GUIDELINES FOR SUBSTANTIATION OF PRODUCT EFFICACY CLAIMS

This document provides general guidance on the submission of efficacy data to support product efficacy claims to ensure consistency and scientific validity.

The substantiation of efficacy claims shall be done in one of three ways:

1. Association with relevant published literature (Appendix A).

2. Research test results using scientifically recognized principles and methods.

3. A combination of research test results with relevant published literature.

Research tests may be conducted using the product's target market and growing system (Appendix B) in replicated "plot" research, or an alternative growing system (Appendix C) that mimics or predicts performance in the target market. Research typically measures specific outcomes, and many times measures differences in plant growth, quality or yield compared to an appropriate experimental control.

Provide Key Product Background Information Based on Claim:

1. Novel Product Composition or Ingredients:
   a) Plant Nutrients - provide guaranteed analysis, derivation statement, and laboratory test method/results to support the guaranteed analysis.

   b) Microbial Products - provide genus, species, and strains (if applicable), and test methodology/results to support identification of species and the number of viable units per cubic centimeter, milliliter, or gram.

2. Crop/Plant Efficacy Claims:
   a) Provide list of crop(s) or group(s) of crops for which the product is recommended with corresponding product and application rates.

Scientific Principles for Efficacy Data and Research

1. **Experimental Design:**
   Use generally accepted experimental methodology that includes appropriate experimental layout, replications, randomization, control treatments and response measures that directly support the product efficacy claim. The appropriate number of replicates will depend on the amount of experimental variation, number of treatments and the size of the treatment difference to be detected.

2. **Proper Control Treatments for Valid Comparisons:**
   a. Must include an appropriate untreated (negative) control that enables clear distinction of the claimed treatment effect without confounding factors. For example, a research test to support an efficacy claim specific to a beneficial substance in a fertilizer product must include a negative control of fertilizer alone to clearly assess the beneficial substance efficacy claim.

b. May include positive controls, such as a comparative standard product, which exhibits known effects like those being claimed.

c. When possible, for experimental designs where a challenge condition is used, control data should be generated in the absence of the challenge condition (e.g., drought, heat, reduction of input).

3. **Location of Research Trials:**
   a. Select relevant test locations based on the 1) proposed claim, 2) target markets and growing systems and 3) sensitivity of the material and claim to soil and environmental conditions.

   b. Research tests to support efficacy claims for improved crop yield or quality should be conducted using the target market growing system (Appendix B). Other efficacy claims may be supported by tests conducted in alternate growing systems (Appendix C).

   c. Research data generated outside the US will be acceptable provided it is applicable to the target growing system, efficacy claims, and meets applicable efficacy data guideline criteria within this document.

4. **Selection of Test Crops:**
   Use specific crop(s) and/or crop groupings (i.e. Fabaceae/legumes, Poaceae/cereal, etc.) that are appropriate to the product efficacy claim and target market.

5. **Number of Research Tests (Locations, Seasons):**
   Identify and substantiate the number of trials, locations and seasons depending on the product efficacy claims, target growing systems, and expected product performance in various soil and environmental conditions.

6. **Statistical Analysis:**
   Not all label claims require submission of supporting data, such as those well accepted and consistent with the scientific community or scientific literature. Rather, efficacy data is required for claims or compositions that are novel or unique. Alternative statistical analysis or research standards may be considered if they are statistically valid and clearly demonstrate the intended effects or claims.

   a. Research tests and data must include statistical analysis appropriate to the experimental design and test objectives. Consultation with a statistician on design and analysis is highly recommended.

   b. A common objective of data analysis is to determine whether a treatment is statistically different than an appropriate control. Null Hypothesis Significant Testing and the P-value (significance level) is a widely used standard to measure evidence of a treatment effect and must typically fall below 0.05% ($P < 0.05$) for statistical significance.

- While the P-value is a commonly recognized standard, the Association may recognize statistical methods other than Null Hypothesis Statistical Testing and P-values, such as regression, Bayesian analysis, nonparametric tests, confidence intervals, etc., if the method validates the test objectives, experimental design and data.

EFFICACY CLAIM APPENDICES

APPENDIX A.

Substantiation of product efficacy claims using scientific literature

1. Identify product claims using the exact wording that appears on the product label.
2. Identify ingredients relevant to the efficacy claim.
3. Identify recommended rates of application on the label.
4. Provide substantiation for the efficacy claim(s) by providing literature that is appropriate based on product composition, application rates, target market growing system, etc. Literature includes peer-reviewed scientific literature and research reports. Other substantiated literature may also be considered.
5. Scientific literature does not include testimonials, abstracts or marketing materials.

APPENDIX B.

Examples of target markets and growing systems

1. Field-grown agriculture
2. Production greenhouse
3. Indoor commercial farming
4. Consumer turfgrass
5. Consumer gardens (flowers, vegetables, potted plants)
6. Professional turf (golf, sports fields)
7. Professional container-grown nurseries
8. Other *(define)*

APPENDIX C.

Examples of alternate growing systems

1. Research greenhouses
2. Growth chambers
3. Rain-out shelters / Lysimeters
4. Laboratories
5. Other *(define)*

Researchers using alternative growing systems may need to justify that the results are applicable to the target market growing system(s) and/or demonstrate that results can be replicated in real-world growing conditions (soil type, pH, climate, etc.).

APPENDIX D.

<u>Descriptive statistics</u>

1. A full and complete reporting of statistics that are relevant to the study question is a fundamental component of reporting any data set.

2. The descriptive statistics should fully disclose the magnitude of treatment effects and variability.

3. Examples of descriptive statistics include:
   a. A measure of central tendency
      i. Mean, median, mode
      ii. Weighted mean (e.g., across soil types)
      iii. Mean adjusted for other factors or covariates (e.g., rainfall, temperature, etc.).
   b. A measure of variation: range, variance, standard deviation, coefficient of variation, or quartiles.

4. The environmental conditions and plant species involved in the estimate will strongly affect the descriptive statistics and should be clearly stated to understand the limitations of the estimates.