European standardization for an harmonized market of plant biostimulants
Producer of
• Organic fertilizers
• Organo-mineral fertilizers
• Specialty fertilizers
• Plant biostimulants based on
  - Vegetal hydrolysates
  - Micro-organisms

Member of:

Certified by:

Innovation and into circular economy since 1971
Present in over 85 countries worldwide

www.italpollina.com/us

➢ 13 commercial offices
➢ 3 R&D Centers
➢ 5 Production sites (4 dedicated on Plant Biostimulants)
The European Committee for Standardization (CEN) develops setting European standards (ENs) that are applied across the whole of the European single market.

CEN brings together the national standards agencies of 34 countries and a network of thousands of technical experts from business federations, commercial and consumer organizations, environmental groups and other societal stakeholders.

CEN will be mandated by the European Commission to develop standards supporting the implementation of the future fertilising products regulation and in this context has created a Technical Committee CEN/TC 455 Plant Biostimulants.
Summary

1) Introductory reminders: the new European regulation for fertilizing products

2) Standardization of plant biostimulants at European level

3) CEN/TC 455 workload

4) Possible common work on analytical methods?
1) Introductory reminders: The new European regulation for fertilizing products
What remains in the legislative process?

- **Released October 2017**
  - **Draft Law:**
  - EPP Rapporteur
  - **IMCO**

- **Released December 2017**
  - **Opinion Committees:**
  - ENV, AGRI, INTA

- **Released December 2018**
  - **Informal “Triology” negotiations**
  - **Informally agreed compromise draft law**

- **Published on JOUE before mid 2019**
  - **Draft Law: Council position in first reading**
  - Released December 2017

- **Application before mid 2022**
  - ADOPTED LAW
EU Fertilizing products regulation: application timeline

Endorsed by COREPER and EP Committees (IMCO, ENVI).

Now:

1. European Parliament
   Plenary vote: March II (week 25-28 March)

2. EU Member States (after plenary vote)
   Council: Formal approval by Council of Ministers

3. Entry into force (after Council approval)
   20 day after publication in EU Official Journal
   Article 42 (amending annexes) and 46 (definition biostimulants/PPP)… shall apply from date of entry into force.
   9 months later: Notification and functioning of Conformity Assessment Bodies

4. Regulation applies after three years after date of entry into force.
Definition of plant biostimulants in the Compromise draft regulation

A plant biostimulant shall be a EU fertilizing product, the function of which is to stimulate plant nutrition processes independently of the product’s nutrient content with the sole aim of improving one or more of the following characteristics of the plant and the plant rhizosphere:

- nutrient use efficiency
- tolerance to abiotic stress
- crop quality traits
- availability of confined nutrients in the soil and rhizosphere
Safety parameters for plant biostimulants in the Compromise draft regulation

<table>
<thead>
<tr>
<th></th>
<th>mg/kg dry matter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadmium (Cd)</td>
<td>1,5</td>
</tr>
<tr>
<td>Hexavalent chromium (Cr VI)</td>
<td>2</td>
</tr>
<tr>
<td>Lead (Pb)</td>
<td>120</td>
</tr>
<tr>
<td>Mercury (Hg)</td>
<td>1</td>
</tr>
<tr>
<td>Nickel (Ni)</td>
<td>50</td>
</tr>
<tr>
<td>Inorganic arsenic (As)</td>
<td>40</td>
</tr>
<tr>
<td>Copper (Cu)</td>
<td>600</td>
</tr>
<tr>
<td>Zinc (Zn)</td>
<td>1500</td>
</tr>
</tbody>
</table>

*Total Chromium must be checked for labelling*
<table>
<thead>
<tr>
<th>Micro-organisms/their toxins, metabolites FOR MICROBIAL BIOSTIMULANT</th>
<th>Sampling plans</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>c</td>
</tr>
<tr>
<td><strong>Salmonella spp</strong></td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td><strong>Escherichia coli</strong></td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td><strong>Listeria monocytogenes</strong></td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td><strong>Vibrio spp</strong></td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td><strong>Shigella spp</strong></td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td><strong>Staphylococcus aureus</strong></td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td><strong>Enterococcaceae</strong></td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td><strong>Anaerobic plate count</strong></td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>unless the microbial biostimulant is an aerobic bacterium</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Yeast and mould count</strong></td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>unless the microbial biostimulant is a fungus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

n= number of units comprising the sample; c= number of sample units giving values over the defined limit
Safety parameters for plant biostimulants in the Compromise draft regulation

<table>
<thead>
<tr>
<th>Micro-organisms/their toxins, metabolites FOR NON MICROBIAL BIOSTIMULANT</th>
<th>Sampling plans</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>c</td>
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<tr>
<td><strong>Salmonella spp</strong></td>
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<td>5</td>
<td>5</td>
</tr>
<tr>
<td><strong>Enterococcaceae</strong></td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

\[n = \text{number of samples to be tested},\]
\[c = \text{number of samples where the number of bacteria expressed in CFU may be between } m \text{ and } M,\]
\[m = \text{threshold value for the number of bacteria expressed in CFU that is considered satisfactory},\]
\[M = \text{maximum value of the number of bacteria expressed in CFU}.\]
Component Material Categories in the Compromise draft regulation

CMC 1: Virgin material substances and mixtures
CMC 2: Plants, plant parts or plant extracts
CMC 3: Compost
CMC 4: Fresh crop digestate
CMC 5: Other digestate than fresh crop digestate
CMC 6: Food industry by-products
CMC 7: Micro-organisms
CMC 9: Nutrient polymers
CMC 10: Other polymers than nutrient polymers
CMC 11: Certain products derived from animal by-products
CMC 12: By-products within the meaning of Directive 2008/98/EC

CMC 7 : Positive list of micro-organisms
Azotobacter spp., Mycorrhizal fungi, Rhizobium spp., Azospirillum spp.
Mandatory Directive/EC Standardization request to CEN-CENELEC

European standards

Voluntary EC Standardization request to CEN-CENELEC

The use of a ‘Harmonised Standard’ referenced in OJEU

Creates a presumption of conformity for a given reported value (no documentation is required to justify methodology)

Conformity assessment

For each relevant criterion, the Notified Body confirms that an acceptable value is reported and checks that the methodology is reliable

If all the criteria are satisfied, the Notified Body authorises the use of the CE-Mark

The use of a ‘Harmonised Standard’ referenced in OJEU

Creates a presumption of conformity for a given reported value (no documentation is required to justify methodology)
2) Standardisation of plant biostimulants at European level
1 European standard

... Replaces 34 different national standards in Europe

... Creates access to a market of approx. 600 million people

... May be used as a reference in another jurisdiction that doesn’t have a relevant standard
CEN – Technical Committees involved on FPR

CEN/TC 455

Plant biostimulants

CEN/TC 223

Soil improvers and growing media

CEN/TC 260

Fertilizers and liming materials
What remains in the Standardization process?

1. Consultation and drafting of the Standardization request
   - Since mid 2016

2. Adopted Law
   - Published in JOEU around April 2019

3. Release of the Standardization request
   - Published May-June 2019

4. Development of Harmonized Standards

5. First biostimulant on the harmonized European market
   - Expected April 2022
Standardization request

About a fifth of all European standards are developed following a standardization request from the European Commission to CEN.

This is a request to draw up and adopt European standards in support of European regulations. European standards, even though developed under a Commission request and for European legislation, usually remain voluntary.

Official text from the European Commission to CEN:

1. Reference to Legislation/Policy
2. Scope – Task – Objectives
3. Work program
   - Standards to be developed
   - Time plan

However, an initial inventory of necessary standards has been completed, and we can deduce the majority of standards needed to support the new European regulation on fertilizing products.
CEN/TC 455 scope

Standardization of sampling, denominations, specifications (including safety requirements), marking and test methods allowing the verification of product claims for plant biostimulants, including microorganisms.

Plant biostimulants are products, based on substances and/or microorganisms, stimulating plant nutrition processes independently of the product’s nutrient content with the sole aim of improving one or more of the following characteristics of the plant:

- nutrient use efficiency;
- tolerance to abiotic stress; or
- crop quality traits; and may be applied to plants or soils.

Excluded are plant protection products, fertilizers, liming materials, soil improvers, growing media, and agronomic additives that are already covered by standardization at European level.
How to participate in CEN/TC 455

Technical Committee

National delegations
34 National Standardization Bodies (3 members)
Voting rights

European Partners
European Commission
EBIC
No Voting rights

Liaison Officers
ISO/TC 134
Other CEN TCs
....
No Voting rights

Mirror committees
More than 30 EN standards must be created!
3) CEN/TC 455 workload
Standards development estimated timeline

FROM PWI TO NWI

PWI = Preliminary work item
NWI = New work item

- Activation of PWI
- Work on PWI
- Validation of PWI
- CEN/TC meeting
- Approval Standardization request
- Enquiry PWI to NWI
- Consideration comments

Standards development estimated timeline

FROM NWI TO PUBLICATION

- Registration of NWI
- Circulation of 1st WD
- Start Enquiry
- End Enquiry
- Drafting (8 months)
  - Ring Tests
- Preparation (3.5 months)
- ENQ (12 w)
- Consideration of comments (max. 8 months)
- Finalisation (2 months)
- Finalisation (2 months)
- FV (8 w)
- Publication

First EC biostimulants (April 2022)

<table>
<thead>
<tr>
<th>Event</th>
<th>Year</th>
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<tbody>
<tr>
<td>Registration of NWI</td>
<td>Nov 2019</td>
</tr>
<tr>
<td>Circulation of 1st WD</td>
<td>March 2020</td>
</tr>
<tr>
<td>Start Enquiry</td>
<td>July 2020</td>
</tr>
<tr>
<td>End Enquiry</td>
<td>Mid Sept. 2020</td>
</tr>
<tr>
<td>Drafting (8 months)</td>
<td>Mid Dec. 2020</td>
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<tr>
<td>Preparation (3.5 months)</td>
<td>Mid July 2021</td>
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<tr>
<td>ENQ (12 w)</td>
<td>Aug. 2021</td>
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<tr>
<td>Consideration of comments (max. 8 months)</td>
<td>Oct. 2021</td>
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<tr>
<td>Finalisation (2 months)</td>
<td>Dec. 2021</td>
</tr>
<tr>
<td>Finalisation (2 months)</td>
<td></td>
</tr>
</tbody>
</table>
WG1 Sampling

WORK TO DO

➢ Sampling

Convenor – Victoria Cadahia
(Aefa-agronutrientes)
Secretary - Spain
WG2 Claims

**WORK TO DO**

- General principle
- Quality criteria for experimental practices
- Nutrient use efficiency
- Tolerance to abiotic stress
- Quality traits
- Availability of confined nutrients in the soil and rhizosphere,

**Convenor** – Céline Durieu
*(Agronutrition)*
**Secretary** - France
WG3 Micro-organisms (incl. pathogens)

WORK TO DO

Pathogens (OECD guidelines?)

- Listeria monocytogenes determination
- Vibrio spp determination
- Shigella spp determination
- Staphylococcus Aureus
- Aerobic plate count determination
- Yeast and mould content determination
WG3 Micro-organisms (incl. pathogens)

WORK TO DO

Pathogens

- Salmonella detection  EN ISO 6579
- Escherichia Coli determination  ISO 16649-2, EN ISO 9308-3, CEN/TR 16193
- Enterococcaceae determination  EN 15788

Convenor – Pier Oosterkamp (Ecostyle)
Secretary - Netherlands
WG3 Micro-organisms (incl. pathogens)

WORK TO DO

Beneficial microorganisms

- Azobacter spp determination
- Mycorrhizal fungi content determination
- Rhizobium spp determination
- Azospillum spp determination
- pH determination
WG4 Other Safety Parameters

WORK TO DO

Heavy metals

- Cd, Pb, Ni, Cr, Cu, Zn determination
  Extraction: EN 13650
  Determination: ISO 11885 Or EN 16319
- Cr VI determination
  EN 15192 or ISO 17075 part 2
- Hg determination
  ISO 16722
- Inorganic As determination
WORK TO DO

- Terminology (4 drafts are on progress)
- Quantity  EN 12580, EN 15238, EN 15761
- Volume
- Chloride content  EN 16195
4) Possible common work on analytical methods?
Possible liaisons for coordination at EU, US and ISO levels

Links with:
- AAPFCO experts,
- Biostimulant Stakeholder Workgroup (BSW)
- ANSI experts
- ...

Ad-Hoc group Beneficial substances / Biostimulants
Possible work

1. Sharing relevant analytical methods which can be the basis for a standard
2. Adoption of the same or at least equivalent definitions
3. Avoid overlapping and need clear burdens with other agriculture inputs:
   - Biocontrol products
   - Pesticides
   - Fertilizing products
   - Biofertilizers
   - Additives
   - Beneficial substances
4. Development of harmonized/global standards to check the claims of the biostimulants, the safety parameters
5. Promoting the use of biostimulants as new tools for farmers for sustainable agriculture
Thanks a lot!

Benoît Planques
ITALPOLLINA - Global Regulatory Manager
Chair of CEN/TC 455
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