

Smlouva o dílo ILS/Service contract ILS

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| <p>mezi Českou agenturou pro standardizaci IČ: 06578705 Biskupský dvůr 1148/5, 110 00 Praha 1, Česká republika; zastoupená Mgr. Zdeňkem Veselým, generálním ředitelem ČAS</p> <p>dále jen „ČAS“,</p> <p>a</p> <p>ILSA S.p.A. VAT-No.: 00871990230 Via Quinta Strada, 28, 36071 Arzignano (VI), Italy; zastoupená Paolo Girelli, Výkonný ředitelka,</p> <p>dále jen „ZHOTOVITEL“.</p> <p>uzavřená dle ustanovení § 2586 a násl. zákona č. 89/2012 Sb., občanského zákoníku.</p> | <p>Between Czech agency for standardization IČ: 06578705 Biskupský dvůr 1148/5, 110 00 Prague 1, Czech Republic; represented for the purpose hereof by Mgr. Zdeněk Veselý, Director General</p> <p>hereinafter referred to as "ČAS",</p> <p>and</p> <p>ILSA S.p.A. VAT-No.: 00871990230 Via Quinta Strada, 28, 36071 Arzignano (VI), Italy; represented for the purpose hereof by Paolo Girelli, Chief Executive Officer,</p> <p>hereinafter referred to as the "CONTRACTOR".</p> <p>concluded in accordance with the provisions of § 2586 et seq. Law č. 89/2012 Sb., the Civil Code of Czech Republic.</p> |
| <p>1. Úvod</p> <p>Podle evropského normalizačního požadavku M / 564 se CEN zavázal podporovat nařízení (EU) 2019/1009 prostřednictvím vývoje technických specifikací (TS) a harmonizovaných evropských norem (hEN).</p> <p>Za tímto účelem Evropská komise a ESVO financují činnosti v CEN / TC 455 na základě konkrétní grantové dohody č. SA / CEN / GROW / EFTA / 564 / 2020-03 „Biostimulanty pro rostliny“ (SA).</p> <p>Pracovní skupina CEN / TC 455 / WG 4 vyvinula podle SA metody, které byly hlasováním potvrzeny jako TS, o kterých se momentálně hlasuje. SA k prokázání platnosti těchto metod vyžaduje uspořádání mezilaboratorní studie (ILS). V případě, že je prokázána validita metody, data z ILS budou zahrnuty do návrhů pro hEN.</p> <p>THOTOVITEL byl vybrán výběrovou komisí CEN jako poskytovatel ILS pro následující metodu, viz tabulka 1. Zpráva o výběru byla registrována od agentury EISMEA jako Ares(2022)1706726.</p> | <p>1 Introduction</p> <p>According to the European standardization request M/564, CEN is committed to support the Regulation (EU) 2019/1009 by the development of Technical specifications (TS) and harmonized European standards (hEN).</p> <p>For this purpose the European Commission and EFTA fund activities in CEN/TC 455 by the specific agreement N° SA / CEN / GROW / EFTA / 564 / 2020-03 “Plant Biostimulants” (SA).</p> <p>CEN/TC 455/WG 4 developed according to the SA methods, which have been confirmed by a vote as TS. The SA requires Inter-laboratory studies (ILS) to proof the validity of these methods. In case that the validity of the methods can be significantly proven, data from the ILS will be included in the drafts for the hEN.</p> <p>The CONTRACTOR was selected by a CEN selection committee as ILS provider for the following method, see Table 1. The selection report was registered by EISMEA as Ares(2022)1706726.</p> |

| Výzva č. | Validace metod v návrhu TS | Popis projektu ve výzvě Project description Call for tender | Popis projektu v tendru Project description Tender | Maximální doba trvání ILS ^{a)} Maximal duration of the ILS ^{a)} | Maximální cena ILS Maximal price ILS |
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| (1) | (2) | (3) | (4) | (5) | (6) |
| 3 | Plant biostimulants – Determination of chromium (VI) FprCEN/TS 17703 | Příloha 1, 1.3/ Annex 1, 1.3 | Příloha 2/ Annex 2 | 10 months | 49 586,78 € |
| a) po podpisu smlouvy/after signature of the contract | | | | | |

Tabulka 1 - Vybraný tender ZHOTOVITELE (podle přílohy 2 a 3)
Table 1 - Selected CONTRACTOR's tender (acc. Annex 2 and 3)

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| <p>2. Předmět smlouvy</p> <p>ZHOTOVITEL je odpovědný za provádění pěti mezilaboratorních studií (ILS) podle tabulky 1.</p> | <p>2 Object of the contract</p> <p>The CONTRACTOR is responsible for the implementation of the five Inter-laboratory studies (ILS) according to Table 1.</p> |
| <p>3. Povinnosti ZHOTOVITELE</p> | <p>3 Duties of the CONTRACTOR</p> |
| <p>3.1 Odpovědnosti převzaté ZHOTOVITELEM:</p> <p>Odpovědnost ZHOTOVITELE zahrnuje následující činnosti:</p> <ul style="list-style-type: none"> • ověřit metody normalizačních projektů podle tabulky 1 sloupce 2. • provést validaci, management a vyhodnocení mezilaboratorních studií podle popisu projektu, tabulka 1, sloupec 3 a 4. • identifikovat nejméně osm účastnických laboratoří a koordinovat jejich práci v ILS. • důvěryhodně spolupracovat s vedoucím projektu SA (ÚNMZ / ČAS). • a včas poskytnout výsledky podle časového harmonogramu tabulky 1 sloupce 5. | <p>3.1 Responsibilities taken by the CONTRACTOR</p> <p>The responsibilities of the CONTRACTOR cover the following activities:</p> <ul style="list-style-type: none"> • validate the methods of the standardization projects according to Table 1 column 2. • perform the validation, management and evaluation of the inter-laboratory studies according to project description Table 1 column 3 and 4. • identify at least eight participation laboratories and coordinate their work in the ILS. • cooperate trustfully with the SA project leader (ÚNMZ/ČAS). • and supply the results timely according to the timeframe Table 1 column 5. |
| <p>3.2 Služby poskytované ZHOTOVITELEM</p> <p>ZHOTOVITEL poskytuje po smluvní období následující služby:</p> <ol style="list-style-type: none"> a) Jmenování vedoucího projektu pro ILS. Koordinuje testy, je kontaktním partnerem pro příslušného vedoucího projektu WG4. b) Přijetí návrhu zkušební metody od vedoucího projektu WG 4. c) Identifikace zúčastněných laboratoří. d) Výběr běžných produktů na trhu, které lze použít k odběru vzorků. e) Příprava plánu validace a potvrzení v pracovní skupině 4. f) Příprava vzorků, případně spikování vzorků. g) Pokyny zúčastněným laboratořím. h) Rozeslání vzorků zúčastněným laboratořím mezilaboratorních studií. i) V případě potřeby pomáhat zúčastněným laboratořím při provádění analýz. j) Shromažďovat, kontrolovat a hodnotit výsledky zúčastněných laboratoří. k) Návrh na zlepšení zkušební metody. l) Vytvoření závěrečné validační zprávy. m) Poskytnutí údajů do přílohy hEN „Výsledky mezilaboratorní studie“ n) Prezentace a diskuse ve WG 4. o) Vyhodnocení komentářů WG 4 a konzultanta HAS. | <p>3.2 Services provided by the CONTRACTOR</p> <p>The CONTRACTOR provides for the contract period the following services:</p> <ol style="list-style-type: none"> a) Nomination of a project leader for the ILS. He coordinates the tests, is contact partner for the relevant WG4 project leader. b) Reception of a draft test method from the WG 4 project leader. c) Identification of the participating laboratories. d) Selection of common products on the market which can be used for sampling. e) Preparation of a validation plan and confirmation in WG 4. f) Preparation of samples, where necessary spiking of samples. g) Instruction to the participating laboratories. h) Distribution of samples to the participating laboratories for the inter-laboratory studies. i) If necessary assist participating laboratories in performing the tests. j) Collect, review and evaluate results from the participating laboratories. k) Proposal for an improvement of test method. l) Compile the validation report. m) Supply of data for the Annex of the hEN “Results of an inter-laboratory study” n) Presentation and discussion in WG 4. o) Evaluation of the comments of WG 4 and the HAS-Consultant. |

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| p) Podpořit příslušnou část návrhu poptávky a zprávy o pokroku. | p) Support the relevant part of the Enquiry draft and progress report. |
| 4. Povinnosti ČAS ČAS poskytne ZHOTOVITELI prostřednictvím sekretáře WG 4 profesionální podporu podle pravidel CEN ¹ . Sekretariát poskytuje konzultantovi HAS a EK informace o postupu jednotlivých ILS spravovaných ZHOTOVITELEM. Sekretariát podporuje ZHOTOVITELE při komunikaci s WG 4 a konzultantem HAS. ČAS poskytuje ZHOTOVITELI včas informace a (požadované) dokumenty a zajišťuje, aby financování CEN bylo vyplaceno co nejrychleji. | 4 Obligations of ČAS ČAS will provide the CONTRACTOR with the professional standardization support of the WG 4 secretary according to CEN-rules ¹ . The secretariat provides the HAS consultant and EC with information about the progress of the individual ILS managed by the CONTRACTOR. The secretariat supports the CONTRACTOR in communicating with WG 4 and the HAS consultant. ČAS provides the CONTRACTOR timely with information and (requested) documents and ensures that the CEN funding is paid as quickly as possible. |
| 5. Fakturace a platba | 5 Invoicing and Payment |
| 5.1 Úhrada výdajů Celková maximální smluvní cena za práci, kterou má ZHOTOVITEL provést, je 49 586,78 € ² . Podrobně rozepsaná celková částka, kterou ZHOTOVITEL obdrží, závisí na nákladech, které ZHOTOVITEL věnoval plnění této smlouvy, a na rozsahu, v jakém věcné příspěvky splnily očekávání WG 4 a HAS konzultanta v článku 3.2 n-p. | 5.1 Reimbursement of expenses The total maximum contract expense allowance for the work to be carried out by the Contractor is: 49 586,78 € ² . The detailed total amount that the CONTRACTOR will receive depends on the costs by the CONTRACTOR in the context of this contract, and on the extent to which the in-kind contributions have met the expectations of WG 4 and HAS consultant in sub-clause 3.2 n-p. |
| 5.2 Časový harmonogram plateb: a) Záloha při podpisu smlouvy SA 35% maximálních nákladů uvedeného ILS viz sloupec 6 tabulky 1; celkem 17 355,37 € b) Po dokončení ILS (poskytování služeb 3.2 l, m, p): 65% maximálních nákladů ILS viz sloupec 6 tabulky 1; celkem 32 231,40 €. c) Vzhledem k povaze nadřazeného požadavku na standardizaci financovaného EK mohou být platby za finalizovaný ILS 5.2 b provedeny, pouze pokud byly vyplaceny příslušné platby z EK CEN a ČAS (viz 5.4). Nadřazený harmonogram plateb požadavku na standardizaci (viz SA) stanoví rámec pro maximální platbu po schválení určitých milníků | 5.2 Payment schedule: a) Pre-financing payment with signature of contract SA: 35 % of the maximal costs of the ILS see column 6 of Table 1; in total 17 355,37 € b) After finalization of the ILS (provision of services 3.2 l, m, p): 65 % of the maximal costs of the ILS see column 6 of Table 1; in total 32 231,40 €. c) Due to the nature of the superordinate EC funded standardization request, payments for the finalized ILS 5.2 b can only be made if the according payments from EC to CEN and ČAS have been disbursed (see 5.4). The superordinate payment schedule of the standardization request (see SA) sets the frame for the maximal payment after certain milestones of |

¹ <https://boss.cen.eu/technicalstructures/pages/tcwg.aspx>

² Financování od CEN činí 60 000 €. UNMZ/ČAS platí 21 % DPH (10 413,22 €).

The total funding from CEN amounts to 60,000 €. UNMZ/ČAS pays 21% VAT (10,413.22 €).

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| <p>projektu a průběžných zpráv. To může způsobit limity pro platby ILS takto:</p> <ul style="list-style-type: none"> • Schválená první průběžná zpráva - 25%; až 12 396,69 €². • Schválená druhá průběžná zpráva a předložení prEN k dotazu (fáze 40.20) 15%; až 7 438,02 €². • Konečná platba: K dispozici je schválená závěrečná zpráva a definitivní text EN (fáze 60.60) - 25%; až 12 396,69 €². <p>Obě strany si tento problém uvědomují. ČAS bude informovat ZHOTOVITELE co nejdříve o zaplacení EC a požádá o faktury, aby nedošlo ke zbytečnému zpoždění plateb.</p> | <p>the project and the interim reports have been approved. This might cause limits for the payment of the ILS as follows:</p> <ul style="list-style-type: none"> • Approved first interim report – 25 %; up to 12 396,69 €². • Approved second interim report and submission of prEN to Enquiry (stage 40.20) 15 %; up to 7 438,02 €². • Final payment: Approved final report and definitive EN text is available (stage 60.60) – 25 %; up to 12 396,69 €². <p>Both sides are aware of this problem. ČAS will inform the CONTRACTOR as soon as possible about the payment of the EC and ask for invoices, in order to avoid an unnecessary delay of the payments.</p> |
| <p>5.3 Dokumentace a účetnictví</p> <p>Platby se uskuteční na základě přijetí faktury ZHOTOVITELE, poskytnuté na žádost ČAS a obsahující údaje, které požaduje ČAS.</p> <p>Faktura musí obsahovat povinný obsah faktury EC, který byl vydán EC DG ENTR I3 dne 2016-03-14 (Příloha 3).</p> <p>Na faktuře musí být uvedena následující identifikační čísla:</p> <p>IČO ČAS: 06578705</p> <p>DIČ ZHOTOVITELE: 00871990230</p> <p>K fakturám za každou ILS 5.2 b musí mít poznámku „BIO-ILSA_ILS“ a musí být přiloženy doklady za služby 3,2 l, m a p a prohlášení o skutečných nákladech na:</p> <ul style="list-style-type: none"> • Nákup vzorků • Standardy prvků pro spikování • Balení a přeprava vzorků • Statistické vyhodnocení • Příprava validační studie • Technická podpora pro účastníky validačních studií • Vydání závěrečné zprávy • Laboratorní servis (testování homogeneity) • Laboratorní servis (zúčastněné laboratoře) <p>Faktury musí být předloženy nejpozději do 3 týdnů po formální žádosti od ČAS o zaslání faktur(y) týkající(ch) se této smlouvy.</p> <p>ZHOTOVITEL má právo vystavit fakturu z vlastní iniciativy, po konzultaci s ČAS, ze které vyplýne,</p> | <p>5.3 Documentation and accounting</p> <p>Payments will be made following receipt of an invoice from the CONTRACTOR, provided on the request of ČAS and with the specifications as indicated by ČAS.</p> <p>The invoice shall follow the EC Mandatory content of an invoice issued by EC DG ENTR I3 on 2016-03-14 (Annex 3).</p> <p>The invoice shall state the following identification numbers:</p> <p>ČAS id. (IČO): 06578705</p> <p>CONTRACTOR VAT id. (DIČ): 00871990230</p> <p>The invoices for each ILS 5.2 b shall have the note "BIO-ILSA_ILS" and shall be accompanied by the evidence for the services 3.2 l, m and p and a declaration of the real costs for:</p> <ul style="list-style-type: none"> • Sample purchase • Element standards for spiking • Sample packing and shipping • Statistical evaluation • Preparation of Validation trial • Technical assistance for participating laboratories • Validation reporting • Laboratory service (homogeneity testing) • Laboratory service (participating laboratories) <p>Invoices shall be presented a maximum of 3 weeks after the formal request from ČAS, to receive the invoice(s) related to this contract.</p> <p>The CONTRACTOR is invited to issue his invoice at own initiative, after consultation with ČAS that the</p> |

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| <p>že bylo dosaženo kroku opravňujícího k jejímu vystavení.</p> <p>Platby ZHOTOVITELI se uskuteční s použitím následujícího bankovního spojení:</p> <p>Název banky:</p> <p>Úplná adresa banky:</p> <p>36071 Arzignano – VICENZA</p> <p>ITALY</p> <p>Číslo účtu v € (EUR):</p> <p>kód IBAN (mezinárodní číslo bankovního účtu):</p> <p>(kód BIC):</p> <p>V případě ukončení smlouvy v souladu s článkem 10 této smlouvy není ČAS povinen k žádným platbám ZHOTOVITELI, s výjimkou plateb za služby poskytnuté do data ukončení. V takovém případě bude částka vypočtena po odečtení již uskutečněných plateb. Pokud platby uskutečněné před ukončením smlouvy překročí částku, která má být při ukončení vyplacena, nadměrnou částku je ZHOTOVITEL povinen vrátit ČAS do 60 dní od data, ke kterému obdrží žádost o platbu.</p> | <p>relevant payment step has been reached.</p> <p>Payments will be made to the CONTRACTOR with the following Bank details:</p> <p>Name of the Bank:</p> <p>Full address of Bank:</p> <p>36071 Arzignano – VICENZA</p> <p>ITALY</p> <p>€ (EUR) Account No:</p> <p>CODE IBAN (International Bank Account Number):</p> <p>CODE BIC:</p> <p>In the event of termination of the contract, corresponding to Article 10 of this contract, no payment shall be due from ČAS to the CONTRACTOR except for services actually rendered up to the date of termination. In such an event, the amount due shall be calculated after deducting any payments already made. If the payments made prior to termination exceed the sum finally due, the additional amount shall be repaid in full by the CONTRACTOR to ČAS within 60 days of receipt of a request for payment.</p> |
| <p>5.4 Platební podmínky související s evropským financováním</p> <p>Platby budou ZHOTOVITELI odeslány až po obdržení financování od Evropské komise/EFTA přes CEN/CCMC v ČAS. Platba proto může být uskutečněna několik měsíců poté, co budou výstupy zaslány Evropské komisi/EFTA nebo CCMC.</p> <p>Platba za předběžné a závěrečné kroky závisí na tom, zda Evropská komise/EFTA přijme předběžné a závěrečné zprávy definované v konkrétní grantové dohodě.</p> <p>Jestliže Evropská komise/EFTA neuhradí dohodnuté částky ČAS a v důsledku toho nebude ČAS schopen uhradit svoje závazky, neponese ČAS za tyto okolnosti odpovědnost. Platby budou splatné pouze tehdy, jestliže ZHOTOVITEL splnil svůj úkol ve stanoveném termínu, ČAS schválil výsledky a ZHOTOVITEL zaslal fakturu.</p> <p>Pokud si Evropská komise/EFTA zpětně vyžádá peněžní prostředky, které již byly vyplaceny ČAS za účelem vyplacení ZHOTOVITELE, a ČAS je již ZHOTOVITELI vyplatil, má ČAS právo vyžádat si tyto peněžní prostředky od ZHOTOVITELE zpět a ten je povinen je ČAS vrátit v přiměřeném čase.</p> | <p>5.4 Payment terms related to European funding</p> <p>The payment will be sent after the receipt of the funding from the European Commission/EFTA via CEN/CCMC at ČAS. The payment may therefore be made up to several months after the deliverables have been sent to European Commission/EFTA or CCMC.</p> <p>Payment of the interim and final steps is dependent on acceptance from the European Commission/EFTA of the interim and final reports defined in the Specific Grant Agreement.</p> <p>If the European Commission/EFTA does not disburse the agreed funds to ČAS and therefore ČAS cannot disburse the money, ČAS will not be held liable for these circumstances. The payments are due only if the CONTRACTOR has fulfilled the tasks within the given time schedule, ČAS has approved the results and the CONTRACTOR has sent an invoice.</p> <p>Should the European Commission/EFTA retroactively reclaim funds already paid to ČAS for the payment of the CONTRACTOR and forwarded by ČAS to the CONTRACTOR, ČAS has the right to reclaim such funds from the CONTRACTOR and the CONTRACTOR is obliged to return the funds by ČAS</p> |

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| <p>V takovém výjimečném případě není od ČAS požadováno žádné další odůvodnění takového vyžádání, kromě příslušných důvodů poskytnutých od Komise/EFTA.</p> | <p>within an adequate time limit. In this exceptional case no further justification for such a reclaim is required from ČAS in addition to the relevant reasons provided by the Commission/EFTA.</p> |
| <p>6. Ustanovení týkající se daňových poplatků</p> <p>ČAS je státní příspěvková organizace, a proto neplatí DPH za služby uvedené v této smlouvě. ZHOTOVITEL je odpovědný za úhradu veškerých daní, které se na něj vztahují, a dalších souvisejících závazků, které mu vznikají v souvislosti s touto smlouvou. ZHOTOVITEL je odpovědný za své pojištění, včetně pojištění odpovědnosti za škodu způsobenou při výkonu povolání.</p> | <p>6 Provisions relating to fiscal charges</p> <p>ČAS is a state contributory organization and therefore does not pay VAT for the services mentioned in this contract.</p> <p>The CONTRACTOR is responsible for all taxes imposed on him/her and other related obligations that arise as a result of this agreement. The CONTRACTOR is responsible for his/her own insurance cover including Professional Indemnity cover.</p> |
| <p>7. Odpovědnost a právní odpovědnost</p> <p>ČAS nenese odpovědnost za jakékoli reklamace vyplývající z této smlouvy a týkající se škod způsobených ZHOTOVITELEM, jeho zaměstnanci nebo třetí stranou. Na ČAS nemůže být směřován žádný požadavek na odškodnění nebo uvedení do původního stavu v souvislosti s takovými reklamacemi.</p> | <p>7 Responsibility and Liability</p> <p>ČAS shall not be responsible for any claims arising out of the present contract and relating to damages caused by the CONTRACTOR, his employees or a third party. No request of indemnity or reinstatement relating to such claims may be addressed to ČAS.</p> |
| <p>8. Důvěrnost informací</p> <p>ZHOTOVITEL nesmí prozradit třetím stranám žádné skutečnosti, informace, znalosti, dokumenty nebo jiné záležitosti, o nichž se dozvěděl nebo na něž byl upozorněn v průběhu plnění této smlouvy, které nejsou běžně známe veřejnosti nebo které nejsou určeny k tomu, aby byly veřejnosti oznámeny.</p> | <p>8 Confidentiality</p> <p>The CONTRACTOR shall not divulge to third parties any facts, information, knowledge, documents or other matters communicated to him or brought to his/her attention during the performance of the contract, which is not available publicly or intended to become available publicly.</p> |
| <p>9. Autorské právo</p> <p>ZHOTOVITEL se zavazuje, že postoupí ČAS (nebo tomu, koho ČAS určí) svá práva na využívání a všechna práva duševního vlastnictví, která mu vzniknou v rámci plnění této smlouvy.</p> <p>Taková postoupená práva zahrnují práva na reprodukování díla včetně práva na publikaci, distribuci, úpravu, překlad, pronájem, zapůjčení, práva na odměnu za kopírování a zapůjčení a rovněž práva na zveřejnění práce (díla), ať jako celku nebo jeho částí, jako souhrn nebo s poznámkami, a včetně práva převést všechny licence na využití a na udělení sublicencí.</p> <p>Převod práv se vztahuje na všechny jazyky a pokrývá všechny v současnosti známé formy využívání, zejména na uvedené zveřejňování jakýmkoli prostředky a prostřednictvím všech systémů grafické podpory, tiskem, fotokopii, mikrofilmami, magnetickými nosiči, počítačově zpracovanými daty, elektronickými daty, včetně internetu, a podobně.</p> | <p>9 Copyright</p> <p>The CONTRACTOR undertakes to assign to ČAS (or as ČAS may direct) his/her rights of exploitation and all intellectual property rights in the works developed in the performance of this Grant Agreement.</p> <p>Such assigned rights include reproduction rights including the publication, distribution, adjustment, translation, renting, loan, the remuneration rights for duplication and loan, as well as the rights of communication to the public of the works, in total or in part, in summary or with comments, and including the right to transfer all exploitation licences and to authorise all sub-licences.</p> <p>The transfer of rights covers all languages and covers all forms of exploitation known at present and no restrictively; publication by all means and via all graphical support systems, by print, press, photocopy, microfilms and via all magnetic, electronic data, including the internet, and similarly.</p> |

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| <p>mikrofilmy a prostřednictvím všech magnetických, počítačových a numerických systémů, paměťových karet, CD-ROMů, filmů, fotografií, slajdů, televizním vysíláním, kabelovým a satelitním vysíláním, na discích a on-line dokumentových serverech.</p> <p>Pro všechny tyto postoupené režimy využívání jsou výše uvedená práva postupována zdarma, a to pro všechny země a po celou dobu trvání platnosti práv duševního vlastnictví.</p> | <p>computerised and numerical support systems, memory cards, CD-ROMs, films, photographs, slides, teledistribution, cable, satellite, disks and online document servers.</p> <p>For all and each of the assigned exploitation modes, rights mentioned above are granted free of charge, for all countries and for the total duration of the intellectual property rights.</p> |
| <p>10. Ukončení</p> <p>Každá ze smluvních stran může bez náhrady ukončit tuto smlouvu zasláním formální jednoměsíční výpovědi. Pokud je smlouva ukončena za strany ČAS, mají obě strany nárok na výplatu odpovídající pouze splněné části smlouvy.</p> <p>V případě závažného porušení smlouvy (zejména trvalá neschopnost dodržet časové termíny, porušování zásad důvěrnosti informací) ze strany ZHOTOVITELE vůči ČAS, na které byl ZHOTOVITEL upozorněn doporučeným dopisem od ČAS, má ZHOTOVITEL tři týdny na to, aby porušení smlouvy odstranil. Pokud nedojde k jeho odstranění, může být smlouva ukončena doporučeným dopisem, aniž by bylo třeba podávat další formální výpověď nebo vyplácet jakékoli náhrady ze strany ČAS.</p> <p>Jestliže ZHOTOVITEL:</p> <ul style="list-style-type: none"> • se trvale dopouští jakýchkoli chyb, i když lehkých, v poskytování svých služeb; • vede soudní při nebo žádost o náhradu jakéhokoli typu proti CEN; • neposkytuje služby vyžadované ČAS ve stanoveném časovém limitu; • neplnil svoje povinnosti v souvislosti s požadavkem na uchování důvěrnosti informací; <p>potom může ČAS tuto smlouvu ukončit s okamžitou platností.</p> | <p>10 Termination</p> <p>Each contracting party may, without compensation, terminate the contract by serving formal notice one month in advance. If the contract is terminated by ČAS, both parties shall be entitled to appropriate payment corresponding only to the part fulfilled of the contract.</p> <p>In the event of a serious infringement (in particular consistent failure to meet deadlines, infringement of confidentiality) by a CONTRACTOR to ČAS, duly noted by registered letter from ČAS, the CONTRACTOR will be given three weeks to resolve the infringement of the contract; if no resolution takes place, the contract may be terminated by registered letter without further formal notice or payment of any compensation whatsoever by ČAS.</p> <p>If the CONTRACTOR:</p> <ul style="list-style-type: none"> • consistently commits any faults, however slight, in the execution of his services; • is at the basis of any law suit or recovery whatever it might be, held against CEN; • does not accomplish the services requested by ČAS in the allowed time limit; • not having fulfilled his obligations with regard to the respect of confidentiality; <p>then ČAS can terminate this contract at once.</p> |
| <p>11. Odstoupení</p> <p>ČAS má právo odstoupit od této smlouvy o dílo, jestliže Evropská komise/EFTA nevyplatí ČAS peněžní prostředky nebo vyžádá navrácení peněžních prostředků již vyplacených ČAS na základě konkrétní grantové dohody, protože jakékoli takové výplaty závisí na akceptování předběžných a závěrečných zpráv definovaných v konkrétní grantové dohodě ze strany EC.</p> | <p>11. Withdrawal</p> <p>ČAS is entitled to withdraw from this Service contract if the European Commission/EFTA does not pay the funds to ČAS or retroactively reclaims funds already paid to ČAS under the Specific Grant Agreement, as any such payment is dependent on EC's acceptance of the interim and final reports defined in the SA.</p> |

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| <p>12. Administrativní ustanovení</p> <p>Veškerá korespondence s ČAS týkající se plnění této smlouvy bude zasílána na následující adresu (s výjimkou faktur):</p> <p>Ing. Stefan Krebs Telefon: - e-mail:</p> <p>Všechny faktury vystavené na ČAS budou adresovány následovně:</p> <p>Ing. Antonín Jedlička Česká agentura pro standardizaci (ČAS), Na Žertvách 132/24, 180 00 Praha 8, Česká republika</p> <p>Veškerá korespondence se ZHOTOVITELEM bude zasílána na následující adresu:</p> <p>Chiara Manoli Telefon: ILSA S.p.A. Via Quinta Strada, 28 36071 Arzignano (VI), -Italy; Email:</p> | <p>12 Administrative provisions</p> <p>All correspondence with ČAS concerning the performance of this contract shall be addressed as follows (with the exception of invoices):</p> <p>Ing. Stefan Krebs Phone: e-mail:</p> <p>All invoices to ČAS shall be addressed as follows:</p> <p>Ing. Antonín Jedlička Czech agency for standardization (ČAS), Na Žertvách 132/24, 180 00 Prague 8, Czech Republic</p> <p>All correspondence with the Contractor shall be addressed as follows:</p> <p>Chiara Manoli Phone: ILSA S.p.A. Via Quinta Strada, 28 36071 Arzignano (VI), -Italy; E-mail:</p> |
| <p>13. Postoupení</p> <p>ZHOTOVITEL nesmí, bez předchozího písemného souhlasu ČAS, jakýmkoli způsobem převést na třetí stranu práva a/nebo povinnosti vyplývající z této smlouvy.</p> | <p>13 Assignment</p> <p>The CONTRACTOR shall not transfer in any other manner the benefit and/or burden of this Grant Agreement to any third party without the prior written consent of ČAS.</p> |
| <p>14. Změny smlouvy</p> <p>Tato smlouva je vyhotovena v počtu 2 stejnopisů, z nichž každý má povahu prvopisu a z nichž po jednom obdrží každá smluvní strana.</p> <p>Tuto smlouvu je možné měnit pouze písemnou dohodou smluvních stran.</p> | <p>14 Alterations to the contract</p> <p>This contract is made in the number of 2 copies, each of which has the nature of an original and one of which is received by each party.</p> <p>The contract may be modified only by written agreement between both parties.</p> |
| <p>15. Platnost</p> <p>Tato Smlouva nabývá platnosti dnem jejího podpisu a účinnosti dnem jejího uveřejnění v registru smluv; ČAS je povinen postupem podle zákona č. 340/2015 Sb., o zvláštních podmínkách účinnosti některých smluv, uveřejňování těchto smluv a o registru smluv (zákon o registru smluv), uveřejnit tuto smlouvu v registru smluv v plném znění. ZHOTOVITEL bere rovněž na vědomí, že registr smluv je veřejně přístupný informační systém veřejné správy, jehož správcem je Ministerstvo vnitra, který slouží k uveřejňování</p> | <p>15 Validity</p> <p>This contract shall enter into force on the day of its signing and shall take effect on the day of its publication in the Register of Contracts; ČAS is obliged to publish this contract in the full text in accordance with Act No. 340/2015 Coll., on Special Conditions of Effectiveness of Certain Contracts, Publication of These Contracts and the Register of Contracts (Act on the Register of Contracts). The CONTRACTOR also acknowledges that the Register of Contracts is a publicly accessible information system of public administration, administered by the Ministry of the Interior, which serves to publish</p> |

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| <p>smluv podle zákona o registru smluv a umožňuje bezplatný dálkový přístup.</p> <p>Pokud se stane, že bude kterékoli ustanovení této smlouvy neplatné, nijak to neovlivní kteroukoli zbývající část této smlouvy.</p> | <p>contracts pursuant to the Act on the Register of Contracts and allows free remote access.</p> <p>If any of the provisions of this contract become invalid, this shall not affect any part of the remaining contract.</p> |
| <p>16. Ustanovení o rozhodčím řízení</p> <p>Všechny spory, které vzniknou v souvislosti s touto smlouvou, budou vyřešeny vzájemným jednáním. Pokud se smluvním stranám nepodaří v průběhu dvou měsíců dosáhnout uspokojivého řešení, souhlasí s tím, že předpokládaný soudní případ předloží pravomoci soudů České republiky.</p> | <p>16 Arbitration clause</p> <p>All disputes arising in the course of this contract will be settled regularly by negotiations. Should the parties fail to reach a satisfactory solution within two months' time, they agree on the jurisdiction of the courts of the Czech Republic of the foreseen legal case.</p> |
| <p>17. Rozhodné právo</p> <p>Tato smlouva podléhá zákonům České republiky a bude vykládána v souladu s nimi.</p> | <p>17 Applicable Law</p> <p>This Agreement shall be governed by and interpreted in accordance with the Law of Czech Republic.</p> |
| <p>Za ČAS / For ČAS</p> <p>.....</p> <p>Mgr. Zdeněk Veselý</p> <p>Generální ředitel/Director General</p> <p>OfficerDatum/Date:</p> | <p>Za ZHOTOVITELE / For the CONTRACTOR</p> <p>.....</p> <p>Paolo Girelli</p> <p>Výkonný ředitelka /Chief Executive</p> <p>Datum/Date:</p> |

Příloženo:

Příloha 1 - Výzva k podávání nabídek pro validaci metod
Příloha 2 - Nabídky předložené ILSA týkající k výzvám č. 3 a ověřená zpráva
Příloha 3 – EC Povinný obsah faktury

Enclosed:

Annex 1 - Call for tenders for the validation of methods
Annex 2 – Tender submitted by ILSA related to call no. 3 and validated selection report
Annex 3 - EC Mandatory content of an invoice

Smlouva o dílo ILS/Service contract ILS

ČAS-UKZUZ SA / CEN / GROW / EFTA / 564 / 2020-03

Příloha 1 / Annex 1

Výzva k podávání nabídek pro validaci metod

Call for tenders for the validation of methods

Consultation for
the validation of the method in
FprCEN/TS 17703 “Plant biostimulants - Determination of chromium(VI)”
(Proficiency test provider for one inter-laboratory studies)

as part of the European Commission Standardisation Request M/564
to the European Committee for Standardisation referring to the
EU fertilising products in support of Regulation (EU) 2019/1009
of the European Parliament and of the Council

1. Background

1.1 Regulation, standardization request and involved standardization bodies

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. In order to facilitate their free movement in the internal market, not only fertilising products, i.e. products intended to provide plants with nutrients, but also products intended to improve plants' nutrition efficiency are covered by the harmonisation.

Different product functions warrant different product safety and quality requirements adapted to their different intended uses. EU fertilising products are therefore divided into product function categories (PFCs) and component material categories (CMCs).

In order to provide the market with the means to claim proof of compliance, Technical Specifications (TSs) followed by harmonised European standards (hENs) have to be developed under this Specific Agreement SA/CEN/564 (SA), related to the European Commission Standardisation Request M/564 ("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.

The current consultation for the recruitment of a proficiency test provider concerns one inter-laboratory study for following PFCs relevant to CEN/TC 455 *Plant biostimulants*:

- PFC 6. Plant biostimulant
 - A. Microbial plant biostimulant
 - B. Non-microbial plant biostimulants, and
- 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. Work has started on 10/2020. The expected duration is 4 years.

CEN/TC 455 *Plant biostimulants* was created in 2017 to set up European Standards for all kinds of plant biostimulants. AFNOR, the French member of the National Standardisation Bodies represented at the European and international level, detains the Secretariat of CEN/TC 455 *Plant biostimulants* and will deal with the administrative management of

the standardisation work.

ÚNMZ, the Czech member of standards networking at European (CEN) and international (ISO) levels, holds the secretariat of CEN/TC 455/WG 4 *Other safety parameters* since September 2017.

Since 2018 ÚNMZ delegated in accordance with Czech law all tasks related to the CEN membership to the Czech Standardization Agency (ČAS). Therefore ČAS will be responsible for the administrative management of the standardisation work in WG 4.

The Czech Standardization Agency was established as a state contributory organization by the Czech Office for Standards, Metrology and Testing (ÚNMZ) pursuant to Act No. 265/2017 Coll., Amending Act No. 90/2016 Coll. their supply to the market, and Act No. 22/1997 Coll., on technical requirements for products and on amendments and supplements to certain acts, as amended.

Since 1 January 2018, the Czech Standardization Agency (ČAS) has taken over all activities related to the development, issue and distribution of technical standards from the ÚNMZ including the fulfilment of membership obligations in European and international standardization organizations. Therefore ČAS will be responsible for the administrative management of the standardisation work in WG 4.

1.2 Results of the call for tender issued on 16. 3. 2021

For the open call published on 16. 03. 2021 only one laboratory applied. This laboratory did not meet the exclusion criteria (score). Therefore the laboratory for the ILS will now be determined by a consultation.

1.3 The related standardization project

Through M/564, the European Commission is requesting the development of 33 CEN Technical Specifications (TS) and 33 European Harmonised Standards (hEN). WG 4 *Other safety parameters* is in charge of developing nine TS and nine hEN. One will contain new method for the analysis of Cr(VI) in Plant Biostimulants.

These methods will be published in a first step as TS without validation, but will have to be validated before they will be in a second step published as harmonized European standards (hEN).

Plant biostimulants - Determination of chromium(VI)

This hEN specifies the method for determination of hexavalent chromium after extraction of different plant biostimulants by ion chromatography.

The proposed hEN will be used for determination of hexavalent chromium – Cr(VI) after extraction of different plant biostimulants using:

- A. Phosphate buffer, for organic and organic-based plant biostimulants;
- B. Alkaline digestion, for inorganic plant biostimulants.

Both procedures use ion chromatography for speciation of different chromium ions in the extract followed by spectrophotometric determination (direct or after post-column reaction) or by ICP-MS determination. The method is able to extract all species of Cr(VI), the adapted conditions of the extraction do not induce reduction of native Cr(VI) to Cr(III), and it does not cause oxidation of native Cr(III) contained in the sample to Cr(VI). For procedure B) alkaline conditions prevent reduction of Cr(VI) and the addition of magnesium and phosphate buffer prevents air oxidation of Cr(III).

The method described in the available standards are relatively well established in control analytical laboratories and they are used for a wide variety of matrices (soil, sludge, biowaste, fertilizers etc.). A preliminary determination of chromium in aqua regia extracts by ICP-AES can reduce the number of the samples where determination of Cr(VI) is necessary. (If the content of aqua regia extractable chromium is lower than the legislative limit for hexavalent chromium then the determination of this individual species is not necessary).

The method will be developed with respect to EN ISO 17075-2 (after improvement of LOQ) and after consideration of EN 15192 and EN 16318 (method B).

The producers will be able to check the quality of their products for compliance with the demanded legislative limits and competent authorities will have a suitable tool for an effective control of the regulatory limits. Consumers and environmental stakeholders will profit from the well-established uniform and reliable control of the products

applied to soil and crops. However, the instruments needed for this method tend to be more prevalent in well-equipped analytical laboratories; in addition, very good staff training is required to conduct this method. Therefore, preliminary determination of total chromium simultaneously with the other elements by ICP-AES can give an indication of the necessity to determine Cr(VI) with this specific method. This stepwise approach can also further minimize the cost for the analyses.

2. Objective

The objective of the current consultation is the recruitment of proficiency test providers for the following inter-laboratory study:

Table 1 – Method and objectives

| Method | Validation of the method in the standardization project | Project description | Project leader in WG 4 |
|-----------------|---|---------------------|-----------------------------|
| FprCEN/TS 17703 | Plant biostimulants – Determination of chromium (VI) | 1. 3 and Annex 3 | Chiara Manoli (ILSA s.p.A.) |

The work of the proficiency test provider implies the coordination of the work of the participating laboratories, which participate in the ILS. Tight cooperation with the individual WG 4 project leader is required.

3. Execution

3.1 Tasks

The tasks of the proficiency test provider are:

- a) Nomination of a project leader for the proficiency test. He/she coordinates the tests, is contact partner for the relevant WG4 project leader and ensures the involvement of the producers in the inter-laboratory tests.
- b) Reception of a draft test method from the WG 4 project leader.
- c) Identification of the participating laboratories¹.
- d) Selection of common products on the market which can be used for sampling.
- e) Preparation of a validation plan and confirmation in WG 4.
- f) Preparation of samples, where necessary spiking of samples.
- g) Instruction of the participating laboratories.
- h) Distribution of samples to the participating laboratories for the inter-laboratory test.
- i) If necessary assist participating laboratories in performing the tests.
- j) Collect, review and evaluate results from the participating laboratories.
- k) Proposal for an improvement of test method.
- l) Compile the validation report.
- m) Supply of data for the Annex of the hEN “Results of a validation study”
- n) Presentation and discussion in WG 4.
- o) Evaluation of the comments of WG 4 and the HAS-Consultant.
- p) Support the relevant part of the Enquire draft and progress report.

3.2 Timeframe

The proficiency test provider must adhere to the following schedule for the milestones in the standardization project:

- S = 02. 06. 2020 Start of the standardization project

¹ The specific agreement with the EC states that a minimum of ten laboratories is required and foreseen for each method. In case this number of laboratories cannot be achieved for justified reasons (method is new, complicated instruments are demanded etc.), WG 4 will have to be asked to adopt a modified validation plan.

- S + 19 months Start of inter-laboratory studies
- S + 28 months Release of inter-laboratory studies
- S + 29 months Support WG 4 project leader and Convenor in the discussion with the HAS Consultant

3.3 Consultation for the validation of the method (proficiency test providers for the inter-laboratory studies)

The CEN/TC 455 *Plant biostimulants* WG 4 Secretariat launches the current open call for the recruitment of proficiency the test provider for the inter-laboratory studies to:

- validate the method of the standardization projects according to Table 1 and subclause 1.3.
- perform the validation, management and evaluation of the inter-laboratory studies according to the tasks 3.1.
- identify and coordinate of the work of the participation laboratories, which participate in the ILS.
- cooperate trustfully with the SA project leader (ÚNMZ/ČAS), WG 4 project leaders (Table 1) and the HAS consultant.
- and supply the results timely according to the timeframe 3.2.

The proficiency test provider will be subcontracted by ČAS.

4. Financial support

There will be a financial support from the European Commission and EFTA for the services described in Table 1 and clause 2 and 3.

The financial support from the European Commission and EFTA is based on the Framework Partnership Agreement (FPA 2014). The subcontractor shall fulfil the conditions of the FPA 2014 (liability, ownership of results, confidentiality...).

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

The terms and schedule for payment by the EU/EFTA was defined in the Specific grant agreement.

5. Criteria for selection

The selection of the applying proficiency test providers is based on the following Knockout criteria:

- The laboratory is according to FprCEN/TS 17703, 6.8 (see Annex 3) equipped with an ion-exchange chromatograph, with UV or visible detector with the capability to fulfil the chromatographic conditions according to FprCEN/TS 17703 Annex A.
 - The laboratory is according to FprCEN/TS 17703, 6.8 (see Annex 3) equipped with a high-performance liquid chromatography (HPLC) with anion-exchange column and UV or visible detector with the capability to fulfil the chromatographic conditions according to FprCEN/TS 17703 Annex 3. This is a Knock-out criterion.
 - The score: the scoring system laid down in Annex 1 will be applied only in case that two or more competitors fulfil the knock-out criteria in the same way.
- 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.

Applicants will be excluded from participating in the call for proposals procedure according to the following **exclusion criteria**:

- The tender does not fulfil the Knock-out criterion 5a.
- The tender does not fulfil the Knock-out criterion 5b.
- The tender does not reach the 65% in total Knock-out criterion.
- 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)*².

The final decision will be taken on the following basis:

² https://ec.europa.eu/oib/doc/tenders-submission-guide_en.pdf, 2.2.3.2

$$\text{Score for tender X} = \frac{\text{cheapest price}}{\text{price of tender X}} * 30 + \frac{\text{total quality score (out of 100) for the Annex 1 criteria of tender X}}{100} * 70$$

6. Replies to tender

Tenders to the calls in clause 3.3 should be sent by email to the Secretary of CEN/TC455/WG 4, Mr Stefan Krebs (see contact details below, krebs@agentura-cas.cz) as soon as possible.

The deadline for all the candidatures is January 10th, 2022. The call for tenders will start on December 13th, 2021:

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

- A CV of the project leader of the validation (ILS).
- A specified proposal how to supply the results of the validation in time, breakdown of tasks and responsibilities.
- A signed declaration, by which the candidate certifies not to be in one of the situations described in the exclusion criteria³.

Please consider that ČAS is not a VAT-payer, so you have to tax the payments⁴.

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.

Late delivery will lead to the non-admissibility of the tender and its rejection from the award procedure for this contract.

The selection and appointment of the tender will be conducted by Stefan Krebs (ÚNMZ/ČAS, Secretary of CEN/TC 455/WG WG 4), Samantha Gagnon (AFNOR, Secretary of CEN/TC 455), Benoît Planques (Chairperson of CEN/TC 455), and Alessia Gaetani (Technical Project Manager CEN/CENELEC Management Centre) and, if possible, a member from the European Commission.

Czech Standardization Agency (ČAS)
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Enclosure:

Annex 1 –Scoring system for the selection criteria for proficiency test providers

Annex 2 – Application form

Annex 3 - Text of_FprCEN_TS_17703_which_contains_the_method_to_be_tested

³ https://ec.europa.eu/oib/doc/tenders-submission-guide_en.pdf, 2.2.3.2

⁴ ÚNMZ/ČAS is a governmental organisation tax exempt. When signing a contract with ČAS, the subcontractor will need to cover the tax payments.

Annex 1 – Scoring system for the selection criteria for the calls for proficiency test providers

| ELEMENTS ADDRESSED IN THE TENDER FO CALL 1-6 | SCORE FOR THE SELECTION of the calls for all five WG 4 Inter-laboratory studies |
|--|---|
| 1. PROFILE | 70% |
| a) Institutional background (equipment and staff) | 45% |
| <i>Ion-exchange chromatograph, with UV or visible detector with the capability to fulfil the chromatographic conditions according to FprCEN/TS 17703 Annex A</i> | 20% * |
| <i>High performance liquid chromatography (HPLC) with anion-exchange column and UV or visible detector with the capability to fulfil the chromatographic conditions according to FprCEN/TS 17703 Annex B</i> | 20% * |
| Staff for sample pretreatment, spiking and homogenization available | 5% |
| b) Personal background | 20% |
| Expertise knowledge of the validated method and validation procedures | 10% |
| Competence in statistics | 10% |
| b) Management competences. Experience or ability to: | 5% |
| • present complex issues in the given context as a definition in an understandable way | 2% |
| • coordinate a group of experts, ensure the consolidation and integration of all contents provided by the participant of ILS | 3% |
| 2. SUPPLY OF RESULTS OF ILS | 10% |
| a) Understanding of tasks and responsibilities | 5% |
| Number of days of work | 1% |
| Comprehension of the scope | 2% |
| Quality of the proposal (clarity, match with description given...) | 2% |
| b) Ability to supply ILS results at specified target dates | 5% |
| Calendar of the proposal vs expected | 5% |
| 3. VALIDATION AND STANDARDIZATION OF THE METHODS | 20% |
| a) Experience in validation and development of methods | 10% |
| Number of projects | 5% |
| Number of years | 5% |
| b) Experience in European and/or International standardization | 10% |
| Number of projects | 5% |
| Number of years | 5% |
| TOTAL | 100% |

* these criteria are Knock-out criteria. This means that the applying lab must be equipped with these both aparatuses and to be able to keep for each the mention criteria. Else their application is not valid.



Annex 2
Application form

**Consultation for
the validation of methods
FprCEN/TS 17703 “Plant biostimulants - Determination of chromium(VI)”
(Proficiency test providers for one inter-laboratory study)**

**as part of the European Commission Standardisation Request M/564
to the European Committee for Standardisation referring to the
EU fertilising products in support of Regulation (EU) 2019/1009
of the European Parliament and of the Council**

A- Contact details of the Applicant (laboratory)

Name of the Proficiency test provider:

Address:

Contact person:

Phone:

Email address:

B- Project leader for the proficiency test and his Curriculum Vitae (maximum 4 pages A4)

Please add CV as a separate document.

C- Information on the costs of the validation

Total costs of the tender: _____ **EUR**

Please provide an estimation of the costs for:

Sample purchase

Element standards for spiking

Sample packing and shipping

Statistical evaluation (service)

Preparation of Validation trial

Technical assistance – Validation

Validation reporting

Laboratory service (homogeneity testing)

Laboratory service (participating laboratories)



D- Please demonstrate compliance with the selection criteria (acc. Annex 1)

| | |
|--|---|
| 1. PROFILE | - |
| a) Institutional background | - |
| <i>Ion-exchange chromatograph, with UV or visible detector with the capability to fulfil the chromatographic conditions according to FprCEN/TS 17703 Annex A</i> | |
| <i>High performance liquid chromatography (HPLC) with anion-exchange column and UV or visible detector with the capability to fulfil the chromatographic conditions according to FprCEN/TS 17703 Annex B</i> | |
| Staff for sample pretreatment, spiking and homogenization available | |
| b) Personal background | - |
| Expertise knowledge of the validated method and validation procedures | |
| Competence in statistics | |
| b) Management competences. Experience or ability to: | - |
| • present complex issues in the given context as a definition in an understandable way | |
| • coordinate a group of experts, ensure the consolidation and integration of all contents provided by the participant of ILS | |
| 2. SUPPLY OF RESULTS OF ILS | - |
| a) Understanding of tasks and responsibilities | - |
| Number of days of work | |
| Comprehension of the scope | |
| Quality of the proposal (clarity, match with description given...) | |
| b) Ability to supply ILS results at specified target dates | - |
| Calendar of the proposal vs expected | |
| 3. VALIDATION AND STANDARDIZATION OF THE METHODS | - |
| a) Experience in validation and development of methods | - |
| Number of projects | |
| Number of years | |
| b) Experience in European and/or International standardization | - |
| Number of projects | |
| Number of years | |



E- Proposal how to supply the results of the validation in time, breakdown of tasks and responsibilities (in a separate document)

F- Declaration and signature

Hereby we certify that all documents provided are veracious and in conformity with reality. We also certify that I had no conflict of interest by submitting the present offer.

Organisation applying:

Signature:

(print name here)

Date :

September 2021

ICS 07.080

English Version

Plant biostimulants - Determination of chromium(VI)

Biostimulants des végétaux - Dosage du chrome(VI)

Biostimulanzien für die pflanzliche Anwendung -
Bestimmung von Chrom (VI)

This draft Technical Specification is submitted to CEN members for Vote. It has been drawn up by the Technical Committee CEN/TC 455.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (FprCEN/TS 17703:2021) has been prepared by Technical Committee CEN/TC 455 “Plant Biostimulants”, the secretariat of which is held by AFNOR.

This document is currently submitted to the Vote on TS.

Introduction

This document was prepared by the experts of CEN/TC 455 'Plant Biostimulants'. The European Committee for Standardization (CEN) was requested by the European Commission (EC) to draft European standards or European standardization deliverables to support the implementation of Regulation (EU) 2019/1009 of 5 June 2019 laying down rules on the making available on the market of EU fertilising products ("FPR" or "Fertilising Products Regulation").

This request, presented as SR M/564, also contributes to the Communication on "Innovating for Sustainable Growth: A Bio economy for Europe". The Working Group 4 "Other safety parameters", was created to develop a work program as part of this Request. The technical committee CEN/TC 455 'Plant Biostimulants' was established to carry out the work program that will prepare a series of standards. The interest in biostimulants has increased significantly in Europe as a valuable tool to use in agriculture. Standardization was identified as having an important role in order to promote the use of biostimulants. The work of CEN/TC 455 seeks to improve the reliability of the supply chain, thereby improving the confidence of farmers, industry, and consumers in biostimulants, and will promote and support commercialisation of the European biostimulant industry.

1 Scope

This document was developed to provide a method for verifying that hexavalent chromium (CrVI) is not present in plant biostimulants in a concentration that exceeds the respective limits outlined in the EU Regulation on Fertilising Products [1].

This document is applicable to all types of plant biostimulants (solid and liquid¹) used in agriculture.

The method described is suitable to quantify the chromium(VI) content in plant biostimulants down to 2 mg/kg.

The results obtained from this method are strictly dependent on the extraction conditions. Results obtained by using other extraction procedures (extraction solution, pH, extraction time, etc.) are not comparable with the results produced by the procedure described in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CEN/TS 17701-1, *Plant biostimulants - Determination of specific elements - Part 1: Digestion by aqua regia for subsequent determination of elements*

CEN/TS 17701-2, *Plant biostimulants - Determination of specific elements - Part 1: Digestion by aqua regia for subsequent determination of elements*

CEN/TS 17702-1, *Plant biostimulants - Sampling and sample preparation - Part 1: Sampling*

CEN/TS 17702-2, *Plant biostimulants - Sampling and sample preparation - Part 2: Sample preparation*

CEN/TS 17704, *Plant biostimulants - Determination of dry matter*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1

chromium(VI) content

amount of chromium(VI) in plant biostimulant determined after extraction with an aqueous salt solution at pH 7,0 to 8,0

Note 1 to entry: The chromium(VI) content is reported as chromium(VI) in milligrams per kilogram (mg/kg), expressed as the dry mass of the sample.

[SOURCE: EN ISO 17075-2:2017, definition 3.1]

¹ According to the definition of “solid form” and “liquid form” to the current EU legislation when it is published.

4 Principle

A preliminary determination of the total chromium in aqua regia extracts by ICP-AES (CEN/TS 17701-1 and CEN/TS 17701-2) could reduce the number of the samples where the determination of chromium(VI) is necessary because if the content of aqua regia (total) extractable chromium is lower than the legislative limit for chromium(VI) then the determination of chromium(VI) is not necessary.

Extractable chromium(VI) is leached from the sample in phosphate buffer at pH 7,0 to 8,0. An aliquot of the filtered extract is analysed for Cr(VI) using ion-exchange chromatography with UV-VIS detection.

5 Chemicals

All reagents used shall have at least analytical grade purity.

5.1 Extraction solution

Dissolve 22,8 g dipotassium hydrogenphosphate $K_2HPO_4 \cdot 3H_2O$ in 1 000 ml water (5.7), adjusted to pH $8,0 \pm 0,1$ with phosphoric acid (5.2). Degas this solution with either argon or nitrogen (5.6) or ultrasonic bath.

Standard practice is to make up a fresh solution each day. However, the solution can be kept for up to one week in a refrigerator at $(4 \pm 3) ^\circ C$ but shall be warmed to room temperature and degassed prior to use.

5.2 Phosphoric acid solution

Seven hundred (700) ml *o*-phosphoric acid, $\rho = 1,71$ g/ml, made up to 1 000 ml with water (5.7).

First add approximately 200 ml of deionised water (5.7) to a 1 000 ml volumetric flask, then add the 700 ml of *o*-phosphoric acid and dilute to the mark with deionised water.

5.3 Potassium dichromate ($K_2Cr_2O_7$), dried for (16 ± 2) h at $(105 \pm 5) ^\circ C$.

5.4 Chromium(VI) stock solution

Dissolve 2,829 g potassium dichromate ($K_2Cr_2O_7$) (5.3) in water (5.7) in a volumetric flask and make up to 1 000 ml with water (5.7). One ml of this solution contains 1 mg of chromium.

The solution can be kept for up to 12 months in a refrigerator at $(4 \pm 3) ^\circ C$ but shall be warmed to room temperature prior to use.

It is also possible to use a commercial standard solution with a certified Cr(VI) concentration that can be connected to national standards. Observe the expiry date or recommended shelf life stated by the manufacturer.

5.5 Chromium(VI) standard solution

Pipette 1 ml of solution (5.4) into a 1 000 ml volumetric flask and make up to the mark with extraction solution (5.1). One ml of this solution contains 1 μg of chromium.

The solution can be kept for up to one week in a refrigerator at $(4 \pm 3) ^\circ C$ but shall be warmed to room temperature prior to use.

A stock solution of hexavalent chromium at this concentration level is an alternative available commercially.

5.6 Argon or nitrogen, oxygen-free

Preference should be given to argon as an inert gas instead of nitrogen because argon has a higher specific mass than air.

5.7 Distilled or deionised water, with a specific conductivity not higher than 0,2 mS/m at 25 °C.

5.8 Magnesium chloride hexahydrate ($\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$)

Dissolve 85,4 g in a 100 mL volumetric flask, dilute with water (5.7), close and mix thoroughly.

6 Apparatus and materials

Usual laboratory equipment and, in particular, the following.

6.1 Suitable mechanical orbital shaker, $(100 \pm 10) \text{ min}^{-1}$.

6.2 Conical flask, of capacity 250 ml, with stopper.

6.3 Aeration tube and flow meter, suitable for a flow rate of $(50 \pm 10) \text{ ml/min}$.

6.4 pH meter, with glass electrode

6.5 Membrane filter, 0,45 μm pore size [polytetrafluoroethylene (PTFE) or polyamide 66].

6.6 Common laboratory glassware and pipettes.

6.7 Vacuum device, suitable for filtration of extraction solution, mobile phase, and sample extracts

6.8 Ion-exchange chromatograph, with UV or visible detector or high performance liquid chromatography (HPLC) with anion-exchange column and UV or visible detector. It is recommended a photo diode array detector (DAD).

6.9 Analytical balance, capable of weighing to 0,1 mg.

6.10 Syringe membrane filters of nylon of 0,45 μm for filtration of standards.

6.11 Suitable vials for HPLC.

7 Procedure

7.1 Sampling and preparation of samples

Sample in accordance with CEN/TS 17702-1. If sampling in accordance with CEN/TS 17702-1 is not possible, details about the sampling shall be given in the test report.

Preparation of samples in accordance with CEN/TS 17702-2. For products that may decompose or react when heated, grinding must be carried out in order to prevent heating.

7.2 Preparation of analytical solution

Weigh (6.9) approximately $(2 \pm 0,1) \text{ g}$ of sample of plant biostimulant to the nearest 0,001 g. Pipette 100 ml of degassed solution (5.1) into a 250 ml conical flask (6.2). Displace oxygen by passing oxygen-free argon (or nitrogen) (5.6) into the flask for 5 min with a volume flow of $(50 \pm 10) \text{ ml/min}$. Remove the aeration tube (6.3), add the sample of plant biostimulant and close the flask with a stopper. Record the extract volume as V_0 .

Shake the conical flask with the sample of plant biostimulant for $30,0 \pm 0,5 \text{ min}$ on a mechanical orbital shaker at $(100 \pm 10) \text{ min}^{-1}$ (6.1) at room temperature to extract the chromium(VI).

Shake the suspension in a smooth circular movement to keep the sample of plant biostimulant from adhering to the wall of the flask and avoid shaking faster than specified.

Immediately after completing the 30 min of extraction, filter the contents of the conical flask through a membrane filter into a glass or plastic vessel with lid. Centrifugation can be used as an alternative to the filtration. Check the pH of the solution. The pH of the solution shall be between 7,0 and 8,0. If the pH of the solution is not within this range, start the complete procedure again.

Consider using a smaller sample mass, if the pH is not between 7,0 and 8,0. In this case, the quantification limit will be increased.

Transfer an aliquot of the filtered extract into a vial (6.11). Instrumental determination of chromium(VI) should be performed as soon as possible and no later than 60 min after the extraction phase.

If the sample is expected to contain a significant amount of chromium(III), 1 ml of magnesium chloride solution (5.8) may be added before displacing oxygen into the 250 ml volumetric flask (6.2) containing the 100 ml of the extraction solution (5.1).

7.3 Chromatographic conditions

Determination of chromium(VI) is performed using the ion chromatographic technique. As the instrumental equipment of the laboratories may vary, no specific applicable instructions can be provided for analysis. However, the operating parameters and examples of the ion chromatographic analysis for chromium(VI) listed in Annexes A and B have been successfully tested and used. Annex A determines chromium(VI) by direct detection of chromate peak at 372 nm. Annex B determines chromium(VI) after a post-column reaction with 1,5-diphenylcarbazide by measuring the absorption peak at 540 nm.

Record the injection volume as V_M and record the area of the chromate peak as A .

7.4 Calibration

The content of chromium(VI) in the sample of plant biostimulant is determined with an external standard calibration.

Prepare calibration solutions from the standard solution (5.5). The chromium(VI) concentration in these solutions should cover the expected range of measurement.

Plot a suitable calibration curve by using at least five standards, diluting a proper volume of standard solution (5.5). Pipette the given volumes of standard solution (5.5) into 10 ml volumetric flasks. Make up to volume with the extraction solution (5.1), mix well, filter (6.10) and transfer a suitable aliquot volume into a vial (6.11).

For example, calibration levels may be prepared as specified in Table 1.

Table 1 — Calibration levels preparation

| | | | | | |
|---|---------------------------|------|------|------|------|
| Volume of the standard solution (5,5) (ml) | 0,50 | 1,00 | 2,00 | 3,00 | 5,00 |
| Final volume (ml) | 10 ml in volumetric flask | | | | |
| Concentration of hexavalent chromium (µg/l) | 50 | 100 | 200 | 300 | 500 |

Transfer an aliquot to a suitable vial (6.11) corresponding for the chromatography system (6.8).

Inject the standards in the chromatographic system (6.8). Introduce the same volume for each standard. It is recommended to inject equal volume for samples. Record the volume injected as V_C in μl .

Plot the chromium(VI) concentrations in micrograms of Cr per millilitre ($\mu\text{g/ml}$) against the measured areas of the peaks of chromate. Plot the chromium(VI) concentration on the x-axis and the area on the y-axis.

7.5 Determination of the recovery rate

The determination of the recovery rate is important to provide information about possible matrix effects which can influence the results.

Spike an aliquot of the solution obtained in 7.2 with a suitable volume of chromium(VI) solution to increase the chromium(VI) concentration by 10 mg/kg. Inject the same volume of this solution as the volume injected in the calibration (recording the area as A_s).

Spike an aliquot of the extraction solution (the same volume as that taken before of the solution obtained in 7.2) with a suitable volume of chromium(VI) solution to increase the chromium(VI) concentration by 10 mg/kg, so that the final volume of this solution is the same as that of the above spiked solution with chromium(VI) solution. Inject the same volume of this solution as the volume injected in the calibration (recording the area as A_{st}).

The area of the chromate peak of these solutions shall be within the range of the calibration curve, otherwise repeat the procedure using a smaller aliquot. The recovery rate shall be between 80 % and 120 %.

NOTE If the added chromium(VI) is not detected or significantly lower than the expected values, this is an indication that the plant biostimulant contains reducing agents. This leads to the conclusion that this plant biostimulant has no chromium(VI) content (below detection limit).

8 Calculation and expression of results

8.1 Calculation of chromium(VI) content

$$w_{Cr(VI)} = \frac{(A - b) \times V_0 \times V_C}{V_M \times m \times F} \quad (1)$$

where

- $w_{Cr(VI)}$ is the mass fraction, expressed in milligrams per kilogram (mg/kg), of soluble chromium(VI) in the plant biostimulant;
- A is the area of the peak of chromate in the chromatogram of the extract of the sample;
- F is the gradient of calibration curve (y/x), expressed in millilitres per microgram ($\text{ml}/\mu\text{g}$);
- b is the intercept of calibration curve (y/x);
- m is the mass of the sample of plant biostimulant taken, expressed in grams (g);
- V_0 is the extract volume of the sample, expressed in millilitres (ml);
- V_C is the injection volume in the calibration, expressed in microlitres (μl);
- V_M is the injection volume in the sample analysis, expressed in microlitres (μl).

Results are based on dry matter.

$$w_{Cr(VI)-dry} = w_{Cr(VI)} \times D \quad (2)$$

where D is the factor for conversion to dry matter:

$$D = \frac{100}{100 - w} \quad (3)$$

where w is the mass fraction of the volatile matter determined using CEN/TS 17704 with another piece of sample, expressed as a percentage.

8.2 Recovery rate (according to 7.5)

$$\eta = \frac{A_s \times (V_1 + V_2) - A \times V_1}{A_{st} \times (V_1 + V_2)} \times 100$$

where

- η is the recovery rate, expressed in percent (%);
- V_1 is the volume of sample solution in the spiked solution, expressed in millilitre (ml);
- V_2 is the volume of chromate standard in the spiked solution, expressed in millilitre (ml);
- A_s is the area of chromate peak of sample solution after adding chromium(VI) as determined in (7.5);
- A is the area of chromate peak in the original sample as determined in (7.3);
- A_{st} is the area of chromate peak of extraction solution after adding chromium(VI) as determined in (7.5).

8.3 Expression of results

The chromium(VI) content is given in milligrams per kilogram (mg/kg) rounded to the nearest 0,1 mg. The content is based on dry matter. The volatile matter, determined according to CEN/TS 17704, is given in percent (%) rounded to the nearest 0,1 %.

9 Test report

The test report shall include the following information:

- a) the chromium(VI) content(s) obtained from 8.1 to the nearest 0,1 mg/kg;
- b) a reference to this document, i.e. CEN/TS 17703:20XX;
- c) a description of the sample tested and details about sampling (7.1), if necessary;
- d) a brief description of the chromatographic technique (i.e. direct detection technique or whether a post-column reaction was used);
- e) the volatile matter of the plant biostimulant in percent (%) to the nearest 0,1 %;
- f) the recovery rate in percent (%);
- g) details of any deviations from the procedure.

Annex A (informative)

Chromatographic conditions for direct detection method

A.1 General

As the instrumental equipment of the laboratories may vary, no generally applicable instructions can be provided for the ion chromatographic analysis. The following parameters have been successfully tested and used.

The method used should be verified using the recovery rate determination (7.5).

A.2 Example of ion chromatographic conditions

A.2.1 Mobile phase reagents

All reagents used shall have at least analytical grade purity.

A.2.1.1 Anhydrous ammonium sulfate, $(\text{NH}_4)_2\text{SO}_4$ (CAS: 7783-20-2).

A.2.1.2 Sodium hydroxide, NaOH (CAS:1310-73-2).

A.2.1.3 Mobile phase stock solution

Dissolve 33,00 g of anhydrous ammonium sulphate and 0,40 g of sodium hydroxide in a volumetric flask and make up to 1 000 ml with water (5.7). This solution is 250 mmol in ammonium sulphate and 10 mmol in sodium hydroxide. Its pH is 8,2. From this solution it is prepared weekly the eluent for chromatography (A.2.1.4). The shelf life is up to four months at 4 °C.

A.2.1.4 Mobile phase

Transfer 100 ml of eluent stock solution (A.2.1.3) into a 1 000 ml volumetric flask and make up to the mark with water (5.7). This solution is 25 mmol in ammonium sulphate and 1 mmol in sodium hydroxide. Check that pH is $8,0 \pm 0,2$. Filter the solution through a membrane filter. The shelf life is up to one week at room temperature.

A.2.2 Instrumental conditions

- Column oven: 30 °C
- Mobile phase: 25 mmol ammonium sulphate and 1 mmol sodium hydroxide (A.2.1.4)
- Column: Anion-exchange column (polymethacrylate resin with quaternary ammonium functional groups), $4,6 \times 75$ mm, with 1 mm pre-column
- Range of wavelength (only for DAD): record the UV spectrum in the range 200 nm – 550 nm
- Wavelength of extracted chromatogram: 372 nm
- Flow rate: 0,9 ml/min
- Injection volume: 50 μl

FprCEN/TS 17703:2021 (E)

- Run time of chromatogram: 5 min
- Equilibrate between injections: 6 min

A DAD diode array detector allows the reliable confirmation of chromate identity by comparing the UV spectrum of the detected peak with a standard chromate spectrum.

Annex B (informative)

Chromatographic conditions for method with post-column reaction

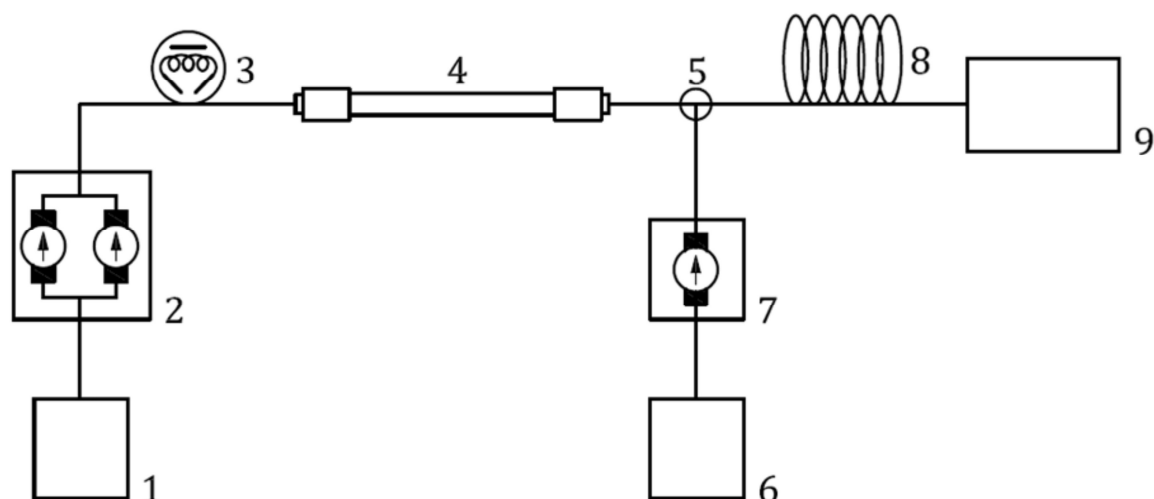
B.1 General

As the instrumental equipment of the laboratories may vary, no generally applicable instructions can be provided for the ion chromatographic analysis. The following parameters have been successfully tested and used.

The method used should be verified using the recovery rate determination (7.5).

B.2 Chromatographic system and apparatus required

The ionic chromatography method with post column reaction is summarized in Figure B.1.



Key

- 1 mobile phase
- 2 LC pump
- 3 injection loop
- 4 analytical column
- 5 zero dead volume tee
- 6 post column reagent
- 7 post column reagent pump
- 8 reaction coil
- 9 detector (MWD or DAD)

Figure B.1 — Diagram of a system for ionic chromatography with post column reaction

The chromium(VI) is analysed using an analytical column packed with an anion exchange stationary phase.

Post-column reagent, containing 1,5-diphenylcarbazide, is added between the column and the reactor coil with the help of a zero dead volume tee.

The reaction coil ensure the proper mixing of the eluent from the column and the post column reagent and the chromium(VI) in solution oxidizes 1,5-diphenylcarbazide to 1,5-diphenylcarbazone. This give a red/violet complex with chromium, which can be quantified at 540 nm with the help of multiple wavelength detector (MWD) or a diode array detector (DAD).

B.2.1 Two suitable liquid chromatography (LC) pumps. One is used to deliver the mobile phase in the system, the other is used to deliver the post column reagent before the reaction coil.

B.2.2 Autosampler or manual injection valve equipped with a sample loop for the injection of a sample.

B.2.3 Thermostated column compartment.

B.2.4 Analytical column packed with an anion exchange stationary phase.

B.2.5 Zero dead volume tee.

B.2.6 Suitable reaction coil.

B.2.7 Detector, either MWD or DAD with the capability to detect at 540 nm.

NOTE In order to maintain the inertness of the configuration, the column and all the capillaries (including the injection loop) are in PEEK.

The use of a guard column is highly recommended in order to extend the life span of the column. A guard column in PEEK packed with polystyrene-divinylbenzene particles is applicable.

B.3 Example of analytical conditions

B.3.1 Mobile phase and post column reagents

All reagents used shall have at least analytical grade purity.

B.3.1.1 Ammonium sulfate, $(\text{NH}_4)_2\text{SO}_4$ (CAS: 7783-20-2).

B.3.1.2 Ammonium hydroxide, NH_4OH (CAS: 1336-21-6) as 28 % NH_3 in water.

B.3.1.3 1,5-Diphenylcarbazide, $\text{C}_{13}\text{H}_{14}\text{N}_4\text{O}$ (CAS: 140-22-7).

B.3.1.4 Methanol, CH_3OH (CAS: 67-56-1).

B.3.1.5 Sulphuric acid, H_2SO_4 (CAS: 7664-93-9) at 98 % purity.

B.3.2 Preparation of the mobile phase

Dissolve $(33,0 \pm 0,1)$ g of ammonium sulphate (B.3.1.1) and 8,0 ml of ammonium hydroxide (B.3.1.2) in a 1 000 ml volumetric flask, fill to the mark with distilled water (5.7).

B.3.3 Preparation of post column reagent

In a 1 000 ml volumetric flask, dissolve 28 ml of sulphuric acid (B.3.1.5) in about 500 ml of distilled water (5.7) and let it stand cooling.

During this time, dissolve $(0,50 \pm 0,01)$ g of 1,5-diphenylcarbazide (B.3.1.3) in 100 ml of methanol (B.3.1.4).

When the acidic solution is cooled, stirring with a magnetic stirrer and mix the diphenylcarbazide solution with the acidic solution and fill to the mark with water (5.7).

B.3.4 Instrumental conditions

- Analytical column: Anion exchange column with alkyl quaternary ammonium as functional group. Length: 250 mm. Internal diameter: 4 mm
- Guard column of length 35 mm and internal diameter 4 mm
- Reaction coil volume: 750 μ l
- Injection volume: 100 μ l
- Mobile phase flow rate: 1,5 ml/min
- Post column reagent flow rate: 0,5 ml/min
- Run time: 10 min

Bibliography

- [1] Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 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 and repealing Regulation (EC) No 2003/2003
- [2] EN ISO 17075-2:2017, *Leather - Chemical determination of chromium(VI) content in leather - Part 2: Chromatographic method (ISO 17075-2:2017)*
- [3] CEN/TS 17724, *Plant biostimulants - Terminology*

Smlouva o dílo ILS/Service contract ILS

ČAS-UKZUZ SA / CEN / GROW / EFTA / 564 / 2020-03

Příloha 2 / Annex 2

Nabídky předložené ILSA týkající k výzvam č. 3 a ověřená zpráva

**Tender submitted by ILSA
related to call no. 3 and validated selection report**

To the kind attention of the
Secretariat of CEN/TC 455/WG4
Mr Stefan Krebs
Czech Standardization Agency (ČAS)

Arzignano, 10th January 2022

Object: Consultation for the validation for the method in FprCEN/TS 17703 “Plant biostimulants – Determination of chromium (VI)” (Proficiency test provider for one inter-laboratory studies) as part of the European Commission Standardisation Request M/564 to the European Committee for Standardisation referring to the EU fertilising products in support of Regulation (EU) 2019/1009 of the European Parliament and of the council

Dear Mr Stefan Krebs,

I am writing to apply for the recruitment of a proficiency test provider for the validation of the method related to the determination of chromium (VI) in plant biostimulants within the European Working Group CEN/TC 455/WG4 “Other safety parameters”.

During more than 10 years, Ilsa laboratory has been participating to inter-laboratory studies concerning the determination of several parameters in matrices such as fertilizers and plant biostimulants. Ilsa laboratory has granted for accreditation according to UNI EN ISO IEC 17025 since 2015. Ilsa's staff has a good expertise in developing and validating new methods of analysis, while being well trained and familiar with the determination of total and hexavalent chromium.

Ilsa will also take advantage of the partnership of UNICHIM, Institution federated to the Italian Standardisation body (UNI) and granted for ISO 17043 accreditation as a proficiency test Provider for more than ten years.

Moreover the working groups acting as mirror groups of CEN/TC 455, 260 and 233 WGs are officially set up and operating at UNICHIM.

For the above reasons, together with the huge and deep experience that UNICHIM will offer within their partnership, Ilsa is suitable for managing the inter-laboratory studies for the validation of the method for the determination of chromium (VI) in plant biostimulants.

ILSA and UNICHIM agree for a total fee for UNICHIM of 15000 €.

Please find enclosed the following documents, required by the Call For Tender:

- The application form (filled and signed);
- Annex 1 - Curriculum Vitae of Mr. Alfonso Iannone, laboratory manager of Ilsa and contact person for this call for tenders;
- Annex 2 - Scheme demonstrating the supply of the results for the inter-laboratory studies;
- Annex 3 - Declaration of honour for Ilsa SpA.

Following, the details of the contact person in relation to the submission of the bid:

Alfonso Iannone
c/o ILSA S.p.A. - Via Quinta Strada, 28 - 36071 Arzignano (VI) - Italy
Phone: e-mail:

Best regards.

Paolo Girelli
CEO of Ilsa SpA

Alfonso Iannone

c/o IL SA S.p.A., Via Quinta Strada, 28, 36071 Arzignano (VI) - Italy



Date of birth 23 Aug 1958 | Nationality Italian

Laboratory Manager

ILSA S.p.A., Arzignano (VI) (Italy)

- Development of new analytical methods, purchase and maintenance of laboratory equipment, quality control of raw materials and products. Participation to inter-laboratory studies and validation of methods. Excellent knowledge in the analytical techniques available in ILS laboratory: elemental analysis, ICP, HPLC, UV-Vis spectrophotometry, GC-MS, ionic chromatography. ILS laboratory has been accredited according to EN ISO 17025 since May 2015 (Laboratory nr. 1529).

July 2006 - Aug. 2010

R&D Manager

O.R.V. Manufacturing, Camignano di Brenta (VI) (Italy)

- Management of the research team, collaboration with other company functions (technical section, production department, quality assurance and sales division).

1987 - 2004

Research Technologist

Montefibre SpA, Acerra (NA) (Italy)

- Coordination of a research team, development of new analytical methods (HPLC, GC, UV-Vis and IR spectroscopy, thermal analysis, electron microscopy).

1984

Five year degree in Chemistry

EQF level 7

Università degli Studi di Napoli "Federico II", Napoli (Italy)

Since 1985

Member of Chemists Order

Chemist order is an Italian organization which comprises all the members of the same profession; the members, which can be also self-employed, must abide by specific regulations of the order, which are related to the exercise of the profession, the lifelong learning and the ethical code of conduct.

Mother tongue(s)

Italian

Other language(s)

| UNDERSTANDING | | SPEAKING | | WRITING |
|---------------|---------|--------------------|-------------------|---------|
| Listening | Reading | Spoken interaction | Spoken production | |
| B2 | B2 | B1 | B1 | B2 |

Levels: A1/A2: Basic user - B1/B2: Independent user - C1/C2 Proficient user

Common European Framework of Reference for Languages

Communication skills

- Good communication skills.
- Excellent relational skills.

Organisational/ managerial skills

- Good organisational skills.
- Good team-leading skills.

Job-related skills

- Excellent organisational skills of laboratory tests..

Digital skills

| SELF-ASSESSMENT | | | | |
|------------------------|------------------|------------------|------------------|------------------|
| Information processing | Communication | Content creation | Safety | Problem solving |
| Independent user | Independent user | Independent user | Independent user | Independent user |

Levels: Basic user - Independent user - Proficient user

[Digital competences - Self-assessment grid](#)

- Good command of Office suite (word processor, spread sheet, presentation software)

Annex 2: Supply of the results of the inter-laboratory studies

| Test provider: Ilisa SpA | | | | | |
|---|--|-----------------------|---------------------|------------|--|
| Call no. 3: Proficiency test providers - Determination of Cr(VI) | | | | | |
| | | | | | |
| Plant biostimulants - CEN TC 455/WG 4 | | | | | |
| Other safety parameters (WI: 455011) | | | | | |
| | | | | | |
| Deadline (expected) | Project phase | Start Date (proposed) | End Date (proposed) | Staff days | Planned activities |
| 02/06/2020 | Start of standardization project | | | | |
| 02/01/2022 | Start of interlaboratory studies | 10/01/2022 | 31/01/2022 | 1,0 | Reception of the draft test method for chromium(VI) determination from the WG4 project leader. Preparation of a validation plan and confirmation in WG4. |
| | Purchase of samples of biostimulant | 25/01/2022 | 20/02/2022 | 2,5 | Selection of common products on the market which can be used for sampling. |
| | Purchase of chromium(VI) standards for spiking | 25/01/2022 | 20/02/2022 | 1,0 | Identification and purchase of certified chromium(VI) standards for spiking of samples. |
| | Spiking of samples of plant biostimulants | 15/02/2022 | 15/03/2022 | 4,0 | Samples of plant biostimulants will be spiked with certified standards of chromium(VI). |
| | Stability tests | 01/03/2022 | 31/05/2022 | 5,0 | Stability tests will be performed to check that the concentration of Cr(VI) in sample is constant during shipping, storage and validation trials. |
| | Homogeneity tests | 01/03/2022 | 31/05/2022 | 5,0 | Execution of homogeneity tests to determine that samples can be used for validation trials. |
| | Identification of participating laboratories | 15/02/2022 | 30/04/2022 | 4,0 | Participating laboratories will be identified in order to perform the validation trials. |
| | Preparation of validation trials | 15/05/2022 | 15/06/2022 | 3,0 | Instruction of the participating laboratories. |
| | Sample packing and shipping | 01/06/2022 | 30/06/2022 | 1,5 | Distribution of samples to the participating laboratories for the inter-laboratories tests. |
| | Validation trials (participating laboratories) | 15/06/2022 | 15/08/2022 | 2,0 | If necessary, participating laboratories will be assisted while performing tests. |
| | Collection of data | 01/08/2022 | 31/08/2022 | 2,0 | Collection of results from the participating laboratories. |
| | Statistical analysis of data | 15/08/2022 | 10/09/2022 | 4,0 | Review and evaluation of results from the participating laboratories. |
| | Validation reporting | 01/09/2022 | 15/09/2022 | 2,0 | Preparation of the validation report. |
| 02/10/2022 | Release of inter-laboratory studies | 10/09/2022 | 30/09/2022 | 1,0 | Presentation of the inter-laboratory studies and discussion in WG4. Supply of data for the Annex of the hEN "Results of a validation study". |
| 02/11/2022 | Support to WG4 Project Leader and Convenor with HAS consultant | 01/10/2022 | 02/11/2022 | 2,0 | Support WG4 Project Leader and Convenor with drafting and progress reporting and evaluation of the comments of WG4 experts and the HAS Consultant. |

NOTES:

The supply of results of the inter-laboratory studies (ILS) related to the validation of the method for the determination of Cr(VI) will be planned in detail in accordance with the requests and needs of the WG4 Project Leader and Convenor. However, a proposal about the schedule of the supply of ILS is included in the attached scheme (annex 2). The table has been realised considering the process and the timing expected for the process of TS/hEN drafting. The expected deadlines are reported in the first column of the table, while the activities provided by Ilisa's laboratory staff are explained in the following columns, together with the proposed start and end dates.

Annex 2
Application form

**Consultation for
the validation of methods
FprCEN/TS 17703 “Plant biostimulants - Determination of chromium(VI)”
(Proficiency test providers for one inter-laboratory study)**

**as part of the European Commission Standardisation Request M/564
to the European Committee for Standardisation referring to the
EU fertilising products in support of Regulation (EU) 2019/1009
of the European Parliament and of the Council**

A- Contact details of the Applicant (laboratory)

| | |
|---|---|
| Name of the Proficiency test provider: | ILSA SpA |
| Address: | Via Quinta Strada, 28 36071 Arzignano (VI) - Italy |
| Contact person: | Alfonso Iannone |
| Phone: | |
| Email address: | |

B- Project leader for the proficiency test and his Curriculum Vitae (maximum 4 pages A4)

Designated person: Mr Alfonso Iannone, manager of the laboratory of Ilsa SpA (CV in Annex 1). Activities related to collection of data, statistical evaluation, validation reporting executed and/or supervised by UNICHIM, institution federated to the Italian standardisation body (UNI).

C- Information on the costs of the validation

Total costs of the tender: 60.000,00 EUR

Please provide an estimation of the costs for:

| | |
|---|-------------|
| Sample purchase | 2.000,00 € |
| Element standards for spiking | 3.000,00 € |
| Sample packing and shipping | 1.000,00 € |
| Statistical evaluation (service) | 3.000,00 € |
| Preparation of Validation trial | 6.000,00 € |
| Technical assistance – Validation | 5.000,00 € |
| Validation reporting | 1.000,00 € |
| Laboratory service (homogeneity testing) | 24.000,00 € |
| Laboratory service (participating laboratories) | 15.000,00 € |

D- Please demonstrate compliance with the selection criteria (acc. Annex 1)

| | |
|--|--|
| 1. PROFILE | - |
| a) Institutional background | - |
| <i>Ion-exchange chromatograph, with UV or visible detector with the capability to fulfil the chromatographic conditions according to FprCEN/TS 17703 Annex A</i> | Ilsa laboratory has been equipped with an Ion-exchange chromatograph with UV-Visible detector since December 2020. The instrument is capable to fulfil the chromatographic conditions according to FprCEN/TS 17703 Annex A. |
| <i>High performance liquid chromatography (HPLC) with anion-exchange column and UV or visible detector with the capability to fulfil the chromatographic conditions according to FprCEN/TS 17703 Annex B</i> | Ilsa laboratory has been equipped with a high-performance liquid chromatograph with anion-exchange column and UV-Visible detector since 2008. The instrument is capable to fulfil the chromatographic conditions according to FprCEN/TS 17703 Annex B. |
| Staff for sample pretreatment, spiking and homogenization available | <p>Ilsa Spa is an Italian company which has been manufacturing products for agriculture since 1956. In 2005 the company realised a research centre with a chemical laboratory equipped for performing a full range of analysis for quality controls of raw materials, fertilisers and plant biostimulants. There are 5 persons working in the laboratory, which are periodically trained and updated according to the last technologies and standards available for the sector. In the laboratory proper equipment for pre-treatment and homogenization of samples is available: for liquid samples bead mills or high-pressure homogenizers may be used, while for solid samples blade grinders may be utilised. Furthermore, ovens and sieves with various mesh sizes may be used, if necessary. Liquid solutions and solid reactants containing certified amount of chromium (VI) have already been used for trials of spiking, as well as a list of qualified suppliers is available to the laboratory for the purchase of certified materials.</p> <p>Spiking of plant biostimulants with chromium (VI) might be a difficult task, as many products contain significant amounts of organic matter which may reduce the hexavalent form of chromium to the trivalent one. Therefore, next to homogeneity tests, stability trials must be performed. It is probable that a period of stabilisation of the samples must be considered before proceeding with the analysis of chromium (VI). Spiking will be performed using certified reactants, which will be added to liquid and/or solid plant biostimulants available on the market.</p> <p>Ilsa Laboratory has been accredited according to EN ISO 17025 since 2015 for 5 parameters. Ilsa aims to add chromium (VI) to the list of accredited parameters when the EN standard will be ready. Ilsa laboratory is managed by a specific software that support the activity of staff, collect all data and allows to keep the traceability of all samples that are analysed. Evaluation of data may be performed using specific software for statistic which are normally available to laboratory staff and periodically updated by IT service.</p> <p>Ilsa laboratory has been participating to national ILS since 2010 for many parameters (both quality parameters and safety parameters) normally tested in organic and organo-mineral fertilisers and in plant biostimulants. These national ILS are organised by UNICHIM, which is a federated entity of UNI, the Italian standardization body.</p> <p>For the organisation of the Interlaboratory-studies (ILS) related to the determination of chromium (VI) in plant biostimulants, Ilsa</p> |

| | |
|--|--|
| | <p>will take advantage of the support of UNICHIM for the following steps of ILS:</p> <ul style="list-style-type: none"> - Definition of protocol of preparation of test materials and analytical control of their chemical and physical characteristics - Check of the requisites of homogeneity and stability of test materials according to the criteria of ISO 13528 and ISO Guide 35 - preparation of the instructions to the laboratories for the execution of tests - collection of results from participant laboratories - statistical evaluation of the results of ILS - co-operation with the project leader in the preparation of the final validation report of the test methods <p>UNICHIM is a proficiency test Provider ISO 17043 accredited by ACCREDIA (the Italian National Accreditation Body)</p> |
| b) Personal background | - |
| Expertise knowledge of the validated method and validation procedures | <p>Ilsa's laboratory staff has been participating to ILS since 2011 and has also been pursuing validation of internal methods of analysis. Therefore, laboratory staff has a good knowledge of validation procedures. Some members of the staff are also members of UNI, the Italian standardisation body and periodically participate to meetings related to ILS, validation of methods and evaluation of new TS.</p> <p>As regards the proposed draft for the determination of chromium (VI), the project leader and the expert of the specific TS/hEN are Ilsa's employees, which may facilitate the communications among the persons involved in the whole project.</p> <p>UNICHIM, which will supervise the activities organised by Ilsa, has a huge expertise in validation procedures as UNICHIM is the Italian National organization (federated to UNI) for the development of Test Standards and Methods in chemistry.</p> <p>The working groups operating in UNICHIM include the majority of experts in Italy in the specific fields while officially representing the mirror groups of CEN/TC 455, 260 and 233.</p> |
| Competence in statistics | <p>Ilsa's staff has a good knowledge in statistics, especially concerning the evaluation of accuracy (trueness and precision) repeatability and reproducibility of the analytical results of a standard measurement method, according to ISO 5725-2.</p> <p>This competence was mainly achieved with specific training during the ISO 17025 accreditation process.</p> <p>In any case, verification of the requisites of test materials (homogeneity, stability) and statistical evaluation of the ILS's data, are planned to be performed by UNICHIM, according to protocols reported in the ISO 17034, ISO Guide 35 and ISO 13528.</p> |
| b) Management competences. Experience or ability to: | - |
| <ul style="list-style-type: none"> • present complex issues in the given context as a definition in an understandable way | <p>Ilsa laboratory staff has always been requested to support all the other department of the company providing the requested information and facilitating the communication in an understandable way. Part of the activities of the laboratory is to prepare technical reports, scientific dossiers, technical sheets of products, research posters and to deliver presentations to clients, sales agents or other stakeholders. Therefore, it is essential for all the staff to be able to present complex issues in an</p> |

| | |
|--|---|
| | understandable way. |
| <ul style="list-style-type: none"> • coordinate a group of experts, ensure the consolidation and integration of all contents provided by the participant of ILS | The laboratory team is supervised by a laboratory manager, who is responsible for all the performed activities. The staff is composed of persons with different backgrounds and expertise. The ILSA laboratory manager has the right attitude to coordinate the staff and to support its activities. Laboratory Manager and the staff both regularly participate in meetings with other experts, focused on activity planning and research projects. |
| 2. SUPPLY OF RESULTS OF ILS | - |
| a) Understanding of tasks and responsibilities | - |
| Number of days of work | 40 days of work, which will be split among all staff working in the laboratory. A detailed plan containing the breakdown of tasks and responsibilities is reported in Annex 2. |
| Comprehension of the scope | <p>Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 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.</p> <p>According to article 13 of this regulation, all EU fertilising products must be in compliance with harmonized standards published in the Standardisation Requests (Ref. M/564). Therefore, the European Committee for Standardisation (CEN) is in the process of drafting Technical Specifications (TSs), followed by harmonized European standards (hENs) for specific parameters.</p> <p>In particular, the Technical Committee for plant biostimulants (CEN/TC 455) is asked to prepare 33 CEN TSs and 33 hENs. Work is expected to start in October 2020 and the estimated duration is 4 years. One of the TS and hEN to be developed regards the determination of chromium (VI).</p> <p>A Project Leader and an Expert have been nominated to develop the hEN by April 2024. Up to date, a draft of the method has been prepared and is under examination of experts and HAS consultant. As soon as a TS will be drafted, specific inter-laboratory studies (ILS) will be organized to validate the proposed method. Ilsa is aware that it is crucial to be able to supply the ILS in time and to collaborate with WG4 Project Leader and Convenor.</p> |
| Quality of the proposal (clarity, match with description given...) | <p>The interlaboratory-studies to validate the method for the determination of chromium (VI) in plant biostimulants are part of a bigger project of standardisation that started in 2020 and has to be completed by April 2024.</p> <p>Ilsa is aware that it is crucial to be able to supply the ILS in time and to collaborate with WG4 Project Leader and Convenor, in order to guarantee that all the deliverables will be supplied on time.</p> |
| b) Ability to supply ILS results at specified target dates | - |
| Calendar of the proposal vs expected | The activities for the validations of the method for the determination of chromium (VI) in plant biostimulants will be developed as reported in Annex 2. Ilsa staff will start to organise the inter-laboratory studies (ILS) by the end of January 2022 and will manage all the activities in order to release the results of ILS |

| | |
|---|---|
| | by the end of September 2022, in order to be able to support WG4 Project Leader and Convenor in the discussion with the HAS consultant in the following months. |
| 3. VALIDATION AND STANDARDIZATION OF THE METHODS | - |
| a) Experience in validation and development of methods | - |
| Number of projects | <p>ILSA laboratory is accredited according to EN ISO 17025 since May 2015. The accredited tests are:</p> <ul style="list-style-type: none"> - Total nitrogen (internal method); - Total nitrogen (UNI EN 15750 Method A); - Ammoniacal nitrogen (UNI EN 15475); - Nitric nitrogen (UNI EN 15476); - Total carbon (Internal method). <p>All these methods, according to ISO 17025 requirements, have been validated. Next to these accredited methods, Ilsa laboratory, since 2005 (year of realisation of the research centre), has been equipped with various instruments which have been allowing to determine many analytical parameters in fertilisers and plant biostimulants and Ilsa staff regularly develops new methods, depending on the requests of the regulatory office, R&D department, industrial department and the market. Up to date, the validated methods used in Ilsa laboratory are 38.</p> <p>UNICHIM is a standardization body and at the same time an accredited provider for the organization of Proficiency Testing. The organization of PTs is a tool used by UNICHIM in the validation process of standardized methods. The standardization activity is carried out through working groups in which numerous Italian experts participate and in particular the mirror groups of Working Groups of CEN TC 455, 260 and 233 are also present.</p> |
| Number of years | <p>Ilsa realised the research centre with the chemical laboratory in 2005. Therefore, Ilsa staff has been working with analytical methods (including validation and development of methods) for more than 15 years.</p> <p>UNICHIM has been validating and standardising methods since its foundation in 1947.</p> |
| b) Experience in European and/or International standardization | - |
| Number of projects | <p>ILSA experience in the International Standardization is developed in the Working Group set up at UNICHIM also acting as mirror group of WG's of CEN TC 455, 260 and 233.</p> <p>Ilsa SpA can count on the support of its regulatory office for all the activities related to European standardization. Up to date, the regulatory team is involved in 6 European Experiences:</p> <ol style="list-style-type: none"> 1. 2017 – ongoing → Member of UNI-CT406-GL04 on plant biostimulants; 2. 2018 – ongoing → Representative of UNI in the CEN/TC455; 3. 2018 – ongoing → member of CEN/TC455/WG2 (Claims); 4. 2018 – ongoing → member of CEN/TC455/WG4 (Other safety parameters); 5. 2019 – ongoing → inside CEN/TC 455/WG4, project leader and expert for the PWI for the determination of chromium(VI) in plant biostimulants. 6. 2018 – ongoing → member of CEN/TC455/WG5 (Labelling and denominations). <p>Furthermore, the regulatory staff participate at the EBIC's internal</p> |

| | |
|-----------------|---|
| | Committees created to support CEN's activities for standardization relating to plant biostimulants (specifically EBIC's Standardization Task Force and Agricultural Committee). |
| Number of years | 3 years |

E- Proposal how to supply the results of the validation in time, breakdown of tasks and responsibilities (in a separate document)

F- Declaration and signature

Hereby we certify that all documents provided are veracious and in conformity with reality. We also certify that I had no conflict of interest by submitting the present offer.

Organisation applying: ILSA SpA 

Signature:

(print name here) 
PAOLO GIRELLI
CEO of Ilsa SpA

Date : 10/01/2022

Declaration on honour on exclusion criteria

The undersigned PAOLO GIRELLI, representing:

| | |
|---|--|
| <i>(only for natural persons)</i> himself or herself | <i>(only for legal persons)</i> the following legal person: |
| ID or passport number: (‘the person’) | Full official name: Ilsa SpA Official legal form: Public limited company (società per azioni) Statutory registration number: Full official address: Via Roveggia, 31 – 37136 Verona (VR), Italy VAT registration number: (‘the person’) |

The person is not required to submit the declaration on exclusion criteria if the same declaration has already been submitted for the purposes of another award procedure of the same contracting authority¹, provided the situation has not changed, and that the time that has elapsed since the issuing date of the declaration does not exceed one year.

In this case, the signatory declares that the person has already provided the same declaration on exclusion criteria for a previous procedure and confirms that there has been no change in its situation:

| Date of the declaration | Full reference to previous procedure |
|-------------------------|--------------------------------------|
| / | / |

I – SITUATION OF EXCLUSION CONCERNING THE PERSON

| (1) declares that the above-mentioned person is in one of the following situations: | YES | NO |
|---|--------------------------|-------------------------------------|
| (a) it is bankrupt, subject to insolvency or winding-up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under Union or national law; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (b) it has been established by a final judgement or a final administrative decision that the person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the applicable law; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (c) it has been established by a final judgement or a final administrative decision that the person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following: | | |
| (i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

¹ The same EU institution, agency, body or office.

| | | |
|---|--------------------------|-------------------------------------|
| eligibility or selection criteria or in the performance of a contract or an agreement; | | |
| (ii) entering into agreement with other persons with the aim of distorting competition; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (iii) violating intellectual property rights; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (iv) attempting to influence the decision-making process of the contracting authority during the award procedure; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (d) it has been established by a final judgement that the person is guilty of any of the following: | | |
| (i) fraud, within the meaning of Article 3 of Directive (EU) 2017/1371 and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (ii) corruption, as defined in Article 4(2) of Directive (EU) 2017/1371 or active corruption within the meaning of Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997, or conduct referred to in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in other applicable laws; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (iii) conduct related to a criminal organisation, as referred to in Article 2 of Council Framework Decision 2008/841/JHA; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (iv) money laundering or terrorist financing, within the meaning of Article 1(3), (4) and (5) of Directive (EU) 2015/849 of the European Parliament and of the Council; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (v) terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (vi) child labour or other offences concerning trafficking in human beings as referred to in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (e) it has shown significant deficiencies in complying with the main obligations in the performance of a contract or an agreement financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by a contracting authority, the European Anti-Fraud Office (OLAF) or the Court of Auditors; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (f) it has been established by a final judgment or final administrative decision that the person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95; | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (g) it has been established by a final judgment or final administrative decision that the person has created an entity under a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office, central administration or principal place of business. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

| | | |
|---|--------------------------|-------------------------------------|
| (h) (<i>only for legal persons</i>) it has been established by a final judgment or final administrative decision that the person has been created with the intent provided for in point (g). | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| (i) for the situations referred to in points (c) to (h) above the person is subject to: <ul style="list-style-type: none"> i. facts established in the context of audits or investigations carried out by the European Public Prosecutor's Office after its establishment, the Court of Auditors, the European Anti-Fraud Office (OLAF) or the internal auditor, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body; ii. non-final judgments or non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics; iii. facts referred to in decisions of entities or persons being entrusted with EU budget implementation tasks; iv. information transmitted by Member States implementing Union funds; v. decisions of the Commission relating to the infringement of Union competition law or of a national competent authority relating to the infringement of Union or national competition law; or vi. decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

II – SITUATIONS OF EXCLUSION CONCERNING NATURAL OR LEGAL PERSONS WITH POWER OF REPRESENTATION, DECISION-MAKING OR CONTROL OVER THE LEGAL PERSON AND BENEFICIAL OWNERS

Not applicable to natural persons, Member States and local authorities

| | | | |
|--|--------------------------|-------------------------------------|--------------------------|
| (2) declares that a natural or legal person who is a member of the administrative, management or supervisory body of the above-mentioned legal person, or who has powers of representation, decision or control with regard to the above-mentioned legal person (this covers e.g. company directors, members of management or supervisory bodies, and cases where one natural or legal person holds a majority of shares), or a beneficial owner of the person (as referred to in point 6 of article 3 of Directive (EU) No 2015/849) is in one of the following situations: | YES | NO | N/A |
| Situation (c) above (grave professional misconduct) | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Situation (d) above (fraud, corruption or other criminal offence) | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Situation (e) above (significant deficiencies in performance of a contract) | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Situation (f) above (irregularity) | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Situation (g) above (creation of an entity with the intent to circumvent legal obligations) | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Situation (h) above (person created with the intent to circumvent legal obligations) | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| | | | |
|---------------------|--------------------------|-------------------------------------|--------------------------|
| Situation (i) above | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
|---------------------|--------------------------|-------------------------------------|--------------------------|

III – SITUATIONS OF EXCLUSION CONCERNING NATURAL OR LEGAL PERSONS ASSUMING UNLIMITED LIABILITY FOR THE DEBTS OF THE LEGAL PERSON

| | | | |
|---|--------------------------|--------------------------|-------------------------------------|
| (3) declares that a natural or legal person that assumes unlimited liability for the debts of the above-mentioned legal person is in one of the following situations: | YES | NO | N/A |
| Situation (a) above (bankruptcy) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Situation (b) above (breach in payment of taxes or social security contributions) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

IV – GROUNDS FOR REJECTION FROM THIS PROCEDURE

| | | |
|---|--------------------------|-------------------------------------|
| (4) declares that the above-mentioned person: | YES | NO |
| Was previously involved in the preparation of the procurement documents used in this award procedure, where this entailed a breach of the principle of equality of treatment including distortion of competition that cannot be remedied otherwise. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

V – REMEDIAL MEASURES

If the person declares one of the situations of exclusion listed above, it must indicate measures it has taken to remedy the exclusion situation, thus demonstrating its reliability. This may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines or of any taxes or social security contributions. The relevant documentary evidence which illustrates the remedial measures taken must be provided in annex to this declaration. This does not apply for situations referred in point (d) of this declaration.

VI – EVIDENCE UPON REQUEST

Upon request and within the time limit set by the contracting authority the person must provide information on natural or legal persons that are members of the administrative, management or supervisory body or that have powers of representation, decision or control, including legal and natural persons within the ownership and control structure and beneficial owners.

It must also provide the following evidence concerning the person itself and the natural or legal persons on whose capacity the person intends to rely, or a subcontractor and concerning the natural or legal persons which assume unlimited liability for the debts of the person:

For situations described in (a), (c), (d), (f), (g) and (h), production of a recent extract from the judicial record is required or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of establishment of the person showing that those requirements are satisfied.

For the situation described in point (b), production of recent certificates issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the person is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions. Where any document described above is not issued in the country concerned, it may be replaced by a sworn statement made before a judicial authority or notary or, failing that, a solemn statement made before an administrative authority or a qualified professional body in its country of establishment.

The person is not required to submit the evidence if it has already been submitted for another award procedure of the same contracting authority². The documents must have been issued no more than one year before the date of their request by the contracting authority and must still be valid at that date.

The signatory declares that the person has already provided the documentary evidence for a previous procedure and confirms that there has been no change in its situation:

| Document | Full reference to previous procedure |
|----------|--------------------------------------|
| / | / |

The above-mentioned person must immediately inform the contracting authority of any changes in the situations as declared.

The above-mentioned person may be subject to rejection from this procedure and to administrative sanctions (exclusion or financial penalty) if any of the declarations or information provided as a condition for participating in this procedure prove to be false.

Full name
PAOLO GIRELLI

Date
10/01/2022

Signature


² The same institution or agency.

Selection report of the proficiency test provider for the interlaboratory studies (ILS) for the project **"Determination of chromium (VI) of CEN/TC 455/WG 4 Other safety parameters as part of the European Commission Standardisation Request M/564 to the European Committee for Standardisation referring to the EU fertilising products in support of Regulation (EU) 2019/1009 of the European Parliament and of the Council**

Dipl. Ing. Stefan Krebs
Czech agency for standardization
Biskupský dvůr 1148/5
110 00 Prague 1
Czech Republic
E-mail:
Phone :

Prague, 4 March 2022

As no laboratory was selected for the proficiency test provider for the inter-laboratory studies on FprCEN/TS 17703 "Plant biostimulants – Determination of chromium(VI)" during the open call for tenders (see Annex 1), a consultation was closed on 2022-01-10 (see Annex 2).

The table below presents the applications received for the position (with the chosen one in blue).

Table 1 – Applications received

| Work items | Proficiency test provider for the Interlaboratory study (ILS) for the method in | Position in the consultation (Table 1) | Applicant |
|------------|---|--|---------------------------|
| 455011 | Plant biostimulants – Determination of chromium (VI) | 3 | Candidate B – ILSA Spa |

The Selection Committee for all this position was composed of:

- Alessia GAETANI PM – CEN-CENELEC Management Centre
- Benoit PLANQUES – Chairman of CEN/TC 455
- Stefan KREBS – Secretary of CEN/TC 455/WG 4
- Florian Miroslav – Convenor of CEN/TC 455/WG 4 (on 2022-02-08 selection committee only)

The selection process followed the procedure as described in the Procurement rules FPA 2014.

1. Stages of the Selection Process

The Selection Committee held a web conference on 2022-02-08 to examine the application received to the consultation (see paragraph 2).

Each member of the Selection Committee declared absence of conflict of interest to participate in the selection of the project leader (see Annex 5).

2. Evaluation of submitted applications

All applications fulfilled the formal criteria mentioned in clause 6 of the consultation and were received within the deadline stipulated. For the detailed evaluation see clauses 2.1 – 2.6.

Each member of the Selection Committee allocated a score per sub criteria between 1-5 points, then the total percentage was calculated based in the established selection criteria presented in the quotation (see Annex 4).

2.1 Position 3: Proficiency test provider for ILS "Determination of chromium (VI)"

➤ Candidate B: ILSA Spa (see Annex 3)

The table below summarises the evaluation of the only application received by the Selection Committee against the criteria and requirements stipulated in the consultation.

| Elements that need to be addressed in the tender | Presence of the requested element | Reference to the annexes | Comments of the Selection Committee |
|--|-----------------------------------|--------------------------|--|
| Completed application form (Annex 2 of the consultation) | Yes | Annex 3.4 | |
| A CV of the project leader of the validation (ILS). | Yes | Annex 3.1 | |
| A specified proposal how to supply the results of the validation in time, breakdown of tasks and responsibilities. | Yes | Annex 3.2 | The price includes 21 % of VAT, which will be paid by UNMZ/CAS |
| A signed declaration, by which the candidate certifies not to be in one of the situations described in the exclusion criteria ¹ . | Yes | Annex 3.3 | |

Timeframe and financial information from the application:

Timeframe needed for the work: 11 months (starting on 2.6. 2021)

| | |
|---|-------------|
| Total costs for this tender | 60 000,00 € |
| Sample purchase | 2 000,00 € |
| Element standards for spiking | 3 000,00 € |
| Sample packing and shipping | 1 000,00 € |
| Statistical evaluation (service) | 3 000,00 € |
| Preparation of Validation trial | 6 000,00 € |
| Technical assistance – Validation | 5 000,00 € |
| Validation reporting | 1 000,00 € |
| Laboratory service (homogeneity testing) | 24 000,00 € |
| Laboratory service (participating laboratories) | 15 000,00 € |

General remarks from the Selection Committee:

As mentioned by ILSA Spa, the selection committee noted the difficulty on the method and agreed on their concern. Nevertheless the selection committee considered that ILSA Spa has now the capacity to carry the tests on with the support of UNICHIM. According to the selection meeting and the score applied, ILSA Spa was selected.

Result of the consideration

After careful consideration of the received application, the Selection Committee decided to select ILSA Spa for Interlaboratory tests for the position of the proficiency test provider acc. to call 3.

The candidate was selected with a total score of 87.8 % (see Annex 4).

¹ https://ec.europa.eu/oib/doc/tenders-submission-guide_en.pdf, 2.2.3.2

3. Results of the Selection Committee deliberations

After a careful consideration of the received application, the Selection Committee decided to select the following candidate:

| Position No. | Applicant |
|---------------------|------------------|
| 3 | ILSA Spa |

Alessia GAETANI
PM CEN-CENELEC Management Centre

Benoit PLANQUES
Chairman of CEN/TC 455

Electre GUILLIER
Secretary of CEN/TC 455

Stefan KREBS
Secretary of CEN/TC 455/WG 4

ANNEXES:

- Annex 1: Selection report for of the proficiency test provider for the interlaboratory studies (ILS) for the project "Determination of chromium (VI) of CEN/TC 455/WG 4 Other safety parameters
- Annex 2 : Consultation
- Annex 3: Application Candidate B on consultation
- Annex 4 : Selection Committee members' evaluation of application on consultation (Table grades and criteria)
- Annex 5: Declarations of non-conflict of interest
- Annex 6: Minutes of the meeting of the Selection Committee

Smlouva o dílo ILS/Service contract ILS

ČAS-UKZUZ SA / CEN / GROW / EFTA / 564 / 2020-03

Příloha 3 / Annex 3

EC Povinný obsah faktury

EC Mandatory content of an invoice

Content of an invoice – 2016-03-14 – EC DG GROW

Supplier information

| Compulsory information for an invoice for all or majority of member states | Compulsory information for an invoice for certain member states only |
|--|---|
| Full name of the supplier | |
| Full address of the supplier | |
| The VAT identification number of the supplier in accordance with ISO Standard under which he supplied the goods and services (for all member states except Bulgaria) | For Bulgaria, Cyprus, Germany, Greece, Romania, Slovakia: Tax reference number of the supplier , in other cases, where your country refrains from allocating a VAT identification number in accordance with ISO Standard for certain cases |
| | For Belgium, Cyprus, Denmark, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Netherlands, Poland Portugal, Romania, Slovenia: <ul style="list-style-type: none"> • Full name of tax representative (if any) of the supplier where the person liable to pay VAT is the tax representative, • Full address of the tax representative (if any) of the supplier where the person liable to pay VAT is the tax representative, • VAT identification number of the fiscal representative in accordance with ISO Standard (if any) of the supplier where the person liable to pay the VAT is the tax representative. |

Customer information

| Compulsory information for an invoice for all or majority of member states | Compulsory information for an invoice for certain member states only |
|--|--|
| Full name of the customer | |
| Full address of the customer | |
| The VAT identification number of the customer in accordance with ISO Standard where the customer is liable to pay the VAT or in case of intra-Community supplies (except for Bulgaria) | For Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Germany, Greece, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovak Republic, Spain: The VAT identification number of the customer in other cases than general rule. |
| | For Belgium, Cyprus, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Netherlands, Poland, Portugal, Romania, Slovenia: <ul style="list-style-type: none"> • Full name of the tax representative (if any) of the customer where the person liable to pay VAT is the tax representative • Full address of the tax representative (if any) of the customer where the person liable to pay VAT is the tax representative • VAT identification number of the fiscal representative (if any) the customer where the person liable to pay the VAT is the tax representative |

Content information

| Compulsory information for an invoice for all or majority of member states | Compulsory information for an invoice for certain member states only |
|---|--|
| <ul style="list-style-type: none"> Sequential number based on one or more series, which uniquely identifies the invoice Date of issue of the invoice Date on which the supply of goods or services was made or completed or the date on which the payment on account was made before any supply, insofar as that a date can be determined and differs from the date of issue of the invoice (except for Bulgaria) Description/nature of the goods or services Quantity of the goods supplied or the extent and nature of the services rendered Price per unit (excluding VAT) (except for Germany) Any discounts or rebates, not included in the unit price (except for Austria) Taxable amount per VAT rate or exemption VAT rate(s) applied Total VAT amount | <p>Where an exemption is involved or where the customer is liable to pay the tax further information should be given accordingly :</p> <ul style="list-style-type: none"> Reference to the appropriate provision of the Sixth directive for: <p>Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France Germany, Ireland Lithuania Luxembourg, Netherlands, Poland, Portugal, Sweden, Spain, UK</p> <p>OR</p> <ul style="list-style-type: none"> Reference to the corresponding national provision for: <p>Czech Republic, Greece, Hungary, Italy, Latvia, Malta, Slovak Republic, Slovenia, Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France Germany, Ireland Lithuania Luxembourg, Netherlands, Poland, Portugal, Sweden, Spain, UK</p> <p>OR</p> <ul style="list-style-type: none"> Any indication that the supply is exempt or subject to the reverse charge procedure for: <p>Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France Germany, Greece, Hungary, Ireland, Luxembourg, Malta, Portugal, Romania, Netherlands, Poland, Sweden, Spain, UK</p> |
| | <p>For Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France Greece, Hungary, Ireland, Italy, Malta, Netherlands, Latvia, Lithuania, Luxembourg, Poland, Portugal, Romania, Slovak Republic, Slovenia, Sweden, Spain, UK:</p> <p>Obligation to mention the amounts on the invoice in the local currency</p> |
| | <p>For Bulgaria, Greece, Hungary, Lithuania, Poland, Romania, UK:</p> <p>Obligation to issue the invoice in one of the official languages</p> |

WARNING: *the issuer of the invoice should follow the VAT legislation in force at the time the invoice is issued*