



BIOSTIMULANTS

Different indications in different jurisdictions - Do Your Homework!

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US EPA Attempted to Provide Guidance

2021

Found it very difficult to separate PGRs from Biostimulants

Draft Guidance received: • 85 comments represented industry/trade groups/growers/law firms; • 69 comments were from private citizens; • 4 comments were from U.S. State governmental agencies [NV, CA (2 comments), and WA]; • 2 comments were from State associations of regulatory officials (AAPCO1 and NASDA2); • 1 comment was from a non-U.S. trade association (EBIC3)

“Plant biostimulants do not have a regulatory definition at the State and Federal level and are not recognized as an independent class of products. As part of the US EPA’s March 2019 Draft Guidance, EPA sought comment on whether it should develop an independent definition of PBS, noting that development of such a definition would require rulemaking”



California Recently Proposed

- ▶ Revise the definition of fertilizing materials to instead mean any commercial fertilizer, agricultural mineral, **beneficial substance**, or organic input material.
- ▶ “Plant biostimulant” means a substance or microorganism, 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 biostimulant’s nutrient content. **The plant biostimulant thereby may improve nutrient availability, uptake, or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield.**

OECD Biopesticide February 2024 Session Proposed the ISO Definition

- ▶ Iso Working Group: ISO/TC134/WG6 Beneficial substances (including Biostimulants)
- ▶ The ISO (International Organization for Standardization) definition of Bio-stimulant. ISO 7851:2022(E) 6.1 Plant Bio-stimulants: 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 bio-stimulant's nutrient content. The plant bio-stimulant thereby improves nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality or yield.



EUROPE

FUNCTION DEFINES THE PRODUCT

products aim solely at improving the plants' nutrient use efficiency, tolerance to abiotic stress, quality traits or increasing the availability of confined nutrients in the soil or rhizosphere.

DEMONSTRATION

The Committee for European Standardisation (CEN) is/has elaborated standards on how to demonstrate that biostimulant claims are justified.

https://standards.cen.eu/dyn/www/f?p=204:7:0:::FS_P_ORG_ID:2279055&cs=1F04757AD7A7D81CCF8FDCBFEF1883680

- An agronomic trait - Then yield.

WATCHOUTS/ BENEFITS



REACH - Reach and studies required for all components.

Only 3 significant (85%) trials needed per claim - Can be from any jurisdiction
CE mark good across the EU

Regulation (EU) 2019/1009 – the Fertilising Products Regulation (FPR) — cross-references the REACH Regulation (EC)1907/2006

The Fertilising Products Regulation requires a Chemical Safety Report and data equivalent to what is specified in Annex VIII of Regulation (EC) 1907/2006 (the REACH chemical regulation), even for substances approved for use in food and/or feed or those produced under 1 tonne per year.

Read the European Standards

SIST-TS CEN/TS 17700-2:2023 - Plant biostimulants - Claims - Part 2: Nutrient use efficiency resulting from the use of a plant biostimulant

Control

Control is defined in EN 17700-1:–1. The different treatments in the test should be:

- Controls: substrate/soil with or without fertilizer,
- Treatments: substrate/soil with or without fertilizer + plant biostimulants.

The same substrate/soil should be used in each treatment and in case of field trials a characterization of the substrate/soil should be done.

Brazil

Changed the Microbial regulations to now cover:

Pest control

Defoliants

Desiccants

Stimulators (Biostimulants)

Growth inhibitors

Inclusion of clear definition of biological activity for control, stimulus/inhibition, desiccants and defoliants, aligned with EBIC.

For other categories Brazil regulates biostimulants separately as biofertilizers



India

« 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, but does not include pesticides or plant growth regulators which are regulated under the Insecticide Act, 1968 (46 of 1968) »

- Biostimulant shall be classified under any of the following categories:
- (a) Botanical extracts, including seaweed extracts;
- (b) Bio-chemicals;
- (c) Protein hydrolysates and amino acids;
- (d) Vitamins;
- (e) Cell free microbial products;
- (f) Antioxidants;
- (g) Anti-transpirants;
- (h) Humic and fulvic acid and their derivatives



India Definitions

- Biochemicals: Specific biomolecule and their combinations
 - ▶ Biochemicals are the molecules that are synthesized/produced in the metabolism of the living organisms. These naturally occurring biochemicals can also be synthesised by chemical synthesis in laboratories.
- Antitranspirants Molecules that close stomata
 - ▶ Anti-transpirants are molecule that reduce transpiration through stomatal closure, increasing resistance to water vapor loss and/or reducing the heat load on leaf. Active ingredients: -
 - ▶ Molecules that close stomata: Abscisic acid (ABA) Phenyl mercuric acetate (PMA)
- Film forming molecules that increase resistance to water vapor loss and increase Active ingredients: One or more of the following molecules Chitosan; Waxes; Alumino-silicate (kaolin); Calcium carbonate (CaCO₃); Calcium oxide (CaO); di-1-p-menthene (pinolene); poly-1-p-menthene; Acrylic polymers; Potassium sulfate (K₂SO₄)

OTHERS

- S.Africa: guideline published in June 2019, “Biofertilizer”, “Plant Biostimulant”, “Plant Growth Enhancer” or “Plant Strengthener” is any substance or micro-organism or combination there of which is applied to seed, plant or root environment capable of **modifying, and improving, plant development** through a collection of different mechanisms of action.
- Chile: Ley 21-349 defines biostimulants as “Biostimulant: substance or mixture of substances or microorganisms, applicable to seeds, plants or rhizosphere, which **stimulate the natural processes of plant nutrition**, in order to improve efficiency in the use of nutrients, abiotic stress tolerance, quality attributes, or availability of immobilized nutrients in the soil or in the rhizosphere
- Argentina (Draft): Any substance or microorganism or mixture of substances and/or microorganisms that is applied to plants, usually in small doses and whose main objective is to improve the **physiological efficiency**, tolerance to abiotic stress and/or quality characteristics of the crop, **regardless of its nutrient content and not intended for the control of diseases or insects**



BE CAREFUL!

ARGENTINA

General Rule:

- Can not register anything that an adverse effect on health or the environment.
- Can present a waiver technically justifying that the product has no toxicological relevance.

Article 2: 9 types of products that require registration

Article 5: requirements for biostimulants

- Must declare mode of action
- Pathogen analysis
- Heavy metals
- Complete analysis
- Manufacturing Details

Thank you for your attention.
Questions?

