

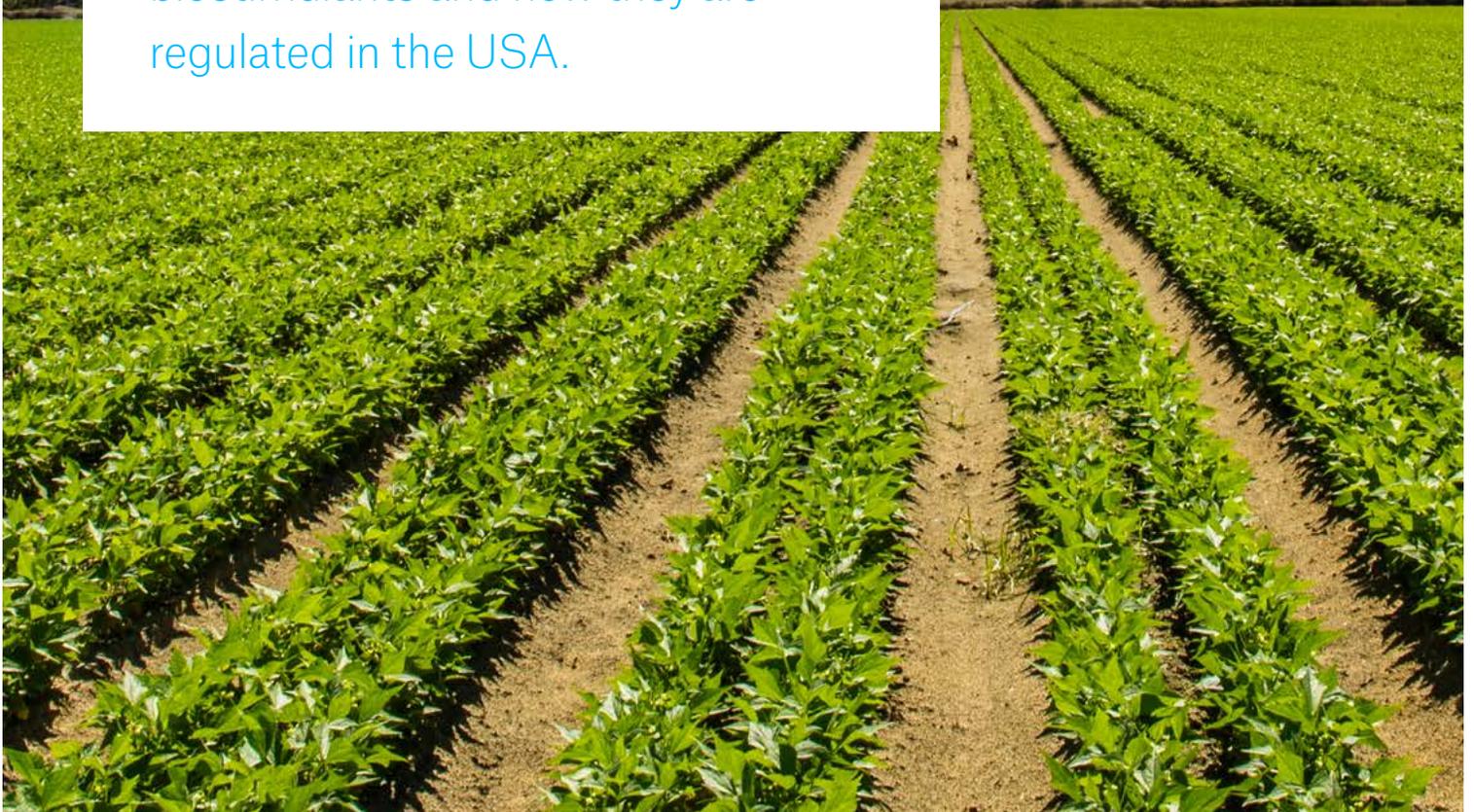
in focus

Biostimulants

Navigating the
United States
regulatory landscape



Biostimulants are an emerging class of products that indirectly impact soil quality and provide plant nutrition. At present, there is no specific biostimulant regulatory framework in the US, meaning that these types of products need to 'fit' into the existing regulatory landscape. With each state having its own set of rules and regulations, navigating this landscape can be a challenge for companies wanting to sell their products on the US market. In this paper, Anne-Laure Guihur, gives an overview of biostimulants and how they are regulated in the USA.



With the world's population anticipated to reach 10 billion by 2050, the agricultural sector faces challenges to feed our growing population. The need to use arable lands more efficiently and increase productivity while also managing recurring environmental stresses, such as drought, heat, and salinity, has become more apparent.

Although abiotic stresses may be mitigated by providing water, nutrients and other treatments, these may not be sufficient to achieve the desired output. Plant biostimulants have been described as a promising category of products to improve yield and quality of the crops and other soil/plant characteristics, by both the scientific community and the industry. There is mounting interest in these products across the world but navigating through the regulatory landscape can be challenging. Companies need to be aware of the ever-changing rules associated with this emerging category of products as they consider bringing them to the United States market.

What is the definition of 'biostimulant'?

Many countries are tackling this question and trying to craft a definition for biostimulant. Europe recently voted on the new European Fertilizer Regulation 2016/0084 which includes a definition for biostimulants and a regulatory path for registrations of these products across the EU Member States. The EU regulation will become effective in 2022 and in the next three years, new standards for processes and methods will be developed.

In the US, 18 **H.R. 2**: Agriculture Improvement Act of 2018 (formerly referred to as the Farm Bill) defines a biostimulant as '*a substance or micro-organism that, when applied to seeds, plants, or the rhizosphere, stimulates natural processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality and yield*'.



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What products are considered biostimulants?

There is a vast array of products that fall under the definition. These products are described in scientific literature as being derived from:

- plant or animal material (such as seaweed and seaweed extracts)
- humic and fulvic acids
- microbial products (plant growth promoting bacteria, bacteria consortia, mycorrhiza, yeast and others)
- protein hydrolysates
- amino acids
- peptides
- non-protein amino acids
- carbohydrates
- carboxylic acids

In the literature, biostimulants have been reported to improve nutrient uptake, to improve growth under stress conditions such as drought, to enhance microbial activity, to increase root growth, and to increase the availability of phosphorous and other elements, such as iron, to the plant.

Biostimulant products are often complex mixtures and frequently there is a lack of characterization and understanding of the composition and mode of action. While positive plant response may have been observed in the laboratory or field, these observations may not be solely related to a single substance but arise from the interaction between many substances in the product. This makes it rather complicated to elucidate the mechanism of action.

There is confusion with respect to whether claims made on biostimulant products would trigger regulatory authority by the US Environmental Protection Agency (EPA) under the US pesticide

regulations. By definition, biostimulant products are not pesticide products. However, pesticidal claims, such as but not limited to, reduction of pests, microbial competition in the soil to eliminate pathogens, stimulation of cell division, cell differentiation & cell enlargement, or acceleration or retardation of ripening are considered pesticides and would trigger the need to register the product as a pesticide at both the federal and state level. The pesticide registration process, at both the federal and state level, can be lengthy and costly. For this reason, companies need to weigh the product claims and market opportunities with the reality of the costs and timelines associated with compliance under the pesticide regulations. To complicate the situation even further, EPA has recently proposed, regardless of the claims, that products containing seaweed extract and humic/fulvic acids (applied foliarly) are plant growth regulators and therefore require pesticide registration.

What is the current regulatory framework?

Since there is presently no specific 'biostimulant' regulatory framework in the US, these types of products need to 'fit' in the existing regulatory landscape. Plant nutrients, trace elements, plant inoculants, soil amendment and vitamin-hormone products are typically¹ exempt from EPA regulation as a pesticide under Title 40 of the Code of Federal Regulations (40 CFR Part 152.6 (g)).

In the absence of federal oversight, these products are regulated by the individual states. All states except Alaska, District of Columbia and Hawaii regulate plant nutrient products. A smaller subset of states regulates plant and soil amendments. Each state has its own set of rules and regulations for each category of product.

As mentioned, in order to market a biostimulant product in the US, it is necessary to 'fit' into the existing categories as either fertilizer, soil amendment, plant amendment or beneficial substance. The choice of one category over the other will depend on the composition of the product, the desired claims/benefits and the supporting data that is available. Unfortunately, the category definitions and requirements are not well harmonized among the states. This leads to not only variations in label formatting and content, but also variations in the types of supporting data required, especially efficacy.



While it may be possible for a biostimulant that is, for instance, sold based on its nutrient content, to achieve one single label across the US, this is not the case for a product that is a soil amendment, plant amendment or beneficial substance. On average, four to five different label versions are needed for a soil/plant amendment in order to meet varying state requirements and label formats. This can be challenging for companies that want to distribute soil/plant amendment products throughout the US.

Companies are also limited regarding the claims they can make for these products. Terms like 'biostimulant' and 'stimulate' are not acceptable in most states. In addition, state regulators may interpret claims regarding improvement in plant growth to be pesticidal thereby triggering the need to register the product as a pesticide.

¹If the product falls under the definition of a plant growth regulator under FIFRA (Federal Insecticide Fungicide Rodenticide Act), then the product will require registration at the US EPA and then at the state level.

What's next?

This year is a busy year for the biostimulant industry; however, it may likely take years before there is a uniform regulatory approach for these types of products.

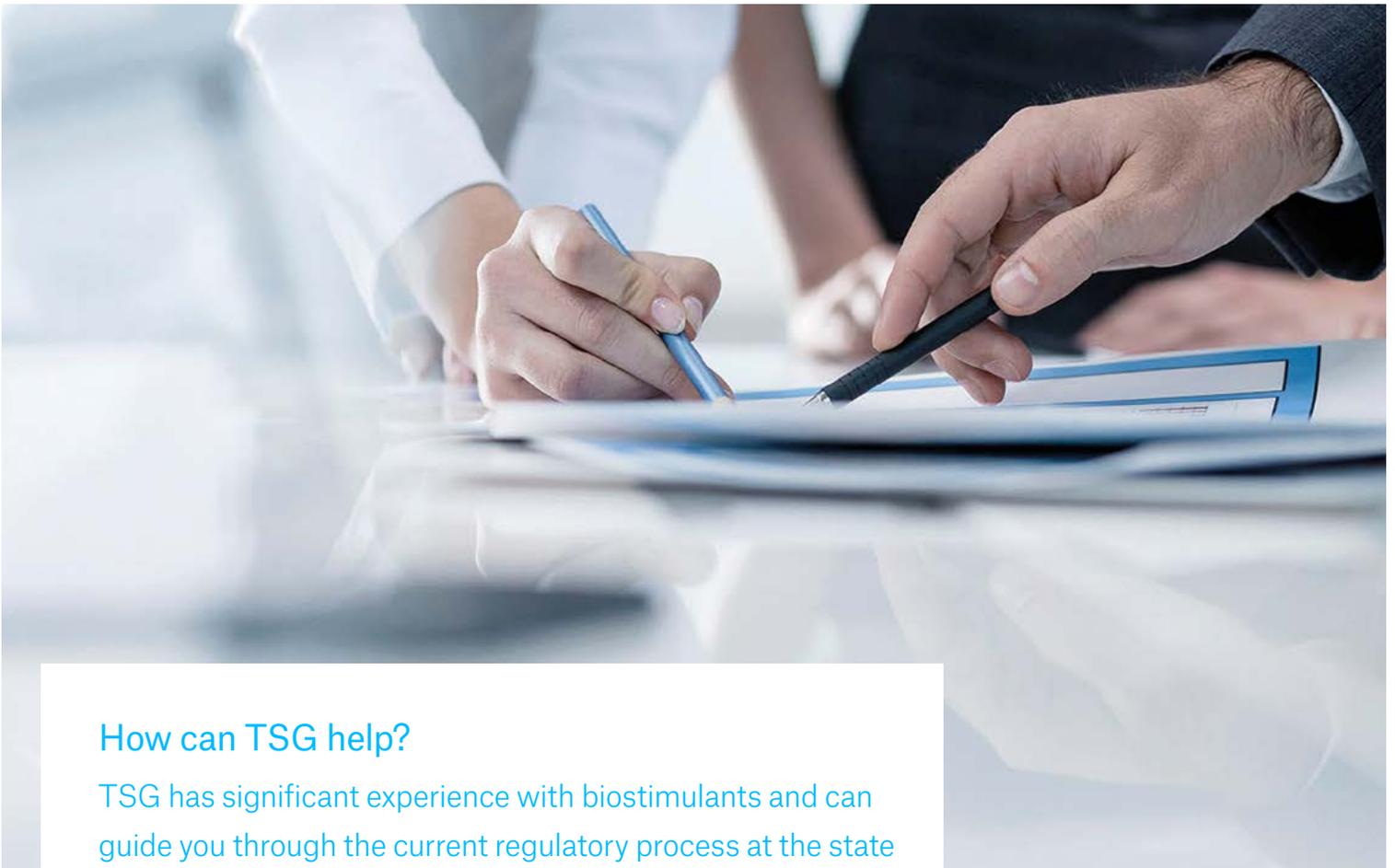
Trade associations have been actively working on this topic for years. The inclusion of statutory language in the Agriculture Improvement Act of 2018 was the first significant step towards federal recognition of this class of products as its own category, which will spur future regulation.

Under the Agriculture Improvement Act of 2018, the Secretary of Agriculture is required to provide a report to the President and Congress within a year of the signing of the Act. The report intends to identify *'any potential regulatory, non-regulatory, and legislative recommendations, including the appropriateness of any definitions for plant biostimulant, to ensure the efficient and appropriate review, approval, uniform national labeling, and availability of plant biostimulant products to agricultural producers.'* The Secretary of Agriculture is also mandated to work with the Administrator of the Environmental Protection Agency, several States, and industry and other stakeholders.

Trade associations such as Biopesticide Industry Alliance (BPIA), the Biostimulant Coalition, and The Fertilizer Institute (TFI), among others, and state agencies, through Association of American Pest Control Officials (AAPCO), Association of American Plant Food Control Officials (AAPFCO) and National Association of State Departments of Agriculture (NASDA), are working together to provide assistance to the US Department of Agriculture (USDA) in preparing the report. They are also proposing options for a path forward on regulating and defining these products, identifying and characterizing the active substances, verifying the claims and assessing risks.

Other countries, including Brazil, China and India, are also actively working on developing legislation for biostimulants. The industry hopes that the work being conducted in the EU and the US can provide a level of uniformity internationally.





How can TSG help?

TSG has significant experience with biostimulants and can guide you through the current regulatory process at the state level. **Our services include:**

- Strategic guidance on the regulatory options to assist clients make commercial decisions
- Preparation and submission of registrations on your behalf and interaction with the state regulators as needed
- Review of efficacy data to identify acceptable claims for labeling and other marketing materials
- Assistance with label review and label development to achieve compliance in the states and minimize the number of label versions needed

In addition, TSG is actively involved in monitoring the current attempts to create a new regulatory pathway for biostimulants at both the federal and state level. This enables us to not only keep our clients informed, but to also plan for upcoming changes in the regulatory landscape that may affect their products.

Interested in discussing
a potential project?

Get in touch:
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TSG Consulting provides companies with high-quality regulatory and scientific consulting services. We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry. This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance.

TSG Consulting has offices in France, Germany, Spain, UK, USA and Canada. TSG is a Science Group (AIM:SAG) company.

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