

Open call for tenders for the selection of one sample manager to be in charge of the preparation, characterization and supply of test samples to be used in the Interlaboratory Studies organised for the European Working Groups CEN/TC 455/WG 3 “Pathogenic and non-pathogenic microorganisms” and CEN/TC 455/WG 5 “Labelling and denominations” 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 provide plants with nutrients, together with fertilising products, 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

- PFC 6: Microbial plant biostimulant (A); Non-microbial plant biostimulant (B)
- CMC 7: Microorganisms.

The work programme has listed out in the SReq (Annex 1) for CEN/TC 455 Plant biostimulants.

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 since April 2020 and the secretariat of CEN/TCWG 5 since July 2019 and has charged 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 sample manager.

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) - 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) – 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) – 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. fungi (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)

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

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

In the FPR, the quantity of a fertilising product has 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.

- 3) 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 (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.

UNICHIM will be in charge of the technical aspects of the standardization work at WG level 3 and 5 and will be responsible for the subcontracting of the laboratories participating to the inter laboratory studies.

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 TS/hEN.

Each ILS should take two to six 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. The period of executing the tests will be November 2021 – April 2022.

3. Execution

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

The responsibilities of the sample manager of test materials include:

- Selection and Preparation of samples, according to the Instructions received by the Project Leader of each ILS
- Purchase of certified reference materials for each of the pathogenic microorganism listed above (typically in the lyophilized form) to be added to the test samples for the ILSs.
- Check of properties, such the bacterial count, according to the requirements established by Project leaders or Convenors (an external laboratory may be used).
- Preparation of different test items and check of the requisites requested for them (in terms of homogeneity and stability (an external laboratory may be used).
- Shipment of test samples to the laboratories participating to ILS (location is internal to EU), assuring refrigerating conditions, when needed.
- Cooperation with UNICHIM, as well as the Project Leaders and Convenors, for solving any problem should rise when running the ILS.
- Expert knowledge of the subject covered by ILS and related analyses.
- Participation to the ILS meeting, if required.

UNICHIM deals with the contracts with the sample manager.

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 scheduled in the Specific grant agreement.

5. Description of ILS

General requirements

- The participant will have extended experience in IL test sample preparation. Proven experience in Certified Reference Materials (CRMs) preparation is preferred.
- For every ILS, the number of test samples prepared shall equal that of participant laboratories (a maximum of 12 laboratories expected for each ILS), with additional aliquots (at least 10) to be used for analytical control of homogeneity and possible supplemental shipment, in case of damage or any other problem occurred during transportation).
- The participant will assure to complete the shipment within three months for each ILS (obviously, not all the ILS will start contemporarily).
- For a single ILS, the test materials shall sent contemporarily.

Test items

- For each ILS, five test items have to be prepared: 1 liquid blend, 1 solid blend and 3 biostimulant products [1 aqueous liquid and 2 solids (pellet, slow release and substrate)].
- The quantity (mass or volume) of each aliquot will be established taking into account that more replicates are requested for each test parameter
- The lyophilized microorganisms will be shipped separately and the laboratories will mix them with test samples according to a defined protocol; preliminary analyses will be requested in order to avoid the presence of inhibitors)
- For WG3 Projects 3 - 6 – 8 – 13 additional six test items (3 pellets and 3 solid blends) have to be prepared, each of them with a different species or genotype, and the laboratories will requested to identify them. Sterilization of test items has required before adding the microbial species. Preliminary analyses have required for verifying the suitability of the correct identification.
- For WG5 Project 3, three liquid test items (liquid, thick liquid and very viscous) have to be prepared for the determination of the density; homogeneity verification has needed. Moreover, a series of packages shall be prepared. A laboratory will have to determine the weight of each one, then will have to send the packages to another laboratory; every 4 laboratories, the packages will be returned to the organizer for an intermediate check.

Test parameters requested to the laboratories for each ILS

N° ILS – WG and Project name	Type of samples	N° of required tests (replicates x samples)	Analyses requested to the provider
1-WG3 - Detection of <i>Shigella spp</i>	5 SAMPLES (1 blend liquid and 1 blend solid and 3 biostimulant products, 1 liquid (water) e 2 solids (pellet, slow release and substrate)	15 (3 rep* 5 samples)	No presence of the target in the starting material
2-WG3 - Detection of <i>Staphylococcus aureus</i>	Same as P #1	15 (3 rep* 5 samples)	No presence of the target in the starting material
3-WG3- Determination of <i>Azospirillum spp</i>	5 samples as P#1 (enumeration) + 6 samples (3 pellets and 3 solid blend) (genetic identification)	15 (3 rep* 5 samples) (enum) + 6 (1 rep * 6 samples) (gen id.)	Homogeneity verification (only for enumeration)
4- WG3- Detection of <i>Listeria</i>	Same as P #1	15 (3 rep* 5 samples)	No presence of the target in the starting material
5-WG3 - Detection of <i>Salmonella spp</i>	Same as P #1	15 (3 rep* 5 samples)	No presence of the target in the starting material
6-WG3 - Determination of <i>Rhizobium spp</i>	5 samples as P#1 (enumeration) + 6 samples (3 pellets and 3 solid blend) (genetic identification)	15 (3 rep* 5 samples) (enum) + 6 (1 rep * 6 samples) (gen id.)	Homogeneity verification (only for enumeration)
7-WG3 - Determination of the anaerobic plate count	Same as P #1	25 (5 rep* 5 samples)	No presence of the target in the starting material
8-WG3 - Determination of mycorrhizal fungi	5 samples as P#1 (enumeration) + 6 samples (3 pellets and 3 solid blend) (genetic identification)	15 (3 rep* 5 samples) (enum) + 6 (1 rep * 6 samples) (gen id.)	Homogeneity verification (only for enumeration)
9-WG3 - pH in microbial products	Same as P #1	25 (5 rep* 5 samples)	Homogeneity verification
10-WG3 - Determination of <i>Enterococcaceae</i>	Same as P #1	25 (5 rep* 5 samples)	No presence of the target in the starting material
11-WG3 - Detection of <i>Vibrio spp</i>	Same as P #1	15 (3 rep* 5 samples)	No presence of the target in the starting material
12-WG3 - Determination of <i>Escherichia coli</i>	Same as P #1	25 (5 rep* 5 samples)	No presence of the target in the starting material
13-WG3 - Determination of <i>Azotobacter spp</i>	5 samples as P#1 (enumeration) + 6 samples (3 pellets and 3 solid blend) (genetic identification)	15 (3 rep* 5 samples) (enum) + 6 (1 rep * 6 samples) (gen id.)	Homogeneity verification (only for enumeration)
14-WG3 - Determination of the Yeast and Mould content	Same as P #1	25 (5 rep* 5 samples)	No presence of the target in the starting material
Quantity (indicated by mass or volume)	6 packages (weighing) + 3 samples (liquid, thick liquid and very viscous) (density)		Homogeneity verification (only density)
Determination of the chloride	Same as P #1	25 (5 rep* 5 samples)	Homogeneity verification

Equipment requested for the preparation of test samples

- Refrigerator and Freezer
- pH-meter
- Sterile graduate pipette and petri dishes
- Electromagnetic Stirrer and coated magnetic bars
- Mixing device for solid samples able to manage almost 10 kg of sample
- Mixing device for solid samples able to manage almost 10 Litres of sample
- 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

All the items necessary for the shipment of test samples will be in charge of the sample manager.

6. Criteria for selection

The selection of the CEN/TC 455 WG 3 *Pathogenic and non-pathogenic microorganisms* and the CEN/TC 455 WG 5 *Labelling and denominations* ILS Sample Manager will be made on basis of the following criteria (as described in Annex 1):

REQUISITES FOR SAMPLE MANAGER

PROFILE

Required expertise and experiences:

- Number of years of practical experience in management of samples in ILS (10 years of activity)
- Proven experience in the management of procedures according to ISO 17043 (5 years of experience)
- Experience in the preparation of Reference Materials and/or Certified Reference Materials (5 years of experience)
- List of Equipment available for ILS

EXPERIENCE IN INTERLABORATORY STUDIES - PROFICIENCY TEST (PTs)

Experience in food and/or fertilizer IL test - PTs

- Number of PTs (at least 5)
- Number of years of experience (5 years)

Experience in preparation and management of IL test involving the presence of microorganisms - PTs

- Number of PTs (at least 5)
- Number of years of experience (5 years)

Experience of laboratory involved in analytical controls

- Experience in microorganism beneficial enumeration (3 years)
- Experience in pH and Chloride determination (ISO 17025 accreditation preferred) (3 years)

ENGLISH LANGUAGE AND COMMUNICATION SKILLS

- English level
- Participation to events/working groups in English

Tenders must score minimum 65% in total. After evaluation, the tenders will ranked using the formula below to determine the tender offering best value for money. A weight of 70/30 has 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 have 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.

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 15/07/2021.

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

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

- Name and contact details of the 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.

CEN/TC 455/WG 3 and WG 5 Secretariat

UNI

Federico Turano

federico.turano@uni.com

UNI - Ente Italiano di Normazione

Via Sannio, 2

20137 Milano

Tel: (+39)02 70024 490

Annex 1

Selection criteria for CEN/TC 455/WG 3 and WG 5 ILS Sample manager

<p style="text-align: right;">ROLE OF THE SUBCONTRACTOR) DELIVERABLE</p> <p>ELEMENTS THAT NEED TO BE ADRESSED IN THE TENDER</p>	<p>SM</p>
<p>PROFILE</p> <p>Years' Experience on ILS - Proficiency Tests (10 years)</p> <p>ISO 17043 Accreditation experience (5 years)</p> <p>Certified Reference Materials Preparation Experience (5 years)</p> <p>Adequacy of equipment</p>	<p>45%</p> <p>15%</p> <p>15%</p> <p>10%</p> <p>5%</p>
<p>EXPERIENCE IN INTERLABORATORY STUDIES - PROFICIENCY TEST (PTs)</p> <p>Experience in food, or fertilizer IL Tests - PTs</p> <p>Number of PTs (at least 5)</p> <p>Number of years (5 years)</p> <p>Experience in preparation and management of IL tests involving the presence of microorganisms - PTs</p> <p>Number of PTs (at least 5)</p> <p>Number of years (5 years)</p> <p>Experience of laboratory involved in Analytical Controls</p> <p>Experience in microorganism beneficial enumeration (3 years)</p> <p>Experience in pH and Chloride determination (ISO 17025 accreditation preferred) (3 years)</p>	<p>50%</p> <p>20%</p> <p>10%</p> <p>10%</p> <p>20%</p> <p>10%</p> <p>10%</p> <p>10%</p> <p>6%</p> <p>4%</p>
<p>ENGLISH LANGUAGE AND COMMUNICATION SKILLS</p> <p>English level</p> <p>Participation to events/working groups in English</p>	<p>5%</p> <p>3%</p> <p>2%</p>
<p>TOTAL</p>	<p>100%</p>

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 (name, website, contact person, phone, email)

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C- Organization Manager Short Curriculum Vitae (maximum 4 A4 pages)

D- Please specify the relative requested quotation for each specific project:

WG	Project (N° and description)	Quotation (comprehensive of analytical tests when required)
WG3	Projects 1 – 2 – 4 – 5 – 7 – 10 – 11 12 – 14	
	Projects 3 - 6 – 8 – 13 (enumeration)	
	Projects 3 - 6 – 8 – 13 (genetic identification)	
	Project 9	
WG 5	Project 2	
	Project 3	

A detailed breakdown of costs is required, specifying the quotation for each of the following item (to be more detailed when necessary):

- Daily rates and number of estimated days for the preparation,
- Consumable, raw material and CRM
- Analytical verifications tests
- Shipment of samples

- Travels

- E- Please specify if the Sample Manger Organization will provide directly by itself for the analytical verification or if it will use another laboratory. In this last case, please provide evidences of the competences of the laboratory involved.
- F- 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
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[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).

(Evaluation of the exclusion criteria:

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: