July 25, 2019

Alexandra Dapolito Dunn
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency

On behalf of our associations, please accept our written comments on the "Draft Guidance for Pesticide Registrants on Plant Regulator Label Claims, Including Plant Biostimulants" [EPA–HQ–OPP–2018–0258; FRL–9986–27] RIN 2070–ZA21.

Plant biostimulants improve natural plant nutritional processes, which results in improved plant health, tolerance to abiotic and other environmental stresses, improving overall growth, quality and yield. In doing so, these products can increase the uptake and utilization of existing and applied nutrients, which reduces the potential for off-farm nutrient runoff into rivers, lakes and streams and the emission of carbon dioxide and other greenhouse gasses. Plant biostimulants also have the ability to increase yield and quality without increasing applied fertilizer, water or planted acres, thus, sustainably enhancing the efficient use of these inputs and natural resources. This makes them a valuable tool for farmers, landscapers, golf course superintendents, and homeowners, among many others.

We appreciate the Environmental Protection Agency's (EPA's) time, attention and effort in preparing and seeking comments on the Draft Plant Biostimulant Guidance (Guidance). We have been interested in EPA's perspective on this emerging category of products and technologies. We, along with many other stakeholders, have sought clarity with respect to the claims our products can make with respect to the existing statutes and regulations under EPA's purview.

Our comments on the draft Guidance document fall into 5 categories: Ongoing regulatory uncertainties, impacts on innovation, economic implications, market access for plant biostimulant products and accessibility for end users.

Ongoing Regulatory Uncertainties

Guidance on Claims

As we have reviewed the draft Guidance, we have encountered a number of areas that need further clarification. Without modification, we are concerned that state regulatory agencies, industry and related stakeholders will continue to have questions regarding how particular plant biostimulant products should be registered and brought to market. Furthermore, we believe the Agency should state that potential outcomes of improved natural plant nutritional processes is better plant health, which may be reflected in an increased tolerance to abiotic and other environmental stress, improved growth, quality and yield.

We appreciate the Agency's efforts in developing several tables (Tables 1-3) that provide claim examples. This is entirely appropriate given that EPA's jurisdiction over pesticide products

under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including those pesticide products known as plant regulators, is based on intent. Moreover, we believe that a list of example claims is helpful for both regulators and industry, with certain caveats. On line 149 of the draft Guidance, EPA acknowledges, "The examples contained in the following tables are not comprehensive lists and may include other synonymous terms." We appreciate this recognition, but think this sentence should be reiterated again to accompany each table included in the document. Our concern is that, going forward, regulatory agencies may only allow those claims specifically listed in those tables.

We believe that the draft Guidance should focus on the claims aspects of FIFRA. Given that, we request that Table 4, which does not include example claims but instead includes a list of materials previously registered with EPA as plant regulators, be deleted, for the following reasons.

1. The introduction of the "substance-based" Table 4 into this draft Guidance is confusing (as to the responsibilities of the company) because it is not claims focused which is in contrast to the intent of the Guidance. By simply following the perceived intent of the guidance under Table 4 as a decision tool, a stakeholder (e.g., a state level registration authority) could restrict a company access to the market (in which numerous other products of like composition are being sold) or impose a substantial economic burden on the product company in order to take the product to market.

2. Further to the above point, the information summarized in Table 4 is of limited value from a guidance perspective as the information contained therein is readily available to the public, to registrants, to registration authorities and other stakeholders. It introduces no new content that is relevant to the draft Guidance document.

3. The inclusion of Table 4 in the draft Guidance also runs counter to not only the historic practices in the US, but to the direction in the European Union (EU) and other markets of global significance for trade. It would be useful for EPA to align with other regulatory authorities on its approach. The legislation recently enacted by the EU Parliament on the marketing of fertilizing products (EU 2019/1009) bases its regulatory framework on a claims-based approach, and explicitly recognizes that the functionality of any single material may be altered by its processing, formulation or use context. Furthermore, the EU legislation treats all biostimulants – materials beyond basic nutrients that aid in plant nutrition processes – as a subset of fertilizing products, rather than pesticides. This action follows the essential logic that such materials – including those cited above as problematic inclusions in Table 4 – are intended for use as materials that enhance the normal functioning of plants through contributions to improved plant nutrition.

For all of the above reasons, the inclusion of Table 4 in the draft Guidance is problematic and likely to lead to unintended consequences and should be removed.

Potential Conflicts with Related Federal Efforts

Additionally, other ongoing activities at the Federal level should be well coordinated with the finalization of the EPA's plant biostimulant Guidance. In particular, Section 10111 of the Agricultural Improvement Act of 2018 included an important provision regarding plant biostimulants. In the law, Congress directed the Secretary of Agriculture to submit a report (within one year of enactment) to the President and Congress that identifies 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 is to prepare the report in consultation with the EPA Administrator, the several States, industry stakeholders, and such other stakeholders the Secretary determines necessary.

Although Congress provided a description of a plant biostimulant, it did so solely for purposes of preparation of the report, and went on to authorize the Secretary to modify that description, as appropriate. The draft Guidance document asks the question as to whether EPA should attempt to define a "plant biostimulant" at this time.

Finally, on a broader scale, given the significance of the statutorily mandated study, we believe it would be premature for EPA to finalize the Guidance until the requisite report has been submitted and Congress and the President have had an opportunity to review and address it. We recommend that any definition be developed in coordination with USDA and other stakeholders as part of the Section 10111 process.

Impacts on Innovation

As the draft Guidance acknowledges, plant biostimulant products "are becoming increasingly attractive for use in sustainable agriculture production systems…which in turn can reduce the use of irrigation water, as well as agrochemical supplements and fertilizers." We agree with this statement and believe that the plant biostimulant industry has a great potential to contribute to agriculture production systems through innovative technological product development. Many of the products on the market today and in development in the coming years will have the ability to help a grower or end user improve their product quality, yield, or both while also reducing their environmental footprint. We believe if the economic implications of the draft Guidance become a reality (described below) that much of the innovative research and development that is ongoing within the plant biostimulant industry will either be delayed or cease altogether.

Economic Implications of Table 4

If EPA's draft Guidance were implemented as written, there would be a potentially significant adverse economic impact on manufacturers, companies producing end-use products, state regulatory agencies, and growers. For manufacturers, we have estimated that the annualized cost could reach or exceed $449 million, totaling over $2 billion for the five-year time period. (See Appendix 1)

Summary of Annualized Costs to Manufacturers (5 years at 5% Discount Rate)

Cost Categories	Increase in Annualized Costs to Manufacturers (thousand $US, Annual Costs for 5 years)	
	Low Estimate[a]	High Estimate
Data Development	$903	$65,417
Federal Registration	$767	$5,893
State Registration	$2,058	$2,032
OMRI	$60	$413
Production Costs: Rebranding, Relabeling, and Changes to Supply Chains and Logistics	$698	$26,167
Annualized Total Costs[b]	$4,485	$99,921
Annualized Total Costs including reduced manufacturers' revenue during registration[c]	$91,708	$449,813

[a] For data development and federal registration the low estimate is based on 250 products and the lowest cost option and the high estimate is based on 750 products and the highest cost option. For state registration, OMRI, and Production Costs, the low estimates are based on the lowest cost option and the high estimates are based on the highest cost option.

[b] The *annualized total costs* do not include the potential lost revenue due to limited marketing opportunities during the registration process, data development costs at the state level, costs related to companies exiting the biostimulant market, and costs to growers who are currently using the products as fertilizers.

[c] The *annualized total costs including reduced manufacturers' revenue during registration* includes the potential revenue that would be lost in California from reduced sales during the registration process based on a low estimate (50 companies at $5 million per company lost revenue in the first two years) and a high estimate (100 companies at $10 million per company each in the first two years).

Market Access for Plant Biostimulant Products

Given the above description of the economic implications of the draft Guidance, it is reasonable to state that many of the plant biostimulant products that are in development may never progress

to market if the draft Guidance is implemented as written. Decisions related to research and development, product testing, registration costs, marketing and other related concerns will have to be made if a more complicated and costly regulatory structure is required for certain plant biostimulant products going forward. Many companies will choose not to pursue the development of certain products and not only will their product never reach the market, but the end users who could have benefitted from them will never have the opportunity to use them.

Availability for End Users

As stated above, the industry, growers, public, and environment all benefit from affordable, innovative agricultural technologies. Additional regulation will likely make these technologies less available to the grower or other end user, either because they are too costly or because industry will be unable to afford the investment in research, development, and the registration process needed to provide these valuable products.

Many of the related stakeholders who have had positive experiences with plant biostimulant products will no longer have streamlined access to these technologies in the future. These include many types of conventional and organic farmers, agricultural retailers, golf course superintendents, and landscape professionals, among many others. Consumers and the other end users who need access to an abundant, affordable food supply and many of these products and services will suffer as a result.

We appreciate your attention in reviewing these comments and the consideration that you can give to them at such time as you turn to finalizing the Guidance. Please feel free to contact us if you have any questions concerning these comments or would like any additional information.

Sincerely,

Agricultural Retailers Association (ARA)
American Seed Trade Association (ASTA)
Biological Products Industry Alliance (BPIA)
Biotechnology Innovation Organization (BIO)
CropLife America (CLA)
Golf Course Superintendents Association of America (GCSAA)
Humic Products Trade Association (HPTA)
National Association of Landscape Professionals (NALP)
The Fertilizer Institute (TFI)
Responsible Industry for a Sound Environment (RISE)
U.S. Biostimulant Coalition (USBC)