

Open call for tenders for the selection of (a maximum 12) Laboratories to participate to the Inter Laboratory Studies organised for the European Working Group CEN/TC 455/WG 3 “Pathogenic and non-pathogenic microorganisms” and the European Working Group CEN/TC 455/WG 5 “Labelling and denominations” projects in the frame of the European Commission Standardisation Request M/564 to the European Committee for Standardisation as regards the EU fertilising products in support of Regulation (EU) 2019/1009 of the European Parliament and of the Council

1. Background

The European Committee for Standardisation (CEN) has been requested to draft harmonised standards and European standardisation deliverables in support of Regulation (EU) 2019/1009 for EU fertilising products which lays 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 and repealing Regulation (EC) No 2003/2003 (FPR).

The FPR aims at promoting an increased use of recycled nutrients to further aid the development of a circular economy and allow a more resource-efficient general use of nutrients, while reducing EU's dependency on nutrients from third countries.

Certain products are being used in combination with fertilisers for the purpose of improving nutritional efficiency, with the beneficial effect of reducing the amount of fertilising products used and hence their environmental impact. Products intended to improve plants' nutrition efficiency, together with fertilising products, i.e. Products intended to provide plants with nutrients have been included within the harmonisation, in order to facilitate their free movement in the internal market.

Different product functions warrant different product safety and quality requirements, suitable to their intended uses. That is the reason why EU fertilising products have classified into product function categories (PFCs) and component material categories (CMCs).

In order to provide the market with the means to claim proof of compliance, development of Technical Specifications (TSs) followed by harmonised European standards (hENs) has been planned under this Specific Agreement SA/CEN/564/2020-03 (SA), related to the SReq. Three CEN/Technical Committees (TCs) will perform the work mandated under this SReq:

- CEN/TC 223 *Soil Improvers and growing media*,
- CEN/TC 260 *Fertilizers and liming materials*, and
- CEN/TC 455 *Plant biostimulants*.

This call concerns the PFC relevant to CEN/TC 455 *Plant biostimulants*:

PFC 6. Plant biostimulant

A. Microbial plant biostimulant

B. Non-microbial plant biostimulant

and the CMC 7: Micro-organisms.

The work programme listed out in the SReq (Annex 1) for CEN/TC 455 Plant biostimulants includes 33 CEN TSs and 33 hENs.

CEN/TC 455 *Plant biostimulants*, created in 2017 to set up European Standards for all kinds of plant biostimulants, has established the following Working Groups:

- WG 1 *Sampling*
- WG 2 *Claims*
- WG 3 *Pathogenic and non-pathogenic microorganisms*
- WG 4 *Other safety parameters*
- WG 5 *Labelling and denominations*

AFNOR, the French member of standards networking at European (CEN) and international (ISO) levels, detains the Secretariat of CEN/TC 455 and has charged of the administrative management of the standardisation work.

UNI, the Italian member of the same standards networking, holds the secretariat of CEN/TC 455/WG 3 *Pathogenic and non-pathogenic microorganisms* since April 2020 and the secretariat of CEN/TCWG 5 *Labelling and denominations* since July 2019 and has charged of the standardisation work at WG (3 and 5) level.

UNI will deal with the secretariat and administrative management of the standardisation work at WG (3 and 5) level.

UNICHIM, on behalf of UNI, is responsible of the technical aspects of the standardisation work at WG level and will be responsible for the subcontracting of the laboratories participating to the inter laboratory studies.

2. Objective

Trough M/564, the European Commission is requesting the development of 33 CEN Technical Specifications and 33 European Harmonised Standards.

Deliverables in charge to WG 3 “Pathogenic and non-pathogenic microorganisms”

- 1) Plant Biostimulants - Detection of *Shigella spp* (TS and hEN)
- 2) Plant Biostimulants - Detection of *Staphylococcus aureus* (TS and hEN)
 - 1) and 2) shall provide a horizontal method to detect the absence/presence of pathogenic microorganisms, which are on the negative list of the FPR.
- 3) Plant Biostimulants - Determination of *Azospirillum spp.* (TS and hEN)
This shall provide a horizontal method for enumeration of *Azospirillum spp.* in plant biostimulants.
- 4) Plant Biostimulants - Detection of *Listeria monocytogenes* (TS and hEN)
- 5) Plant Biostimulants - Detection of *Salmonella spp* (TS and hEN)
 - 4) and 5) shall provide a horizontal method to detect the absence/presence of pathogenic microorganisms, which are on the negative list of the FPR.
- 6) Plant Biostimulants - Determination of *Rhizobium spp.* (TS and hEN)
This shall provide a horizontal method for enumeration of *Rhizobium spp.* in plant biostimulants.
- 7) Plant Biostimulants - Anaerobic plate count (TS and hEN)

This shall provide a horizontal method for enumeration of microorganisms able to grow and form colonies in a solid medium after anaerobic incubation at 30°C, thereby verifying that they are not present in plant biostimulants (as long as the biostimulant itself is not an anaerobic bacteria).

8) Plant Biostimulants - Determination of *mycorrhizal fungi* (TS and hEN)

This shall provide a horizontal method for enumeration of *mycorrhizal fungi* in plant biostimulants.

9) Plant Biostimulants - Determination of the pH for liquid microbial plant biostimulants/pH in microbial products – Determination of pH (TS and hEN)

This shall establish the methodology for the determination of pH in microbial plant biostimulant products in accordance to the FPR.

10) Plant Biostimulants - Determination of *Enterococcaceae* (TS and hEN)

11) Plant Biostimulants - Detection of *Vibrio spp.* (TS and hEN)

12) Plant Biostimulants - Determination of *Escherichia coli* (TS and hEN)

10), 11) and 12) shall provide a horizontal method to determine and quantify the presence of pathogenic microorganisms, which are on the negative list of the FPR

13) Plant Biostimulants - Determination of *Azotobacter spp.* (TS and hEN)

This shall provide a horizontal method for enumeration of *Azotobacter spp.* in plant biostimulants.

14) Plant Biostimulants - Determination of the yeast and mould content (TS and hEN)

This shall provide a horizontal method to determine and quantify the presence of Yeast and Mould in the plant biostimulant when the plant biostimulant is not really yeast or fungi.

15) WI Plant Biostimulants - Determination of microorganisms concentration (TS and hEN)

This shall provide an analytical method for the determination of intentionally added microorganisms expressed as the number of active units per volume or weight, or in any other manner that is relevant to the microorganism, e.g. colony forming units per gram (cfu/g).

16) WI Plant Biostimulants – Preparation of sample for microbial analysis

This shall provide a method for preparing samples of different Plant Biostimulant Products suitable for microbial analysis

Deliverables in charge to WG 5 “*Labelling and denominations*”

1) Plant Biostimulants – Terminology (TS and hEN)

2) This shall refer to:

1: Claims

2: Terms relating to components

3: Terms relating to application method

4: Terms related to sample preparation

5: Terms relating to physical form

6: Others terms relating to plant biostimulants

3) Plant Biostimulants – Quantity (indicated by mass or volume) (TS and hEN)

In the FPR, the quantity of a fertilising product has to be expressed (mass or volume). The TS/hEN will specify a reference method for the determination of a quantity of plant biostimulants in bulk and in packages, with a precision level adequate to validate any quantity declaration made.

4) Plant Biostimulants - Determination of the chloride (TS and hEN)

This shall provide quantification of chloride, assuring check of the conformity of CE marked plant biostimulants with the requirements of the FPR.

The procedure includes the recovery of chloride by a sample treatment with nitric acid solution, followed by titration with silver nitrate standard solution and potentiometric measurement by using either a silver ion selective electrode plus a reference electrode or a commercially combined electrode.

The European deliverables (Technical Specifications and European Harmonised Standards) will:

- Support the development of standardisation activities in new areas and make possible the implementation of the FPR
- Enable commercialisation of the PFCs within the EU Single market
- Allow the industry to fulfil the requirements stipulated in the FPR
- Help government and competent authorities to effectively monitor compliance of the products
- Provide Consumers and environmental stakeholders with well-established, uniform and reliable control of plant biostimulants applied to soil and crops
- Provide Laboratories with reference document on how to properly take samples for analysis.

It is foreseen that 16 inter-laboratory studies (ILS) (14 related to WG 3 and 2 related to WG 5) need to be initiated in order to determine the applicability and precision of the test methods described in the above listed European Standards (candidate harmonized):

Developed by CEN/TC 455/WG 3 “Pathogenic and non-pathogenic microorganisms”

1. *EN Plant biostimulants - Detection of Shigella spp*
2. *EN Plant biostimulants - Detection of Staphylococcus aureus*
3. *EN Plant biostimulants - Determination of Azospirillum spp*
4. *EN Plant biostimulants - Detection of Listeria*
5. *EN Plant biostimulants - Detection of Salmonella spp*
6. *EN Plant biostimulants - Determination of Rhizobium spp*
7. *EN Plant biostimulants - Determination of the anaerobic plate count*
8. *EN Plant biostimulants - Determination of mycorrhizal fungi*
9. *EN Plant biostimulants - Determination of the pH for liquid microbial plant biostimulants/pH in microbial products – Part 1: Determination of pH*
10. *EN Plant biostimulants - Determination of Enterococcaceae*
11. *EN Plant biostimulants - Detection of Vibrio spp*
12. *EN Plant biostimulants - Determination of Escherichia coli*
13. *EN Plant biostimulants - Determination of Azotobacter spp*
14. *EN Plant biostimulants - Determination of the Yeast and Mould content*

Developed by CEN/TC 455/WG 5 “Labelling and denominations”

15. *EN Plant biostimulants – Quantity (indicated by mass or volume)*

16. *EN Plant biostimulants - Determination of the chloride*

Each ILS should take three to eight months, hiring from a maximum of 12 laboratories. The goal is to obtain results, of at least eight laboratories, proving the validity of the standards while evaluating their performances. In order to do so, the hired laboratories shall run the protocols described in the working drafts on the samples received from the WG requesting the test.

3. Execution

In this context, CEN/TC 455 *Plant biostimulants* WG 3 and WG 5 Secretariat launches this open call for the recruitment of laboratories for the ILS mentioned above.

The responsibilities of the Laboratories include:

- The proper conduct of the analyses requested following the protocol (Technical Specification) provided from the WG
- Cooperation with the Project Leader, Convenors and UNICHIM in order to solve any problem should rise when running the ILS
- Expert knowledge of the subject covered by the respective ILS and related analyses
- Participation to the ILS meeting, if required

Every laboratory can candidate to several ILS, provided the availability of at least one technician every two ILS is assured.

(Please note that several test samples have to be analysed for each ILS).

UNICHIM deals with the contracts with Laboratories.

4. Financial support

There is a financial support from the European Commission and EFTA (European Free Trade Association) for the execution of all scheduled ILS.

The subcontractor shall fulfil the conditions of the FPA 2014 (Framework Partnership Agreement) for liability, ownership of results, confidentiality....

The assignment of the task and execution of the work will be dependent upon European Commission/EFTA funding.

The financial steps have been defined in the Specific grant agreement.

5. Description of ILS

General requirements

- The participant laboratories will follow the protocol that will be sent by the WG and have to assure to be able to perform the analyses in the requested timing (generally immediately after the arrival of products in the laboratory)
- A laboratory can participate to several ILS: all the products related to the same ILS will be sent to all participating laboratories at the same time, but the different ILSs will be conducted not at the same time, spreading them in the period November 2021 – April 2022

ILSs related to the Objectives listed in Section 2: Projects #1-14 WG3 and Project #2 for WG5.

- For each one of these project the laboratories participant will receive 5 products (1 blend liquid and 1 blend solid and 3 biostimulant products, 1 liquid (water) e 2 solids (pellet, slow release and substrate).
- For each test item more replicates are requested, in particular:
 - Three replicates for WG3 Projects 1 – 2 – 4 – 5 – 11 (detection of target microorganism)
 - Five replicates for WG3 Projects 7 – 10 – 12 – 14 (enumeration of pathogen microorganism) and Project 9 (determination of pH) and for WG5 Project 2 (determination of Chloride content)
 - Three replicates for WG3 Projects 3 - 6 – 8 – 13 (enumeration of beneficial microorganism, together with genetic identification. Six items (3 pellets and 3 solid blend) are supplied, each of them with a different species or genotype and the laboratories will be requested to identify them.
 - WG3 Projects 3 - 6 – 8 – 13: It is mandatory to perform both the enumeration and the genetic identification. A partnership with other laboratories or research Centres to this purpose is admitted.
- For each ILS the laboratory will have to declare to be able to perform the analyses requested and to have the necessary facilities and instrumentation according to the following list

Requested Equipment for microbiological Enumeration or detection

- Equipment common to WG3 P 1-2-3-4-5-6-7-8-10-11-12-13-14
 - Apparatus for dry sterilization (oven) or wet sterilization (autoclave)
 - Drying cabinet or oven, capable of operating between 25 °C and 50 °C
 - Incubators
 - Water baths (25 – 50 °C)
 - Refrigerator and Freezer
 - Sterile loops of approximate diameter, 3 mm (10 µl volume)
 - pH-meter
 - Sterile graduate pipette and petri dishes
 - Electromagnetic Stirrer and coated magnetic bars
 - Stomacher
- Specific Equipment required for WG3 P 3-6-8-13 Enumeration
 - Microscope at 100x
 - Binocular
- Specific Equipment required for WG3 P 3-6-8-13 DNA Analysis
 - Centrifuge capable to reach at least 13,000 rpm
 - Binocular
 - PCR

Requested Equipment for chemical analyses

- Equipment for WG3 P 9 (pH)
 - Calibration buffer solutions
 - pH-meter with an accuracy of 0,01 pH unit with combined electrode and automatic temperature compensation
- Equipment for the WG5 P 2 (Cl) (it is possible to use an automatic titrator with similar or better performances):
 - Electromagnetic Stirrer and coated magnetic bars
 - Glass burettes Class A (0,02 mL reading accuracy) or automatic pipettes (0,0002 mL reading accuracy)
 - One-mark volumetric (100 – 1000 mL) and graduated (100 mL) Class A glass flask

- Potentiometer with reading accuracy of 0,1 mV
- Balance with 0,01 g precision

ILSs related to the Objectives listed in Section 2: Project #3 WG5 (Quantity and Volume).

- Liquid test items: the laboratories will receive 3 samples (liquid, thick liquid and very viscous) and for each product they will have to determine the density: 5 determination for each product will be requested
- Solid determination: in this case the laboratories will receive a series of packages and they will have to weight them and determine the weight of each one (5 replicates). After having done the determination, each laboratory will have to send the packages to another laboratory (or to the ILS reference site for an intermediate check) according to the instructions received by the organization. In this case the respect of timing will be particularly important
- Equipment requested
 - Weighing Instrument capable of weighing to the nearest 0,1 g in the range 5 -3000 g
 - Density meter capable of reading at six decimal places or alternatively a Density kit capable to read to the nearest 0,1 ml
 - Water bath at 20 °C

6. Criteria for selection

The selection of the CEN/TC 455 WG 3 *Pathogenic and non-pathogenic microorganisms* laboratories and the CEN/TC 455 WG 5 *Labelling and denominations* laboratories will be made on basis of the following criteria (as described in Annex 1). For each ILS a maximum of 12 laboratories will be accepted.

LABORATORIES REQUIREMENTS

PROFILE

Required expertise and experiences:

- Number of years of practical experience as Test Laboratory (5 years of activity as laboratory)
- Experience in food, feed, cosmetic, pesticide, biocide or fertilizer analyses (as described in Annex 1)
 - Evidences: participation to Proficiency Testing (PTs)
 - Evidences: published scientific works
 - Any other evidences
- For some analysis it is appreciated an accreditation ISO 17025 or GLP certification
- Number of Analysts involved in the ILSs (if a laboratory wants to participate to several ILSs, a minimum of 1 different analyst every two ILS projects is required)
- List of Equipment available for ILSs

EXPERIENCE IN VALIDATION OF METHODS

Experience in the development and validation of methods

- Number of projects (at least 3) and number of projects validated and accredited ISO 17025 (at least 1)
- Number of years of experience (3 years)

Experience in the participation of inter-laboratory tests

- Number of total PTs (at least 3) and number of PTs in the topic to be standardised (at least 1)
- Number of years (3 years)

ENGLISH LANGUAGE AND COMMUNICATION SKILLS

- English level of the contact person

- Participation to events/working groups in English

Tenders must score minimum 65% in total. After evaluation, the tenders will be ranked using the formula below to determine the tender offering best value for money. A weight of 70/30 is given to quality and price, as explained here below:

$$\text{Score for tender X} = \frac{\text{cheapest price}}{\text{price of tender X}} * 30 + \frac{\text{total quality score (out of 100) for all award criteria of tender X}}{100} * 70$$

The specific requirements for each ILS are detailed in Annex 1.

Exclusion criteria of applicants from participating in the call for proposals procedure are the following:

- The tenders' score is lower than 65% in total
- The offer was received after the deadline
- The offer is not complete (see the elements requested in section 6)
- The tenders are subject to a conflict of interest
- They are in any of the situations described in the exclusion criteria of the *Guide for tenderers Submitting bids in response to a call for tenders published by the Office for Infrastructure and Logistics – Brussels (OIB)*¹.

A maximum of 12 laboratories will be accepted for each ILS.

7. Replies to tender

Tenders should be sent (**only by email**) to the Secretary of CEN/TC455/WG 3 and CEN/TC 455/WG 5, Federico Turano (federico.turano@uni.com) as possible and at the latest by 2021-05-21.

Each candidate shall submit the completed form (Annex 2) and the following information in the tender:

- Name and contact details of the laboratory candidate
- A declaration certifying compliance with the requirements of the call for tenders
- A signed declaration, by which the candidate certifies not to be in one of the situations described in the exclusion criteria (see exclusion criteria in section 5)
- The name of a contact person in relation to the submission of the bid

Tenders must be clear and concise, with continuous page numbering, and must be written in English. They must be signed by the tenderers or their duly authorised representative. They also must be perfectly legible so that there can be no doubt as to words and figures.

The selection and appointment of the Laboratories will be conducted by Federico Turano (Secretary of CEN/TC 455/WG 3 and CEN/TC 455/WG 5), Samantha Gagnon (AFNOR, Secretary of CEN/TC 455), Benoît Planques (Chairperson of CEN/TC 455), Alessia Gaetani (CEN Cenelec Management Center Project Manager), an expert from UNICHIM in support of the WGs Secretary, the WG3 and WG5 convenors and, if possible, a member from the EC.

¹ https://ec.europa.eu/oib/doc/tenders-submission-guide_en.pdf

CEN/TC 455/WG 3 and WG 5 Secretariat

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Selection criteria for CEN/TC 455/WG 5 Laboratories

CALL No. (project)	1	2
ROLE OF THE SUBCONTRACTOR	Lab	Lab
	WI=0045503 0 Plant	WI=00455006 - Plant
DELIVERABLE	biostimulant s - Determinati on of the chloride	biostimulants - Quantity/volu me
ELEMENTS THAT NEED TO BE ADDRESSED IN THE TENDER		
PROFILE	60%	60%
Years of laboratory experience (5 years)	15%	20%
Experience in food, feed, cosmetic, pesticide, biocide or fertilizer analyses	5 years 27%	3 years 30%
ISO 17025 Accreditation /GLP certification (yes or not)	10%	5%
Number of technicians (at least 1 every two ILS)	3%	2%
Adequacy of equipment (yes or not)	5%	3%
VALIDATION OF METHODS	35%	35%
Experience in the development and validation of methods	20%	25%
Number of projects (at least 3)	5%	15%
Number of years (3 years)	5%	5%
Number of projects validated and accredited ISO17025 or validated according to GLP certification (at least 1)	10%	5%
Experience in the participation of IL tests - PTs	15%	10%
Number of PTs (at least 3) and number of PTs in the topic (at least 1)	10%	7%
Number of years (3 years)	5%	3%
English language and communication skills	5%	5%
English level of the contact person	3%	3%
Participation to events/working groups in English	2%	2%
TOTAL	100%	100%

Annexe 2: Call for Tender Form



Answer to a call for Tender in compliance with FPA rules 2014

A- Contact details of the Expert

Name: Position: Phone: Email address: Personal website (if any):

B- Information about the organisation/s the expert is working (name, website, contact person, phone, email)

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C- Laboratory Manager and Technical Supervisors Short Curriculum Vitae (maximum 4 A4 pages)

D- Please specify the position you are applying for and the relative requested quotation for:

WG	Project (N° and description)	Quotation

E- Please describe and prove evidence of the required skills and expertise for the ILS related project you are applying for (half a page maximum including your proposed approach)

Yes	No	Skills and expertize	Short description of the evidence of the required skills and expertise for the role you are applying for

[Insert here the selection criteria presented in annex 1]

I certify that all documents provided are veracious and in conformity with reality and certify not to be in any situation described below:

- a) subject of a non-likely judgment of recourse for a professional infringement
- b) to be in an irregular tax situation or in an irregular special taxation situation
- c) to provide with incomplete or erroneous information

I also certify that I had no conflict of interest by submitting the present offer.

Signed:

On behalf of: (print name here)

Annexe 3: Declaration of absence of Conflicts of interest that has to be signed and inserted in the answer

I certify that all documents provided are veracious and in conformity with reality and certify not to be in any situation described below:

- a) subject of a non-likely judgment of recourse for a professional infringement
- b) to be in an irregular tax situation or in an irregular special taxation situation
- c) to provide with incomplete or erroneous information

I also certify that I had no conflict of interest by submitting the present offer and I am not concerned by any exclusion criteria (see below).

Candidates or tenderers are excluded from participation in procurement procedures if:

(a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

(b) they have been convicted of an offence concerning their professional conduct by a judgment which has the force of res judicata;

(c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;

(d) they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed;

(e) they have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the European union's financial interests;

(f) following another procurement procedure or grant award procedure financed by the Community budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations)

Signed:

On behalf of: (print name here)

Date: