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On behalf of our associations, please accept our written comments on the “Draft Guidance for Plant Regulator Products and Claims, Including Plant Biostimulants.” [EPA–HQ–OPP–2018–0258-0170 (RIN 2070-ZA21; Notice).

Plant biostimulants improve natural plant nutritional processes, which result in improved plant health, tolerance to abiotic and other environmental stresses, and improved overall growth, quality and yield. In doing so, these products can increase the uptake and utilization of existing and applied nutrients, which reduce 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. In addition, we applaud the Agency for referencing the 2018 Farm Bill and the 2019 USDA Report to Congress on Plant Biostimulants and their inclusion of various definitions for plant biostimulants and not attempting to define the term in this guidance. In the long run, we would like to underscore the importance of federal and state authorities reaching an agreed-upon definition. Industry prefers the 2019 Alternative Definition 2, included in the USDA report, as the future legal definition.

We believe the current version of the draft guidance is improved from the previous version, which was released in March of 2019. That said, we have several comments and related recommended changes and clarifications.

Our comments on the draft Guidance document are below, with specific recommended changes for EPA to consider before the guidance document is finalized.

| General Comments on Text | | | |
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| Page Number | Text from Guidance | Comments | Proposed Change to Text from Guidance |
| Title Page | Draft Guidance for Plant Regulator Products and Claims, Including Plant Biostimulants | Title page: Industry recommends the title be changed to “ <i>Guidance for Plant Regulator and Plant Biostimulant Products and Claims</i> ” as the current title of the document could be interpreted to categorize plant regulators closely with plant biostimulants. We believe they are separate and distinct categories of products. | Title could more appropriately read: “Guidance for Plant Regulator and Plant Biostimulant Products and Claims” |
| 4 | <p>Background</p> <p>Plant biostimulants (PBS) are an increasingly popular category of products containing naturally-occurring substances and microbes that are used to stimulate plant growth, enhance resistance to plant pests, and reduce abiotic stress.”</p> | <p>Not all substances used are naturally-occurring. They can also be synthetic or transformed from natural substances.</p> <p>Furthermore, it should be clarified if the meaning of natural is intended by EPA as used for “Biochemical pesticides are naturally occurring substances” which EPA considers as natural, or synthetic equivalents.</p> <p>This is partly discussed in the document later when, for example, seaweed extracts (i.e., modified by extraction) are mentioned.</p> | <p>We request the following modification to the current text:</p> <p>Plant biostimulants (PBS) are an increasingly popular category of products containing naturally-occurring substances, derived from natural materials (processed), and synthetic materials, and microbes.</p> |

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| 5, 6, 7, and 10 | Based on the plant regulator definition contained in FIFRA section 2(v), many PBS products and substances may be excluded or exempt from regulation under FIFRA depending upon their intended uses as plant nutrients (e.g., fertilizers), plant inoculants, soil amendments, and vitamin-hormone products (see Tables 1a-1c and Table 2). | The Guidance document references Appendix A, which includes nutritional chemicals as an exclusion; and then goes on to say, “ <i>many PBS products and substances may be excluded or exempt from regulation under FIFRA depending on their uses as plant nutrients (e.g., Fertilizers), plant inoculants, soil amendments, and vitamin-hormone products</i> ”. The term, “nutritional chemicals”, while specifically cited in FIFRA section 2(v), is notably absent from the EPA reference. Industry believes that this leaves a significant gap in governance of what is within or outside the authority of FIFRA. | We request that in all places in the Guidance where the language from FIFRA or the CFR is cited regarding the substances that “may be excluded or exempt from regulation”, the full citation should be used, including the term “nutritional chemicals”. Despite the current lack of a definition for the term “nutritional chemicals”, we believe it is essential that all excluded categories at FIFRA Section 2(v) be referenced in this Guidance document should this term be defined in the regulations in the future. |

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| 5 | The Agency, however, when evaluating whether a product is a pesticide, considers not only the claims being made for the product, but also, among other things, product composition. | To evaluate whether a product is a pesticide the “intent” of product use is a fundamental consideration as set forth in the FIFRA definition of a pesticide: e.g., “any substance ...intended for use as...”. We recommend that “intent” as a consideration in evaluating whether a product is a pesticide should be added to this sentence. | We suggest the text be modified to include “intent” as follows: The Agency, however, when evaluating whether a product is intended for a pesticidal purpose , considers not only the claims being made for the product, but also, among other things, product composition. |
| 11 | Table 3. Footnote 2. “All of the above are examples of “altered behavior” of plants via the physiological action of plant regulators. It is understood that many of the claims in this table can be made for non-plant regulators (e.g., fertilizers).” | We appreciate EPA’s inclusion of this footnote. We believe it is helpful in recognizing that these examples and the way they are defined helps to clarify what is meant by “altered behavior”. The verbs ‘enhance’ and ‘promote’ are often used to describe the benefits of plant nutrients and other substances that “aid the growth of beneficial plants”. We believe it creates confusion and overlap to also allow them plant regulator claims. The verbs “induces/stimulates” has been used more customarily to have a similar meaning when associated with plant regulator claims. We believe a few modest tweaks could make this very useful. | In Table 3, we recommend removing “enhances/promotes”, “enhance” and “promote(s)” and inserting “induce(s)/stimulate(s)” in the places they appear. |

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| 11 | <p>Substances that have no other use than as plant regulators or pesticides.</p> <p>and the first full paragraph of this section.</p> | <p>We believe the assertion that the substances discussed in this section generally have no other use other than as plant regulators is inappropriately absolute and needs to be softened.</p> <p>There is supporting literature concerning the plant biostimulant activity of several of these products, and such activity is alluded to in a number of the examples.</p> <p>Moreover, it is entirely possible that further research will document additional non-pesticide uses for these substances.</p> | <p>We recommend that the section title and first paragraph be modified as follows:</p> <p>Substances that <u>may</u> have no other use than as plant regulators or pesticides.</p> <p>.....These substances are generally recognized as likely to have no other significant commercially valuable use....</p> <p>....The Agency recognizes that ongoing research may identify new plant regulator substances that are not currently known to the scientific community, as well as plant regulator substances that also have non-plant regulator modes of action.</p> |

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| 12-13 | Glutamic acid and other examples | Some substances such as the amino acid glutamic acid are naturally present at low levels in materials, but not responsible for the claimed effect of the product. Some clarity could be provided. | <p>We recommend adding the text below as a separate paragraph after "...Haroun et al., 2011)." At the end of this section of the guidance:</p> <p>Materials naturally containing such substances as mentioned above should not necessarily be considered only plant regulators as long as the material is not containing higher-than-normal concentrations of the said substance, or the material is not chosen for its content of the said substance, and that no activity claimed is reasonably considered to be due to the content of the said substance.</p> |

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| <p>13-14</p> | <p>“In the natural environment, the plant foliage is not typically exposed to CPPAs, humic substances, and HAs. Therefore, when applied to the foliage of plants, CPPAs and HAs likely would have no other significant commercially valuable use, either alone or in combination with other substances, except for use as a plant regulator (i.e., as a pesticide).”</p> | <p>We believe the assertion that HAs derived from terrestrial deposits of lignite and similar materials have modes of action like Complex Polymeric Polyhydroxy Acids (CPPAs) is incorrect.</p> <p>We request that the Agency consider the information below and delete references to HAs:</p> <p>HAs have never been individually registered as a plant regulator with the EPA and are only included as a nutrient carrier in combined ingredient products like CPPAs. The current text incorrectly attributes HAs - a known inert ingredient - to have pesticidal activity as a component of CPPAs’ composition.</p> <p>The phrase, “likely would have no other significant commercially valuable use, either alone or in combination with other substances, except for use as a plant regulator (i.e., as a pesticide)” is problematic as it could be interpreted as an attempt to use the guidance document as a rulemaking tool.</p> <p>HAs have significant, commercially valuable uses, either alone or in combination with other substances. For example, a number of researchers have established that foliar application of humic acid improve plant</p> | <p>We request that the following text be considered in place of the current text pertaining to CPPAs and HAs on pages 13, 14.</p> <p><u>Complex Polymeric Polyhydroxy Acids (CPPAs)</u>: These substances are mixtures of organic acids that elicit auxin-like responses in plants. CPPAs are covered by patents and registered as plant regulators. However, as applied to the soil or seeds, CPPAs may have additional modes of action that would not be considered to be plant regulator activity by the Agency. These non-plant regulator modes of action may include but are not limited to: increased antioxidant activity in plants, reduced leaching and loss of nitrogen; buffering of the soil solution to improve nutrient uptake and efficiency; changes in soil cation exchange capacity; and promotion of beneficial soil microbe activity.</p> <p>Alternatively, the entire example entitled “Complex Polymeric Polyhydroxy Acids (CPPAs) and Humic Acids (HAs) could be deleted. The introductory paragraph to “Substances that may have plant regulator and non-plant regulator activity” explains fully the additional modes of action that may not be plant regulator activity.</p> |
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| | | <p>growth and uptake of nutrients. HAs have nutritional mechanisms such as chelating and complexing of nutrients, which are not plant regulator modes of action.</p> <p>EPA has already authorized the use of Humic Acids as inert ingredients with pesticide products designated as Minimum Risk, 40 CFR 152.25(f)(2)(iv), Table 2. No further agency review or approval is required for these uses under FIFRA. Overturning this previous rule making, specific to inert status, would require a notice and comment rulemaking process.</p> | |

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| 14 | <p>Seaweed extracts (SWE): Derived from diverse species of seaweed, SWE have been well documented to have plant regulator activity with the capacity to have direct physiological... to elicit the observed plant growth effects.</p> | <p>This paragraph makes no mention of the non-plant regulatory aspects of seaweed extracts, which have also been documented in the scientific literature and which are acknowledged by the Agency in the top paragraph on page 15 “For example, if a product containing seaweed extracts or humic acids is intended for use....under FIFRA.” We therefore find this paragraph presenting only the plant regulatory actions of seaweed extracts to be problematic as it could be interpreted as an attempt to use the guidance document as a rulemaking tool.</p> | <p>We suggest adding clarifying text to the seaweed extract paragraph that recognizes the non-plant regulatory functions of seaweed extracts such a reduction in abiotic stress or nutrient assimilation as follows:</p> <p>Derived from diverse species of seaweed, SWE have been well documented to have plant regulator activity with the capacity to have direct physiological effects on growth, yield, maturation, and produce quality (Briceno-Dominguez et al., 2014; Di Filippo- Herrera et al., 2018; review by Shukla et al., 2019) and non-plant regulator activity alleviating abiotic stress on plants, or for providing increased nutrient assimilation from the soil. The bioactivity of such extracts...</p> <p>.....The presence of phytohormones and other phytohormone-like plant growth substances (i.e., naturally-occurring plant regulators) when present in seaweed extracts in sufficient concentrations may be responsible for the observed plant regulator activity (Battacharyya et al., 2015; Craigle, 2011; Stirk and Novak, 2003; Shukla et al. 2019; and Stirk et al., 2014), while other constituents are responsible for non-plant regulator growth responses.</p> <p>Alternatively, the entire example entitled “Seaweed extracts” could be deleted. The introductory paragraph to “Substances that may have plant regulator and non-plant regulator activity” explains fully the additional modes of action that may not be plant regulator activity.</p> |
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| 15 | The paragraph “Conventional chemical plant regulators ... and/or plant regulator activity.” | This paragraph is not clear. It seems to suggest that “novel substances” are anything formed from an extraction procedure. Most chemical extractions will lead to modified substances from the original organic material. EPA suggests that such an extract would be within FIFRA only. It is suggested that this paragraph be clarified, and not to exclude derived materials. | We suggest this paragraph be modified as follows: Novel substances may be present in plant biostimulant products that were not present in the original plant source material, but were formed as a result of the extraction methods and/or post-extraction processing (Shukla, et al. 2019). Novel substances that may be present in plant biostimulant products as a result of extraction and/or post-extraction procedures may require further scrutiny under FIFRA by the Agency to determine if they have the potential for pest control and/or plant regulator activity. It is not implied that chemical extraction of materials resulting in a novel substance is necessarily automatically to be regulated under FIFRA. |
| 15 | “Review of such “multiple use” products may be conducted by the Agency under PRIA Code M009.” | We appreciate the Agency pointing to the use of the PRIA M009 review as way for companies to investigate the regulatory requirements of a substance/product. However, the current language in the Guidance document makes the process appear to be mandatory. | We recommend the inclusion of language clarifying that this review is a voluntary process, such as: "Review of such "multiple use" products may be conducted by the Agency under PRIA Code M009, Non-FIFRA Regulated Determination. This determination is not required by the Agency, and such a request is at the discretion of the applicant. " |

We appreciate your attention in reviewing these comments in your work to finalizing the Guidance and sincerely hope that it can be concluded as soon as possible. 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)
Council of Producers and Distributors of Agrotechnology (CPDA)
CropLife America (CLA)
CropLife Canada
Fertilizer Supplements Advisory Committee (FSAC)
Golf Course Superintendents Association of America (GCSAA)
Humic Products Trade Association (HPTA)
National Association of Landscape Professionals (NALP)
Responsible Industry for a Sound Environment (RISE)
The Fertilizer Institute (TFI)
U.S. Biostimulant Coalition (USBC)