Frequently Asked Questions
Certified Biostimulant Program
Revised: August 1, 2024

Program Questions

1. **What is being certified?**
   Certified Biostimulant is a voluntary program that certifies that information to support label claims of a biostimulant product conforms to the *United States Biostimulant Industry Guidelines to Support the Safety, Composition and Efficacy of Plant Biostimulant Products*. It provides a consistent framework for reporting a minimal dataset on safety, composition, and efficacy tests conducted on the product. The program assures the existence of such data without disclosing the results. The program certifies that proper experimental protocols were used to test efficacy, without making any assertion on the efficacy of the product for any claims made.

2. **Does this program certify products are effective?**
   The Certified Biostimulant program does not verify or certify product efficacy. Rather the program certifies proper experimental protocols were followed in product testing according to the efficacy testing requirements in the U.S. Industry Standard. This program certifies that data or published literature was provided to demonstrate testing was completed for product claim(s) listed on the label. The certification does not require a specific threshold to demonstrate efficacy.

3. **Who is developing the evidence to meet the product composition standard to be submitted by the applicant?**
   The application asks for evidence of product composition; therefore, each manufacturer or retailer applicant is responsible for providing a Guaranteed Analysis or active ingredient concentration in accordance with the U.S. Industry Guidelines (Section 3.1, page 8). As outlined in the U.S. Guideline, the minimum amount should be expressed as a percentage weight by weight (% w/w) or in recognized units of potency (e.g., Colony Forming Units CFU/g, percentage of weight, or other appropriate expressions of composition). Analytical methods for identifying the substance(s) should be provided and any process provided must be repeatable under standard laboratory conditions. Product composition should be reported by a third-party testing facility/laboratory of the applicant's choice. Further information on composition of specific products can be reviewed in section 3.1 of the U.S. Industry Guideline.

4. **Who will review the applications to verify the product conformance to the standard once they have been submitted?**
   Product conformance is determined by application completeness. Evidence of all necessary elements outlined in the U.S. Industry Guideline for Efficacy, Safety, and Composition must be included for a product to be deemed conformant. These elements are explained in detail in the U.S. Industry Guideline developed by the Biostimulant Industry Workgroup and published by BPIA and TFI. Efficacy is not directly determined, instead deemed conformant if the evidence is provided to show that proper experimental design and methodology were used to support the results.

   The TFI application review for the process certification verification will be conducted by internal TFI experts and as necessary by other third-party reviewers with expertise in agronomic or soils research. Reviewers will determine conformance based on the applicant's ability to provide complete evidence based on requirements outlined by the U.S. Industry Guideline.

5. **If my product is not certified, is there an independent review or appeals process?**
   Applicants may be denied an award for non-compliance with requirements. The applicant may appeal a denial on a case-by-case basis. Appeals must be sent to TFI staff within 30 days after the

applicant is informed of the denial status. The appeal shall be in writing and provide a rationale for the request. The appeal shall include all pertinent information to support the appeal. The Appeals and Complaints Subcommittee has final authority over any appeals and shall decide on the appeal within 30 days after receipt of notification. Applicants denied an award may reapply at their discretion.

The Appeals and Complaints Subcommittee has the responsibility to make determinations on appeals and complaints submitted by Biostimulant Certification program applicants or Certification holders. The responsibilities of the Appeals Subcommittee and its members include:

- Being available to serve on ad hoc three (3) member Appeals or Complaints Panels to hear individual or groups of appeals, as needed.
- Giving due consideration to appeals.
- Arrange for notification of the results of appeals determinations
- Tracking appeals and dispositions.

The Appeals and Complaints Subcommittee shall consist of three (3) independent members - knowledgeable in soil science but not affiliated with any biostimulant or fertilizer manufacturing company. A pool of qualified individuals will be identified for possible participation on the appeals committee. The three individuals selected will be based on availability and willingness to conduct the review. The list of candidates serving on the Appeal and Complaint Subcommittee, will consist of university staff and/or others who helped review the industry efficacy, safety, and composition guidelines.

6. **Was the industry involved in developing the standard and the requirements for the certification?**
   Requirements for the certification program were taken directly from the *United States Biostimulant Industry Recommendations to Assess the Efficacy, Composition, and Safety of Plant Biostimulant Products* (members of TFI and BPIA). Industry participants including representatives from biostimulant manufacturers (large and small), retailers, and laboratories were brought together in early 2022 to form the Biostimulant Certification Task Force. This Task Force developed the framework for the evidence-based application based on the standard for efficacy, safety, and composition referenced above. The full Biostimulant Council and other stakeholders and groups who are not TFI members were regularly briefed on the program and reviewed the full program. All comments were incorporated and addressed.

7. **Is it common for associations to manage certification programs? Will the program be branded as a TFI program?**
   It is very common for industry associations to run product certification programs. Great examples from other industries would be the BRC's product certification for food safety (Global Food Safety Initiative), or the Packaged Ice Association's product safety certification for packaged ice. Because of TFI's unique position as a trade association, it is best positioned to manage this program.

   Additionally, for marketing purposes we will market the program as "Certified Biostimulant Program" rather than "TFI Certified Biostimulant Program" since this is an independent review process and we want to convey that message to stakeholders. Within certain stakeholder groups, such as regulators, it will be helpful to associate the Certified Biostimulant Program with TFI because of the association's reputation in bringing together a cross-section of industry experts and its commitment to impartiality and objectivity.

8. **Is USDA developing a biostimulant certification?**
   No, USDA does not offer a biostimulant certification program. They do have a process verification program (PVP) that may include one or more agricultural or food processes or portions of processes where self-described process points are supported by a documented quality assurance management system and independently verified by a qualified AMS auditor.

   The PVP process is designed to ensure that manufacturers are following self-described process controls to produce consistent products; not specific to biostimulant products. The auditors do not assess efficacy or safety, but rather verify that the manufacturer has implemented a quality assurance system and that the documented process controls are being followed. It is also important to note that the Certified Biostimulant Program mentioned in the previous answer is a voluntary, industry-driven program and not a government-regulated program. To learn more, visit https://www.ams.usda.gov/services/auditing/process-verified-programs.

   There are many types of certification programs, where companies may choose to complete multiple certifications for their products. USDA's PVP program might satisfy certain requirements for a company but doesn't achieve the Certified Biostimulant program objective to give retailers a tool to assist in their evaluation of biostimulant products.

9. **Will the program be accepted by the industry?**
   The survey conducted by TFI indicates strong support for the program. Of the 27 companies participating approximately 70% were likely to apply for an award.

10. **Do Private labels also have to be certified?**
    The definition of a private label are products manufactured by one company (the manufacturer) but sold under the brand name of another company (the retailer). As such, manufacturers, retailers, or the distributor of the private label product shall obtain a certification award for each private product label The fee for this type of product certification will be $750 every two years for members and $1,500 every two years for non-members. The cost can be covered by the manufacturer or the company marketing the product under a private label.

11. **Can a manufacturer or retailer use a certified plant biostimulant ingredient to certify other products they sell?**
    It is possible to use certification for an ingredient from a single manufacturer for other products with a higher per acre application rate. However, to certify multiple products with the same ingredient the product must 1) have identical claims, 2) provide data to support the recommended application dose, and 3) have no other ingredient changes in the product. This approach allows for flexibility in formulating products using the same certified biostimulant ingredient. For example, if a certified plant biostimulant product has been assigned an identification number, it may be permissible to use that certification for other product labels with the same or higher per acre application rate of the same biostimulant. Applicants should specify changes in application rates that correspond to changes in the biostimulant ingredient concentration and provide an explanation for application rate changes. All other ingredients must remain the same. However, a separate certification application must be provided for each product for evaluation and approval by TFI. The fee for this type of product certification will be $750 every two years for members and $1,500 every two years for non-members.

12. **Can a company request to align their biostimulant certification with the state registration label timeline?**
    Yes, Companies may request to renew their biostimulant certification to realign with a states label registration timeline. However, the realignment request shall only be allowed to shorten the certification period to obtain uniformity with the state label registration timeline. Otherwise, certification renewals will occur on or before the product expiration date. Renewals will not occur on a calendar or fiscal year basis.

13. **What fees are associated with participating in the program?**
    There will be two fees to participate – an application submittal fee and a renewal fee. The renewal fee occurs every 2 years after the initial application is submitted.
    - Members
        - Application fee: $1,800 USD/product
        - Renewal fee (every 2 years; no changes to product): $750 USD/product
        - *If there are any changes to the product, rather than a renewal, the company must re-submit the product Application and Application Fee ($1,800 USD).*
    - Non-Members
        - Application fee: $5,500 USD/product
        - Renewal fee (no changes to product) $1,500 USD/product
        - *If there are any changes to the product, rather than a renewal, the company must re-submit the product Application and Application Fee ($5,500 USD).*
    - *The certification identification will list a 6 year expiration date. There are to be attestations from biostmulant manufacturers on product claims and formulation changes every two years. Modifications to product active ingredients constitute a formulation change. Any reported changes will suspend the current certificaiton until a new application is submitted and approved.*

14. **How does the program align with individual state regulations? Have states been involved with the criteria established for this program?**
    The TFI Biostimulant Certification Task Force developed the program. This Task force included Industry participants including representatives from biostimulant manufacturers (large and small), retailers, and laboratories. In addition, Dr. Mark LeBlanc who is the State Director, Indiana State Chemist and Seed Commissioner (responsible for regulating fertilizer and biostimulants in the state) actively participated on the Task Force. Dr. LeBlanc was very helpful and provided much support for the program. We have kept AAPFCO very aware of the progress on the program and they have been supportive of the effort. The intent is to use the package developed for certification as a single package for adoption by all states. We recognize that some states may want additional information, but we plan to update the certification webpage with those additional requirements so that companies are well aware of any additional requirements.

    Further, the "Industry Guidelines" used as the basis for this program was developed over the course of several years, hundreds of hours were volunteered by industry representatives with significant input received from reviewers representing the Association of American Plant Food Control Officials (AAPFCO,) Academia, commodity organizations, regulatory professionals, and other industry associations.

Application Questions

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1. **My product contains a proprietary ingredient. What information will be shared publicly about participants of the program?**
   While the program does not require or ask for confidential information, TFI has policies in effect to protect any submitted data. However, a web portal of certified products containing the company name; company website, product name; product category (i.e. one of the 5 product types identified in the standard), sales staff contact name, email and phone number; certification expiration date; certification identification (ID) number; link to the product label; label claims; SDS; and the full efficacy workbook (or CBI redacted information efficacy workbook.) The information appearing on the TFI website is a marketing and promotion tool for the companies that participate. TFI wants to highlight and promote companies in the program as a benefit of participation. It should be noted that all expired certified products will be removed from the web portal.

2. **What is the minimum number of original and/or published research studies that should be provided per product? Would only one be valid?**
   The number of studies required is dependent on the number of claims made on the product label. Two datasets must be provided for each claim and each crop grouping. Each study must meet all the requirements outlined by the U.S. Industry Guidelines.

3. **Does published literature need to follow the same original research requirements outlined by the standard?**
   Published literature should demonstrate the trials, when appropriate, are randomized and replicated, and have appropriate controls and statistical analysis in line with the standard. Published literature that supports the same label guarantees, composition (including derived by statements), application rates and claims could be used to support efficacy testing. For example, humic acid that was derived from leonardite at a concentration of 3.5% and applied at the same label rate and supported increased yield could be used by a different product that used the same parameters.

4. **How many crop(s) and/or crop groupings must be tested to support label claims?**
   According to the Certification Program standard, applicants must provide:
   - A written rationale for the crop groupings used
   - If no crop groupings used, a rationale is required to explain why
   - Two datasets to support each claim for each crop group defined above.

   However, a good example of crop groupings are identified in the European Union standard (e.g. Utilize 3 Crop Groupings (Broadacre; Woody Perennials; and Vegetables/Ornamentals).

   For further guidance, please see text from the U.S. Industry Standards, Section 2.2.3, page 6

5. **What testing for contaminants is required to demonstrate proper safety?**
   Heavy metals contamination tests are required for all products due to their low cost, ready availability, and due to the requirement by AAPFCO for all new product registrations.

   Microbial pathogen testing should be conducted on all products to ensure they are safe and effective in their end-use application. Target-specific methods for common pathogens such as E. coli, Salmonella, and Fecal coliforms are inexpensive and readily available in testing laboratories.

Other contaminants: You should describe your manufacturing process to either justify no other contaminants could be introduced during the manufacturing process or test for those contaminants that through your product testing, R&D, or trials have occurred and test for those contaminants listed in this section.

For products that use fermentation, Enterococci must be tested. Given the challenge of finding a laboratory that can run the analysis for Vibrio and Shigella, this requirement is temporarily waived.

6. **My product contains plant nutrients. What kind of controls are required?**
If a product is intentionally adding nutrients, then trials must include a positive control. Otherwise, a positive control is not necessary. If the nutrient concentration is less than the threshold in the table below, the applicant may be exempt from providing a positive control.

Maximum amount of Nutrient allowed in product without a need for a plant nutrient control

Nutrients	Quantity of nutrient applied (lb/A) per soil application	Quantity of nutrient applied (lb/A) per foliar application
N	9	2
P2O5	9	1.3
K20	9	2
Mg	2	0.5
Ca	6	1
S	4	0.7
B	0.4	0.1
Co	0.04	0.004
Cu	0.4	0.022
Fe	13	0.2
Mn	3	0.13
Mo	0.04	0.003
Zn	0.9	0.13

7. **What NUE (Nutrient Use Efficiency) calculations are appropriate to claim increase in NUE?**
NUE equation should be provided, defined, and explained in the methods section of the research report if an NUE claim is made. Applicants using a NUE claim should use one of the equations listed in the table below to demonstrate NUE. Increased yield alone is not necessarily an indicator of increased NUE.

NUE Definitions and Equations adapted from Table 1.1 and 1.2 of the EU Standard, "*Plant biostimulants - Claims - Part 2: Nutrient use, efficiency resulting from the use of a plant biostimulant*"

NUE Index	Calculation	Interpretation

IE = Internal utilization efficiency of a nutrient (kg yield per kg nutrient uptake)	IE = (Y/U)	Ability of a plant to transform nutrients acquired from all sources (soil, fertilizer) into economic yield (grain). Depends on genotype, environment and management.
PFP = Partial factor productivity of supplied nutrient (kg Harvest product per kg nutrient applied)	PFP = Y/F or PFP = (Yo/F) + AE	More important for farmers because it integrates the use efficiency of both indigenous and applied nutrients. High indigenous soil nutrient supply (Yo) and high AE are equally important for PFP.
NE = Nutrient export of a plant nutrient in a plant (plant part or total plant)	NE = Y x C	Calculates the quantity of nutrient exported in the part of interest, with same level of nutrition in all treatments (through fertilizers and/or environment) Evaluates how much nutrient is indeed recovered into the part of interest.
RE = Apparent crop recovery efficiency of supplied nutrient	RE = (U-Uo)/F	RE depends on the congruence between plant demand and nutrient made available to the plant by fertilizers and/or other environment resources. RE is affected by the application method (amount, timing, placement, N (*or nutrients)* form) and factors that determine the size of the crop nutrient sink (genotype, climate, plant density, abiotic /biotic stresses)
PE = Physiological efficiency of acquired Nutrient Kg yield increase per kg increase in Nutrient Uptake from fertilizer or/and environment	PE = (Y-Yo)/ (U-Uo)	Ability of a plant to transform nutrients acquired from fertilizer or environment into economic yield.
AE = Agronomic efficiency of supplied nutrient (kg yield increase per kg nutrient applied)	AE = (Y-Yo)/F or AE = RE x PE	Product of nutrient recovery from mineral or organic fertilizer (RE) and the efficiency with which the plant uses each additional unit of nutrient (PE). AE depends on management practices that affect RE and PE.

Where: *F* is the amount of nutrient(s) made available to the plant by fertilizers and/or other environment resources; *U* is the amount of nutrient acquired by the plant biomass (total biomass or biomass in the part of interest); *Y* is crop yield (could be interpreted in different manners - harvested part or total biomass); and *C* is concentration of the plant nutrient in the part of interest

8. **What types of environment and soils information is required in the efficacy field testing (e.g., specific designation of chemical and/or physical properties, climate factors)?**
Studies must include description of soil physical properties (i.e. texture, soil series) and climatic zones. Soil chemical properties (i.e. nutrient tests) are recommended for all studies but required if making any soil chemical claims (i.e. nutrient use efficiency or nutrient uptake claims.)

   For abiotic stress claims, data is required to substantiate the presence and absence of abiotic stressor (additional climate data).

   For claims tested under abiotic conditions, applicants must specify claim is "under abiotic stress." For example, if 100% of the trials are under, "drought conditions," then the claim would have to

say "improved yield under abiotic stress." The applicant must have one trial that supports "improved yield" under no stress to remove "under abiotic stress" from label claim.

9. **My product claims include a soil health claim. How is this evaluated in the Certified Biostimulant Program?**
   Per the current AAPFCO definition of biostimulants, which this Certification relies on, soil health claims are not biostimulant claims. Furthermore, soil health can be difficult to define or characterize. This Certification does not comment on soil health: claims related to soil health may be allowed by individual states, but they are outside of the scope of Certified Biostimulant program.

10. **How do applicants handle FIFRA (Federal Insecticide, Fungicide and Rodenticide Act) claims vs plant biostimulant claims?**
    The Biostimulant Certification Program follows the AAPFO definition and supports claims in accordance with the approved AAPFCO definition.

11. **Do trials need to be conducted in the United States?**
    Original Research – In accordance with the Standard, 50% of field trials must be conducted in the U.S. for any yield or quality claims. Greenhouse trials can be conducted globally and are not subject to the requirement that yield and quality studies must be conducted in the U.S.

    Published Research – There are no geographic requirements for published research.

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