

## REGULATORY OVERSIGHT OF BIOSTIMULANTS

### PROBLEM STATEMENT

Technological advances to discover and develop natural products that can increase plant health and productivity will lead to the introduction of many more plant biostimulant products to the marketplace. To encourage development of these important sustainable products to the market, the industry must have a clear, consistent and predictable process for product introduction. Critical to this is the development of a regulatory framework that recognizes and defines “biostimulants”, provides for a human and environmental safety review commensurate with risk, and establishes a single federally sanctioned product label, recognized by State regulatory authorities. A clear US regulatory path that is harmonized with international jurisdictions for these products will serve to provide consistency and enhance credibility for the industry globally.

### CURRENT STATE

Developers of new biostimulants claim their products impact the physiology of the plant in ways that enable the plant to achieve more of its true growth potential by enhancing nutrient availability and uptake, which in turn improves overall health and thus, tolerance to environmental stress. Although impacting the physiology of the plant, biostimulants do not alter plant growth in a manner consistent with traditional plant regulators registered as pesticides by EPA. These products provide benefits that also differ from those in categories excluded from FIFRA such as plant inoculants, soil amendments, nutrients and trace minerals. Consequently, developers must choose to either (1) limit the actual plant benefits they claim and register their product on a state by state basis as a nutrient, plant inoculant or soil amendment or (2) extend their claims and register their product under FIFRA, even though the claims may not scientifically qualify as pesticidal or plant growth regulator (PGR).

State registration is implemented by individual state Departments of Agriculture with coordination by the American Association of Plant Food Control Officials (AAPFCO). Designed for traditional fertilizers, this approach is unnecessarily complex, as requirements are inconsistent from state to state, results in multiple product labels and does little to ensure the human and environmental safety of products before commercialization. Furthermore, AAPFCO does not recognize the term “biostimulant” and, therefore, the states forbid use of the term “biostimulant” on the label, which prevents companies from making legitimate, data supported claims, which limits how a company describes and differentiates their product. In many cases, biostimulant companies are instructed by some states that their products are not “true” fertilizers and, thus, exempt from any regulation.

Therefore, while the length of time to registration and commercialization of these “orphaned” products on a state basis may be shorter and less costly than registering as a pesticide with EPA,

the state to state differences, multiple labels, inconsistent product descriptions and other issues add uncertainty and cost to this path to market for this emerging segment of agricultural inputs.

Registering a biostimulant as a plant regulator or pesticide with EPA provides a straightforward path to market for many companies as the data requirements for biological pesticides are codified and the Agency is experienced in reviewing data and information to support registration. However, being designed for pesticidal products, the data required is overly burdensome for biostimulant products and the time to registration uncertain and lengthy. Recent EPA attempts to provide clarity of what types of biostimulant products may fall within FIFRA regulation, while appreciated by the industry, have failed to provide a scientifically reasonable and uniformly fair path to market for the broad scope of biostimulant products seeking commercialization. Even under the broadest interpretation of EPA's FIFRA authority, which would be legally tenuous and likely unnecessarily burdensome for the industry, many biostimulant products would likely still fall outside any regulatory jurisdiction.

The current regulatory status for biostimulants is untenable for the industry as a whole, and the industry believes that now is the time to investigate and implement a regulatory process that addresses aspects that are unique to emerging biostimulant technologies and the companies that develop and market them.

#### NEEDS OF THE INDUSTRY

There is an immediate need to define biostimulants within a regulatory context in the United States. BPIA has recommended adoption of the European Biostimulants Industry Council (EBIC) definition of biostimulants, as it more clearly defines the space between pesticides and fertilizers that is now occupied by biostimulants. Additionally, the EBIC definition will soon to be the legally recognized EU definition. The EBIC definition is as follows:

*Plant biostimulants contain substance(s) and/or micro-organisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and crop quality.*

In addition to the establishment of a regulatory definition for biostimulants and the ability to refer to products as such, the product developers and relevant stakeholders (including growers, ag retailers, academics, food industry) need:

- A clear, consistent and predictable process for market entry;
- Clarity on claims associated with the term biostimulant;
- Global harmonization of standards and practices (to the extent possible within differing regulatory and legal structures);
- One label for all states (US);

- A clear approach for registration of active ingredients that may have dual use (under certain conditions may have plant health properties but under others may act as a pesticide);
- Adherence to industry practices that enhance credibility in the marketplace; and,
- Uniform enforcement of regulations at the state and federal levels.

### SHORT TERM

As indicated above, establishment of a definition for biostimulants and associated product claims is essential. Concurrently, EPA should clarify their interpretation of the term “plant regulator” and work to define both “plant biostimulant” and “nutritional chemical” to delineate products considered pesticidal from those that are not.

Members of BPIA and the Biostimulants Coalition (BC) recently met with individuals from the EPA/Office of Pesticide Programs, Office of General Counsel and Biopesticides and Pollution Prevention Division. EPA continues with the review of their guidance document intended to provide clarity on label claims that can be used for biostimulant products. EPA plans to post the guidance document and seek public comments from interested stakeholders, with the expectation that the guidance will be issued by the end of the current fiscal year (September). EPA is also considering a subsequent rulemaking process to develop definitions for terms such as, ‘plant biostimulant’, and ‘nutritional chemical’ the latter which is listed in FIFRA as an excluded category but was never defined. BPIA and the BC are supportive of these actions and will continue to interact with EPA on these important steps as appropriate.

Further, the imposition of the current EPA requirements for registering a biopesticide may result in costs and time frames that may not be commensurate to the risks being managed. As was concluded in Europe, the need to have a regulatory process that is commensurate with the risks presented by biostimulants is central to the creation of a new category (biostimulants) that is distinct from “inorganic (or traditional) fertilizers” and “pesticides”.

### LONG TERM

While this short-term clarity may be helpful, biostimulant developers, growers, regulators and consumers ultimately require establishment of a regulatory framework designed specifically for biostimulants. Otherwise, the fundamental issues described above will not be resolved and attempts to reinterpret EPA’s authority based upon decades-old terminology and definitions will persist creating unintended consequences for both the biostimulant and fertilizer industries.

To meet these needs, various options were discussed culminating in an exploratory discussion with USDA/APHIS on May 16, 2017. The discussion outlined the challenges and complexities of bringing biostimulants to market without clear definitions and oversight, as well as overlaps and

gaps in regulatory authorities at the state and federal level. Industry needs were described and some discussion was held as to whether USDA/APHIS could provide a leadership role in helping industry achieve those needs. Regulations and guidance documents associated with the Plant Protection Act claim some jurisdiction over “plant growth enhancers,” which APHIS defines in a way that closely follows some definitions for biostimulants.

While USDA/APHIS acknowledged the issues and industry desires, there are limitations under the APHIS Plant Protection Act to address all concerns. However, the Agency did offer to consider creation of a working group with representatives from the Ag Marketing Service, Plant Protection and Quarantine, other USDA programs such as the National Institute of Food and Agriculture, other relevant Federal agencies, AAPFCO, the National Plant Board and industry to review and develop a means to achieve a harmonized framework for biostimulants.

Working with the USDA is one approach that is very early in the exploratory phase. If the work continues to advance in development of a clear regulatory pathway for biostimulant products at the federal level, there will be much work involved and it will take years to accomplish. However, considering the shortcomings and gaps created by seeking to invoke existing food, fertilizer, human and environmental safety laws and regulations to fairly, effectively and efficiently regulate biostimulants will require the engagement of several state and federal agencies to chart a path forward.

While other options must be explored, the EPA will continue to claim oversight of some biostimulants and consequently, the industry must continue to explore with the Agency a means to gain further clarity under the current patchwork system. The industry recognizes that use of FIFRA or the PPA authorities, without amendment or modification, to regulate biostimulants likely will not result in a scientifically-accurate, comprehensive and appropriate framework for the full scope of products that should be considered as non-pesticidal, non-fertilizer biostimulants. To that end, the industry is prepared to initiate efforts with state and federal officials to develop a more suitable and workable framework for the oversight of biostimulants.