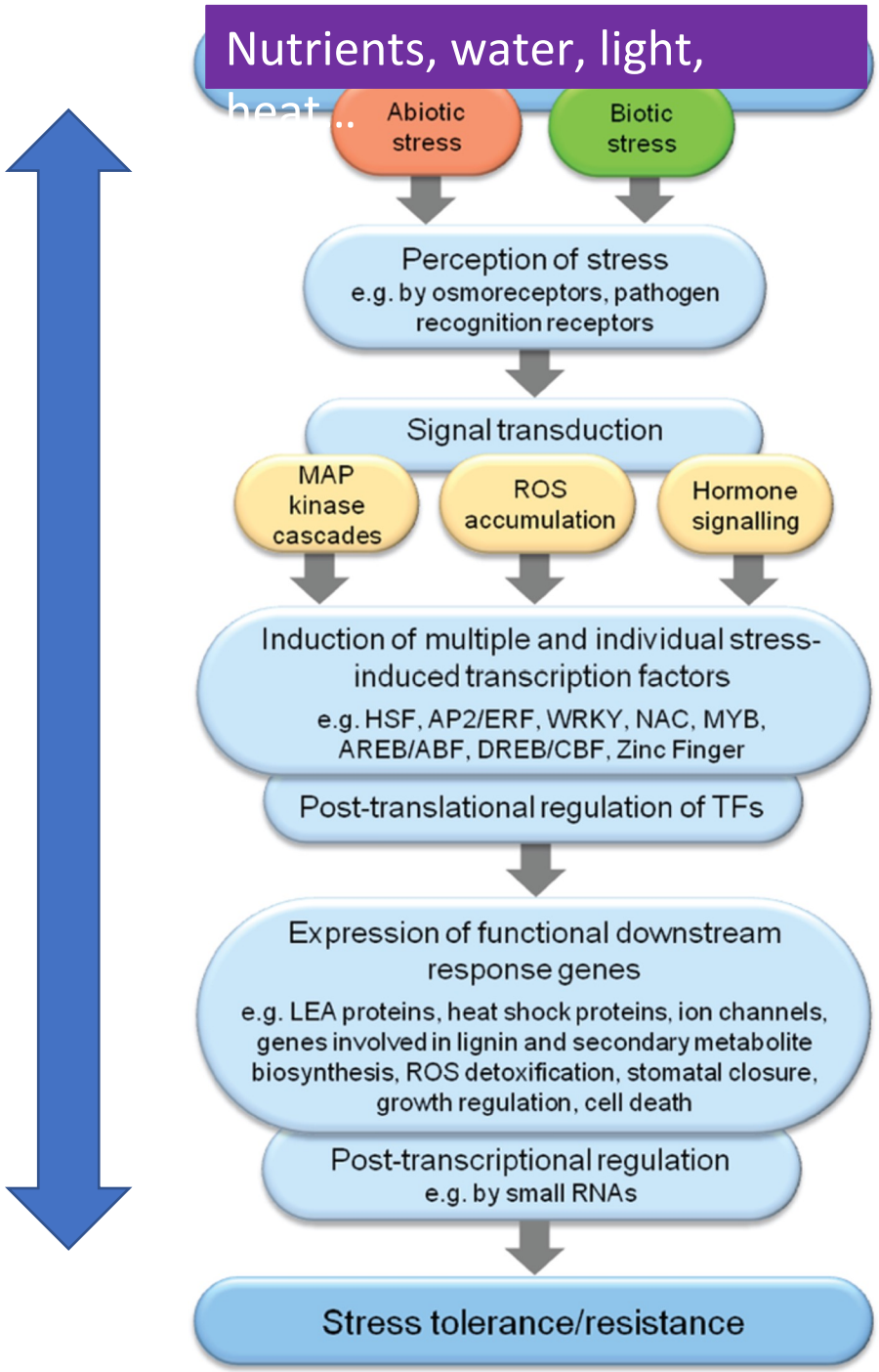
EPA Questions

EPA Definition of Plant Regulator:

"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"

Q1: From an academic perspective, how do you interpret/view the Environmental Protection Agency's current definition for plant regulator?:

In other words, what types of substances would you consider to fall under this definition and why?

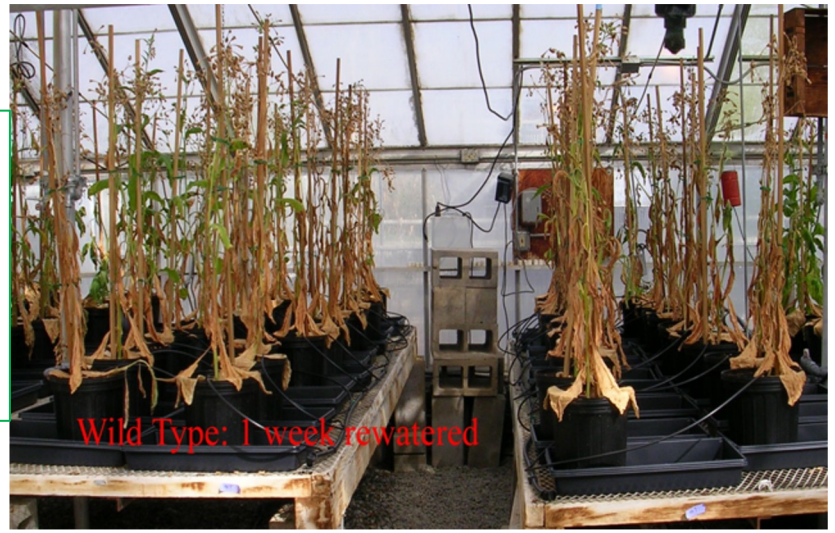


Transgenic manipulation of drought perception and plant response in tobacco (Cytokinin regulation)

6 weeks well watered

1 week severe drought

1 week rewatered



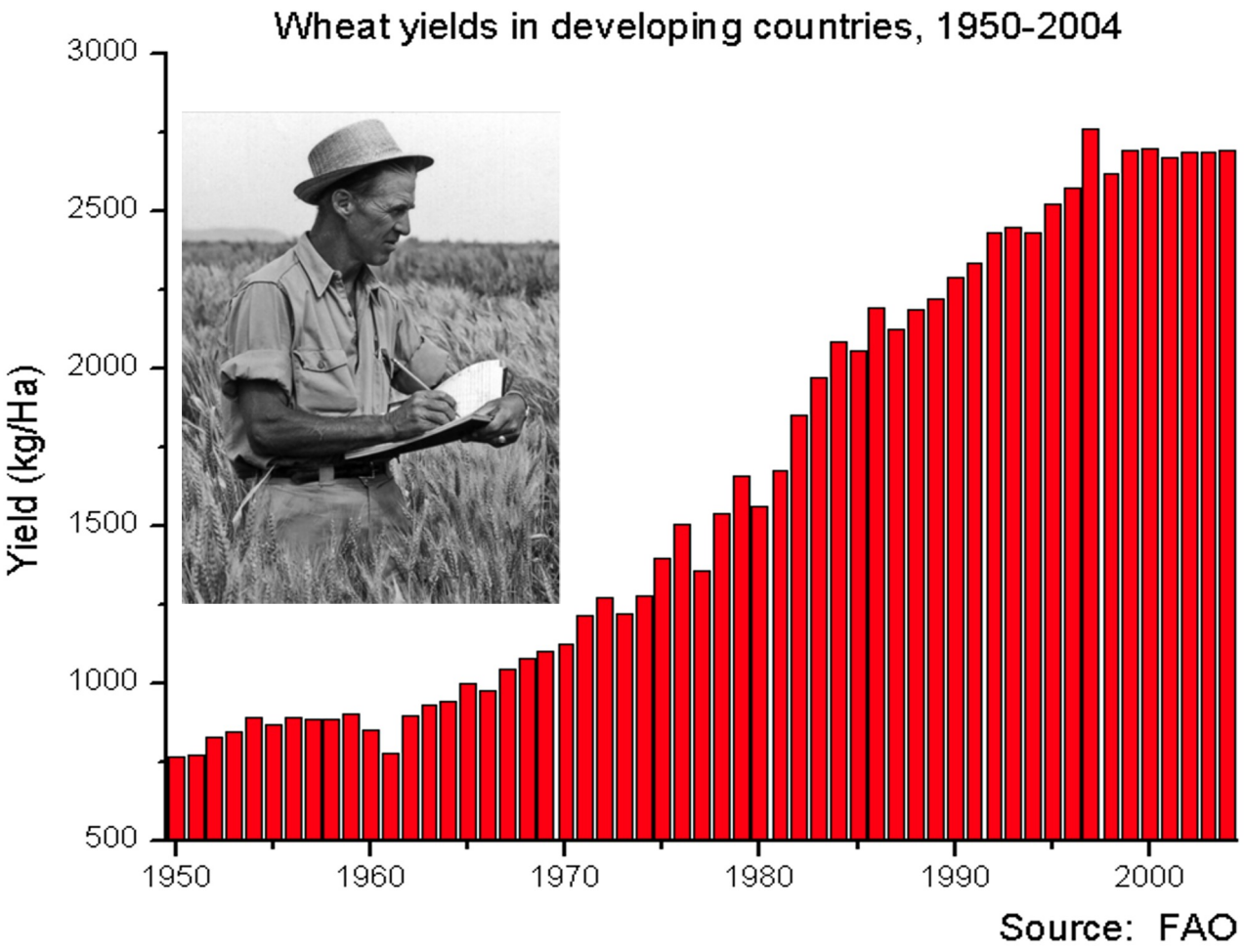
Wild type

Transgenic with altered Cytokinin response pathway.

Rivero et al., PNAS (2007); Plant Physiol (2009); Plant Cell Physiol. (2010)

Gibberellin Manipulation was the Foundation of the Green Revolution

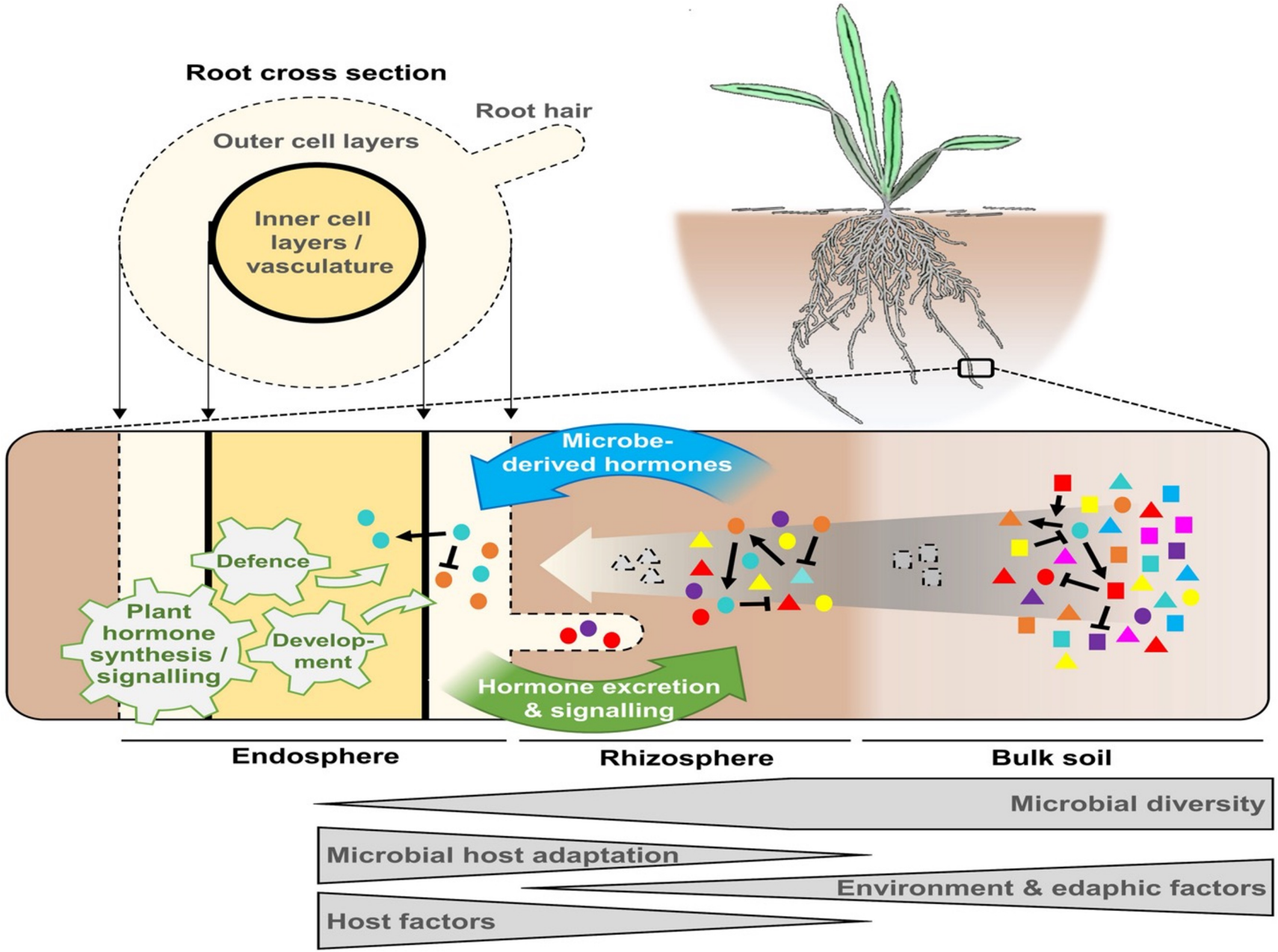
500% Increase in wheat, rice and corn yield



The semidwarf varieties that increase productivity 500% and fed the world, did so by changing the plant hormone gibberellic acid response.

Hormone Metabolism and Signaling in Plants. http://dx.doi.org/10.1016/B978-0-12-811562-6.00004-9 Jiayang Li, Chuanyou Li and Steven Smith. Published by Elsevier

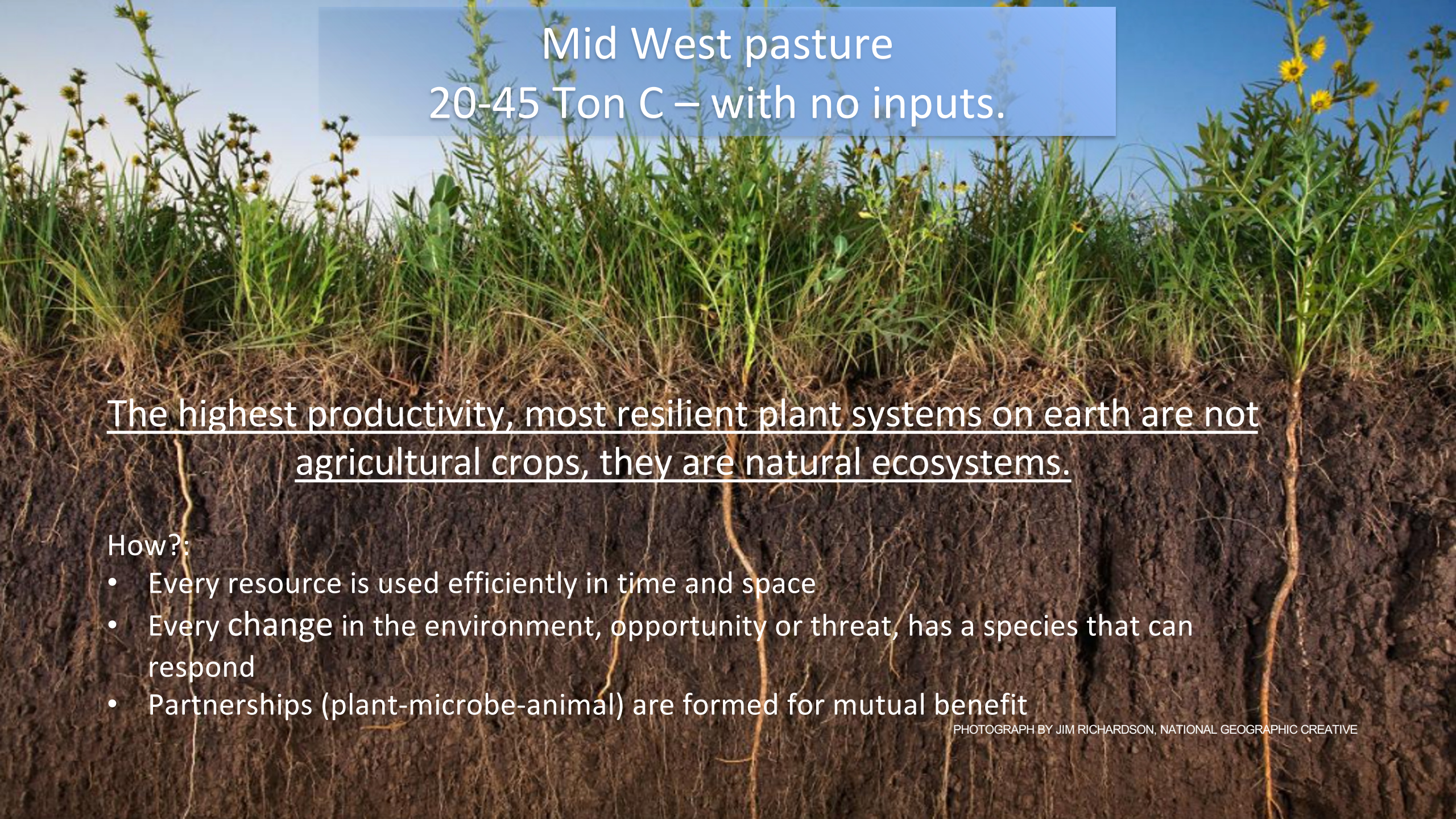
Soil and Plant Associate Microbes Regulate Plant Growth



THE SOIL MICROBIOME IS A KEY PLAYER IN CROP PRODUCTIVITY

- Microbial abundance and diversity is a key measure of soil health.
- Plant development and tolerance to stress is strongly mediated by soil microbes.
- Both plant and the microbial community, produce and metabolize plant regulators in a mutually beneficial partnership.

The Plant Journal, Volume: 105, Issue: 2, Pages: 518-541,
First published: 17 December 2020, DOI: (10.1111/tpj.15135)



Mid West pasture
20-45 Ton C – with no inputs.

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How?:

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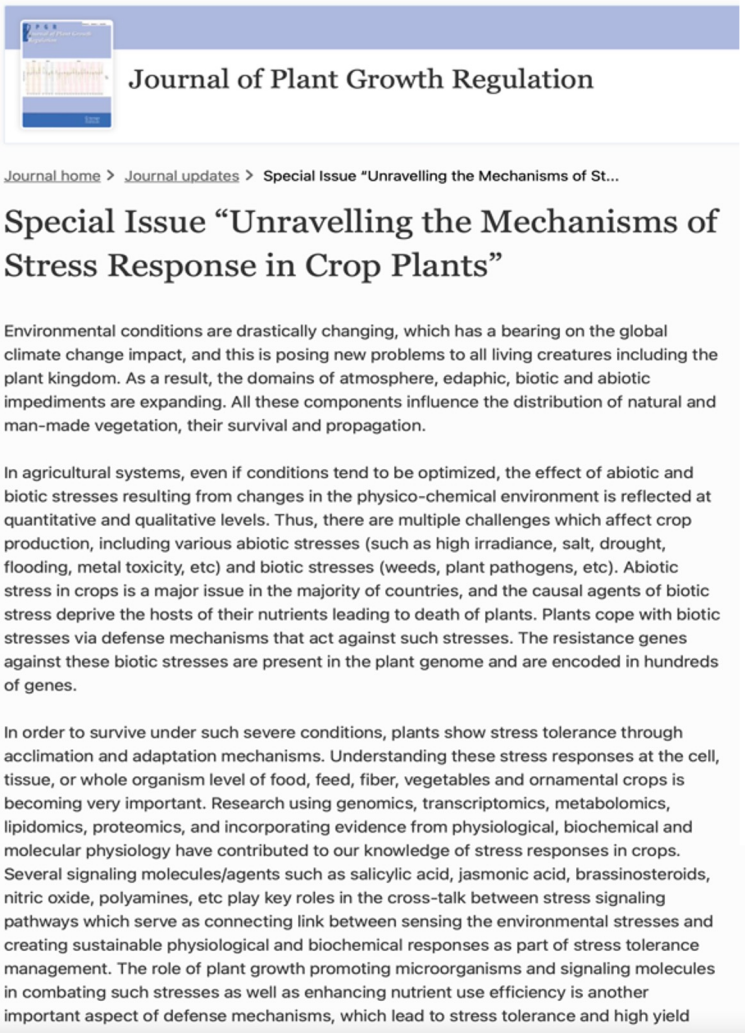
PHOTOGRAPH BY JIM RICHARDSON, NATIONAL GEOGRAPHIC CREATIVE

INCREASING EVIDENCE THAT PLANT RESPONSE TO STRESS IS MEDIATED BY PLANT GROWTH REGULATORY NETWORKS

2022



Journal of Plant Growth Regulation

Journal home > Journal updates > Special Issue "Unravelling the Mechanisms of St...

Special Issue "Unravelling the Mechanisms of Stress Response in Crop Plants"

Environmental conditions are drastically changing, which has a bearing on the global climate change impact, and this is posing new problems to all living creatures including the plant kingdom. As a result, the domains of atmosphere, edaphic, biotic and abiotic impediments are expanding. All these components influence the distribution of natural and man-made vegetation, their survival and propagation.

In agricultural systems, even if conditions tend to be optimized, the effect of abiotic and biotic stresses resulting from changes in the physico-chemical environment is reflected at quantitative and qualitative levels. Thus, there are multiple challenges which affect crop production, including various abiotic stresses (such as high irradiance, salt, drought, flooding, metal toxicity, etc) and biotic stresses (weeds, plant pathogens, etc). Abiotic stress in crops is a major issue in the majority of countries, and the causal agents of biotic stress deprive the hosts of their nutrients leading to death of plants. Plants cope with biotic stresses via defense mechanisms that act against such stresses. The resistance genes against these biotic stresses are present in the plant genome and are encoded in hundreds of genes.

In order to survive under such severe conditions, plants show stress tolerance through acclimation and adaptation mechanisms. Understanding these stress responses at the cell, tissue, or whole organism level of food, feed, fiber, vegetables and ornamental crops is becoming very important. Research using genomics, transcriptomics, metabolomics, lipidomics, proteomics, and incorporating evidence from physiological, biochemical and molecular physiology have contributed to our knowledge of stress responses in crops. Several signaling molecules/agents such as salicylic acid, jasmonic acid, brassinosteroids, nitric oxide, polyamines, etc play key roles in the cross-talk between stress signaling pathways which serve as connecting link between sensing the environmental stresses and creating sustainable physiological and biochemical responses as part of stress tolerance management. The role of plant growth promoting microorganisms and signaling molecules in combating such stresses as well as enhancing nutrient use efficiency is another important aspect of defense mechanisms, which lead to stress tolerance and high yield

NATURE 2022

REVIEWS

Check for updates

Plant hormone regulation of abiotic stress responses

Rainer Waadt[1,2], Charles A. Seller[3], Po-Kai Hsu[3], Yohei Takahashi[3], Shintaro Munemasa[4] and Julian I. Schroeder[3]

Abstract | Plant hormones are signalling compounds that regulate crucial aspects of growth, development and environmental stress responses. Abiotic stresses, such as drought, salinity, heat, cold and flooding, have profound effects on plant growth and survival. Adaptation and tolerance to such stresses require sophisticated sensing, signalling and stress response mechanisms. In this Review, we discuss recent advances in understanding how diverse plant hormones control abiotic stress responses in plants and highlight points of hormonal crosstalk during abiotic stress signalling. Control mechanisms and stress responses mediated by plant hormones including abscisic acid, auxin, brassinosteroids, cytokinins, ethylene and gibberellins are discussed. We discuss new insights into osmotic stress sensing and signalling mechanisms, hormonal control of gene regulation and plant development during stress, hormone-regulated submergence tolerance and stomatal movements. We further explore how innovative imaging approaches are providing insights into single-cell and tissue hormone dynamics. Understanding stress tolerance mechanisms opens new opportunities for agricultural applications.

2022

Journal of Plant Growth Regulation

Journal home > Journal updates > Special Issue: Phytohormone-like Plant Growth R...

Special Issue: Phytohormone-like Plant Growth Regulators: Plant Responses, Stress Mitigation, and Crosstalk

Recently discovered natural plant growth substances that have phytohormone-like regulatory roles are polyamines (putrescine, spermidine, spermine etc.), sugars (glucose, sucrose, trehalose etc.), neurotransmitters (serotonin, melatonin, dopamine, acetylcholine and GABA), strigolactones and karrikins. In recent years, several studies have focused on the factors and mechanisms that regulate plant growth and development, as well as the functioning of signaling pathways in plant cells. The application of these phytohormone-like plant growth regulators (PGRs) at low concentration would help to bring rapid and significant changes in the phenotypes of plants; as well as boost growth, translocation of nutrients from source to sink, increase economic part of plants and productivity of crops under normal and adverse conditions.

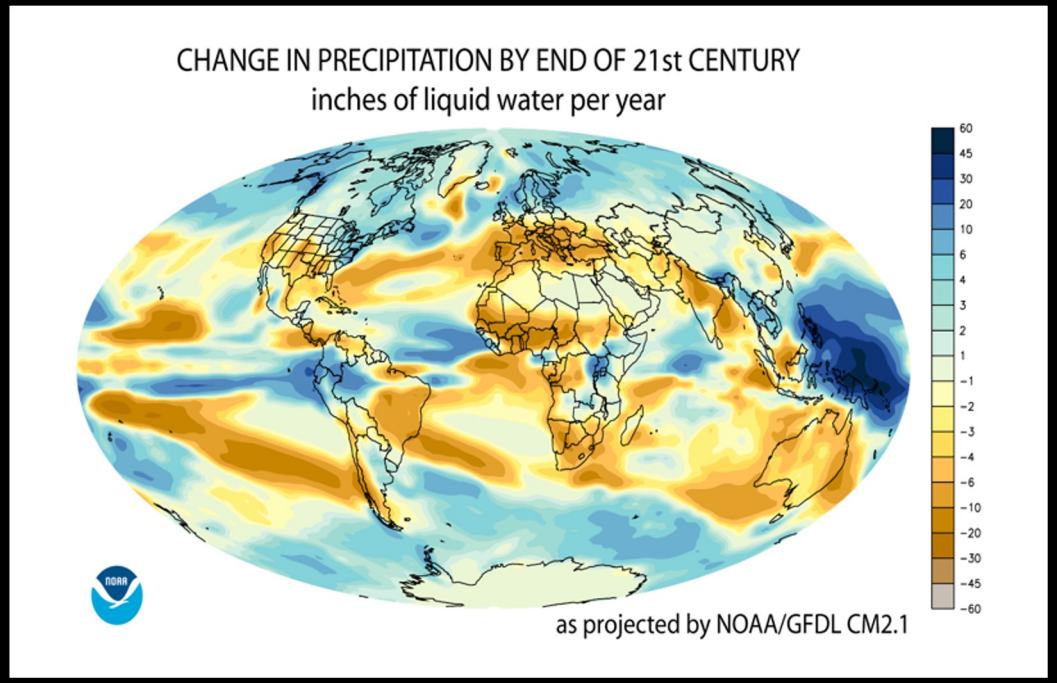
Polyamines play important roles in diverse plant growth and developmental processes and in environmental stress responses. With the development of molecular biotechnology techniques, there is increasing evidence that polyamines, whether applied exogenously or produced endogenously via genetic engineering, can positively affect plant growth, productivity, and stress tolerance. Saccharides play an important role in the life of plants: they are structural, storage and respiratory substrates, and intermediate metabolites of many biochemical processes. Sugar-metabolizing enzymes and sugar transporters are important in regulating plant growth and development, such as in the vegetative to generative phase transition. Neurotransmitters have emerged as potential signaling molecules in the last decade of investigations in various plant systems. They have been found to play important roles in plant life including-organogenesis, flowering, ion permeability, photosynthesis, circadian rhythm, reproduction, fruit ripening, photomorphogenesis, adaptation to environmental changes. Likewise, strigolactones and karrikin molecules regulate different biological processes, but overlapping functions have been reported as well, in which both molecules can have either similar or opposite effects.

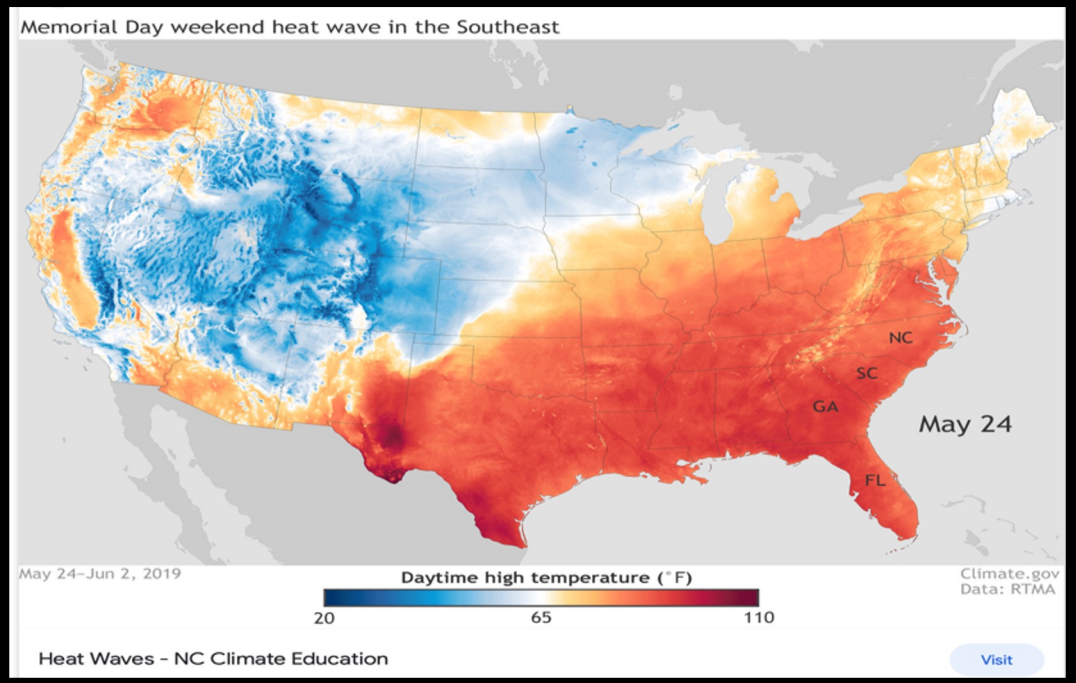
A better understanding of the uptake, transport, metabolism, signalling process, mechanisms and the crosstalk of these PGRs has increased our knowledge of the

The EPA Definition of a Plant Regulator is Fundamentally Flawed (my opinion!)

- The definition was developed when synthetic plant regulators were predominantly utilized as herbicides and preceded our modern scientific understanding of plant growth and development.
- It is established science that all aspects of plant growth and plant response to environment are mediated through plant and microbial plant regulators.
- All abiotic stresses responses and adaptations are mediated by changes in the plant regulatory system.
- Many of the most important traditional and molecular breeding improvements have been achieved by manipulating plant hormone (regulator) pathways.

Climate Change: Rainfall, Heat, Drought, Flood, Frost…….





USA Today, Jan 10, 2022

https://www.winemag.com/2021/04/26/france-wine-harvest-frost/

EPA Questions (cont)

1. From an academic perspective, how do you interpret/view the Environmental Protection Agency's current definition for plant regulator:

Naturally occurring plant regulators (plant or microbial origin) are found universally in all plant life (all plant foods eaten by man or animal – even that bowl of salad) and pose no substantial human health or environmental threat when present or used at concentrations that beneficially alter plant growth and development.

Summary Table of Endogenous Levels of natural PGR's in Plants

Biostimulants have far lower hormone concentrations than crop plants.

BPIA data

PGR	Crop	Endogenous Range	Stress/ Ripening concentration (if applicable)	Source
Auxins				
Crops	Corn/Maize	20-240 ng/g FW	IAA100-300 ng/g FW IBA 1500 ng/g FW	**IAA:** Takeshi, 2011; Li et al, 2018; Zhao et al., 2016; LaClere et al., 2010; Gao et al., 2018; Nishimura et al., 2006; Tian et al., 2008; Li et al., 2020; El-Mergawi and Abd El-Wahed, 2020 Sugawara et al., 2009 **IBA:** Ludwig-Müller et al., 1997; Sugawara et al., 2009
Crops	Soybean	0.1-250 ng/g FW	100-200 ng/g FW	Bawa et al., 2020; Mao et al., 2017; Peng and Zhou, 2009; Mao et al., 2017; Zhang et al., 2007; Yang et al., 2017; Wu et al., 2017; Nonokawa et al., 2007
Crops	Rice	4-48 ng/g FW		Sugawara et al., 2009; Du et al., 2013; Huang et al., 2019; Liu et al., 2019; Kim et al., 2006; Guo et al., 2020; Jin et al., 2021; Liu et al, 2011
Crops	Tomato	9-70 ng/FW		Higashide et al., 2014; Silva et al., 2018; Jahan et al., 2021; Kojima et al., 2002; Fellner et al., 2001; Ding et al., 2013; Mariotti et al., 2011; Mariotti et al., 2011
Biostimulants	*Ascophyllum nodosum*	0.1-0.62 ng/g FW		Wally et al., 2013
Biostimulants	*Ecklonia maxima*	0.01 ng/g FW		Wally et al., 2013; Stirk et al., 2004
Biostimulants	*Macrocystis Pyrifera*	0.001-0.002 ng/g FW		Stirk et al., 2004
Cytokinins				
Crops	Corn/Maize	8-45 ng/g FW	75-1000 ng/g FW	Li et al, 2018; Gao et al., 2018; Liu et al,. 2018; Wang et al., 2020
Crops	Soybean	0.5-26 ng/g FW		Mao et al., 2017; Zhang et al., 2007; Wu et al., 2017; Nonokawa et al., 2007; Lee et al., 2012
Crops	Rice	0.50-40 ng/g FW		Liu et al., 2011; Tsago et al, 2020; Tao et al., 2020; Zhang et al., 2022; Li et al., 2022
Biostimulants	*Ascophyllum nodosum*	0.1-0.62 ng/g FW		Wally et al., 2013
Biostimulants	*Ecklonia maxima*	0.01 ng/g FW		Wally et al., 2013; Stirk et al., 2004
Biostimulants	*Macrocystis Pyrifera*	0.001-0.002 ng/g FW		Stirk et al., 2004

EPA Questions:

3. Do you have any thoughts on drawing a clear line between affecting hormonal state of a plant and plant response?

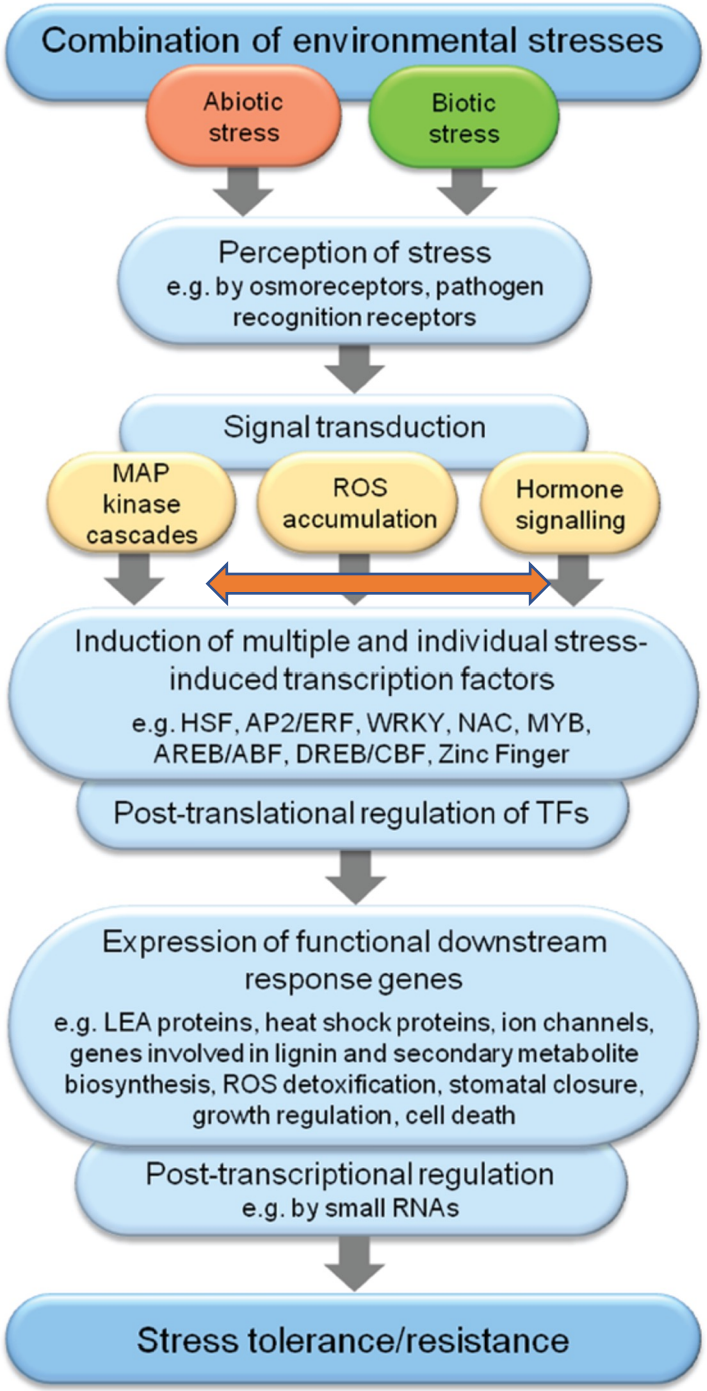
- There is no clear line - anything that alters plant response (even water and nutrients) does so by affecting hormonal state.

5. In a slide that you presented at the Biological Products Industry Alliance annual meeting you provided a diagram that appears to contain information to suggest there is some overlap between what plant biostimulants do and what plant regulators do. Would you be able to walk through the diagram with us in some more detail?

Applying biostimulants to achieve these goals? = ???
Plant Regulator or…'Fertilizing Product'

Applying hormones/PGR's to achieve these goals = Pesticide
- 'Fertilizers' also do this but are exempted under 40CFR

Demonstrated biostimulant mediated responses.



Cytokinin, ABA, Eth, Brassinoteroids..(PGR's)

Naturally occurring PGR's at concentrations found in healthy plants are entirely safe. (Spinach)

These changes in plant regulator network and plant growth and development also occur in response to nutrients, water, and any environmental stress

Hormone and peptide mediated processes (Cyt, GA, IAA, SL..)

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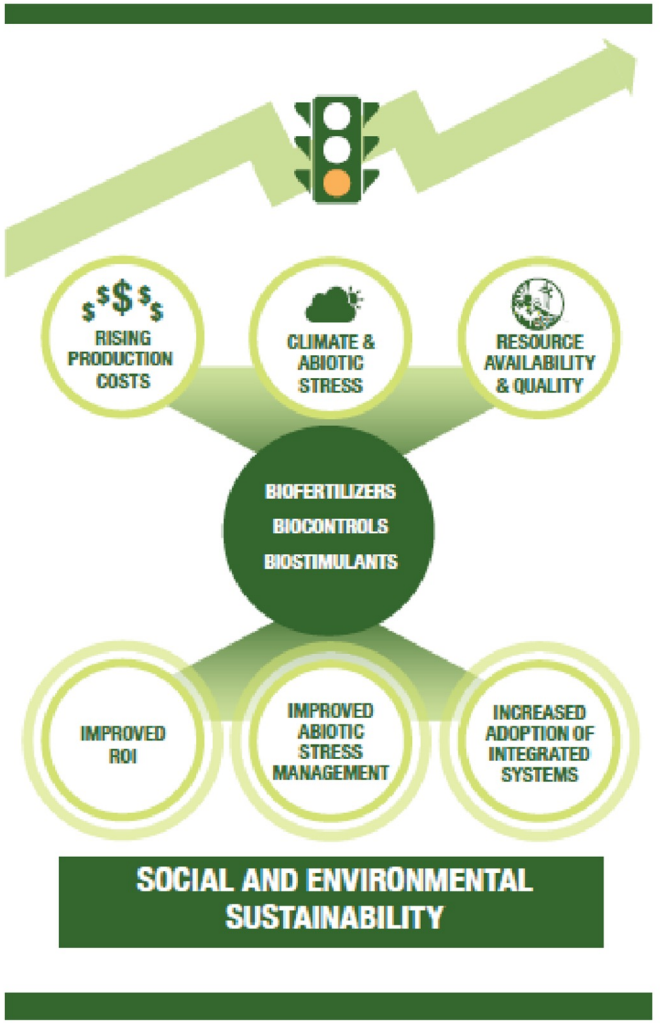
Opinion and Recommendations

- The current EPA definition of plant regulators does not recognize modern biological knowledge and clearly constrains our ability to meet the agricultural and environmental challenges of our time.
- The majority of countries (China, Brazil, EU, LATAM, Canada..) have recognized this and allow biostimulant use under ‘fertilizer’ type laws, not ‘pesticide’ laws.
- Development of genetic, molecular or biostimulant approaches to address climate change or improve nutrient and water use efficiency will, by definition, involve changes in Plant Growth Regulation. That is neither dangerous nor undesirable.



Opinion

Amend 40 CFR § 152.6 –

(g) *Products intended to aid the growth of desirable plants.* A product of any of the following types, intended only to aid the growth of desirable plants, is not a "plant regulator" under section 2(v) of FIFRA, and therefore is not a pesticide:

(1) A plant nutrient product, ….

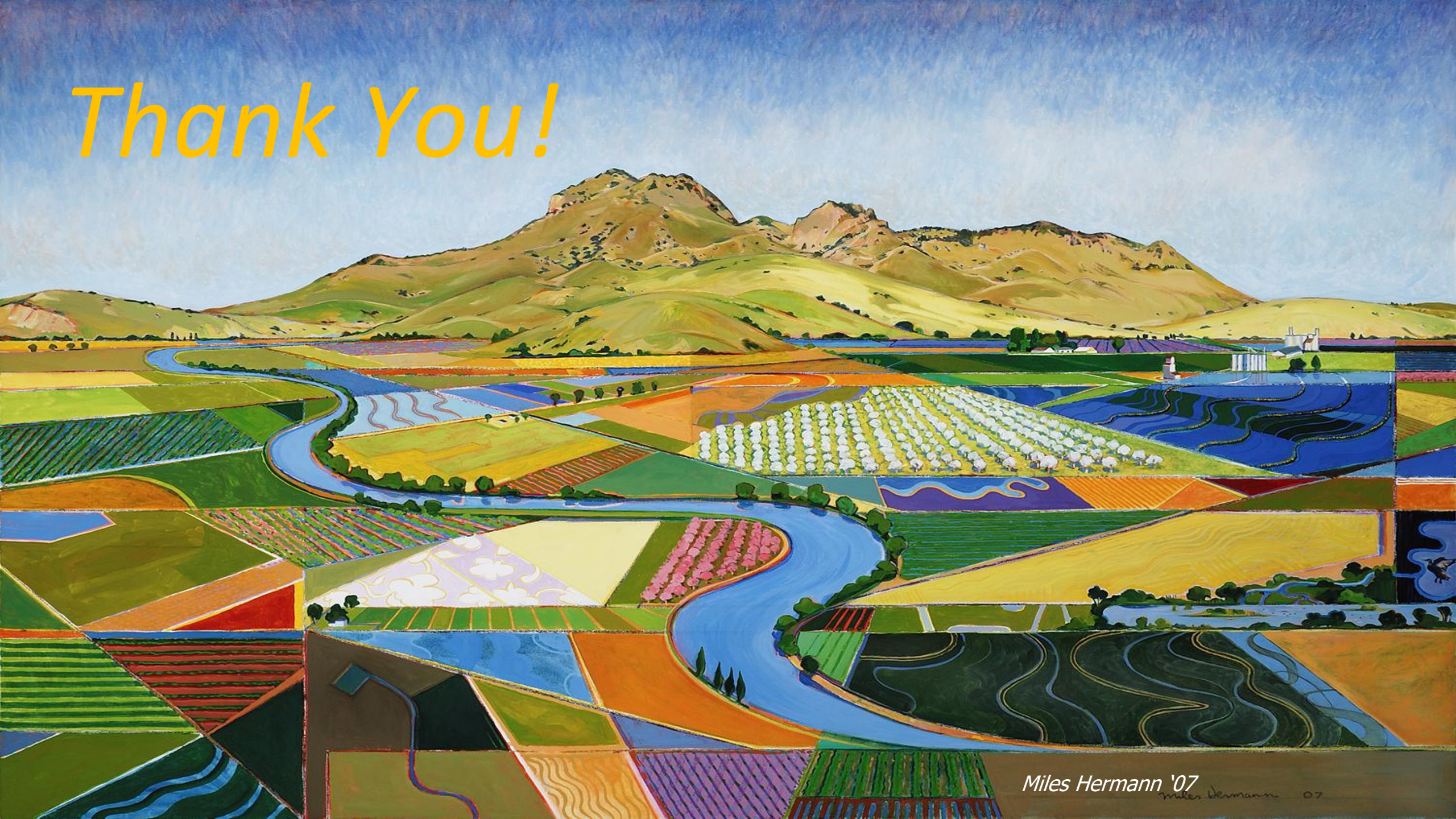
(2) A plant inoculant product ….

(3) A soil amendment product ….

ADD:

(4) A plant biostimulant product defined as follows: *Plant biostimulant means a substance, micro-organism, or mixture thereof, that, when applied to seeds, plants, the rhizosphere, soil, or other growth media, act to support a plant's natural processes independently of the biostimulant's nutrient content, including by improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield.*

Thank You!



Global Biostimulant Regulations

USDA Version II

Plant biostimulant is a substance (s), microorganism (s), or mixtures thereof, that when applied to seeds, plants, the rhizosphere, soil or other growth media, act to support a plant's natural nutrition processes independently of the biostimulants nutrient content. The plant biostimulant thereby improves nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality or yield.

Marker Bill HR 7752

Plant biostimulant means a substance, micro-organism, or mixture thereof, that, when applied to seeds, plants, the rhizosphere, soil, or other growth media, act to support a plant's natural processes independently of the biostimulants nutrient content, including by improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield.

EU FPR 2019/1009

Plant biostimulant means a product stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere: (a) nutrient use efficiency (b) tolerance to abiotic stress; (c) quality traits

ISO TC 134

Plant biostimulant means a substance(s) and/or microorganism(s) whose function, independent of the nutrient content, when applied to seeds, plants or the rhizosphere is to stimulate natural processes to enhance/benefit one or more of the following : nutrient uptake, nutrient efficiency, tolerance to abiotic stress, crop quality, yield"

Global Biostimulant Regulations

Chile Law 21349
Plant Biostimulant: a substance or mixture of substances or micro-organisms, applicable to seeds, plants or rhizosphere, which stimulate the natural nutritional processes of plants, with the aim of improving efficiency in the use of nutrients, tolerance to abiotic stress, quality attributes, or the availability of nutrients immobilized in the soil or in the rhizosphere.

India SO 882
Plant biostimulant means a substance or microorganism or a combination of both whose primary function when applied to plants, seeds or rhizosphere is to stimulate physiological processes in plants and to enhance its nutrient uptake, growth, yield, nutrition efficiency, crop quality and tolerance to stress, regardless of its nutrient content

China NY/T 3831-2021
Plant biostimulant means an ingredient that enable plants to stimulate their growth through the synthesis of growth-promoting substances and/or through nutritional processes that are not affected by nutrient substances. Achieve the goals of improving plant nutrient utilization or absorption rate, improving resistant of abiotic stress and/or improving crop quality traits

Ecuador Resolution 31 Edition 6 2021
Plant Biostimulants are products that act on the physiology of plants in different ways and by different pathways to promote their growth and development; In addition, they improve their metabolism and adaptation to adverse conditions or stress. When applied to plants or soil, they improve vigor, productivity and/or crop quality by stimulating physiological processes that benefit growth and responses to biotic and/or abiotic stress. As a result, the plant is more vigorous, there is a more efficient use of nutrients, and higher productivity and quality of the harvest. In general, they work through different mechanisms than fertilizers, without depending on the availability of essential nutrients in their composition. Therefore, they are not used to replace fertilizers, but can be used together to achieve greater and better plant growth.

Listening Session on Plant Biostimulants and The Executive Order on Advancing Biotechnology and Biomanufacturing Innovation

What is the biostimulant market today and tomorrow?

Mark Trimmer

Managing Partner, DunhamTrimmer LLC

Board Chair, BPIA

January 31, 2023

BIOLOGICAL PRODUCTS

Source: DunhamTrimmer® LLC

BIOSTIMULANTS[1]

MICROBIALS

- NUTRIENT USE EFFICIENCY (NUE) (BIOFERTILIZERS)[2]
- PLANT GROWTH PROMOTION (PGP)

NON-MICROBIAL

- PLANT & SEAWEED EXTRACTS
- AMINO ACIDS
- ORGANIC ACIDS
- INORGANIC COMPOUNDS

[1] Biostimulants are products which elicit one or more of the following effects: 1) mitigate abiotic stress; 2) enhance crop quality; 3) improve nutrient assimilation. Their functions are typically classified as NUE (Nutrient Use Efficiency) or PGP (Plant Growth Promotion).

[2] Biofertilizers are Microbials used to enhance plant nutrient uptake from soil (NUE).

- N-fixing bacteria make up the largest segment.
- N-fixing bacteria for non leguminous crops make up the fastest growing segment.
- Other NUE microbials include mobilizers and solubilizers or chelators of specific nutrients such as P, K, S, Zn, Fe.

PGP Microbials target other biostimulant properties beyond NUE.

Non-microbial biostimulants may target either NUE or other PGP effects.

- Amino Acids and Seaweed Extracts are the fastest growing segments.
- Seaweed Extracts are a complex mixture of components including plant hormones, phenolic compounds, and other active substances.
- Amino Acid products include peptide fractions.
- Organic acids are mainly humic and fulvic acids used as soil amendments.

BIOCONTROLS

BIOPESTICIDES[3]

BIOCHEMICALS[4]

- PLANT EXTRACTS
- ORGANIC ACIDS
- PGRs
- SEMIOCHEMICALS

MICROBIALS[5]

- BACTERIA
- FUNGI
- PROTOZOA
- VIRUSES
- YEASTS
- OTHERS

[3] Biopesticides are derived from natural materials such as plants, bacteria and certain minerals. Biopesticides target specific pests and are inherently less toxic than synthetic pesticides.

[4] Biochemicals include Plant Extracts (largest by sales volume), Organic Acids, PGRs (plant hormones e.g. cytokinins, auxins, etc), and Semiochemicals (allelochemicals and pheromones).

MACROORGANISMS[6]

- INSECTS
- MITES
- NEMATODES

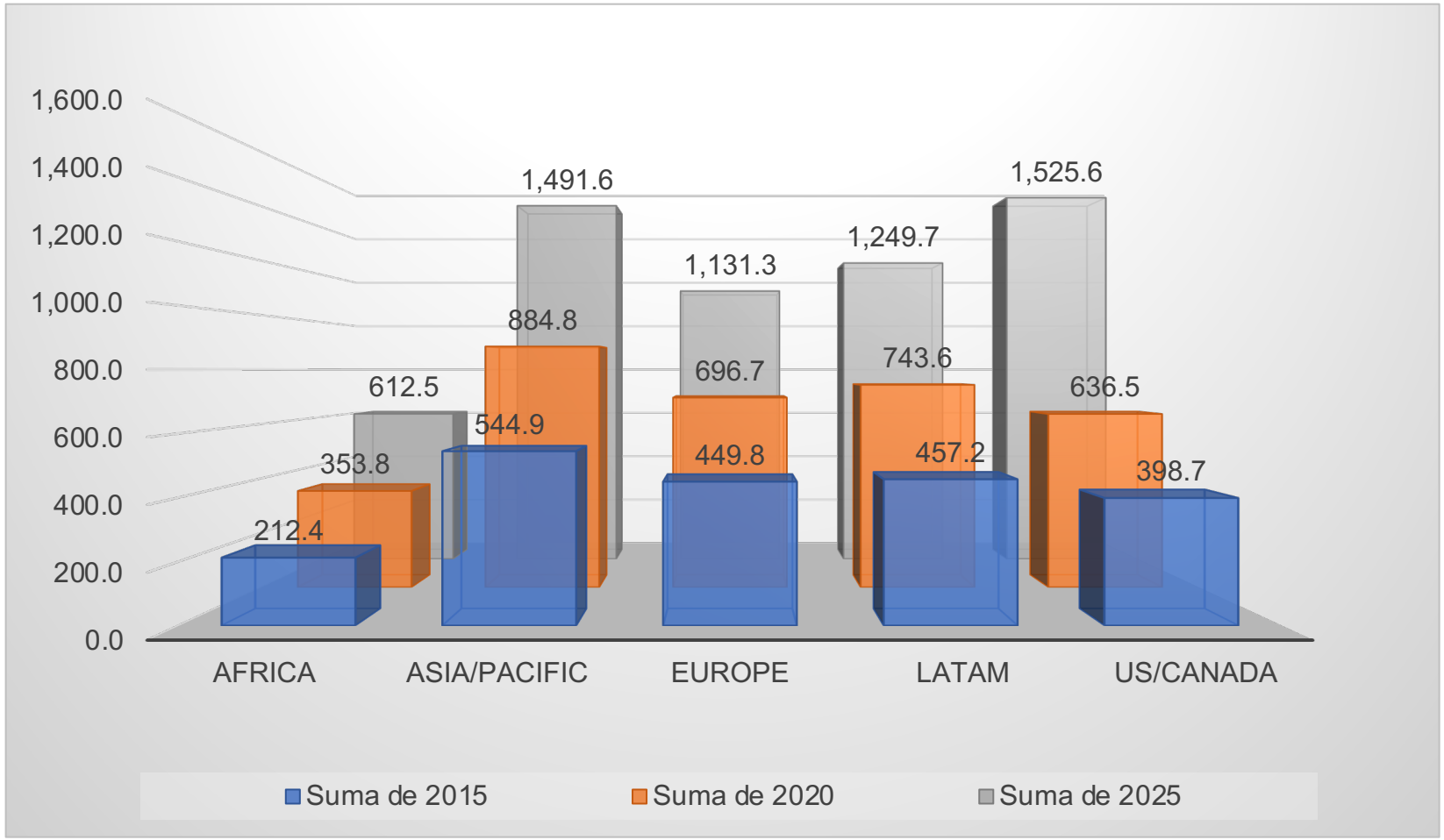
[5] Microbials refer to products based on bacteria, fungi, viruses, and protozoans. Microbials comprise the largest market of biopesticides.

- Bacteria, followed by fungi, make up the largest groups commercially (>90%).
- Biggest challenges relate to product formulation with regard to shelf-life, stability, and performance enhancement.

[6] Macroorganisms include insects, mites, and nematodes. Insects & mites are the largest groups.

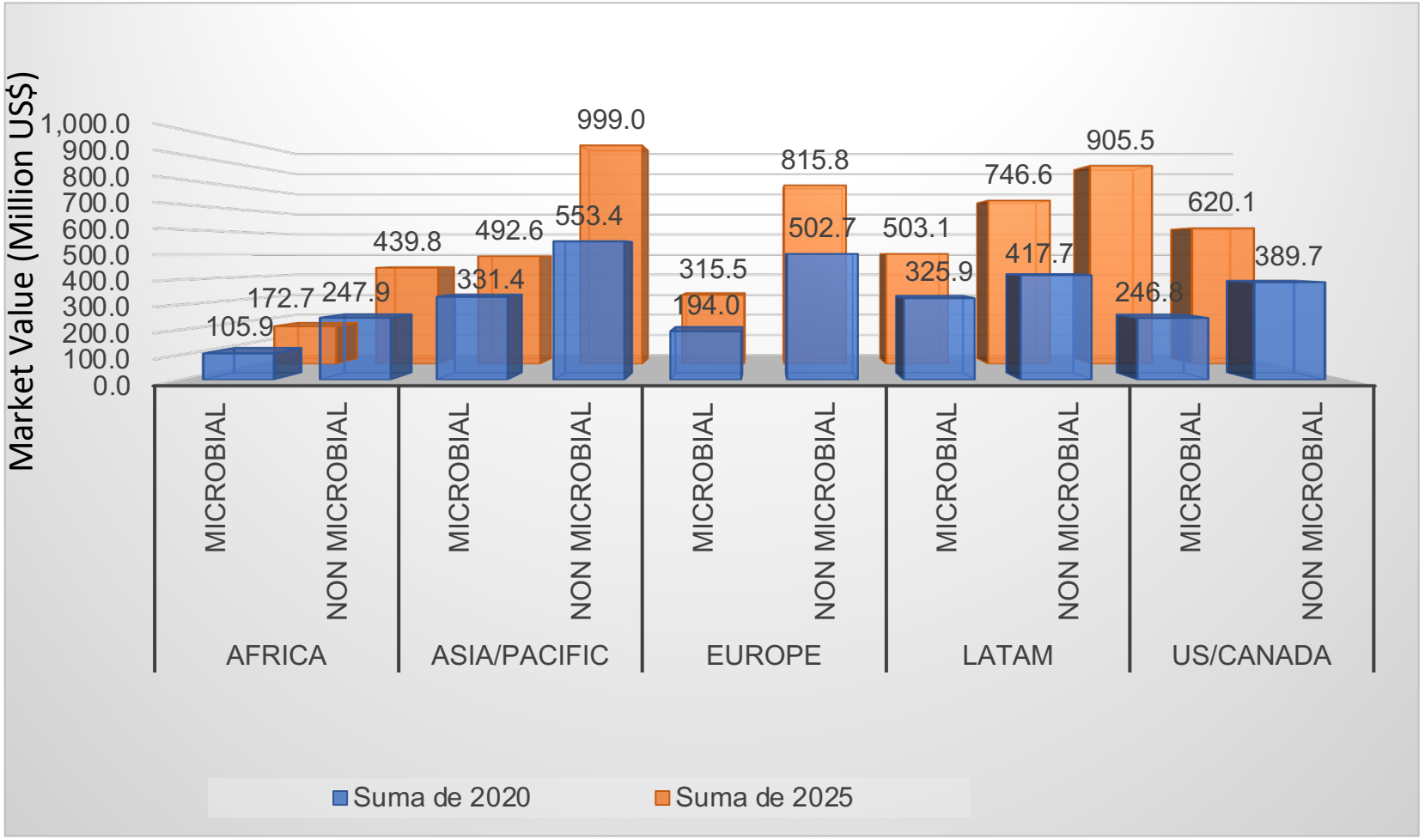
- Unique in that the live organism is used in the form of eggs, larvae, pupae, or adults.
- The most important challenge in this category is logistics — shipping live organisms that require special care to survive.
- Normally not classified as Biopesticides but rather Biocontrols.

Global Biostimulant Market



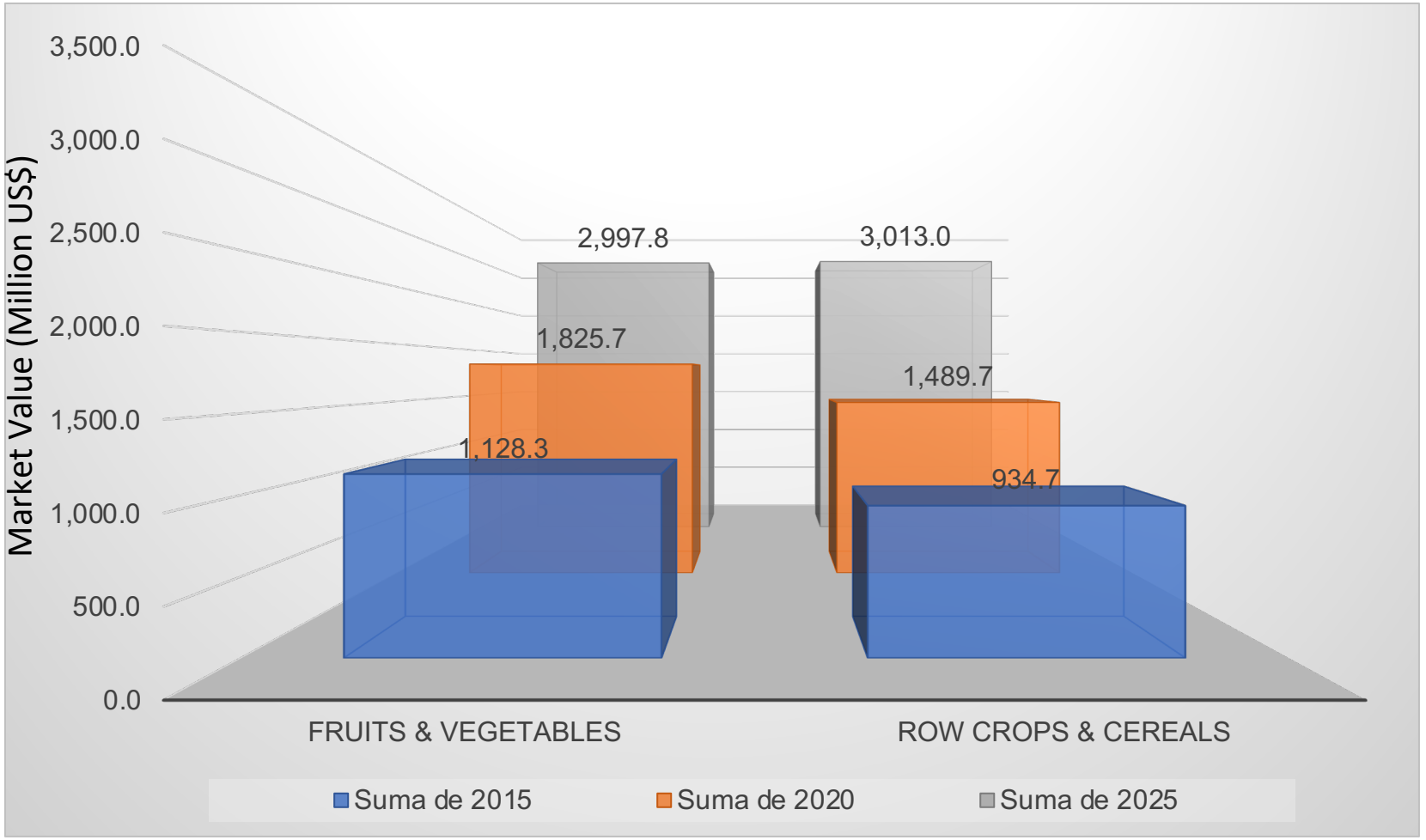
- US/Canada trails other regions today
- Future growth in US/Canada projected to be driven by broad adoption of microbial N fixing and other nutrient use efficiency products

Global Biostimulant Market



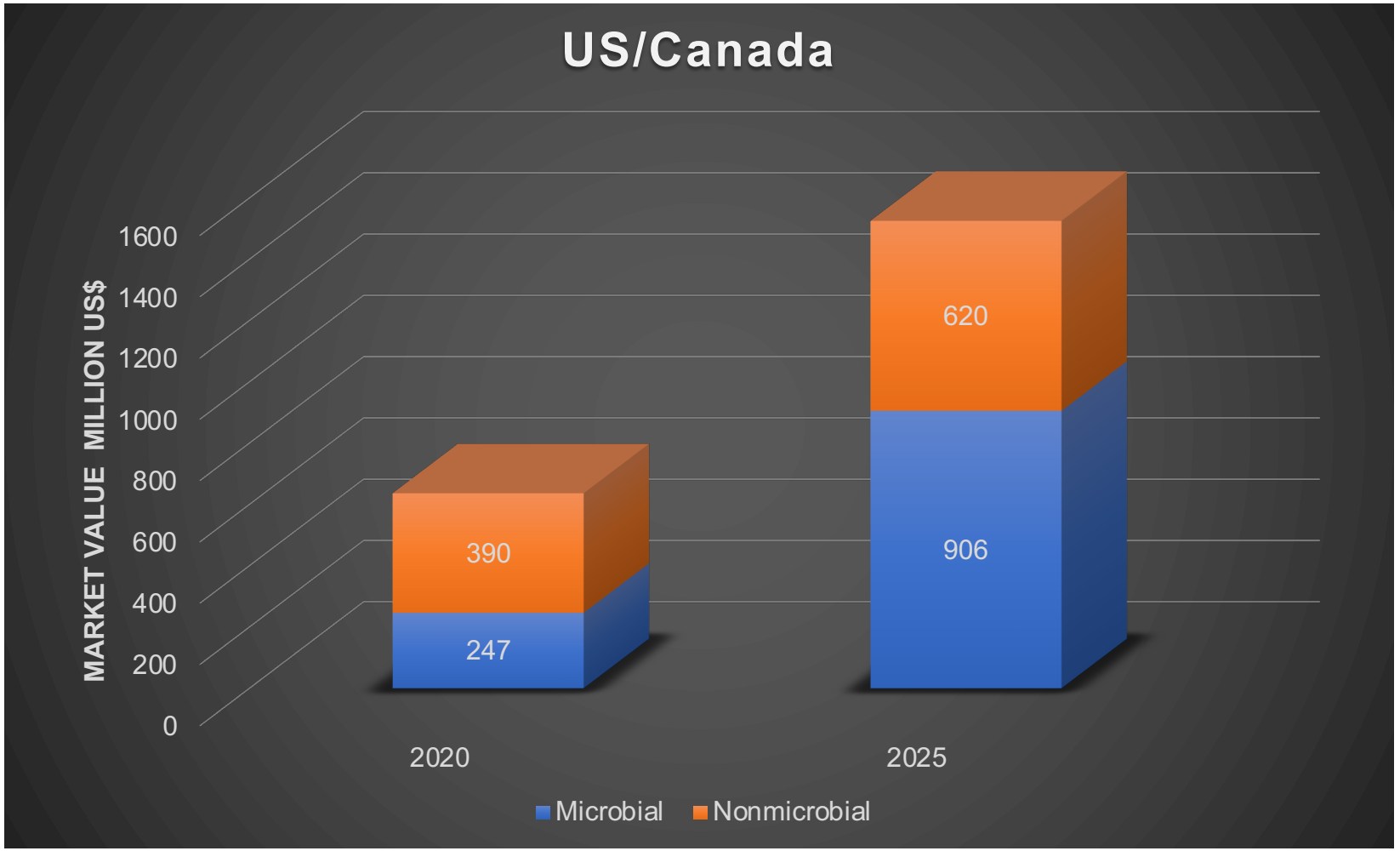
- Non-microbial products growth more dominant in most regions
- US/Canada growth driven by explosive expansion in microbial products

Global Biostimulant Crop Market

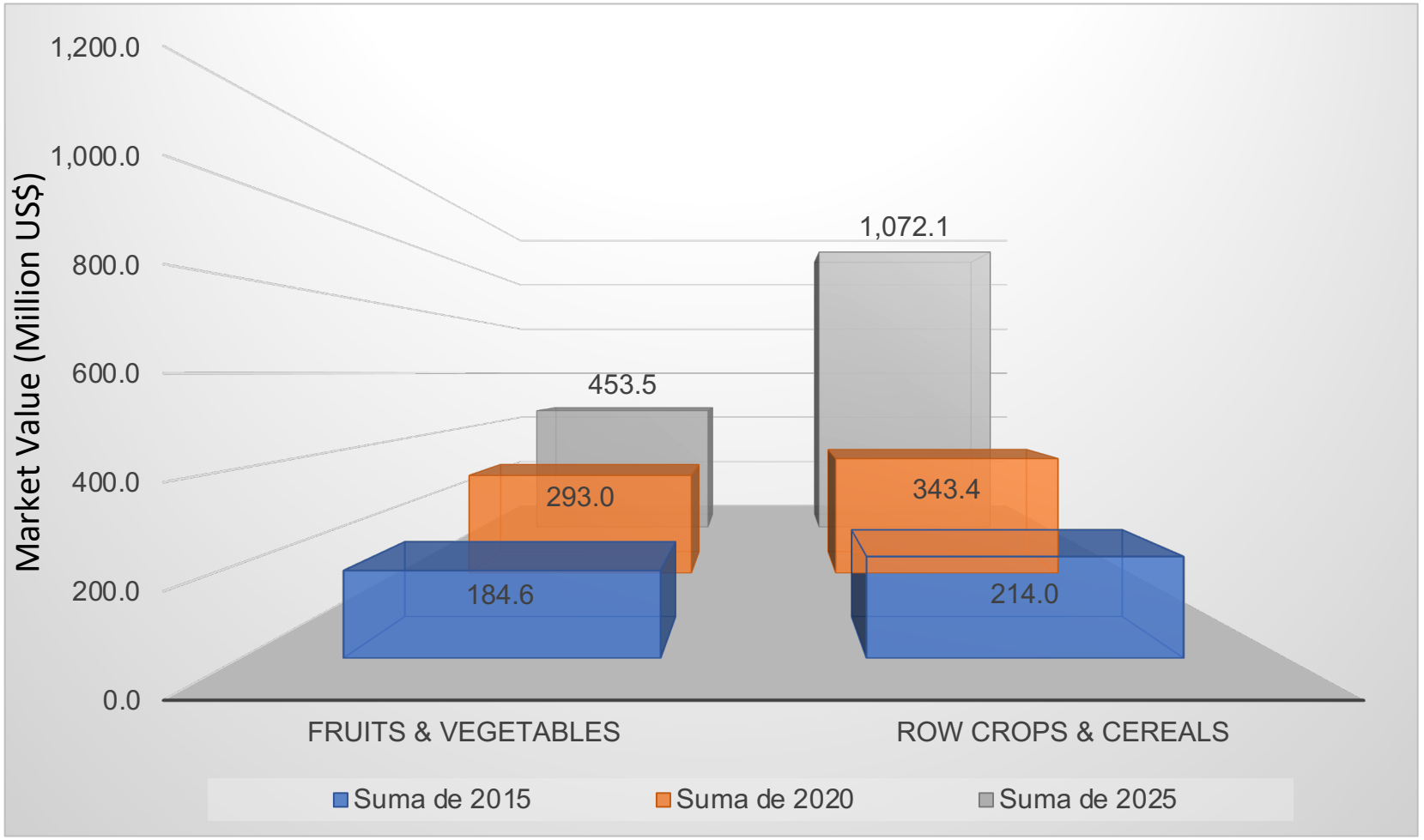


- Biostimulants are used in all crop types to mitigate abiotic stress and improve use efficiency of both nutrients and water
- In contrast, biopesticide use is more concentrated in fruit and vegetable crops

Global Biostimulant Market

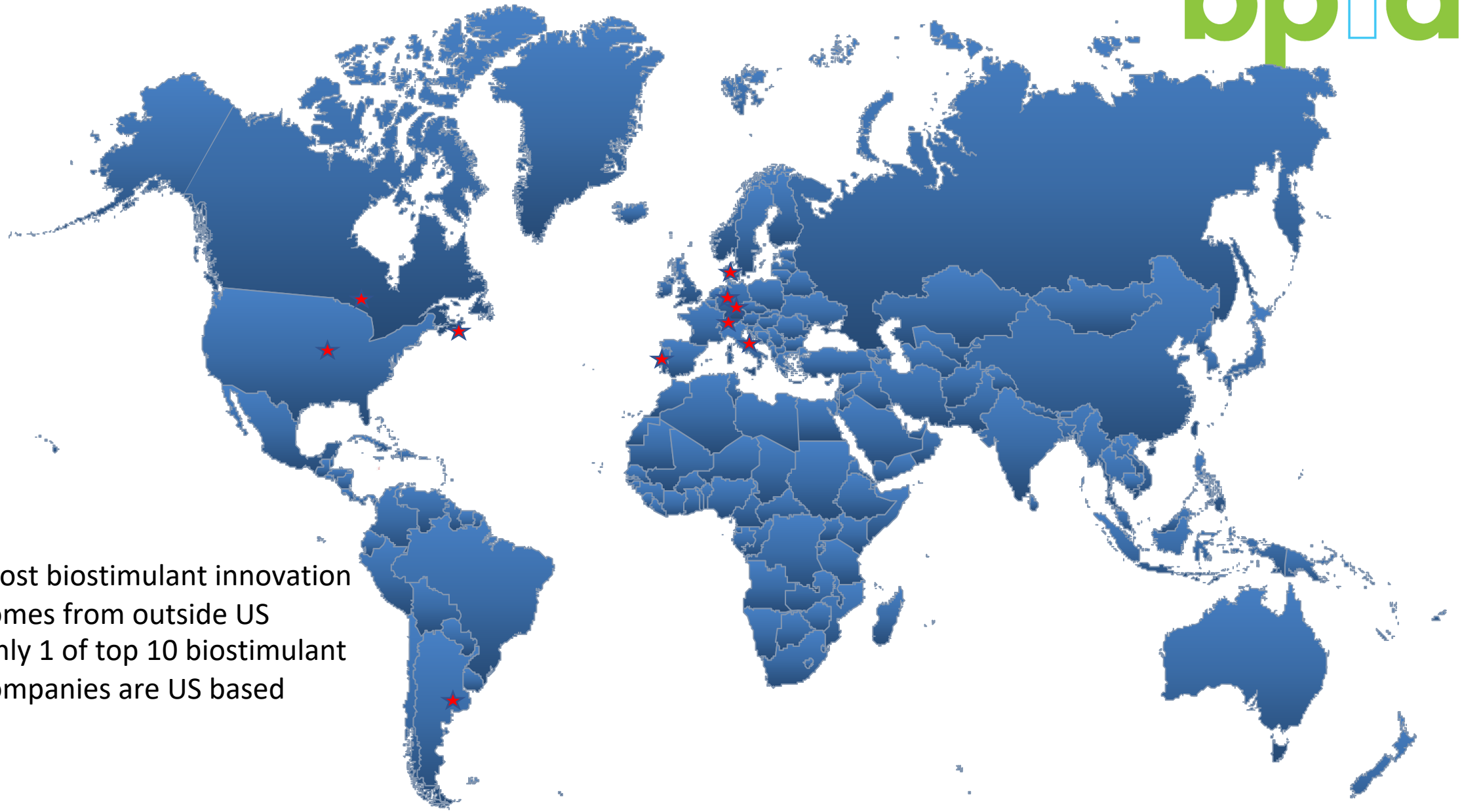


US/Canada Biostimulant Crop Market



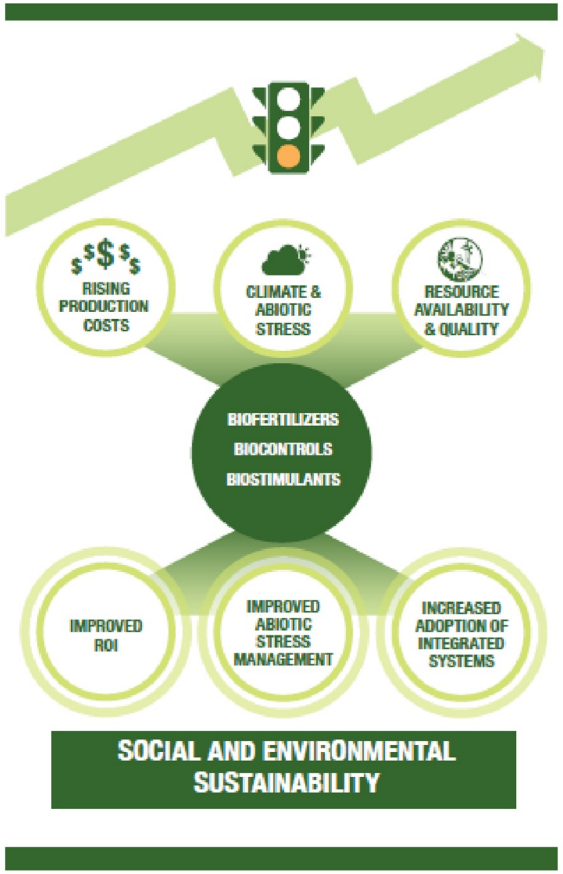
- Increasing use in row crops anticipated in US/Canada market due to growth of microbial N fixing products
- US/Canada market expected to skew strongly in favor of row crop use

Biostimulant Innovation Sources



Most biostimulant innovation comes from outside US
Only 1 of top 10 biostimulant companies are US based

Biostimulant Market Drivers



- Enhance the crop's ability to tolerate weather extremes
- Mitigate resource limitations allowing crop to "do more with less"
- Allow crops to perform closer to full genetic potential
- Biostimulants support more sustainable use of resources
- Meet consumer and societal demands for sustainable production

bpia

- Consumer awareness of sustainability growing thanks to communication efforts from a wide range of sources
- Hundreds of labels from governments, non-governmental organizations, industry and grower associations
- Creating growing expectations and demands that food producers and marketers will utilize sustainable practices

Biostimulant Market Summary

Market growth influenced by multiple factors

Promoters

- Consumer sustainability demands
- Willingness to pay for quality
- Government policies supporting sustainable production practices
- Growers seeking technologies to mitigate abiotic stress
- Industry developing biostimulant technologies

Barriers

- Asynchronous, conflicting regulations
- Cost of market entry
- Impact of economy and commodity pricing on grower ability to pay

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DunhamTrimmer®
International Bio Intelligence

Challenges Facing The Plant Biostimulant Industry In The United States

David Hiltz

Chair, BPIA Biostimulant Innovation Committee

Executive Member, TFI Biostimulant Council

Director at Large, European Biostimulant Industry Council

Director, Global Regulatory Affairs, Acadian Plant Health

The World Is Adopting Plant Biostimulant Use

Canada regulates plant biostimulants as "supplements" under the CFIA Fertilizer Act

Industry lobbies USDA/EPA/AAPFCO for a definition and an appropriate path to market 2012 - ?

In 2022 ISO Fertilizer group TC-134 publishes a definition for biostimulant

Brazil regulates some plant biostimulants as "biofertilizers", industry is lobbying for clarity

Chile in 2022 published Resolution 6725 defining and regulating plant biostimulants

EU Fertilizer Products Regulation 1009 published in 2019, formally defining plant biostimulants and creating a new category for them

China in 2021 published updated fertilizer regulation NYT 3831 defining plant biostimulants

India modernized their fertilizer regulations in 2021 with SOE 882 (E), defining and creating a new category for plant biostimulants

South African companies seeking regulatory clarity

Austrian regulators are studying global direction

US Plant Biostimulant Industry Goals & Needs

1. Formal Recognition of the Plant Biostimulant Category
2. An Established National Definition of a Plant Biostimulant
3. Clarity On Allowed and Prohibited Claims for Plant Biostimulants
4. A Clear and Defined Pathway to Market Across All 50 States
5. Appropriate Regulation of Composition, Safety and Efficacy
6. Protection of the Principle of Multi-Use Based on Product Function
7. Alignment With Existing Global Regulations for Harmonization

Industry Goal # 1 :

Recognition of Plant Biostimulant Category

- The term “plant biostimulant” is not simply a marketing term
- It is instead a category of fertilizing material designed to compliment plant genetics, fertility, and crop protection currently utilized in modern agriculture
- We seek formal regulatory acknowledgement of this new category of fertilizing materials, as has already occurred in other global markets

Industry Goal # 2 :

National Definition of a Plant Biostimulant

As detailed in the 2019 USDA “Report to the President of the United States and Unites States Congress on Plant Biostimulants” and the subsequent 2022 “Plant Biostimulant Act”, we seek a formal federal definition as follows:

- *“A plant biostimulant is a material that contains a substance(s), microorganism(s), or mixtures thereof, that, when applied to seeds, plants, the rhizosphere, soil or other growth media, act to support a plant's natural nutrition processes independently of the material’s nutrient content. The plant biostimulant thereby improves nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality or yield.”*

Industry Goal # 3 :

Clarity On Allowed Plant Biostimulant Claims

- Many of the globally accepted claims associated with plant biostimulants have been challenged as triggering FIFRA regulation

- EPA has been drafting a proposed “Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants” for many years

- We seek formal clarification of FIFRA plant regulator claims as well as those deemed outside of FIFRA oversight, including those globally associated with fertilizer materials including plant biostimulants

Industry Goal # 4:

A Clear Pathway to Market In All 50 States

- Plant biostimulants are a category of fertilizing materials; however fertilizers are not regulated at the Federal level

- State fertilizer Officials (AAPFCO) have been working to define a proper category for plant biostimulants via drafting of a “Model Fertilizer Bill”

- We seek adoption of modernized Fertilizer Regulations across ALL states and removal of any Federal impediments to their adoption

Industry Goal # 5:

Appropriate Safety and Efficacy Assessment

- Plant biostimulants manufactures should be able to demonstrate the composition, safety, and efficacy of their products

- However, many biostimulants are derived from natural products and have been safely and effectively used in agriculture for decades

- We seek regulations that are appropriate and do not impose unreasonable burden that could stifle biostimulant use and innovation

Industry Goal # 6:

Multi-Use Principle of Fertilizing Materials

- Some fertilizers and plant biostimulants may exhibit crop protection activities when used at significantly different rates and/or timings

- Global Fertilizing Products regulations like EU 1009/2019 recognize the principle of multi-use (e.g. copper as a micronutrient or fungicide)

- We seek regulation that defends the principle of multi-use whereby plant biostimulants are defined by what they do (function) and not by what they contain

Industry Goal # 7:

A Regulation Allowing Global Harmonization

- Manufacturers of plant biostimulants often operate globally; regulatory alignment would reduce workload and allow common positioning

- Many countries have already defined plant biostimulants and enabled clear pathways to market by amending existing fertilizer regulations

- We seek regulation that draws upon existing definitions, regulatory language and allowable claims to allow for global harmonization

Global Harmonization Is Already Occurring

Biostimulant Characteristic	Biostimulant Act	EU 2019/1009	ISO TC 134	Chile Res 6725	India SO 882
Includes substances, microorganisms or mixtures	√	√	√	√	√
Benefits independent of nutrient content	√	√	√	√	√
Stimulate/ support natural/physiological processes	√		√		√
Stimulate/ support natural nutrition processes		√		√	
Improves nutrient availability	√			√	√
Improves nutrient use efficiency	√	√	√	√	√
Improves nutrient uptake	√		√		√
Improves tolerance to abiotic stress	√	√	√	√	√
Improves crop quality		√	√	√	√
Improves yield			√		√
Consequential growth, development, quality & yield improvement	√				√

A Long Process, But It Can Be Done (EU example)

After ~10 Years of Discussion in USA, The Time To Finalize is Now…

Listening Session on Plant Biostimulants

Overview of industry-government efforts to date

David Beaudreau Jr.

DCLRS

1/31/23

State and Federal Efforts on Plant Biostimulants

- Federal Agency Involvement
  - EPA Guidance
  - USDA report and progress
- State Regulators, AAPFCO model bill
- Industry Recommended Guidelines
- Congress: Plant Biostimulant Act

Who is Supporting the Effort?

Biotechnology
Innovation
Organization

THE
FERTILIZER
INSTITUTE

BIOSTIMULANTS COUNCIL

EPA: Background on Guidance

❖Background:

- EPA has been in process of developing **Draft Guidance for Plant Regulators and Claims, Including Plant Biostimulants** since 2014.
- Intended to address state regulator and manufacturer concerns regarding product registrations.
- First published draft (March 2019) met with significant industry opposition:
  - Table 4. Identified certain substances as plant regulators, regardless of claims.
  - Seaweed extracts, humic and fulvic acids and other active ingredients considered plant regulators requiring registration and significant disruption to the industry.

EPA: Revised Guidance

- <u>Plant Biostimulant Industry Analysis of EPA guidance:</u>
- Latest version published in FR 11/30/20, yet to be finalized
- Recognized PBS as unique product category encompassed by plant regulators and may fall within FIFRA excluded categories: plant nutrient, inoculant and soil amendment.
- Stated *consequences* of using plant nutrient, inoculant or soil amendment lead to better plant growth, yield, etc., provides additional distinction from plant regulators.
- Removed table 4 but seaweed extracts, humic/ fulvic acids identified as plant regulators.
- Recognized that products can have multiple functions.
- Cites PRIA M009 category to confirm FIFRA registration - additional guidance would be required.

USDA

- 2018 Farm Bill authorized USDA to perform a study on plant biostimulants.
- Dec 2019, USDA's Report to The President and Congress finalized.
- Report provided 6 options for USDA and other stakeholders to consider.
- August 2020, USDA Roundtable Discussion on Plant Biostimulants
- February 2022, USDA Ag Outlook Forum

State Regulators, AAPFCO

- In 2020, AAPFCO created a Biostimulant Committee to develop a Model Bill, called the Uniform Beneficial Substances Bill.
- At August 2022 Meeting: Voted to move these items to “Tentative” Status
- Bill includes:
  - Plant Biostimulant Definition (USDA Alternative Definition 2)
  - Uniform Label for Plant Biostimulants
  - Provisions for Unlawful acts, inspections, sampling and analysis
- Uniform Bill could be voted to “official” at the AAPFCO meeting in mid Feb. 2023
- Once finalized, individual states can adopt this bill and incorporate into their existing state fertilizer or soil amendment laws.

Biostimulant Guidelines

- Standards Implementation Team: Industry volunteers developed a document titled, “United States Biostimulant Industry Recommended Guidelines to Support Efficacy, Composition, and Safety of Plant Biostimulant Products”

- Published in Journal of Regulatory Science in 2022.

- Goal of document was to develop guidelines for:
  - Verification of Plant Biostimulant Efficacy Claims
  - Verification of Plant Biostimulant Composition
  - Conducting a Plant Biostimulant Safety Assessment

  Included in the report is an explanation of how to best use the guidelines.

Plant Biostimulant Act

Currently, there is no consistent and predictable path to market for plant biostimulant products in the United States.

H.R. 7752, Plant Biostimulant Act: Introduced in 117th Congress by Reps. Panetta (D-CA) and Baird (R-IN)

The Plant Biostimulant Act would:

- Establish a uniform national definition for “plant biostimulant”;
- Amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to exclude plant biostimulants from being regulated under the Act;
- Establish a definition for nutritional chemical;
- Amend the definition for a vitamin hormone product;
- Require the U.S. Environmental Agency (EPA) to review and revise existing Code of Federal regulations to include these new and revised definitions;
- Require USDA to study how plant biostimulant products can contribute to soil health.

Thank you

Additional questions?

- David Beaudreau
- Email: dbeaudreau@dclrs.com

Listening Session on Plant Biostimulants and The Executive Order on Advancing Biotechnology and Biomanufacturing Innovation

INDUSTRY RECOMMENDATIONS

January 31, 2023

Industry Has Focused on Two Federal Initiatives

Industy Goals*:

National, legal definition for plant biostimulants

Ability to use the term “biostimulant”

Ability to make biostimulant claims

Clear, consistent, predictable process to market

One label for all states

Safety assessment

Dual uses for active ingredients

Global consistency

Credibility for the industry

USDA

Report to Congress on Plant Biostimulants (required by 2018 Farm Bill, submitted to Congress 2019, No further action)

USDA-led Biostimulant Work Group

(Inactive)

EPA

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

(Delayed)

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

USDA recommended definition of Plant Biostimulant*

"A plant biostimulant is a material that contains a substance(s), microorganism(s), or mixtures thereof, that, when applied to seeds, plants, the rhizosphere, soil or other growth media, act to support a plant' s natural nutrition processes independently of the material's nutrient content. The plant biostimulant thereby improves nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and **consequent growth**, **development**, **quality** or **yield**."

following: ''Such term shall not include a plant biostimulant.''; and

(2) by adding at the end the following:

''(pp) PLANT BIOSTIMULANT.—The term 'plant biostimulant' means a substance, micro-organism, or mixture thereof, that, when applied to seeds, plants, the rhizosphere, soil, or other growth media, act to support a plant's natural processes independently of the biostimulant's nutrient content, including by improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield.

''(qq) NUTRITIONAL CHEMICAL.—The term 'nutritional chemical' means compound or mixture, including a plant biostimulant, that interacts with plant nutrients in

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, 2022 (5:13 p.m.)

* USDA proposed definition in consultation with the EPA in "Report to the President of the United States and Unites States Congress on Plant Biostimulants"

GOAL	PROGRESS TO DATE IN THE UNITED STATES	% ACHIEVED
National, legal definition for plant biostimulants	Definitions proposed in USDA Secretary's 2019 Report to Congress; "Preferred Definition" in Plant Biostimulant Act	
Ability to use the term "biostimulant" for products	None	
Ability to make biostimulant claims on product labels and marketing materials	None	
Clear, consistent and predictable process to market	Draft EPA Guidance on PBS Claims; Options in USDA Report to Congress	
One label for all States and US territories	None	
Safety Assessment	Industry developed voluntary guidelines; International Standards Organization (ISO) and European Committee for Standardization (CEN)	
Dual uses for active ingredients	None	
Global Consistency	Preferred definition consistent with EU definition; Industry standards consistent with EU discussions and CFIA standards	
Credibility for the plant biostimulant industry	~30% YOY growth internationally	

Success Factors

- **USDA Leadership:** A facilitated process engaging stakeholders to implement recommendations from the report.
- **EPA Collaboration:** Consulting with EPA and the States; aligning Guidance efforts
- **States:** Coordination with NASDA, AAPFCO and AAPCO to advance goals of biostimulant and agricultural industries with state regulators
- **International:** Coordination with EBIC and other industry affiliated groups, as well as regulatory bodies
- **Standards Bodies:** Engagement of ISO, others to participate in standard setting efforts now underway
- **Industry:** Deliver high-quality recommendations for standards and criteria process and content within the targeted timeline
- **All:** Build the base of stakeholder participation and support, across the ag value chain as a requisite for effective implementation

Relevance Of President Biden's E.O. 14081 to the Biostimulant Industry

- **Section 3. Harnessing Biotechnology and Biomanufacturing R&D to Further Societal Goals**
- **Section 5. Building a Vibrant Biomanufacturing Ecosystem**
- **Section 6. Bio-Based Products Procurement**
- **Section 7. Biotechnology and Biomanufacturing Workforce**
- **Section 8. Biotechnology Regulation Clarity and Efficiency**
- **Section 12. International Engagement**

The Biostimulant Industry's Most Critical Need

Implementing Section 8. Biotechnology Regulation Clarity and Efficiency of E.O. 14081

Dusting off the USDA Secretary's 2019 Report to The President and Congress and, under the Aegis of the E.O. 10481 and the Coordinated Framework for Biotechnology, directing USDA to work with Federal and State Agencies, the Biological Products Industries, the Agricultural Community, and Academia to establish a coordinated, clear, predictable, harmonized and science-based path to market for biostimulants.

Report to the President of the United States and United States Congress on Plant Biostimulants Submitted by the United States Department of Agriculture (USDA) in Consultation with the Environmental Protection Agency (EPA) on December XX, 2019

Table of Contents

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