

Contract No. ►	CN-3711
Council/EDQM contact point for contract matters ►	XXX
Council/EDQM contact point for technical matters ►	XXX



ACT OF ENGAGEMENT (Framework Co-operation Agreement)

This Act of Engagement lays down the terms and conditions of the agreement between the OMCL (as described below), and the Council of Europe - European Directorate for the Quality of Medicines & HealthCare (EDQM), hereinafter Council/EDQM¹ for the provision of the Sampling and Testing Programmes of Centrally Authorised Products

The signature of this Act of Engagement by the OMCL alone shall not constitute or imply any sort of contractual commitment on the part of the Council/EDQM. This Act shall become contractually binding only **upon signature by a Council/EDQM authorised staff member** (see Section B).

The OMCL shall:

1. Fill in the below sections **Contact details of the OMCL** and **Bank details**. Ensure that the "Name" of the OMCL and the "Account holder" are the same.
2. Sign the Act of Engagement (See Section B) and send a signed copy to the Council/EDQM (See Contact person details above).

OMCL information	Legal personality ² ►	☐ Natural person	☒ Legal person	☐ Consortium
	Name and address ►	Státní ústav pro kontrolu léčiv/State Institute for Drug Control Šrobárova 48, 100 41 Praha 10		
	Representative ►	MUDr. Tomáš Boráň, Director		
	Contact person ►	XXX		
	Consortium's coordinator (for consortia only) ³ ►			
	VAT n° (if any) ►			
	Country and registration n° (if any) ►			
	Email (Contact person) ►	XXX		
Phone number (Contact person) ►	XXX			

¹ Which has its seat 7 allée Kastner, CS 30026, F-67081, Strasbourg, France

² The Council/EDQM reserves the right to reserve documentary evidence.

³ In case of the OMCL being a consortium, this field – as well as all remaining fields in this table – must include information concerning the coordinator only.

Bank details	Account holder ⁴ ▶	Státní ústav pro kontrolu léčiv/State Institute for Drug Control		
	IBAN n° (if available) ▶	XXX	Full bank account n° (for non-IBAN countries only) ▶	
	Bank name and Branch ▶	Česká národní banka	BIC/SWIFT Code ▶	XXX
	Bank Address ▶	Na Příkopě 864/28, Praha 1, postcode 11503, Czech Republic	Account currency ⁵ ▶	CZK - Czech Koruna

⁴ The name of the OMCL and the name of the account holder must coincide. In case of the OMCL being a consortium, the name of the consortium's coordinator and the name of the account holder must coincide.

⁵ The OMCL ensures that the indicated bank account can receive payments in the currency of the contract.

A. Terms of reference/Table of unit fees

Preamble

Regulation (EC) n° 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (EMA) stipulates that "EMA shall be responsible for co-ordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products" (Article 55). In particular, EMA shall undertake the co-ordination of the monitoring, under practical conditions of use, of medicinal products which have been authorised within the Union (Article 57.1(c)), and the "co-ordination of the supervision of the quality of medicinal products placed on the market by requesting testing of compliance with their authorised specifications by an Official Medicines Control Laboratory (OMCL) or by a laboratory that a Member State has designated for that purpose" (Article 57.1(r)).

The Council/EDQM is the hosting organisation of the European Network of Official Medicines Control Laboratories including EEA member states (EEA OMCLs Network) and is in the exclusive position to co-ordinate the work of the above-mentioned laboratories with regard to the common activities of the OMCL network. The EMA and the Council/EDQM have, therefore, concluded a co-operation agreement entrusting the Council/EDQM with the task of co-ordinating the organisation and execution of the individual Sampling and Testing Programmes of Centrally Authorised Products (CAP) and/or Active Pharmaceutical Ingredients (APIs) of such products by OMCLs in conformity with the procedures and templates of these Programmes, as agreed between the EMA, EDQM and the OMCL Network.

Nature of Services

- Annual Programme: yearly sampling and testing programme performed during the duration of the Agreement on Centrally Authorised Products selected each year using a risk-based approach by the EMA secretariat, in collaboration with the EMA Scientific Committees and agreed with the Council/EDQM and CAP Advisory Group. On a yearly basis, it will be decided by both parties whether each of the biological products selected within the annual programme for the following year will be tested in one or two OMCLs, depending on the proposed testing parameters and the knowledge available in the network. The decision will also be based on previous experience gained and discussed at the CAP Advisory Group. The rates applied will differ depending on whether the biological product is tested in 1 or 2 OMCLs (refer to the Contributions section).

Insulin products shall be tested by a single OMCL and shall be charged as chemical products.

The ad-hoc sampling and testing activities requested on finished products and/or Active Pharmaceutical Ingredients described below are encompassed under the Annual Programme for financial and reporting purposes:

- ad-hoc sampling and testing of Centrally Authorised Products requested by EMA following a Committee for Medicinal Products for Human Use (CHMP)/Committee for Medicinal Products for Veterinary Use (CVMP) decision.
 - Ad-hoc sampling and testing performed on Active Pharmaceutical Ingredients (API) upon request by a member state or EMA whenever samples are available from a manufacturing site where there is a suspicion of Good Manufacturing Practices (GMP) non-compliance.
 - ad-hoc testing of finished product(s) as an exceptional part of the Parallel Distribution Programme to be performed if there are concerns on the authenticity of the product.
- Generics Programme: yearly sampling and testing programme performed on Centrally Authorised Generic Products with the same or different dosage forms and containing the same Generic INNs for which ideally there are developed common test methods available from previous testing experience in the OMCL network, selected by the EMA in collaboration with the Council/EDQM and CAP Advisory Group.
 - Biosimilars Programme: one Biosimilar Product Group will be selected every year taking into consideration the capacities of the OMCL Network and upon agreement of both Council/EDQM and EMA. The Biosimilar Product Group agreed to be tested is documented in the minutes of the CAP Advisory Group meeting. For each Biosimilar Products Group, the activities can include development of common tests methods, product sampling

and testing (collectively 'biosimilars project'). Therefore, several biosimilars projects are expected to run simultaneously in different phases. Each biosimilars project should be completed within a three-year period.

- Parallel Distribution Programme: yearly programme performed on Centrally Authorised Products that are subject to parallel distribution. Each year a number of Centrally Authorised Products will be selected by the EMA in collaboration with the Council/EDQM and sampled from the parallel distribution chain. The label check will be performed on site and the authenticity of the sample will be verified by means of the scanning of the unique identifier, where possible. No testing of the finished product will be performed unless there are concerns raised on the authenticity of the product. If testing is required, the rates applicable to product testing activity will be applied.
 - Nitrosamines Programme: the purpose of this yearly programme is to test for nitrosamines presence in human medicinal products (finished product) selected on a risk based approach and randomly. The risk based product selection of this programme should be agreed between EMA, Council/EDQM and the CAP Advisory Group. If needed, other experts may be consulted for input.
1. In the framework of the procedures for each of the individual sampling and testing Programmes of Centrally Authorised Products and/or APIs of such products, the OMCL is responsible for testing the samples provided by the Council/EDQM and shall deliver the test reports in accordance with the Results Data Sheet supplied (where applicable) – as detailed in the "Individual CAP testing template" – and with the test protocol (Standard Operating Procedures [SOPs] included, where applicable). Each request to participate in a product testing will be made via an official Purchase Order from the Council/EDQM with reference to this agreement. The Purchase Order will be sent by email together with the completed "Individual CAP testing template" as included in Appendix 1. The OMCL shall acknowledge receipt and acceptance of the work by returning by email the "Individual CAP testing template" signed by the authorised person.
 2. The deadline for submitting the report to the Council/EDQM will be specified in the "Individual CAP testing template". After receipt of the Results Data Sheet and test samples, the OMCL shall duly communicate to the Council/EDQM using the acknowledgement of receipt. The OMCL shall, without delay, inform the Council/EDQM of any actual or anticipated difficulty in meeting this deadline. Where necessary, the Council/EDQM may appoint another OMCL during the course of testing. Results Data Sheets, test samples and all required reference substances relevant to the CAP testing will be sent by the Council/EDQM to the OMCL. The approximate date of shipment will be specified in the "Individual CAP testing template". This deadline will be met provided that there is no delay during the sampling phase of the product concerned.
- If a temperature monitoring device is included together with the materials sent by the Council/EDQM, this doesn't have to be returned to the Council/EDQM. The PDF report should be sent back to the Council/EDQM as per the instructions provided when samples are dispatched to the OMCL.
3. The testing report shall be of the highest possible scientific quality, prepared in accordance with the procedures and guidelines adopted by the EU/EEA OMCL network for centrally authorised products (current versions available on CAPnet). The Results Data Sheet provided by the Council/EDQM shall be completed and accompanied where necessary by graphs and printouts of the instrument used. Furthermore, it shall be ensured that testing is performed under a quality assurance system, which is in compliance or moving progressively towards compliance with the standard ISO/IEC 17025:2017, and for which assessment by external bodies can be documented.
 4. Subcontracting of CAP Sampling and Testing Program by the testing OMCL to third parties shall only be allowed on an exceptional basis (for specific individual test parameters) and on prior approval of the Council/EDQM. When subcontracting activities are approved by the Council/EDQM, this must follow the rules of good practice as laid down in ISO/IEC 17025:2017 as well as the rules defined under this Agreement.

Contributions

Contributions for testing are based on the rules for the calculation of funding for co-ordination and analysis of centrally authorised products as established by agreement between the Council/EDQM and EMA.

The Council/EDQM shall provide the testing OMCL with an appropriate contribution for the testing and reporting referred to in **Nature of Services**, and as detailed in the official purchase order and Individual CAP testing template. The financial contribution of the Council/EDQM to the testing OMCL is defined in the table below. These fees shall be annually adjusted after monitoring the inflation rate, measured by means of the Harmonised Index of Consumer Prices published by Eurostat pursuant to Regulation (EU) No 2016/792. The monitoring exercise shall take place no earlier than in 2025, and thereafter on an annual basis. Any adjustment, in line with inflation, to rates established in accordance with this Agreement shall become applicable, at the earliest, on 1 January of the calendar year following the calendar year in which the monitoring exercise took place. By way of derogation from Part C Article 6, the annual adjustment shall be communicated to the OMCL in writing in accordance with Part C Article 8, without the need of a countersigned amendment.

Fees are indicated in **EUR - Euro** without VAT. For the VAT regime to be mentioned on the invoice(s), please refer to Article 4.2 of the Legal Conditions (See Section C. below).

Type of product	Fee
Annual CAP programme / Ad-hoc testing activities*	
Chemical/pharmaceutical product and Insulins	
Product testing	€ 3.405 (<i>per product/API, per testing OMCL</i>)
Biological/veterinary immunological product⁶	
Product testing	€ 7.750 (<i>per product/API, per testing OMCL <u>if one OMCL is involved in the testing</u></i>) € 6.200 (<i>per product/API, per testing OMCL <u>if two OMCLs are involved in the testing</u></i>)
Generics CAP programme*	
Product testing	€ 7.046 (<i>per Generics INN product group</i>)
Biosimilars CAP programme*	
Product testing	€ 7.750 (<i>per product group, per testing OMCL <u>if one OMCL is involved in the testing</u></i>) € 6.200 (<i>per product group, per testing OMCL <u>if two OMCLs are involved in the testing</u></i>)
Method development fee	€ 11.743 (<i>per Biosimilar Products Group</i>)
*Additional costs might be requested – to be justified and accepted by the Council/EDQM.	

⁶ Additional exceptional payment, e.g. coverage of animal testing. Product dependent. Value to be agreed upon by EDQM on a case-by-case basis.

Type of product	Fee
Parallel Distribution Programme*	
Testing of additional parameters (when applicable)	€3.405 (per chemical product, per testing OMCL) €7.750 (per biological product, per testing OMCL <u>if one OMCL is involved in the testing</u>) €6.200 (per biological product, per testing OMCL <u>if two OMCLs are involved in the testing</u>)
Nitrosamines Programme*	
Product testing	€3.405 (per chemical product, per testing OMCL) €7.750 (per biological product, per testing OMCL <u>if one OMCL is involved in the testing</u>) €6.200 (per biological product, per testing OMCL <u>if two OMCLs are involved in the testing</u>)
*Additional costs might be requested – to be justified and accepted by the Council/EDQM.	

As per the binding cooperation agreement signed between the Council/EDQM and the EMA, financial extensions can be granted to cover exceptional costs, such as the purchase of reagents or consumable materials of special grade, not usually available in a normal OMCL environment. The OMCL shall inform the Council/EDQM that additional costs are foreseen to seek the Council/EDQM agreement before the beginning of the project; an estimation of the costs should be provided, where possible.

When applicable, the amounts of these extensions will be:

- a) Payable only when i) a complete report of acceptable quality is submitted to the Council/EDQM and ii) evidence of these exceptional costs incurred is duly documented (invoices and explanatory note) and presented to the Council/EDQM. Documented evidence shall be provided at the latest when delivering the testing report.
- b) Paid to the OMCL within 60 days of receipt of a complete report complying with the criteria for acceptance of test reports agreed by the EU/EEA OMCL Network, and of receipt of the documented evidence for the exceptional costs.

For Generics Programmes and Biosimilar programmes:

In case of re-test using the MAH method, due to an out-of-specification result obtained by testing according to the INN-Test Protocol, an extension of the contribution may be granted to the testing OMCL to cover exceptional costs.

An additional exceptional payment may be foreseen under special circumstances, e.g. coverage of animal testing, following previous written agreement by the Council/EDQM.

Duration

This Agreement takes effect as from the date of its signature by both parties and is concluded until:

31/12/2027

At the end of its initial term, the Agreement will be tacitly renewed for successive periods of 36 (thirty-six) months, unless either party notifies the other in writing of its intention to terminate the contract at the latest 6 (six) months before the renewal date. Renewal does not change or postpone any existing obligations.

B. Declaration of Agreement and Signature

I, the undersigned, acting on my own behalf or as a representative of the OMCL indicated below, hereby:

- Declare having the authority to represent the OMCL;
- Declare that the information provided to the Council/EDQM under this procedure is complete, correct and truthful.
- Acknowledge, in signing this document, that I have been notified that if any of the statements made or information provided prove to be false, the Council/EDQM reserves the right to terminate any existing contractual relations related to such statements or information;
- Express consent to any audit or verification that the Council/EDQM may initiate by any means on the information provided under this procedure;
- Declare that neither I, nor the OMCL I represent, are in any of the situations listed in the exclusion criteria below:
 - have been sentenced by final judgment on one or more of the following charges: participation in a criminal organisation, corruption, fraud, money laundering, terrorist financing, terrorist offences or offences linked to terrorist activities, child labour or trafficking in human beings;
 - are in a situation of bankruptcy, liquidation, termination of activity, insolvency or arrangement with creditors or any like situation arising from a procedure of the same kind, or are subject to a procedure of the same kind;
 - have received a judgment with res judicata force, finding an offence that affects their professional integrity or serious professional misconduct;
 - do not comply with their obligations as regards payment of social security contributions, taxes and dues, according to the statutory provisions of their country of incorporation, establishment or residence;
 - are an entity created to circumvent tax, social or other legal obligations (empty shell company), have ever created or are in the process of creation of such an entity;
 - have been involved in mismanagement of the Council/EDQM funds or public funds;
 - are or appear to be in a situation of conflict of interest;
 - are retired Council/EDQM staff members or are staff members having benefitted from an early departure scheme;
- Declare that neither I, nor the OMCL I represent, are in a situation of a conflict of interests or a potential conflict of interest in relation to this procedure. I have been notified and understand that a conflict of interests may arise, in particular, from economic interests, political or national affinities, emotional or family ties or any other type of shared relationship or interest;
- Undertake to update the Council/EDQM with significant information changes within a reasonable time. Significant information changes include, but are not limited to change of legal status, ownership, name and address, loss of licence of registration, filing bankruptcy, suspension or debarment by any national or local governmental agency or assimilated;
- Accept without any derogation all the terms of the Legal Conditions as reproduced in the present document and understand that its signature **shall constitute signature of the contract** with the Council/EDQM subject to the signature of this Act by a representative of the Council/EDQM.

For the OMCL ▼			For the Council/EDQM ⁷ ▼		
Signature	OMCL ►	Státní ústav pro kontrolu léčiv/State Institute for Drug Control		Signatory ►	XXX
	Signatory ►	MUDr. Tomáš Boráň, director		Place of signature ►	In Strasbourg
	Place of signature ►	In Prague		Date of signature ►	30 / 07 / 2024
	Date of signature ►	2 / 8 / 2024		Signature ►	XXX
	Signature ►	XXX		Signature ►	XXX

⁷ On behalf of the Secretary General of the Council/EDQM.

C. Legal Conditions

Article 1 GENERAL PROVISIONS

- 1.1 The OMCL undertakes, on the conditions and in the manner laid down by common agreement hereafter excluding any accessory verbal agreement, to provide the list of Deliverables reproduced in the Terms of reference (see Section A above) related to the present contract.
- 1.2 The present contract is composed, by order of precedence, of:
 - a) the Act of Engagement, in its entirety (cover page, Sections A and B and the present Legal Conditions and any Appendices) and
 - b) any subsequent Order.
- 1.3 Any general purchasing terms and conditions of the OMCL shall never prevail over these legal conditions. Any provision proffered by the OMCL in its documents (general conditions or correspondence) conflicting with the clauses of these legal conditions shall be deemed void, except for any clauses, which may be more favourable to the Council/EDQM.
- 1.4 For the purposes of this Contract:
 - a) "Contract" shall refer to the documents described in 1.2, above;
 - b) "Council/EDQM" shall mean the Council of Europe, the European Directorate for the Quality of Medicines & HealthCare;
 - c) "Deliverables" shall mean the services or goods as described in the Terms of reference;
 - d) "Parties" shall mean the Council/EDQM and the OMCL;
 - e) "OMCL" shall mean the legal or physical person selected by the Council/EDQM for the provision of the Deliverables. This person may equally be referred to as the "Service Provider" or the "Consultant".

Article 2 DURATION

The contract is concluded until the day specified in Section A of this Act of Engagement and takes effect as from the date of its signature by both parties. The contract may be renewed in accordance with the conditions laid down in Section A of the Act of Engagement. The Deliverables shall be executed in accordance with the timeframe indicated in the Terms of reference and in any subsequent Order form.

Article 3 OBLIGATIONS OF THE OMCL

3.1 General obligations

- 3.1.1. The OMCL bears sole responsibility for all the decisions made and the human, technical, logistic and material resources used in the context of the Contract in order to provide the Deliverables, with due respect for the Council/EDQM's needs and constraints, as contractually defined.
- 3.1.2. The OMCL recognises that it is subject to a general obligation to provide advice, including, but not limited to, an obligation to provide any relevant information or recommendations to the Council/EDQM. In this context, the OMCL shall supply to the Council/EDQM all the advice, warnings and recommendations necessary particularly in terms of quality of Deliverables, security and compliance with professional standards. The OMCL also undertakes to inform the Council/EDQM as soon as it becomes aware, during the execution of the Contract, of any initiatives and/or adopted laws and regulations, policies, strategies or action plans or any other development related to the object of the Contract.

3.2 Intellectual property rights

3.2.1. Information supplied by the Council/EDQM

Any intellectual property rights over information supplied to the OMCL by the Council/EDQM to complete the services referred to in Part A remain with the Council/EDQM. The Council/EDQM may, however, on prior application by the OMCL, authorise the OMCL to use the information supplied. When giving the OMCL such authority, the Council/EDQM will inform the OMCL of any conditions to which such use may be subject. That said, under no condition will the Council/EDQM authorise the OMCL to publish or share the information provided by the Council/EDQM under this agreement.

3.2.2. Deliverables produced under the agreement

- i) The OMCL cedes to the Council/EDQM, on an exclusive basis, throughout the entire world and for the entire duration of copyright protection all rights in the deliverables referred to in Part A. Such rights shall include in particular the right to use, reproduce, represent, publish, adapt in any form and on any kind of support, the deliverables, or any part thereof, submitted by the OMCL under the contract. The Council/EDQM reserves to exercise the above-mentioned rights for any purpose falling within its activities, in particular for the establishment of monographs and reference standards. Notwithstanding the provision above, the Council/EDQM may, on prior application by the OMCL, authorise the OMCL to use the Deliverable(s) referred to above. When giving the OMCL such authority, the Council/EDQM will inform the OMCL of any conditions to which such use may be subject.
- ii) The OMCL guarantees that use by the Council/EDQM of the items supplied under the contract and referred to in Part A will not infringe the rights of third parties. However, should the Council/EDQM incur liability as the result of any such infringement, the OMCL will compensate it in full for any damage it may suffer in consequence. Unless agreed otherwise by the Parties, any written documents prepared by the OMCL under the contract shall be written in English or French and produced on a word processing file. In case the Parties agree that a written document shall be prepared in a language other than English or French, a summary in English or French shall be included in the said document.

- iii) Unless agreed otherwise by the Parties, all written documents of more than 1,500 words shall be preceded or accompanied by a text summarising the subject and main conclusions and shall not, unless specifically required, exceed 5,000 words.
- iv) The OMCL guarantees that the Deliverables conform to the highest academic standards.
- v) Any intellectual property rights of the OMCL over methods, knowledge and information which are in existence at the date of the conclusion of the Contract and which are comprised in or necessary for or arising from the performance of the Contract shall remain the property of the OMCL. However, in consideration of the fees payable pursuant to the Contract the OMCL hereby grants the Council/EDQM a non-exclusive and free licence for the entire world and for the entire period of protection by the applicable intellectual property rights law for the use of such methods, knowledge and information insofar as they are an integral part of the Deliverable(s).
- vi) If the Deliverable(s) result(s) in the provision of a training session and provided the training materials are not the property of the Council/EDQM, the OMCL shall grant the participants in the training a non-exclusive licence for the entire world and for the entire period of protection by the applicable intellectual property rights law for their own professional use of those training materials.

3.3 Samples supplied by the Council/EDQM

Any samples supplied by the Council/EDQM may only be used for the intended purpose except upon written instruction or agreement by the Council/EDQM. If samples are necessary, the Council/EDQM shall ship them to the OMCL using an appropriate courier service at its own expense. In case of the loss of the samples during the transport the Council/EDQM shall replace the samples. The OMCL shall be responsible for the proper receipt, storage and use of the samples. The Council/EDQM shall not be liable for any damage caused by the samples' use. Any samples that remain after the execution of the contract shall be destroyed by the OMCL without further delay and the Council/EDQM shall be notified thereof.

3.4 Health and social insurance of the OMCL or its employees

The OMCL shall undertake all necessary measures to arrange for health and social insurance during the entire contract. The OMCL acknowledges and accepts in this regard that the Council/EDQM shall not assume any responsibility for any health and social risks concerning illness, maternity or accident which might occur during the performance of work under the contract.

3.5 Fiscal obligations

The OMCL undertakes to inform the Council/EDQM about any change of its status with regard to VAT, to observe all applicable rules and to comply with its fiscal obligations in:

- 1) submitting a request for payment, or an invoice, to the Council/EDQM in conformity with the applicable legislation;
- 2) declaring all fees received from the Council/EDQM for tax purposes as required in his/her/its country of fiscal residence.

3.6 Loyalty and confidentiality

- 3.5.1. In the performance of the present contract, the OMCL will not seek or accept instructions from any government or any authority external to the Council/EDQM. The OMCL undertakes to comply with the Council/EDQM's directives for the completion of the Deliverables and to refrain from any word or act that may be construed as committing the Council/EDQM.
- 3.5.2. The OMCL shall observe the utmost discretion in all matters concerning the contract, and particularly any matters or data that have been or are to be recorded that come to the OMCL's attention in the performance of the contract. Unless obliged to do so under the terms of the contract, or expressly authorised to do so by the Secretary General of the Council/EDQM, the OMCL shall refrain at all times from communicating to any person, legal entity, government or authority external to the Council/EDQM any information which has not been made public and which has come to the OMCL's notice as a result of dealings with the Council/EDQM. Nor shall the OMCL seek to gain private benefit from such information. Neither the expiry of the contract nor its termination by the Council/EDQM shall lift these obligations.

3.7 Disclosure of the terms of the contract

- 3.6.1. The OMCL is informed and gives an authorisation of disclosure of all relevant terms of the contract, including identity and price, for the purposes of internal and external audit and to the Committee of Ministers and to the Parliamentary Assembly of the Council/EDQM with a view to these latter discharging their statutory functions, as well as for the purpose of meeting the publication and transparency requirements of the Council/EDQM or its donors. The OMCL authorises the publication, in any form and medium, including the websites of the Council/EDQM or its donors, of the title of the contract/projects, the nature and purpose of the contract/projects, name and locality of the OMCL and amount of the contract/project.
- 3.6.2. Whenever appropriate, specific confidentiality measures shall be taken by the Council/EDQM to preserve the vital interests of the OMCL.

3.8 Use of the Council/EDQM's name

The OMCL shall not use the Council/EDQM's name, flag or logo without prior authorisation of the Council/EDQM.

3.9 Data Protection

- 3.9.1. Without prejudice to the other provisions of this Contract, the Parties undertake, in the execution of this Contract, to comply at all times with the legislation applicable to each of them concerning the processing of personal data.
- 3.9.2. Where the OMCL, pursuant to its obligations under this Contract, processes personal data on behalf of the Council/EDQM, it shall:
 - i) Process personal data only in accordance with written instructions from the Council/EDQM;

- ii) Process personal data only to the extent and in such manner as is necessary for the execution of the contract, or as otherwise notified by the Council/EDQM;
- iii) Implement appropriate technological measures to protect personal data against accidental loss, destruction, damage, alteration or disclosure. These measures shall be appropriate to the harm which might result from any unauthorised or unlawful processing, accidental loss, destruction, or damage while having regard to the nature of the personal data which is to be protected;
- iv) Take reasonable steps to ensure the reliability of the OMCL's employees having access to the personal data and to ensure that they have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality and thus agree to comply with the data protection obligations set out in this Contract;
- v) Obtain written consent from the Council/EDQM prior to any transfer of possession or responsibility for the personal data to any subcontractors. If the Council/EDQM chooses to authorise subcontracting, the same data protection obligations as set out in this contract shall be imposed on the subcontractor by way of a contract. The OMCL shall remain fully liable to the Council/EDQM for the performance of that subcontractor's obligations.
- vi) Notify the Council/EDQM within five working days if it receives:
 - a) a request from a data subject to have access (including rectification, deletion and objection) to that person's personal data; or
 - b) a complaint or request related to the Council/EDQM's obligations to comply with the data protection requirements.
- vii) Provide the Council/EDQM with full assistance in relation to any such request or complaint and assist the Council/EDQM to fulfil its obligation to respond to the requests for rectification, deletion and objection, to provide information on data processing to data subjects and to notify personal data breaches;
- viii) Allow for and contribute to checks and audits, including inspections, conducted or mandated by the Council/EDQM or by any authorised third auditing person. The OMCL shall immediately inform the Council/EDQM of any audit not conducted or mandated by the Council/EDQM;
- ix) Not process nor transfer personal data outside the jurisdiction of a Council of Europe Member State without the prior authorisation of the Council/EDQM and provided that an adequate level of protection is guaranteed by law or by ad hoc or approved standardised safeguards (such as binding corporate rules) in the jurisdiction of the recipient;
- x) Make available to the Council/EDQM all information necessary to demonstrate compliance with the obligations under the contract in connection with the processing of personal data and the rights of data subjects;
- xi) Upon the Council/EDQM's request, delete or return to the Council/EDQM all personal data and any existing copies, unless the applicable law requires storage of the personal data.

3.10 Parallel Activities

Where the OMCL is a natural person who is employed in parallel to this Contract, they hereby confirm that they:

- a) have been granted approval from their employer to perform paid services for the Council/EDQM under this Contract, and/or
- b) have been granted leave during the performance of their obligations under this Contract.

3.11 Other obligations

- 3.10.1. In the performance of the present contract, the OMCL undertakes to comply with the applicable principles, rules and values of the Council/EDQM.
- 3.10.2. The Staff Regulations and the rules concerning temporary staff members shall not apply to the OMCL.
- 3.10.3. Nothing in this contract may be construed as conferring on the OMCL the capacity of a Council/EDQM staff member or employee.

Article 4 FEES, EXPENSES AND MODE OF PAYMENT

4.1 Ordering

- 4.1.1. Each time a Service Request is sent, the selected OMCL undertakes to take all the necessary measures to send it **signed** to the Council/EDQM within the deadline indicated in the Terms of Reference (see Section A above).
- 4.1.2. A Service Request is considered to be legally binding when the relevant Purchase Order is sent to the OMCL.
- 4.1.3. In return for the fulfilment by the OMCL of its obligations under each Service Request, the Council/EDQM undertakes to pay the OMCL the fees as indicated in the relevant Purchase Order, in the currency specified in the Table of fees.
- 4.1.4. Amounts/Fees indicated in this Contract and in each Purchase Order are final and not subject to review.

4.2 VAT

- 4.2.1. Should the OMCL not be subject to VAT, the amount invoiced shall be net fixed amount. Should the OMCL be subject to VAT, the amount shall be invoiced as indicated in Articles 4.2.2 to 4.2.4.
- 4.2.2. Should the deliverables be taxable in France, the amount invoiced shall be VAT inclusive. For services physically carried out in France, OMCLs who do not have a French VAT number must register with the French Fiscal Authorities: Directorate for non-resident tax / sie.entreprises-etrangeres@dgfip.finances.gouv.fr / 10, rue du Centre / 93465 Noisy-le-Grand Cedex / + 33 (0)1 57 33 85 00; or, depending on the OMCL, OMCLs without a French VAT number are required to register for VAT purposes at the VAT One Stop Shop (VAT OSS) of their choice. The invoice shall indicate the total amount without taxes, the rate and the amount of the VAT and the total amount 'including all taxes'. The invoice shall also stipulate the following statement: "French VAT collected by the OMCL and paid to the One-Stop shop in [Address/Country] under the OSS identification number [No. XX]".
- 4.2.3. Should the deliverables be taxable in another EU country, and unless otherwise agreed between the Parties, the Council/EDQM will provide the OMCL with an exemption certificate prior to the signature of the contract. The exemption certificate sent by the Council/EDQM should be retained by the OMCL and presented to the relevant tax authorities to justify tax-free invoicing. In accordance with Article 2 b) of Council Directive 2001/115/EC, the following should be stated in the invoice: "*Intra-Community sale/service to an exempted organisation: Articles 143 and 151 of Council Directive*

2006/112/EC' and should indicate the final total amount excluding VAT. In case the CoE will not be in a position to provide the said certificate, the Council/EDQM will pay the invoice with VAT included.

- 4.2.4. Should the deliverables be taxable in a non-EU country, the amount invoiced will not include VAT if the local (national) legislation allows for it, or if the Council/EDQM enjoys tax exemption through other means in the country concerned. Otherwise, it shall include VAT.

4.3 Invoicing and payment

- 4.3.1. For each Order completed, and upon acceptance of the Deliverable(s) by the Council/EDQM, the OMCL shall submit an invoice or a request for payment by email to finances@edqm.eu and in the currency specified in the Table of fees, in conformity with the applicable legislation.
- 4.3.2. Before accepting the Deliverable(s), the Council/EDQM reserves the right to ask the OMCL to submit any other document or information that may serve the purpose of establishing that the Contract has been duly executed.
- 4.3.3. In the case of event organisation, the OMCL shall in any case submit any document that proves that the event took place, including but not limited to an attendance sheet broken down into half days specifying the location, date(s) and time(s) of the event(s) or activity(ies), to be individually signed by each participant and the OMCL.
- 4.3.4. The payment for the Deliverables to be paid by the Council/EDQM shall be made within 60 calendar days of submission of the invoice described in Article 4.3.1, subject to the submission of the Deliverable(s) described in the Terms of reference and its/their acceptance by the Council/EDQM.
- 4.3.5. Advance payments are subject to a written agreement between the parties, on an order by order basis, and should be paid within 60 calendar days from the date of the Purchase Order concerned.

4.4 Other expenses

- 4.4.1. In the event of the OMCL's employees being required to travel for the purposes of the contract, and provided the Terms of reference do not stipulate that the fees already include travel and subsistence expenses, the Council/EDQM undertakes, subject to its prior agreement, to reimburse travel and subsistence allowances in compliance with the Council/EDQM applicable Rules.⁸
- 4.4.2. Travel expenses referred to under 4.4.1 will be reimbursed on the basis of the rail fare (first class) or air fare (tourist class) upon presentation of an invoice on the letterhead of the relevant vouchers. Subsistence expenses (including travel expenses within the locality visited) will be reimbursed at the applicable daily rate.
- 4.4.3. In the event of the OMCL's employees being required to travel for the purposes of the contract, the duration of the OMCL's employee's travel and stays will be covered by an insurance policy with the insurers AIG EUROPE (Policy No. 9.502.001). A telephone helpline is available in case of emergency +32 2 739 9991 (EN) or +32 2 739 9990 (FR). The said insurance will cover specific risks related to travel and stay of the OMCL's employee (including medical costs related to unforeseen illness or accident, repatriation, death, cancellation of journey or flight, theft or loss of personal possessions). The insurance policy does not cover persons over 80 years of age.

Article 5 BREACH OF CONTRACT

- 5.1. In the event that:
- 1) the OMCL does not satisfy the conditions laid down in this contract or those resulting from any modifications duly accepted in writing by both parties, in accordance with the provisions of Article 6 below; or
 - 2) the Deliverables provided as referred to under Article 1.1 do not reach a satisfactory level; or
 - 3) the OMCL is in any of the situations listed in Article 11.2.
- the Council/EDQM may consider there to have been a breach of contract and may consequently refuse to pay to the OMCL the amounts referred to in Article 4.1 and Article 4.4 above.
- 5.2. In the cases described in paragraph 5.1 above, the Council/EDQM reserves further, at any moment and further to prior notification to the OMCL, the right to terminate the contract in all or in part. In case of termination, the Council/EDQM shall pay only the amount corresponding to the deliverables actually and satisfactorily provided at the time of termination of the contract and shall request reimbursement of the sums already paid for Deliverables not provided. In case of partial termination, the obligations of the parties shall endure for all deliverables which are not subject of the notification of termination.
- 5.3. The outstanding sums shall be paid to the Council/EDQM's bank account within 60 calendar days from the notification in writing by the Council/EDQM to the OMCL regarding the outstanding sums to be paid.

Article 6 MODIFICATIONS

- 6.1. The provisions of this contract cannot be modified without the written agreement of both parties. This agreement may take the form of an exchange of emails provided it is done using the contact details specified in Article 8.
- 6.2. Any modification shall not affect elements of the contract which may distort the initial conditions of the tendering procedure or give rise to unequal treatment between the tenderers.
- 6.3. This contract may not be transferred, in full or in part, for money or free of charge, without the Council/EDQM's prior authorisation in writing.
- 6.4. The OMCL may not subcontract all or part of the Deliverables without the written authorisation of the Council/EDQM. If authorised to subcontract by the Council/EDQM, the OMCL shall ensure compliance with all contractual conditions by all authorised subcontractors. The OMCL shall remain fully liable to the Council/EDQM for the performance of that subcontractor's obligations.

⁸ CM/Del/Dec(2010)1089/11.3 appendix 9 <https://rm.coe.int/rules-reimbursements-experts/1680a722b0>

Article 7 CASE OF FORCE MAJEURE

- 7.1. In the event of force majeure, the parties shall be released from the application of this contract without any financial compensation. Force majeure is defined as including the following: major weather problems, earthquake, strikes affecting air travel, attacks, a state of war, health risks or events that would require the Council/EDQM or the OMCL to cancel the contract.
- 7.2. In the event of such circumstances each party shall be required to notify the other party accordingly in writing, within a period of 7 calendar days.

Article 8 COMMUNICATION BETWEEN THE PARTIES

- 8.1. The Contact point within the Council/EDQM is indicated on the cover page of the Act of Engagement (See page 1 above).
- 8.2. The OMCL can be reached through the means indicated in the Act of Engagement (see page 1 above).
- 8.3. Any communication is deemed to have been made when it is received by the receiving party, unless the Contract refers to the date when the communication was sent.
- 8.4. Electronic communication is deemed to have been received by the receiving party on the day of successful dispatch of that communication, provided that it is sent to the addressees listed in paragraphs 1 and 2 above. Dispatch shall be deemed unsuccessful if the sending party receives a message of non-delivery. In this case, the sending party shall immediately send again such communication to any of the other addresses listed in paragraphs 1 and 2 above. In case of unsuccessful dispatch, the sending party shall not be held in breach of its obligation to send such communication within a specified deadline, provided the communication is dispatched by another means of communication without further delay.
- 8.5. Mail sent to the Council/EDQM using the postal services is considered to have been received by the Council/EDQM on the date on which it is registered by the department identified in paragraph 1 above.
- 8.6. Formal notifications made by registered mail with return receipt or equivalent, or by equivalent electronic means, shall be considered to have been received by the receiving party on the date of receipt indicated on the return receipt or equivalent.

Article 9 ACCEPTANCE

The provision of Deliverables referred to in this contract shall be the subject of a written acceptance. If acceptance is refused, the Council/EDQM shall inform the OMCL accordingly, giving reasons, and may set new modalities for the provision of the Deliverables. If acceptance is refused again, the Council/EDQM may terminate the Contract in whole or in part without previous notice and without paying any financial compensation.

Article 10 CONSORTIUM

- 10.1. The OMCLs have full responsibility for carrying out and complying with the terms of the contract.
- 10.2. The OMCLs are jointly and severally liable. If a OMCL fails to implement its part of the contract, the other OMCLs become responsible for the carrying out of the Deliverables, unless the Council/EDQM expressly relieves them of this obligation.
- 10.3. In case of breach of contract, where applicable, the Council/EDQM will claim back the amounts paid but that were not due under the contract. The coordinator of the consortium is fully liable for repaying the debts of the consortium; even if it has not been the final recipient of those amounts.
- 10.4. The internal roles and responsibilities of the OMCLs are divided as follows:
 - 10.4.1 The OMCLs must designate a coordinator.
 - 10.4.2 Each OMCL must:
 - (i) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the performance of the contract, change in legal status or technical, organisational or ownership situation, circumstances affecting the award of the contract or compliance with the requirements of the contract;
 - (ii) submit to the coordinator in good time:
 - any other documents or information required by the Council/EDQM under the contract, unless the contract requires the OMCL to submit this information directly;
 - any information requested by the coordinator in order to verify the state of performance of the Deliverables under the contract, the proper implementation of the contract and compliance with the other obligations under the contract.
 - (iii) give the other OMCLs access to any pre-existing industrial and intellectual property rights needed for the performance of the contract and compliance with the obligations under the Agreement.
 - 10.4.3 The coordinator must:
 - (i) monitor that the Deliverables are carried out timely and properly, in accordance with the terms of the contract;
 - (ii) act as the intermediary for all communications between the OMCLs and the Council/EDQM (in particular, providing the Council/EDQM with the information described in Article 10.4.2(ii) immediately), unless the agreed otherwise by the Parties;
 - (iii) request and review any documents or information required by the Council/EDQM and verify their completeness and correctness before passing them on to the Council/EDQM;
 - (iv) before starting performance of the contract, submit this list of pre-existing rights (Article 10.4.2(iii)) to the Council/EDQM.
 - (v) submit the Deliverables to the Council/EDQM in accordance with the timing and terms of the contract;
 - (vi) Payments shall be made by the Council/EDQM to the coordinator. Payments to the coordinator shall discharge the Council/EDQM from its payment obligation. The coordinator must ensure that the distribution of the payments between the OMCLs are made without unjustified delay.

The coordinator may not subcontract the above-mentioned tasks.
- 10.5. The OMCLs must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written 'consortium agreement' between the beneficiaries, which may cover:
 - a) internal organisation of the consortium;
 - b) distribution of the Council/EDQM payment(s);

- c) additional rules on rights and obligations related to pre-existing rights and results (including intellectual and industrial property rights), specifying the owner and persons that have a right of use;
 - d) settlement of internal disputes;
 - e) liability, indemnification and confidentiality arrangements between the OMCLs.
- The consortium agreement must not contain any provision contrary to the contract.

Article 11 CHANGES IN THE OMCL'S SITUATION OR STANDING

- 11.1. The OMCL shall inform the Council/EDQM without delay of any changes in their address or legal domicile or in the address or legal domicile of the person who may represent them.
- 11.2. The OMCL shall also inform the Council/EDQM without delay:
 - a) if they are involved in a merger, takeover or change of ownership or there is a change in their legal status;
 - b) where the OMCL is a consortium or similar entity, if there is a change in membership or partnership.
 - c) if they are sentenced by final judgment on one or more of the following charges: participation in a criminal organisation, corruption, fraud, money laundering, terrorist financing, terrorist offences or offences linked to terrorist activities, child labour or trafficking in human beings;
 - d) if they are in a situation of bankruptcy, liquidation, termination of activity, insolvency or arrangement with creditors or any like situation arising from a procedure of the same kind, or are subject to a procedure of the same kind;
 - e) if they have received a judgment with *res judicata force*, finding an offence that affects their professional integrity or serious professional misconduct;
 - f) if they do not comply with their obligations as regards payment of social security contributions, taxes and dues, according to the statutory provisions of their country of legal domicile;
 - g) if they are or are likely to be in a situation of conflict of interests.
 - h) if they are or if their owner(s) or executive officer(s), in the case of legal persons, are included in the lists of persons or entities subject to restrictive measures applied by the European Union (available at www.sanctionsmap.eu).

Article 12 SECURITY AND ACCESS TO THE COUNCIL/EDQM

If the performance of the present contract requires access to the Council/EDQM's premises or information system by the OMCL's employees, the OMCL undertakes to carry out a background check on the employees assigned to the Council/EDQM in order to prevent and control risks to the security of the Council/EDQM's staff, property and information. The OMCL undertakes to provide only employees whose background does not demonstrate incompatibility with the performance of duties within the Council/EDQM.

Article 13 DISPUTES

- 13.1. Any dispute regarding this Contract shall - failing a friendly settlement between the Parties - be submitted to arbitration.
- 13.2. The Arbitration Board shall be composed of two arbitrators each selected by one of the parties, and of a presiding arbitrator, appointed by the other two arbitrators; in the event of no presiding arbitrator being appointed under the above conditions within a period of six months, the President of the Tribunal Judiciaire of Strasbourg shall make the appointment.
- 13.3. Alternatively, the parties may submit the dispute for decision to a single arbitrator selected by them by common agreement or, failing such agreement, by the President of the Tribunal Judiciaire of Strasbourg.
- 13.4. The Board referred to in paragraph 2 of this Article or, where appropriate, the arbitrator referred to in paragraph 3 of this Article, shall determine the procedure to be followed.
- 13.5. If the parties do not agree upon the law applicable the Board or, where appropriate, the arbitrator shall decide *ex aequo et bono* having regard to the general principles of law and to commercial usage.
- 13.6. The arbitral decision shall be binding upon the parties and there shall be no appeal from it.

Article 14 ADDRESSES AND BANK DETAILS OF THE PARTIES

The bank details of the OMCL are indicated in the Act of Engagement. The bank details of the Council/EDQM are the following:

Bank address: F-67075 Strasbourg Cedex, France
 Bank name: Société Générale Strasbourg
 Code IBAN: XXX
 SWIFT Code: XXX

APPENDIX 1

INDIVIDUAL CAP TESTING AGREEMENT TEMPLATE | Choose an item. |

Agreement No.:	CN-
OMCL Name – Country:	 Choose an item.
Name of authorised person:	
Purchase Order No.:	
CAP Project Number - Name	CAP 20 / -
Reference of the data sheets supplied to the OMCL:	PA/PH/CAP ()
Deadline for report submission by the OMCL:	 Click here to enter a date.
Shipment of data sheets, test samples and all required reference substances relevant to the testing⁹:	Semester, Year
Payment <i>(As per Appendix 2)</i>:	
Choose an item. Total	0,00 € 0,00 € Hit F9 to calculate total €
Additional information:	

Reception date at the OMCL: | Click here to enter a date. |

Signature of authorised person:

X

⁹ Provided that there is no delay during the sampling phase of the product concerned.