

RECOMMENDATIONS FOR U.S. BIOSTIMULANT EFFICACY CLAIMS: A ROBUST SCIENCE-BASED STANDARD

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CONTEXT OF PARTICIPATION AND DISCLOSURES

- Employed by Koch Biological Solution
- Koch is a member of TFI
- Represent Koch's interests in biological products to TFI
- Asked by TFI to help represent their interests at a January 2019 Biostimulant Workshop
- Led the Efficacy Claims sub-group
- Resulting work product was not in reference to any specific biostimulant product, Koch or otherwise

OVERVIEW OF TOPICS

- Background/genesis
- Efficacy claim categories and subcategories
- Acceptable data sources
- Trial/assay campaign components to substantiate an efficacy claim
- Representative crop data
- Provisional biostimulant status
- Closing

BACKGROUND/GENESIS

GENESIS OF THE CRITERIA 2019 JANUARY BIOSTIMULANT INDUSTRY WORKSHOP

Workstreams

Regulatory & Legal	Fred Betz, Regulatory Strategies; Pam Howlett, Bayer
State Coordination	Britt Aasmundstad, NASDA; John Breen, Actagro
Criteria & Standards	Amy Roberts, Lallemand; Terry Stone, Agrinos

Criteria & Standards Sub-groups

Terms & Definitions	Terry Stone, Agrinos
Composition	Mike Frodyma, NewLeaf
Safety	Amy Roberts, Lallemand
Efficacy Claims	Carlos Reyes, Koch Biological Solutions

Efficacy Claims Team

Carlos Reyes, Koch Biological Solutions
Jane Fife, 3Bar Biologics
Paul Loida, Bayer
Clara Mamone, Indigo Ag
Dion Pearce, Pathway Biologic
Shade Sabitu, Pivot Bio
Elizabeth Wozniak, Cytozyme

Special acknowledgement to:

- Patrick Brown, Ph.D., Professor of Plant Sciences, University of California-Davis
- Kellye Eversole, Executive Director, International Alliance for Phytobiomes Research
- Matthew Kleinhenz, Ph.D., Professor/Extension Specialist, The Ohio State University

DEFINITION PLANT BIOSIMULANT

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

CRITERIA & STANDARDS WORKSTREAM CONSENSUS ON EFFICACY CLAIMS

- Employ good scientific practices
- Repeatable
- Measurable
- Appropriate positive and negative controls
- Experimental design and statistical evaluation
- Representative crops evaluated
- Multiple locations for field testing
- Rates/concentration tested reflect the product commercial label

EFFICACY CLAIM CATEGORIES AND SUBCATEGORIES

RECOGNIZED BIOSTIMULANT EFFICACY CLAIM CATEGORIES AND SUB-CATEGORIES

- Yield
- Quality
- Tolerance to Abiotic Stress
- Nutrient Use Efficiency
- Establishment or Early Season Advantage

RECOGNIZED BIOSTIMULANT EFFICACY CLAIM CATEGORIES AND SUB-CATEGORIES

- *Yield - An increase in marketable output of the primary raw commodity that is traded, per unit of production setting*
- Quality
- Tolerance to Abiotic Stress
- Nutrient Use Efficiency
- Establishment or Early Season Advantage

RECOGNIZED BIOSTIMULANT EFFICACY CLAIM CATEGORIES AND SUB-CATEGORIES

- Yield
- *Quality - An improvement in the desired attribute(s) of a cultivated organism in terms of human or animal nutrition, marketing, aesthetics, or composition, found within the primary raw commodity that is traded, per unit of production setting*
- Tolerance to Abiotic Stress
- Nutrient Use Efficiency
- Establishment or Early Season Advantage

RECOGNIZED BIOSTIMULANT EFFICACY CLAIM CATEGORIES AND SUB-CATEGORIES

- Yield
- Quality
- *Tolerance to Abiotic Stress - A measure of a plant's ability to withstand a physical or chemical factor which leads to damage of vital processes causing impaired growth and development, loss of production or premature death*
- Nutrient Use Efficiency
- Establishment or Early Season Advantage

RECOGNIZED BIOSTIMULANT EFFICACY CLAIM CATEGORIES AND SUB-CATEGORIES

- *Tolerance to Abiotic Stress - subcategories*
 - Water - Insufficient or excessive amounts
 - Temperature - Too low or too high in soil or ambient at planting or during the season
 - Salinity - Excessive salt in the soil and/or irrigation water
 - Light - Under or over exposure
 - Agrochemical - Negative effects of some agrochemicals

RECOGNIZED BIOSTIMULANT EFFICACY CLAIM CATEGORIES AND SUB-CATEGORIES

- Yield
- Quality
- Tolerance to Abiotic Stress
- *Nutrient Use Efficiency - A measure of a plant's ability to acquire and utilize nutrients from the environment for a desired outcome*
- Establishment or Early Season Advantage

RECOGNIZED BIOSTIMULANT EFFICACY CLAIM CATEGORIES AND SUB-CATEGORIES

- *Nutrient Use Efficiency - subcategories*
 - Nutrient availability - A measure of accessibility or readiness of nutrients in the environment for uptake by a plant
 - Uptake efficiency - A measure of nutrient movement from the external environment into a plant
 - Utilization efficiency - A measure of a plant's marketable output in relation to nutrients available from the external environment

RECOGNIZED BIOSTIMULANT EFFICACY CLAIM CATEGORIES AND SUB-CATEGORIES

- Yield
- Quality
- Tolerance to Abiotic Stress
- Nutrient Use Efficiency
- *Establishment or Early Season Advantage - A measure of ability for early season rapid growth and development*

RECOGNIZED BIOSTIMULANT EFFICACY CLAIM CATEGORIES AND SUB-CATEGORIES

- *Establishment or Early Season Advantage – subcategories*
 - Rapid establishment and/or early season growth - Increased emergence rate, stand uniformity and/or count
 - Increased biomass - A greater amount of plant growth per unit area, early in the season, shortly after establishment or bud break
 - Improved regrowth after breaking dormancy or harvest in perennials - A greater success in continued growth
 - Healthier appearance – A quantitative or semi-quantitative evaluation of plant's general appearance as greener and healthier

ACCEPTABLE DATA SOURCES

TRIAL/ASSAY GENERAL GUIDELINES FOR ACCEPTABLE DATA SOURCES

- *In situ* trial data are preferred for all claims
 - Actual open field or commercial greenhouse production settings, urban landscape, etc.
- Laboratory/growth chamber, and/or experimental greenhouse data are acceptable for some claims
 - When appropriate conditions for side by side comparison are not available or cannot be “artificially created” *in situ*
 - With and without salt stress or cold stress in the
- Data generated outside of the US (a minority share) are acceptable for some claims

TRIAL/ASSAY GENERAL GUIDELINES FOR ACCEPTABLE DATA SOURCES

Acceptable data source(s) for each claim type

<u>Claim Category</u>	<u>Data Source</u>				
	Lab/Growth		Experimental		
	In Situ	Chamber	Greenhouse	U.S	ex-U.S.
Yield	Blue	White	White	Blue	White
Quality	Blue	White	White	Blue	White
Nutrient Use Efficiency	Blue	Blue	Blue	Blue	Blue
Abiotic Stress Tolerance	Blue	Blue	Blue	Blue	Blue
Est./Early Season Advantage	Blue	Blue	Blue	Blue	Blue

TRIAL/ASSAY CAMPAIGN COMPONENTS

TRIAL/ASSAY CAMPAIGN COMPONENTS TO SUBSTANTIATE EFFICACY CLAIMS

Report sufficient detail whereby an identical trial/assay campaign and its data analysis can be re-created

- Protocol
- Conditions
- Experimental Design
- Control Data
- Application and Treatments
- Methods of Assessment
- Data and Analysis
- Report

TRIAL/ASSAY CAMPAIGN COMPONENTS TO SUBSTANTIATE EFFICACY CLAIMS

- Protocol - Has a clearly stated objective that encompasses the claim(s) and contains all the information to execute as described in the subsequent sections
 - Conditions
 - Experimental Design
 - Control Data
 - Application and Treatments
 - Methods of Assessment
 - Data and Analysis
 - Report

TRIAL/ASSAY CAMPAIGN COMPONENTS TO SUBSTANTIATE EFFICACY CLAIMS

- Protocol
- **Conditions - Provide a general site description that includes the relevant physical, environmental, crop and management conditions that help understand the context of the experiment**
- Experimental Design
- Control Data
- Application and Treatments
- Methods of Assessment
- Data and Analysis
- Report

TRIAL/ASSAY CAMPAIGN COMPONENTS TO SUBSTANTIATE EFFICACY CLAIMS

- Protocol
- Conditions
- **Experimental Design - Use an appropriate experimental design that provides sufficient statistical power to detect the effect claimed at the required-p value**
- Control Data
- Application and Treatments
- Methods of Assessment
- Data and Analysis
- Report

TRIAL/ASSAY CAMPAIGN COMPONENTS TO SUBSTANTIATE EFFICACY CLAIMS

- Protocol
- Conditions
- Experimental Design
- **Control Data - Generated in the absence of the biostimulant treatment and/or in the absence of a challenge condition, such as drought**
 - Also applies to formulations that contain non-biostimulant substances known to possibly contribute to fulfilling the claim
- Application and Treatments
- Methods of Assessment
- Data and Analysis
- Report

TRIAL/ASSAY CAMPAIGN COMPONENTS TO SUBSTANTIATE EFFICACY CLAIMS

- Protocol
- Conditions
- Experimental Design
- Control Data
- **Application and Treatments - Conditions and products need to be commercially relevant and representative of how/where the biostimulant will be used, including formulation**
- Methods of Assessment
- Data and Analysis
- Report

TRIAL/ASSAY CAMPAIGN COMPONENTS TO SUBSTANTIATE EFFICACY CLAIMS

- Protocol
- Conditions
- Experimental Design
- Control Data
- Application and Treatments
- **Methods of Assessment - Thoroughly define the type of assessment and how it was made and identify the claim it's intended to substantiate**
 - Yield reported in commercially recognized units
 - Quality reported in commercially recognized USDA grades
- Data and Analysis
- Report

TRIAL/ASSAY CAMPAIGN COMPONENTS TO SUBSTANTIATE EFFICACY CLAIMS

- Protocol
- Conditions
- Experimental Design
- Control Data
- Application and Treatments
- Methods of Assessment
- **Data and Analysis - Statistical analysis of the resulting data directly supports each claim found on the label**
 - The level of confidence compared to “untreated”, i.e., “non-biostimulants treated” for all claims should be 90% probability ($p < 0.1$) or greater for each individual trial/assay, or meta-analysis of the combined data set, for a minimum of 3 locations
- Report

TRIAL/ASSAY CAMPAIGN COMPONENTS TO SUBSTANTIATE EFFICACY CLAIMS

- Protocol
- Conditions
- Experimental Design
- Control Data
- Application and Treatments
- Methods of Assessment
- Data and Analysis
- **Report - Data/details to fulfill the preceding requirements**
 - The purpose of the trial/assay campaign
 - An executive summary of the findings
 - Results in the form
 - Separate data summary and statistical analysis in support of each claim
 - Raw data clearly identifying the claim it supports
 - Written interpretation of the findings and how they support the claim

REPRESENTATIVE CROP DATA

TRIAL/ASSAY CAMPAIGN REPRESENTATIVE CROP DATA

Crop Groups, Crop Sub-groups, and Crop Members

1. Agronomic Crops
 - a) Monocotyledon: corn, rice, wheat, sugarcane, oil palm, etc.
 - b) Dicotyledon: soybean, cotton, alfalfa, hemp, peanut, sunflower, canola, kidney beans etc.
2. Fruit Crops*
3. Other Fruit & Nut Crops*
4. Vegetable Crops*
5. Other Crops*

	Hierarchy	Crop Scope	Data Example
6. Horticulture Crops*	Specific crop	Single crop	corn
7. Forestry Crops*	Crop Subgroup	Dicotyledon	soybean, cotton
8. Turf Grasses*	Entire Crop Group	Agronomic Crops	rice, alfalfa
9. Fungi*	All Crop Groups	9 Crop Groups	one crop in each subgroup

The product must demonstrate statistically significant positive effects on each crop at a single location over a minimum of 3 years, or in a minimum of 3 field locations in the same year

*Crop Sub-groups and Crop Members not shown

PROVISIONAL BIOSTIMULANT STATUS

BIOSTIMULANT EFFICACY CLAIMS

PROVISIONAL STATUS

- When a product is able to meet all other criteria (e.g. Enviro/Human Safety, Identification, Characterization) required for a “certification”, but unable to completely fulfill the efficacy claim requirements, e.g.,
 - Only one instead of three statistically significant trials locations or assays for a specific crop
 - A demonstrated agronomically favorable data trend in support of the efficacy claim, but the inability to demonstrate statistical significance
- In such cases the product may be granted a one-time provisional status for a period of 2 years

BIOSTIMULANT EFFICACY CLAIMS

PROVISIONAL STATUS

- The product can be sold on the market as a “provisional biostimulant” during the two year period
 - Applicant is encouraged to use the two year period to fulfill the efficacy claim requirements
 - Provisional status is revoked on the 2 year anniversary if the efficacy claim requirements are not fulfilled
 - Full certification may be applied for anytime during provisional status period
 - Provisional status cannot be extended or re-applied for a product

BIOSTIMULANT EFFICACY CLAIMS

A ROBUST SCIENCE-BASED STANDARD

- Offers a harmonized framework
- Open architecture to accommodate future methods/techniques and technologies
- Not overly prescriptive, thus encourages innovation
- “Provisional” status provides a path to market for bandwidth or financially challenged start-ups, while maintaining scientific integrity
- Accommodates agriculture, floriculture, fungiculture, horticulture, silviculture and turf
- Further legitimizes the biostimulant space and instills confidence in the end user (grower)



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