



BUSINESS PLAN

CEN/TC 455 "Plant Biostimulants"

EXECUTIVE SUMMARY

Business environment

- The biostimulants market is growing quickly, driven by economic and socio-political factors. The European Biostimulants Industry Council (EBIC) has estimated that the market is growing steadily at 10% or more per year, with future growth predicted at the same levels for the foreseeable future.
- The EU legislation in the field of plant biostimulants: Fertilising Products Regulation (FPR) (EU) No 2019/1009 (as described in some detail in this document).
- The interested parties concerned:
 - Consumers from farmers to end-users;
 - Plant biostimulants industry;
 - Official and private auditing & control bodies;
 - European Commission, DG GROW.
- The application sectors include agriculture, horticulture, forestry, gardening, and landscaping; customers include the general public, as well as public and private sector bodies.
- EBIC favours an EU-wide obligation to apply CEN/TC 455 standards as the basis for labelling and product declaration to facilitate pan-European trade and has supported the development of a European Union Regulation on fertilising products including plant biostimulants to bring this about.

Benefits

- Facilitating the trade of plant biostimulants by developing standardised methods of testing that have the confidence of the industries that purchase and use these materials.
- Helping to eliminate barriers to trade plant biostimulants in Europe and possibly beyond.
- Consumer confidence in the manufacturer of plant biostimulants and in the minimal environmental impact of biostimulants.

Priorities

- Development of harmonised European standards mandated by the European Commission in support of the new Fertiliser Regulation.

- Participation to the Commission Experts Group on Fertilising Products (CEG-FP) to follow the implementation of the FPR.

1 BUSINESS ENVIRONMENT OF THE CEN/TC 455

CEN/TC 455 sets up European Standards for all kinds of plant biostimulants as defined as a EU fertilising product 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 or the plant rhizosphere: (a) nutrient use efficiency, (b) tolerance to abiotic stress, (c) quality traits or (d) availability of confined nutrients in the soils or rhizosphere per EU regulation No 2019/1009. Excluded are plant protection products, fertilisers, liming materials, soil improvers, growing media, and inhibitors that are already covered by standardisation at European level.

Standardisation in this Committee includes sampling, denominations, specifications (including safety requirements such as heavy metals and pathogens), and test methods allowing the verification of product claims for Plant Biostimulants and marking.

Currently, the most important task of CEN/TC 455 is the elaboration of standards within European Commission Standardisation Requests supporting the European Regulation laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009: Fertilising Products Regulation (FPR) (EU) No 2019/1009

The elaborated standards within future standardisation requests will be considered as official methods of sampling and analysis, to obtain the presumption of conformity and can be used as reference for official controls if they are as such referenced in Community law. The establishment of European Standards for methods of sampling and analysis is of utmost importance to guarantee uniform application and control of the European legislation in all Member States, and to support the national regulatory framework.

Standardised methods of sampling and analysis are an indispensable element in guaranteeing a high level of quality and safety for European Commission plant biostimulants. Since July 2019, the Fertilising Products Regulation (FPR) has entered into force.

The elaboration of the standards is undertaken in cooperation with the broadest possible range of interested groups, including international and European level associations and regulatory bodies. Cooperation with European Biostimulants Industry Council (EBIC), is regarded as essential and can be realised by circulation of the relevant documents and by participation of observers in meetings of working groups and plenary meetings. In addition, CEN/TC 455 maintains a close relationship to the EC's DG GROW-Commission Experts Group on Fertilising Products (CEG-FP) and relevant Ad'Hoc groups. Within this framework, CEN/TC 455 delegates observers regularly to attend the meetings of the CEG-FP, as agreed with CEN.

1.1 Description of the Business Environment

Plant biostimulant means a product 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 or the plant rhizosphere: a) nutrient use efficiency; b) tolerance to abiotic stress; c) quality traits; d) availability of confined nutrients in soil or rhizosphere." This definition also covers products that act on the plant (including seeds and all stages of a development of a plant) indirectly by acting on the soil microbiome. Biostimulants may therefore be applied to the plant or to the soil/substrate. Biostimulants occupy a unique and newly recognized place in the spectrum of crop inputs; they are part of a suite of products that enhance plant nutrition and soil fertility, that are inextricably linked.

The use of biostimulants in agriculture corresponds to several of the principles of the circular economy:

1. Reducing the finite resources required for production and consumption;
2. Distinguishing between biological and technical materials;
3. Using materials in a way that optimizes their flows and increases natural stocks;
4. Requiring innovative products and rethinking production systems; and
5. Increasing system resilience.

Most plant biostimulants raw materials are renewable resources like plant and seaweed extracts or are re-valORIZED animal by-products from the agrifood chain or industrial processes, and participate to the circular economy.

Biostimulants help improving agricultural yields and quality while allowing plants to use fertilizers more efficiently, thus making the use of other inputs more sustainable. Some biostimulants make soil nutrients more available to plants, thus recycling in situ nutrients that would otherwise be lost in the environment.

Biostimulants can help to reduce the flow of inputs into the biological cycle of agriculture to the amount needed for optimal use, thus contributing to creating a more balanced system to meet growing demands with fewer unwanted impacts.

1.2 Quantitative Indicators of the Business Environment

The biostimulants market is growing quickly, driven by economic and socio-political factors. EBIC has estimated that the market is growing steadily at 10% or more per year¹, with future growth predicted at the same levels for the foreseeable future.

EBIC estimates that biostimulants are applied to at least 3 million hectares in Europe, based on information provided by respondents to EBIC's informal survey in 2013², showing that more than 6.2 million hectares are treated with biostimulants in Europe (defined as the European Economic Area) every year. This is higher than the total in 2011, but could be due to either the broader coverage of this survey (EBIC has more than twice as many members today) or market growth. The responding companies only account for a portion of the entire market, so the total area is likely to be much higher. At the same time, multiple applications to the same hectare are counted separately in these figures, and the responses from EBIC members suggest that about half of this area is due to repeated applications, thus EBIC's estimate that biostimulants are applied to at least 3 million hectares in Europe.

Another sign of market growth is the number of new users. EBIC asked respondents to indicate how many of their recently acquired farmer customers are new users of biostimulants. Roughly half appear to be using biostimulants for the first time. Other customers may be switching from another supplier, but many are also expanding their use of biostimulants (in terms of area treated, range of products and/or types of crops being treated). Because biostimulants have not been widely used in the past, many growers adopt them on a trial basis on a limited area for one or two seasons before scaling up their use. Growth rates between customer numbers and area treated/sales are therefore not related in a linear fashion.

The factors driving this continued growth are multiple:

¹ <http://www.biostimulants.eu/2011/12/economic-overview-of-the-european-biostimulants-sector/>

EBIC calculated compound growth rates on the basis of sales and hectares treated via a questionnaire provided to member companies in 2011. Most growth rates ranged between 10% and 31% for companies that have been in the biostimulants business for at least the past decade. To avoid distorting our analysis, EBIC excluded growth rates of very young companies, which show an abnormally high rate due in part to the low base at start-up as well as two companies that had a significantly lower annual growth rate over the past decade due to a very strong starting position in 2000

² <http://www.biostimulants.eu/2013/04/2013-overview-of-the-european-biostimulants-market/>

- Biostimulant use is spreading from some pioneer countries to a wider number, both within Europe and the rest of the world. Related to this, biostimulants companies are expanding their professional networks and connecting with new global distributors who are helping them tap previously inaccessible markets;
- The biostimulants sector has developed new innovative products targetting specific agronomic needs, thus attracting new customers;
- Biostimulant products were initially used primarily in organic production and on high-value fruit and vegetable crops. They are increasingly being introduced in conventional crop production to respond to economic and sustainability imperatives;
- Recent high and volatile prices for inputs like fertilisers have created incentives for farmers to optimise the efficiency of input use;
- In response to consumer demands for healthy food products with minimal environmental impacts (and related policies) growers are looking for ways to use synthetic chemicals and mineral fertilisers more efficiently and effectively. Biostimulants are therefore increasingly seen as a way to improve the return on their investment in other inputs and as a way to respond to consumer demands for “softer” agricultural practices.

The full economic impact of biostimulants can only be calculated by considering the efficiency gains they provide. Statistics are too patchy and definitions too variable to accurately estimate the value or volume of the European biostimulants market with precision. However, based on the value of annual total value of biostimulants sales in Europe reported by respondents to EBIC’s 2013 survey, €500 million would be a reasonable estimate.

The difference between this number and some lower estimates might depend on whether the figure includes only sales to end-users or distributors, or both these sales and the sale of biostimulant substances that could be directly applied but are incorporated into more complex product formulations. According to EBIC’s 2013 survey, about 20% of respondents sell their products only as intermediates with no direct application. The vast majority produce all or most of their products for direct application. It is not clear if this is a representative breakdown for the sector as EBIC membership may seem most relevant to producers with a direct link to farmers.

With regard to employment, it is difficult to estimate the total number of jobs until much more exhaustive data can be gathered, because the vast majority of biostimulant companies are small and medium enterprises (SMEs).³ The respondents of the 2011 and 2013 surveys together employ about 2000 people in Europe to work on biostimulants⁴, and every respondent reported a growing employment trend for their company in Europe. Between one-third and 100% of these jobs are reported to be knowledge-intensive, depending on the company.

Most of the respondents to EBIC’s questionnaire indicate that they have fewer than 100 employees, and certainly fewer than 250 FTEs⁵ working on biostimulants. Furthermore, a high proportion⁶ of biostimulant companies are located outside of dominant economic centres, thus providing a welcome source of knowledge-intensive jobs in rural areas and small cities.

While market value and employment are important figures for determining the economic impact of a sector, two other important criteria must be taken into account in the case of biostimulants: increased efficiency of other agricultural inputs and enhanced quality of output, both of which influence farmer

³ Respondents reported only 20-30 large (>250 employees) companies, with the rest of the sector being SMEs. Some 200 companies have been reported in Europe thus far.

⁴ Many have additional employees working on other value chains.

⁵ FTE = full-time equivalent

⁶ According to current information: about 75% of the sector.

profitability.

Among other beneficial effects, biostimulants can increase nutrient use efficiency so that farmers receive a better return on their investment in fertilisers. This also reduces nutrient losses and the related environmental impacts (and thus the cost of clean-up).

EBIC members also report that their products raise yields and improve water use efficiency. All of these benefits have been widely tested and documented in field trials.

It is difficult to generalise because the exact level of the impacts depends on the crop in question, the original state of the soil, how well managed crops already are and a number other factors.

The biostimulants sector is investing significantly in research to meet the needs of this rapidly expanding market.

According to 2013 responses, most of the respondents to EBIC's questionnaires invest between 3% and 10% of their annual turnover in research and development, but some re-invest an even higher share in innovation. Many companies have between 10% and 33% of their staff involved in R&D activities with a few companies slightly below that range. In addition, respondents of the 2011 survey reported almost 150 R&D partnerships with universities and other public research institutes. While most of these are in Europe, they also include partners in Australia, Brazil, Canada, Chile, Ghana, Mexico, New Zealand, Turkey and the United States.

It generally takes 2-5 years to bring new products to market and it is important to elaborate European Standards for a fair market and to be able to compare the different biostimulants in the same manner.

Table 1. Indicative list of some of the crops to which biostimulants are currently applied in Europe

Woody perennials	Vegetables and ornamental and PMA crops (include: roots and salad)		Broad acres: combinable and processing products
Citrus	Broccoli	Onions	Barley
Pome fruits	Cabbage	Peppers	Maize
Stone fruits	Carrots	Potato	Rice
Grapes (table)	Cauliflower	Salad	Wheat
Grapes (wine)	Cucumber	Squash	Oilseed rape
Olives	Eggplant	Strawberry	Sugar beet
	Garlic	Tomato	
	Melons	Watermelon	
	Flowers & ornamentals		
	Nursery		
	Turf		

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC 455

The future availability of European Standards elaborated by CEN/TC 455 will take into account the view of the members and the interested parties concerned. That implies the creation of a European harmonised comprehensive list of methods that provide repeatable and reproducible results. Time-consuming duplication of research to choose an appropriate method may be avoided.

The harmonised methods can be an effective tool for the industry to check whether internal and different legal requirements that exist in different countries are fulfilled.

A cooperation with ISO/TC 134 "*Fertilizers, soil conditioners and beneficial substances*" could be envisaged in order to compile and harmonise methods regarding plant biostimulants (beneficial substances, as defined by ISO/TC 134) at the international level.

Consequently, a number of European Standards (methods on sampling and sample preparation and analytical methods) could be proposed to be adopted as International Standards.

In March 2016, the European Commission put forward a legislative proposal on fertilising products, as announced in the circular economy action plan. The EU regulation No 2019/1009 covers a wider range of fertilising products that now includes plant biostimulants.

To guarantee a uniform application and control of the European legislation in the field of plant biostimulants in all Member States, the European Commission elaborated a standardisation request to define the need of European Standards that will be applied to all EU plant biostimulants.

The development of harmonised European Standards will ensure the emergence of a specific product family in the agricultural input sector that will have the greatest benefit to industry, consumers and regulators.

3 PARTICIPATION IN THE CEN/TC 455

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognised European or international organisations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the national standards organisation in your country.

4 OBJECTIVES OF CEN/TC 455 AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of CEN/TC 455

4.1.1 General objectives

The availability of standardised horizontal methods is of utmost importance to fulfill the requirements of a free movement of goods in the common market. The basis for a uniform judgment of plant biostimulants in Europe is set up by standardised methods of sampling and analysis.

Scope of CEN/TC 455 “Plant Biostimulants”

Standardisation 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 and defined by agronomical claims (e.g.: nutrient use efficiency, tolerance to abiotic stress, crop quality traits) and may be applied to plants or soils.

Excluded are plant protection products, fertilisers, liming materials, soil improvers, growing media, and inhibitors that are already covered by standardisation at European level.

4.1.2 European Commission Regulation on fertilising products: Fertilising Products Regulation (FPR) (EU) No 2019/1009

In the framework of the new European Commission Regulation on fertilising products with an expanded scope that henceforth includes, in addition to mineral fertilisers and liming materials, organic and organo-mineral fertilisers, soil improvers, growing media, the plant biostimulants and other products intended for fertilising purposes, CEN/TC 455 is considering in cooperation with the Commission new fields of standardisation in order to elaborate the necessary standards in a similar way as performed in the frame of the existing EC-Regulation. Cooperation with other CEN- Committees, for example CEN/TC 223 "Soil improvers and growing media" and CEN/TC 260 "*Fertilisers and liming materials*" have also be taken into account.

The most important task of CEN/TC 455 is the elaboration of European Standards within the EU-standardisation request supporting the European Regulation Fertilising Products Regulation (FPR)(EU) No 2019/1009 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009.

These European Standards include sampling, denominations, specifications (including safety requirements), marking and test methods allowing the verification of product claims.

In this context, the participation by the Chairperson as an observer in the EU Commission Experts Group on Fertilising Products (and sub-group) meetings to represent CEN/TC 455 have ensured the promotion of the application of these future Standards and that the needs expressed by European Commission on this topic are met.

4.2 Identified strategies to achieve the proposed CEN/TC 455 objectives.

4.2.1 General objectives

Based on the considerations above, CEN/TC 455 has the following objectives and strategic directions for its future work:

At the present time, priority will be given to the development of harmonised European Standards mandated by the European Commission in support of the new fertilising products Regulation regarding the plant biostimulants sector.

These future harmonised European Standards will provide means to check whether requirements of the new fertilising products Regulation are met. Furthermore, quotable reference documents for legislation and a reliable basis for labelling plant biostimulants and appropriate consumer information shall be provided.

Finally, European trade and market access shall be facilitated.

4.2.2 Work organisation

In order to reach these objectives, CEN/TC 455 has put in place the following work organisation:

- The committee uses the possibility of meetings of experts in Working Groups (see Table 2);
- Project leaders are appointed for the different projects, as needed;
- The committee uses electronic means of communication by electronic document circulation using the CEN document server;
- The committee uses the possibility to adopt new work items with a "preliminary" status (PWI), in the cases where methods shall be validated and time-consuming ring tests will have to be organised, or in cases where experimental work has to be performed before the elaboration of

standardisation documents;

- The development of Standards could be elaborated in synergy with other relevant WGs from CEN/TC 223 and CEN/TC 260;
- Only projects that will be funded by the European Commission and/or other public funds will be covered by the work programme.

Table 2. Indicative list of working groups in CEN/TC 455

Working group	Name	Secretariat	Convenor	Secretary
WG 1	<i>Sampling</i>	Czech Republic	Jaroslav HOUCEK	Stefan KREBS
WG 2	<i>Claims</i>	France	Celine DURIEU	Olivier TEITGEN
WG 3	<i>Pathogenic and non-pathogenic microorganisms</i>	Italy	Manuele RICCI	Federico TURANO
WG 4	<i>Other safety parameters</i>	Czech Republic	Miroslav FLORIAN	Stefan KREBS
WG 5	<i>Labelling and denomination</i>	Italy	Manuel ISCERI	Federico TURANO

To ensure full cooperation, CEN/TC 455 is in cooperation/liaison with the following European bodies:

- EC (European Commission) - DG GROW-CEG-FP;
- EBIC

To ensure full cooperation between Technical Committees of CEN and ISO, the CEN/TC 455 is also in liaison with the following Technical Committees:

- CEN/TC 223 "*Soil improvers and growing media*";
- CEN/TC 260 "*Fertilisers and liming materials*";
- CEN/TC 454 "*Algae and algae products*";
- CEN/TC 463 "*Microbiologie of the food*";
- ISO/TC 34/SC 9 "*Microbiology of the food chain*";
- ISO/TC 134 "*Fertilizers, soil conditioners and beneficial substances*".
- *SABE Circular Economy Topic Group (CE-TG)*

4.2.3 Work priorities

Since July 2016, the European Commission and CEN worked together to elaborate a standardisation request regarding the fertilising products in relation to the Fertilising Products Regulation (FPR) (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products.

As the application of Fertilising Products Regulation (FPR) (EU) 2019/1009, which means when the first EU biostimulants can be placed on the Union market, will be on the 16th July 2022 and considering the time needed to elaborate harmonised European Standards, the European Commission has asked to develop standards into two steps: first as Technical Specification (24 months), then harmonised European Standards (24 months).

The Standardisation Request M/564 mandates the elaboration of 33 technical specifications and harmonised standards to CEN/TC 455. The themes have been dispatched as follows:

CEN/TC 455/WG 1: Sampling

2 standards

CEN/TC 455/WG 2: Claims
5 standards

CEN/TC 455/WG 3: Pathogenic and non-pathogenic microorganisms
16 standards

CEN/TC 455/WG 4: Other safety parameters
7 standards

CEN/TC 455/WG 5: Labelling and denominations
3 standards

An official discussion about a possible revision of the SReq M/564 started by the creation of a SRAHG in May 2021. The revised standardization request foresees the elaboration of additional methods (none of them affected to CEN/TC 455), the revision of the target dates for certain projects and additional interlaboratory studies (ILS).

4.3 Environmental aspects

CEN/TC 455 does not elaborate standards that address environmental issues. However, some of the analytical methods proposed for plant biostimulants analysis account for the possible contamination by hazardous materials. Furthermore, it has been stated at several meetings that the attendees and experts within Working Groups of CEN/TC 455 are very much aware of the environmental aspects related to the use of biostimulants in agriculture.

Some of the methods of analysis elaborated by CEN/TC 455 are instruments for controlling special quality parameters of plant biostimulants pertaining to heavy metal content or pathogens. Biostimulants are intended to be applied onto agricultural land and therefore can have an impact on the environment. There is an urgent need to reduce any potential adverse influence of biostimulants in the environment by taking into account these potential contaminations by hazardous materials. Therefore, the main goal for CEN/TC 455 is the elaboration of analytical methods for an effective control of hazardous material content.

Regarding the test methods themselves, CEN/TC 455 is mindful of the potential hazards to operatives and to the environment arising from the chemicals used in analysis. However, the quantities involved are small, they are monitored and well-contained.

Whilst conscious of the need to minimise environmental harm from the application of the methods developed by CEN/TC 455, the TC must ensure that the steps taken are not disproportionate to the potential hazard. CEN/TC 455 needs to be aware that changes to existing methods (such as changing the reagents used) can have unintended financial or legal consequences, such as method re-validation and, for experimental methods, can result in requiring a change in a pre-established regulatory or control limit.

Nevertheless, whenever a current method is being reviewed or when NWIPs are tabled, CEN/TC 455 shall make a risk-based assessment of environmental harm to determine if there is a strong case for alternative reagents or procedures to be considered. Furthermore, CEN/TC 455 shall include a standing item regarding environmental risk on the agendas of WGs and Plenary sessions to facilitate the raising of these issues.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC 455 WORK PROGRAMME

There are a number of factors that might impact the completion of the CEN/TC 455 work program,

including the following:

- the new requirements of the standardisation request under discussion, particularly those related to the ILS;
- the lack of statistical analysis for the methods developed in accordance with ISO 5725-1 and ISO 5725-2;
- the lack of available resources following the adoption of new work items with the bare minimum of member bodies prepared to undertake active participation; and,
- the difficulty in finding enough laboratories/research institutes willing to participate in interlaboratory trials in order to validate test methods that are studied (lack of participants, time and funds).