European Biostimulants Industry Consortium

Plant Biostimulants:
Thoughts on labelling and post-registry control

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DG Entreprise Working Group 4

www.biostimulants.eu

EBIC members

- Agrinos
- Agronutrition
- Arysta LifeScience
- Atlantica Agricola
- Bioatlantis
- Biolchim
- Biovert
- Borregaard
- Brandon Products
- Daymsa
- Grabi Chemical
- Green Has Italia
- Green Universe Agriculture
- IAB
- Ilex EnviroSciences
- ILSA
- Intermag
- Italpollina
- L. Gobbi
- Lida Plant Research
- OGT
- Omex
- Roullier
- Servalesa
- Sicit 2000
- Taminco
- Tradecorp
- Valagro
- Verdera

Objectives of EBIC

- Create a truly European market for plant biostimulants
- Secure a regulatory framework that reassures farmers that plant biostimulants on the market are effective, safe and profitable
- Foster demand for plant biostimulants, factors include:
  - Ability to mix with other inputs as appropriate (e.g. growing media, fertilizers, etc.)
  - Farmers confidence that they will be able to sell crops treated with biostimulants
  - Demonstrated effectiveness and justified product claim
  - Clear distinction between PPP and biostimulants

What will optimal regulation achieve?

+ Profitability
+ Sustainability
+More produced from less

+ Safe, affordable, high-quality food

+ Reputable products
+ Sector perceived as responsible

+Sustainable agriculture
+Dynamic, job-creating SMEs
+European exports and influence

Definition of biostimulants agreed by WG1

"Plant biostimulants means a material which contains substance(s) and/or micro-organisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and crop quality, independent of its nutrient content."

General requirements for plant biostimulants

A plant biostimulant marked may be placed on the European market only if:

- it acts as a plant biostimulant in an effective manner as defined by the claims;
- relevant sampling, analysis, and if required, test methods are available;
- under normal conditions of use it does not adversely affect human, animal, or plant health, or the environment;

Labelling of straight plant biostimulants (1)

In addition to requirements in other Community rules (e.g. CLP legislation), plant biostimulants should be labelled with the following information:

Labelling requirements that would apply to all plant biostimulants (*continued on next slide)*

- An indication of EU registration (e.g. a European registration number, the words "EC Plant Biostimulant"... TBD)
- Product name
- Active constituents in descending order of abundance (some constituents may be expressed in general terms such as "natural plant extracts")
- Registry claims (i.e. to which part(s) of the regulatory definition do the claimed benefits correspond?)
- Minimum guaranteed content *(e.g. Number of colony-forming units or spores, minimum content (range) of marker substances...)
- Indications of the dose rates and suitable conditions of use
- Net mass or volume for fluid biostimulants at time of manufacture measured and expressed as kg or L

* Not necessarily active substances, as in the case of plant and seaweed extracts, where it would be the extract itself that is measurable, rather than the variable (and multiple) active substances it contains. The freedom for the producer to identify the appropriate markers is particularly important where synergies of substances may be at play.

Labelling of straight plant biostimulants (2)

***Labelling requirements that would apply to all plant biostimulants** (continued)*

- Expiration date
- Storage and handling recommendations;
- Mark of the manufacturer and the trade description of the product;
- Batch code
- Responsible person (manufacturer, importer or distributor): name or trade name, address

Labelling that is required if relevant for the product

- Detailed claims (where the applicant claims more detailed benefits than the general regulatory definition of biostimulants, e.g. What kind of quality improvements can be expected or which abiotic stresses are specifically tolerated)
- Any major nutrients (N, P_2O_5, K_2O, MgO, CaO, $S0_3$) that are present in amounts exceeding 1% shall be listed;
- Oligo-elements that are present in amounts exceeding 0,01% shall be listed;
- For the nutrients: specify type (e.g. inorganic or organic), performance characteristics (e.g. water soluble or chelated)
- Mark of quality (purely voluntary)

Labelling of plant biostimulants mixed with other products covered by the future revised regulation

In addition to requirements in other Community rules (e.g. CLP legislation), plant biostimulants should be labelled with the following information:

Labelling requirements that would apply to all plant biostimulants

- An indication of EU registration
- Product name
- Registry claims (i.e. to which part(s) of the regulatory definition do the claimed benefits correspond?)
- Minimum guaranteed content (e.g. Number of colony-forming units or spores, minimum content (range) of marker substances...)
- Concentration in the mixture expressed in kg/T or mL/L
- Indications of the dose rates and suitable conditions of use
- All labelling requirements for the other component of the mixture as outlined in the appropriate section of the revised regulation.

Labelling that is required if relevant for the product

- Detailed claims

* Not necessarily active substances, as in the case of plant and seaweed extracts, where it would be the extract itself that is measurable, rather than the variable (and multiple) active substances it contains. The freedom for the producer to identify the appropriate markers is particularly important where synergies of substances may be at play.

General requirements for labelling

- The items of information shall be **clearly separated by means of a printed border** from any other information provided, with the exception of the batch code which may be printed elsewhere on the package
- **If the plant biostimulant is packaged, the information shall appear on the packages or on labels attached.** The labels printed on the package must be placed in a conspicuous position and must be and must remain visible, indelible and clearly legible.
- **If the plant biostimulant is delivered in bulk, the same information shall appear on the accompanying documents.** In the case of plant biostimulant delivered in bulk direct to the end-user by the manufacturer, the documents containing the labelling information shall accompany the goods and be accessible for inspection purposes, whether the goods are in loose form or in generic packaging.

Languages

- The labelling and the accompanying documents must appear in at least the national language or languages of the Member State in which the plant biostimulant is marketed.

Packaging

- In the case of packaged EC plant biostimulants, the package must be closed in such a way or by such a device that, when it is opened, the fastening, fastening seal or the package itself is irreparably damaged. Valve sacks may be used.

Post-registry controls

There are two elements to post-registry controls:

- **Traceability**: The manufacturer should maintain files, ready for consultation by the authorities, that allow traceability back to the raw materials
- **Quality control**: Products on the market should be subject to random checks of quality
  - EBIC suggests that the responsibility for quality control be distributed among member states but coordinated centrally. This would allow for an efficient control of products and avoid duplicate controls, taking into account the fact that products are likely to be commercialized in more than one country.
  - Quality controls should be conducted with the analytical methods specified in the registration application (see next slide). **Tolerances** between the declared and the actual values would necessarily be related to the analytical method(s) in question. Therefore the definition of tolerances should be related to the definition of the analytical method(s). This will help to address the differences between extremely diverse biostimulants, such as UCVB substances (e.g. Seaweed extracts), substances that have much more uniform characteristics, and microbial products.

Methods to verify guaranteed content

- The variable nature of plant biostimulant products mean that **there is no single method or set of met**hods for testing the guaranteed content.
- Therefore, **any company registering a product must specify the appropriate method(s) in the registration dossier**:
  - Reference to a standardized method where one exists
  - Detailed description of the bespoke testing method where no standardized method is available
  - Reference to an independent laboratory or other owner of an appropriate analytical method that is protected by intellectual property rules
  - Related tolerances should be specified.

To learn more about biostimulants

www.biostimulants.eu

www.biostimulants2012.com

The voice of plant biostimulants in DG Enterprise's WGs

Fertilisers Working Group

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Ad hoc WGs on the revision of Reg (EC) 2003/2003