

## **ECHA/2011/25**

**Multiple framework contract  
with re-opening of competition  
for the provision of scientific support services**

**Open procurement procedure  
Contract notice: OJ 2011/S 98-159742**

**Specifications  
model contract**

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## 1. THE SERVICES (TECHNICAL SPECIFICATIONS)

### 1.1. BACKGROUND

#### 1.1.1. *The European Chemicals Agency and REACH*

Established on 1 June 2007, the European Chemicals Agency (hereinafter referred to as ECHA or the Agency) is at the heart of the new regulatory system for chemicals in the European Union set out in the REACH Regulation (REACH)<sup>1</sup>. It has also been playing an important role in the new Regulation on the Classification, Labelling and Packaging of substances and mixtures (CLP)<sup>2</sup> since 2008. These legislative acts are directly applicable in all Member States without the need for their transposition into national law. The purpose of the REACH and CLP system is to ensure a high level of protection of human health and the environment and to facilitate the free circulation of substances within the single market. In addition, REACH promotes alternative methods to animal tests to assess the hazards of chemicals, and enhances competitiveness and innovation. REACH is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle. More information about the Agency, its structure and activities can be found on the Agency website<sup>3</sup>.

ECHA's mission is to manage all REACH and CLP tasks by carrying out or co-ordinating the necessary activities, in order to ensure a consistent implementation at Community level and to provide Member States and the European institutions with the best possible scientific advice on questions related to the safety and the socio-economic aspects of the use of chemicals. This is achieved by ensuring a credible decision-making process, using the best possible scientific, technical and regulatory capacities and by working independently in an efficient, transparent and consistent manner. Efficient knowledge and information management are thus necessary for the smooth and reliable functioning of the Agency.

Manufacturers and importers will be required to gather information on the properties of their substances and to register the information in a central database run by the Agency. Where available data are not adequate to meet the requirements of the REACH Regulation, additional testing may need to be carried out. However, before embarking on animal testing, alternative methods for hazard assessment and all other options must be considered. These alternative ways of fulfilling the information requirements are laid down in Annex XI of the Regulation and include read-across, (Q)SAR and grouping.

From this perspective, the Agency supports the further development of the (Q)SAR Application Toolbox and thus facilitate grouping of substances and data gap filling under REACH.

#### 1.1.2. *The OECD QSAR Toolbox project and the need for ontologies*

The (Q)SAR Application Toolbox development was initiated by the OECD secretariat. The first phase (proof of concept) was carried out as part of the OECD activities to increase the regulatory

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<sup>1</sup> Regulation (EC) No. 1907/2006

<sup>2</sup> Regulation (EC) No. 1272/2008

<sup>3</sup> [http://www.echa.europa.eu/home\\_en.asp](http://www.echa.europa.eu/home_en.asp)

acceptance of (Q)SAR methods when data are lacking. The OECD has started the development of a (Q)SAR Application Toolbox as a means of making QSAR technology more easily accessible. The first version was released in March 2008, followed by an update (version 1.1) released in November 2008.

In November 2008, the Agency launched a service contract for the second phase (ECHA/2008/20/ECA.203, Service Contract for the Development of the (Quantitative) Structure-Activity Relationship ((Q)SAR Application Toolbox). The project management of the four-years project is carried out in close cooperation with the OECD secretariat. Version 2.0<sup>4</sup> was released under the name 'QSAR Toolbox' in October 2010, and updated with version 2.1 in February 2011. Version 3.0 is planned for release in October 2012.

The fundamental features of the Toolbox are:

- Identification of relevant structural characteristics and potential mechanism or mode of action of a target chemical.
- Identification of other chemicals that have the same structural characteristics and/or mechanism or mode of action.
- Use of existing experimental data to fill the data gap(s).

The QSAR Toolbox application faces the situation that experimental data are spread over various databases and may be annotated according to different terminologies. For example “oral (gavage)” and “gavage” is the same term, but would not be recognised by the software as the same without the help of ontology, i.e. controlled toxicology vocabularies and their interrelations. Hence, this creates difficulties to find and assign all relevant experimental data to one group for subsequent read-across and data gap filling. Furthermore new databases are being developed and will be published over the next few years.

The QSAR Toolbox is a project aimed at combining, in an integrated way, various predictive toxicology methods. All these predictive approaches share the need of highly structured information as a starting point: the definition of ontology and of controlled vocabularies is a crucial requirement in order to standardise and organise the chemical toxicological databases on which the predictive toxicology methods build on.

The development of controlled toxicology vocabularies is needed to improve the usage of experimental data for read-across in the QSAR Toolbox. An organ and effect ontology is necessary to query data from different repositories. The ontology will allow combining results from the databases in the QSAR Toolbox with data from commercial systems and with databases that are under development. Ontologies will support the data management in the QSAR Toolbox application and maximise the use of experimental data from different sources for read-across and data gap filling.

### **1.1.3. *The concept of ontology for test data***

In information science, ontology is a formal representation of a set of concepts within a domain and the relationships between those concepts. It is used to reason about the properties of that domain and may be used to define the domain.

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<sup>4</sup> The QSAR Toolbox can be downloaded for free via the website [www.qsartoolbox.org](http://www.qsartoolbox.org).

In the development of software tools, such as the QSAR Toolbox, the availability of an *ad hoc* ontology amplifies the value of the information contained in databases, and is crucial to their expansion / sustainability. It contributes to the necessary standardisation and rational organisation of data, thus facilitating both vertical (e.g., within one toxicological endpoint) and horizontal (e.g., through different endpoints) retrievals. The aim is to provide an automatic and unique way of describing and linking endpoint information in a standardised way, able to be processed automatically by the software, with minimal human interaction. The ontology concept has to be flexible so that it can be grown over time as new data become available.

Overall, ontology can be described as follows:

- All the fields in the toxicological databases are standardised
- Ontology permits distinction among different synonyms, homonyms and related terms. This functionality is essential when integrating data from different toxicological databases. For example, toxicity effects named as “oral (gavage)” and “gavage” in different databases will not be recognised automatically as the same route of exposure without the intervention of ontology. The ontology provides the common vocabulary for data integration – showing the preferred names for a concept and the synonyms and properties associated with it.
- Ontology gives the opportunity to establish restrictions (rules). Example: the Mutagenicity Test Condition is restricted to have certain test species only. In the case of *in vitro* bacterial mutagenicity, all items for this endpoint are bound to have *Salmonella typhimurium* or *Escherichia coli* as a test species, and not other species such as mouse, rats, hamsters, etc.
- Ontology allows avoiding errors. For example, if uterus is accompanied by the restriction “has species sex = only female”, it becomes impossible to have “neoplastic or non-neoplastic lesions in uterus” as test result for male species.
- Ontology supports the community sharing and reuse of information, e.g., the integration of existing ontologies into larger schemes.
- Ontology enables automatic reasoning.
- Ontology is essential for toxicity data aggregation from different sources to allow access to information to be used for read across and grouping.

#### 1.1.4. Existing toxicity data standards

Since the construction of formal ontology is a well developed field of informatics, it is important to follow established principles, as e.g., the Open Biomedical Ontologies (OBO) Foundry<sup>5</sup> principles of ontology development.

A widely used language for the ontology construction is the Web Ontology Language (OWL)<sup>6</sup>, that provides a formal description of concepts, terms, and relationships within a given knowledge domain. OWL provides formal computational definitions, as well as tools for reasoning, in order

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<sup>5</sup> <http://www.obofoundry.org/>

<sup>6</sup> <http://www.w3.org/TR/owl-ref/>

to facilitate ontology development and ontology maintenance. An open source tool is the Protégé Editor<sup>7</sup> (a Stanford University software) that facilitates the OWL ontology development.

Even though several ontologies for the biomedical field have been developed (e.g. Gene Ontology<sup>8</sup>), and are publicly available at e.g., the Bio-portal ontology depository<sup>9</sup>, no systematic ontology for toxicological effects and predictive toxicology is covered by OBO Foundry or Bio-portal ontology depositories. The neighbouring ontologies (such as several anatomy<sup>10</sup> and pathology ontologies, OBI<sup>11</sup> ontology for biomedical investigation) can be reused partially for the development of the ontological support for the QSAR Toolbox. Existing work shall be reused as far as possible, such as results from the OpenTox<sup>12</sup> and DevTox<sup>13</sup> project. OpenTox is an EU funded project (FP7) to develop open source tools for supports the use of ontologies for controlled vocabulary use, representation and integration of data, and resource description. However, a major part of the ontology for toxicological effects and predictive toxicology will have to be developed from scratch.

At present, two important standard data formats for reporting test data are publicly available: the OECD Harmonised Templates<sup>14</sup> and the ToxML<sup>15</sup> (Toxicology XML standard) schema (Leadscope inc.). The OECD Harmonised Templates are used to store data for easy data exchange. The IUCLID5<sup>16</sup> application has implemented this reporting standard, which has been accepted by many national and international regulatory authorities. The ToxML schema has the capability for accommodating large amounts of toxicity data at different levels of complexity. It should be emphasised that these are schemas, but are not ontologies as needed for improving the data use in the QSAR Toolbox.

#### **1.1.5. Endpoints to be covered**

The ontologies, which shall primarily be developed for the QSAR Toolbox, are intended to cover, under different Specific contracts, all endpoints available in the QSAR Toolbox that are relevant for the REACH regulation. It is assumed that a considerable overlap among endpoints exists regarding test conditions description and that therefore work from one endpoint can be re-used for others. Test outcomes are considered to be more test specific and can potentially be re-used within groups of similar tests.

The grouping of endpoints as below is an indicative list, Specific Contracts may require work on ontologies related to study designs which cover one or more endpoints of interest and will be outlined in the specifications for the Specific Contracts:

1. Carcinogenicity, Repeated Dose Toxicity, and Reproductive Toxicity (common organs, but different effects for each organ)
2. Acute systemic effects
3. Eye Irritation/Corrosion, Skin Irritation/Corrosion, Skin Sensitisation.

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<sup>7</sup> <http://protege.stanford.edu/>

<sup>8</sup> <http://www.geneontology.org/>

<sup>9</sup> <http://bioportal.bioontology.org/>

<sup>10</sup> <http://sig.biostr.washington.edu/projects/fm/index.html>

<sup>11</sup> [http://obi-ontology.org/page/Main\\_Page](http://obi-ontology.org/page/Main_Page)

<sup>12</sup> <http://www.opentox.org/>

<sup>13</sup> <http://www.devtox.org/infpartner.htm>

<sup>14</sup> [http://www.oecd.org/site/0,3407,en\\_21571361\\_43392827\\_1\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/site/0,3407,en_21571361_43392827_1_1_1_1_1,00.html)

<sup>15</sup> <http://www.leadscope.com/toxml.php>

<sup>16</sup> <http://iuclid.eu/>

4. Genotoxicity
5. Toxicokinetics / Metabolism

## 1.2. DESCRIPTION OF TASKS

### 1.2.1. *Nature of the tasks*

The services required are related to the definition of ontology, and the development of controlled toxicological vocabularies in view of standardising and organising the chemical toxicological databases in the QSAR Toolbox and potentially for other projects if appropriate. The requested services will focus on human health endpoints.

What follows is a non-exhaustive list of activities planned for the required services:

- Review of relevant and available information related to ontology and re-use of identified relevant pieces of existing work as a basis for the service (e.g. OECD Harmonised templates and ToxML schemas, Web Ontology Language (OWL)<sup>17</sup> and OBO Foundry (Open Biomedical Ontologies)<sup>18</sup>, OpenTox<sup>19</sup>)
- Definition of
  - Classes of concepts and hierarchical relationships (e.g. test system, sex, species, route, metabolic activation)
  - Controlled vocabularies (ontologies) related to each endpoint with internal rules and restrictions
  - Restriction rules
  - Synonymous, homonymous
- Description of terms such as Study design, Strain/species, Route of exposure, Biomarker, Organs, Effects
- Association of each attribute in a toxicological dataset with an entry in the ontology
- Compilation of all relevant terms and harmonisation of vocabulary of the databases in the Toolbox (data integration)
- Establish relationships between classes, object and numeric properties for each term and rules (restrictions)
- Reporting the project results in an appropriate software

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<sup>17</sup> <http://www.w3.org/TR/owl-ref/>

<sup>18</sup> <http://www.obofoundry.org/>

<sup>19</sup> <http://www.opentox.org/>

## 1.2.2. Organisation of the tasks

### (a) Agency and OECD Project Managers and Coordination Group

A Coordination Group will be put in place, comprising staff from the Agency and the OECD. This team will encompass scientific and technical expertise with members having experience with the QSAR Toolbox and its needs regarding ontologies.

#### Administrative Project management

The build of the system will be formally managed by an Agency Project Manager nominated by the Agency, as the financial and contractual management falls within the responsibility of the Agency. The Agency project manager will represent the Agency in contacts with the Contractor and the OECD Secretariat on matters related to the work to be achieved and ensure that the contractor meets his obligations within the limits and the terms of the contract.

#### Technical and scientific project management

The OECD Secretariat will also nominate an OECD Project Manager who will be responsible for the **day to day contact and monitoring of the work** to be achieved under the Specific Contract.

#### Coordination group

Other members of the Coordination Group will provide scientific and technical input in particular for detailing the functional specifications of the system. They will also be in charge of reviewing and accepting the deliverables.

### (b) Stakeholders: OECD (Q)SAR Application Toolbox Management Group

During the project, the OECD (Q)SAR Application Toolbox Management Group will be consulted by the Coordination Group. Reasons for consulting the OECD (Q)SAR Application Toolbox Management Group can be for example the acceptance of deliverables.

### (c) Meetings and deliverables presentations

In principle, within two weeks after entry into force of a Specific Contract, the OECD Project Manager and the Agency Project Manager will organise a kick-off meeting with the Contractor to officially discuss in detail the planning and other organisational aspects of the project. This meeting will also officially start the work. The format and place will be specified in the Specific Contract. Members of the Coordination Group will attend.

Regular telephone or video conferences will be organised to 1) discuss the project status and the activities for the subsequent months; 2) discuss technical issues; 3) present deliverables at milestones to the Coordination Group by the contractor.

The frequency of meetings will depend on the size and complexity of the project and will be stipulated in the Specific Contracts.

Additional meetings may be requested to take place either in Helsinki or Paris and will be stipulated in the Specific Contracts.



### 1.3. DESCRIPTION OF DELIVERABLES

#### 1.3.1. *Requirements for deliverables*

Requirements as described in this section shall be understood as minimum requirements which can be further complemented in the specifications of a given Specific Contract.

##### (a) Formal requirements

All deliverables shall be drawn up in the English language. The English language shall be used throughout the projects duration for all communication, reports and other documentation, as this is the working language of ECHA.

Possible formats for deliverables include (non-exhaustive list):

- Reports
- Detailed work plan
- Quality assurance plan
- Change management plan
- IT depository for storing project results

##### (b) Substantial requirements

###### (i) General requirements

All deliverables shall undergo thorough quality reviews by the Contractor before being submitted to the Agency for acceptance. Each deliverable will be assessed to verify that it conforms to the description of work.

###### (ii) Specific requirements

##### Progress reports

The Contractor shall provide regular progress reports to the responsible Project Manager at the Agency and the OECD Secretariat, in the layout specified in the Specific Contracts. The frequency of reporting (in general monthly) may differ depending on the size and complexity of the service or project and will be stipulated in the Specific Contracts.

The report will include:

- A summary of the activities, milestones, deliverables, delivery dates and budget execution;
- The risks identified and the problems encountered.

Progress reports, which have been agreed by the Coordination team, will form part of the deliverables.

##### Minutes

The Contractor will produce meeting minutes for all meetings, documenting discussion points and clearly stating the results of the meeting and all decisions taken. A first draft version must be

circulated within five working days of the meeting. Within five working days the Coordination group shall provide its comments and the Contractor shall submit the finalised minutes to the Coordination Group.

### **1.3.2. *Acceptance of deliverables***

#### **(a) Acceptance procedure**

Official acceptance of the work carried out will take place at milestones if specified in the Specific Contract and at the end of the Service Contract according to the default procedures described below.

When a document is submitted to the Agency for review, a review cycle of T1/T2/T3/T4 will apply, where:

- T1 refers to the number of working days needed by the Coordination Group to review the deliverable and provide the Contractor with comments on the deliverable. The Coordination Group has the possibility to consult the OECD (Q)SAR Application Toolbox Management Group.
- T2 refers to the number of working days allotted to the Contractor to provide its position to the comments raised by the Coordination Group. This position will be flagged by the Coordination Group using the following status:
  - “To be implemented”;
  - “To be discussed”;
  - “No action” with the appropriate justification. “No action” refers to comments that do not impose any action to be taken by the Contractor.

Comments for which the position of Contractor is "To be discussed" or for which the Coordination Group does not agree with the given position will be discussed during a review meeting (its format can also be a telephone or video conference). A meeting decision ("No Action" or "To be implemented") will be made and recorded in the meeting minutes made by the Contractor.

- T3 refers to the number of working days allotted to the Contractor to implement the meeting decisions and release an updated version of the deliverable.
- T4 refers to the number of working days needed by the Coordination Group to verify the correct implementation of the reviewers' remarks. The Coordination Group has the possibility to consult the OECD (Q)SAR Application Toolbox Management Group.

The Contractor must take into account the expected acceptance time when planning the project deliverables.

The Coordination Group can reject a document by interrupting the review cycle when there is evidence that the quality of the deliverable is too low or when there is evidence that the objective of the document is not met.

No document is accepted by default. When the responsibility of a delay in the review process is clearly identified on the Coordination Group side, the Contractor must alert the Coordination Group.

After T4, the Coordination Group will accept the deliverable only when all meeting decisions have been implemented successfully. In any other situation the Coordination Group may reject the deliverable or ask the Contractor to resume from T3.

Unless specified otherwise in the request for services for a Specific Contract, the default review cycle for a document is as follows:

- T1: 10
- T2: 5
- T3: 5
- T4: 5

Following final acceptance, the Coordination Group will issue a Certificate of Acceptance.

The Contractor is to provide the required reports and documents in accordance with the conditions of the Specific Contract.

#### Final Acceptance

Although some deliverables may be accepted at the end of a work period to allow project subsequent steps to be executed, there will be a Final Acceptance at the end of the project.

The Coordination Group will present final deliverables for consultation to the OECD (Q)SAR Application Toolbox Management Group.

A provisionally accepted deliverable may be rejected during final acceptance of all deliverables. In such case, the review cycle must re-apply to the deliverable and if satisfactory, another final acceptance procedure must be called.

In the case the deliverables have been satisfactory, the Coordination Group shall deliver a Certificate of acceptance that shows the acceptance date and mentions any reservations it may have regarding the services.

A copy of the Certificate of acceptance shall be attached to the final invoice.

#### (b) Acceptance criteria

These will be defined in the request for services for a Specific Contract, in light of the nature of the deliverables there under.

## **1.4. DESCRIPTION OF RESOURCES**

### **1.4.1. *Requirements for the Resources***

The requirements for the profile indicated hereafter shall be applicable to all resources involved in the implementation of the Framework Contracts. These requirements may be further defined in the service requests for Specific Contracts. Where justified by the specific nature of tasks to be

performed by the expert, as applicable, the Agency may stipulate at the level of Specific Contracts further required knowledge and skills.

#### Expert in human health toxicology

##### Education:

- University degree in a relevant subject such as health sciences, toxicology or pathology

##### Knowledge and skills:

- In depth knowledge on pathology and evaluation of toxicological data for human health endpoints to be covered<sup>20</sup>
- Good knowledge of regulatory requirements on testing methods for human health hazard assessment
- Proficiency level of B1 in English

##### Experience

- Minimum of 5 years of experience in a relevant field

#### **1.4.2. Volume of Resources**

- The estimated volume for the framework contract over its entire duration is between 160.000 and 360.000 EUR

Please note that these amounts are indicative and that the Agency is not bound by these numbers.

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<sup>20</sup> An overview of relevant endpoints can be found under:  
[http://echa.europa.eu/doc/publications/practical\\_guides/pg\\_report\\_robust\\_study\\_summaries.pdf](http://echa.europa.eu/doc/publications/practical_guides/pg_report_robust_study_summaries.pdf)

## **2. THE CONTRACT**

### **2.1. THE FRAMEWORK CONTRACTS**

#### **2.1.1. *The subject of the contract***

The subject of the contract is the provision of scientific services in order to develop ontologies (controlled vocabularies).

#### **2.1.2. *The nature of the contract***

The Contracts are multiple framework Service Contracts with reopening of competition<sup>21</sup>.

The contractual relationship between the Agency and the successful tenderers will be governed by a special type of Contract known as a “Framework Contract”. It should be stressed that Framework Contracts involve no direct commitment and, in particular, do not constitute orders per se. Instead, they lay down the legal, financial, technical and administrative provisions governing the relationship between the Agency and the Contractor during their period of validity. Actual orders will be placed after the Framework Contract is signed and in force, through “Specific Contracts” concluded in implementation of the Framework Contract. The draft Framework Contract specifies the basic conditions applicable to any assignment placed under its terms. Signature of the Framework Contract does not place the Agency under any obligation to place an assignment. The Framework Contract does not preclude the Agency from assigning tasks in the areas set out above to other Contractors or from having these tasks carried out by the Agency staff.

The Agency intends to establish Framework Contracts with a minimum of three and a maximum of ten contractors.

There will be reopening of competition for each Specific Contract<sup>22</sup>.

#### **2.1.3. *Starting date of the contract and duration of the tasks***

The Contract shall enter into force on the date on which it is signed by the last contracting Party. The indicative intended date for signing the Framework Contracts is in the third quarter of 2011.

The Frameworks Contract will be concluded for a duration of four years. The Agency has the right to cancel the Framework Contract at any point. The execution of the tasks may not start before the Contract has been signed. The period of execution of the tasks may be extended, only with the written agreement of the contracting parties, before the end of the period originally stated in the Contract.

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<sup>21</sup> Article 88 of the Financial Regulation and Art. 117 of the Implementing Rules of the Financial Regulation. For further information see e.g. Section 3.4 in “Explanatory Note - Framework Agreements - Classic Directive” at [http://ec.europa.eu/internal\\_market/publicprocurement/docs/explan-notes/classic-dir-framework\\_en.pdf](http://ec.europa.eu/internal_market/publicprocurement/docs/explan-notes/classic-dir-framework_en.pdf)

<sup>22</sup> See section 2.2

#### **2.1.4. *Place of performance***

The place of performance of the tasks shall be the Contractor's premises. In exceptional cases, travel outside the normal location may be required, at the request of the Agency.

#### **2.1.5. *Terms of payment***

The terms of payment will be laid down in the Specific Contracts.

Payments shall be made in accordance with Articles I.3, I.5 & II.4 of the model Framework Contract.

The schedule and the procedure for the approval of payments and the documents to be submitted are described in Articles I.5, II.4, II.5 and II.7 and in Annex I to the model Framework Contract referred to above and in the Specific Contracts.

#### **2.1.6. *Guarantees***

The Agency shall not require the Contractors to provide financial guarantees.

#### **2.1.7. *Liability***

##### **(a) Joint Offers**

Partners in a joint offer assume joint and several liabilities towards the Agency for the performance of the contract as a whole.

Statements saying, for instance:

- that one of the partners of the joint offer will be responsible for part of the contract and another one for the rest, or
- that more than one contract should be signed if the joint offer is successful

are thus incompatible with the principle of joint and several liability. The Agency will disregard any such statement contained in a joint offer, and reserves the right to reject such offers without further evaluation on the grounds that they do not comply with the tendering specifications.

##### **(b) Subcontracting**

Certain tasks provided for in the contract may be entrusted to subcontractors, but the main contractor retains full liability towards the Agency for performance of the contract as a whole. Accordingly:

- the Agency will treat all contractual matters (e.g. payment) exclusively with the main contractor, whether or not the tasks are performed by a subcontractor
- under no circumstances can the main contractor avoid liability towards the Agency on the grounds that the subcontractor is at fault

During execution of the contract, the contractor will need the Agency's express authorisation to replace a subcontractor with another and/or to subcontract tasks for which subcontracting was not envisaged in the original offer.

Tenderers must inform the subcontractor(s) and include in their sub-contracting documents that Article II. 17 of the contract may be applied to sub-contractors.

Once the contract has been signed, Article II.13 of the above-mentioned contract shall govern the subcontracting.

### **2.1.8. Data Protection**

Any personal data included in or relating to the Contract, including its execution shall be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The data shall be processed solely for the purposes of the performance, management and monitoring of the Contract by the Agency Data Controller without prejudice to possible transmission to the bodies charged with a monitoring or inspection task in application of Union law. The Contractor shall have the right of access to his/her personal data and the right to rectify any such data. Should the Contractor have any queries concerning the processing of his/her personal data, s/he shall address them to the Agency Data Controller. The Contractor shall have right of recourse at any time to the European Data Protection Supervisor.

Where the Contract requires the processing of personal data, the Contractor may act only under the supervision of the data controller, in particular with regard to the purposes of the processing, the categories of data which may be processed, the recipients of the data, and the means by which the data subject may exercise his/her rights.

The data shall be confidential within the meaning of Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data. The Contractor shall limit access to the data to the staff strictly necessary for the performance, management and monitoring of the Contract.

The Contractor undertakes to adopt appropriate technical and organisational security measures having regard to the risks inherent in the processing and to the nature of the personal data concerned in order to:

- a) prevent any unauthorised person from having access to computer systems processing personal data, and especially:
- b) unauthorised reading, copying, alteration or removal of storage media;
- c) unauthorised data input as well as any unauthorised disclosure, alteration or erasure of stored personal data;
- d) unauthorised persons from using data-processing systems by means of data transmission facilities;
- e) ensure that authorised users of a data-processing system can access only the personal data to which their access right refers;
- f) record which personal data have been communicated, when and to whom;
- g) ensure that personal data being processed on behalf of third parties can be processed only in the manner prescribed by the Agency;
- h) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or erased without authorisation;
- i) design its organisational structure in such a way that it meets data protection requirements.

## **2.2. THE SPECIFIC CONTRACTS**

### **2.2.1. *Launching of a Service Request for a Specific Contract***

The Agency draws up the tender documents, consisting of the invitation to tender, the model contract and the technical specifications<sup>23</sup>. In the invitation to tender, the Agency indicates the modalities of the re-opening of competition, such as the final date of submission of offers and the total maximum budget. The model contract takes the form of a Fixed Price order, whereby the invoicing is based on the acceptance of the deliverables by the Agency, independently of the real workload. The specifications lay down the requirements for the services, including the deliverables, and for the resources, including the specific requirements for the profile.

The Agency sends the tender documents to all framework contractors simultaneously by registered postal mail and by e-mail. The paper copy sent by postal mail has authority. The framework contractors must acknowledge receipt of the tender documents.

### **2.2.2. *Preparation and submission of a tender for a Specific Contract.***

The Framework contractor's tender in response to the service request for the Specific Contract must contain a technical proposal and a financial proposal.

The technical proposal must contain a proposal for the services and a proposal for the resources. The proposal for the services must include a detailed work plan and a quality assurance plan, where applicable. The proposal for the resources must contain a presentation of the expert or the team of experts, the roles and responsibilities, as well as the CV(s) of the proposed expert(s). Pre-defined CV forms must be used. All information indicated in the CV has to be correct and accurate. Contractor's staff proposed must match the required profile description and the specific needs indicated in the Service Request.

The financial proposal must include the price and the reimbursables, where applicable. The total price must be based on the estimation of the number of days for each expert and on prices per person-day equal to or below the maximum price per person-day indicated in the financial proposal for the Framework Contract. The total price must be equal to or below the maximum budget indicated in the service request. The prices must be all-inclusive. However, travel expenses shall be reimbursed, but only in case of work performed at a location other than the contractor's premises, as indicated in the service request.

Before the final date for the submission of tenders, contact may be made on the tenderers' initiative, in exceptional circumstances, in order (and only for this reason) to obtain additional information aimed at clarifying the nature of the contract. Such requests for further information may be made only in writing with the subject indication, « ECHA/2011/25/SR [...]» to the following e mail address: [contracts-team@echa.europa.eu](mailto:contracts-team@echa.europa.eu). The Agency is not bound to reply to requests for additional information made less than five working days before the deadline for submission of tenders. Insofar as it has been requested in good time, the questions raised and the additional information provided by the Agency will be sent by e-mail simultaneously to all framework contractors.

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<sup>23</sup> See section 4.2.3



Before the final date for the receipt of tenders, contact may in exceptional circumstances be made on the Agency's initiative, in order to inform interested parties of an error, a lack of precision, an omission or any other material shortcoming in the drawing up of the documents of the invitation to tender.

The final date for submission of bids will be at least 10 working days after the date of dispatch of the service request.

Tenders must be:

- a) either sent by registered mail, posted no later than the final date for submission, (date as postmark); to the following address:

European Chemicals Agency (ECHA)  
Invitation to tender No: ECHA/2011/25/SR [...]  
Financial Unit R1  
PO Box 400  
Annankatu 18  
00121 Helsinki  
Finland

- b) or sent by courier services, no later than the final date for submission (date of deposit slip), to the following address:

European Chemicals Agency (ECHA)  
Invitation to tender No: ECHA/2011/25/SR [...]  
Financial Unit R1  
Annankatu 18  
00120 Helsinki  
Finland

- c) or delivered by hand, in person or by an authorised representative no later than 16:00 hours Helsinki time on the final date for submission, (date of acknowledgement of receipt by the Agency) to the address mentioned above.

Tenderers shall observe precisely the above indications in order that tenders reach their specified destination in due time. Evidence of timely submission by post or courier service will be constituted by the date of the postmark or the date of the deposit slip. In the case of hand-delivery, the signed and dated receipt will serve as evidence. Late submission will lead to the rejection of the tender from the award procedure for this contract. Tenders sent by e-mail or by fax will also be non admissible. Envelopes found open at the opening session will also be rejected. Consequently, tenderers must ensure that their tenders are packed in such a way as to prevent any accidental opening during their mailing.

### 2.2.3. Opening and evaluation of a tender for a Specific Contract.

The opening of the tenders will not be public.

The tenders will be evaluated against the following award criteria. Specific contracts shall be awarded under the best-value-for-money procedure. The contracts will be awarded to the most cost-effective tenders.

The following award criteria will be applied for the award of the Specific Contract:

No	Qualitative award criteria	Weighting (maximum points)
AW1	Quality of the offered services	35
AW2	Quality of the offered resources	35
	Total number of points	70

The tenders are assessed according to the above qualitative award criteria and the weighting applicable to each criterion.

Tenders scoring less than 60% in the overall points total or less than 50% in the points awarded for a single criterion will be excluded from the rest of the assessment procedure.

Technical Merit	
TM	$TM = (AW1 + AW2)$

The Technical Merit (TM) is evaluated as follows: a maximum of 70 points are given for the award criteria applied. The offers are ranked according to the above mentioned formula, in which:

- AW1 = Award Criterion 1
- AW2 = Award Criterion 2
- 70 = Maximum points to be awarded

Price	
P	$P = (P_{min}/P_o) \times 30$

The **Price criterion (P)** is evaluated as follows: a maximum of **30 points** is given to the lowest price offer. The offers are ranked according to the following formula:

$$P = (P_{min}/P_o) \times 30$$

in which:

P = Classification of each price offer (points to be awarded)

P<sub>o</sub> = Price of each offer: total price

P<sub>min</sub> = Minimum price offered among all tenders

30 = Maximum points to be awarded

<b>Final Evaluation</b>	
X	X = TM + P

The contracts will be awarded to the most economically advantageous tenders on the basis of the following criteria:

- Technical Merit (TM) (70 points)
- Price (P) (30 points)

During the evaluation, after the opening of tenders, contact may in exceptional circumstances be made on the Agency's initiative, where a tender requires clarification or in order to correct material errors made in drawing up a tender. Please note that in any event such contact may not result in a modification of the terms of the tender.

#### **2.2.4. Award of a Specific Contract.**

The Agency will inform tenderers of decisions reached concerning the award of the specific contract, including the grounds for any decision not to award a contract or to cancel the procedure.

If a written request is received from any non-successful tenderer, the Agency will inform the tenderer of the characteristics and relative advantages of the successful tender, the total price and the name of the successful tenderer. However, certain information may be withheld where its release would impede law enforcement or otherwise be contrary to the public interest, or would prejudice the legitimate commercial interests of economic operators, public or private, or might prejudice fair competition between them.

After the period of validity of the tender has expired, conclusion of the contract shall be subject to the tenderer's agreement in writing.

The Agency shall not sign the Specific Contract with the successful tenderer until a standstill period of 14 calendar days has elapsed, running from the day after the simultaneous dispatch of the notification letters to the tenderers informing them of the award decision, in case the value of the Specific Contract exceeds the threshold referred to in Article 158 of the Implementing Rules. The procurement procedure may be concluded by a contract signed by the parties.

### **3. THE PROCUREMENT PROCEDURE**

#### **3.1. PREPARATION AND SUBMISSION OF THE TENDER**

##### **3.1.1. *Preparation of the tender***

###### **(a) General**

Tenders must be clear and concise, with continuous page numbering, and assembled in a coherent fashion (e.g. bound or stapled, etc.).

Tenders must be written in one of the official languages of the European Union.

Tenders must include the following information:

- all the information and documents requested by the Agency in order to assess the tender;
- the price in euros;
- one specimen signature of an authorised agent (preferably in blue ink) on the legal entity form<sup>24</sup>, and a statement from the same agent confirming the validity of the tender;
- the name and contact details of a contact person in relation to the submission of the bid.

If this is not included, the tender may be excluded from the procedure for the award of the contract.

Since tenderers will be judged on the content of their written bids, these must make it clear that they are able to meet the requirements of the specifications.

###### **(b) Content of the tender**

#### ***Section One: Administrative proposal***

##### **Eligibility documentation**

The competition is open to any physical person or legal entity coming from countries within the EU and any other physical person or legal entity from a third country that has concluded with the European Union a specific agreement in the area of public contracts, under the conditions provided for in that agreement.

In practice, the participation of applicants from third countries that have concluded a bilateral or multilateral agreement with the European Union in the area of public contracts must be allowed, under the conditions provided for in that agreement.

To identify himself the tenderer must fill in a Legal Entity Form and a Financial Identification Form:

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<sup>24</sup> See section 4.3.1

The **Legal Entity Form**<sup>25</sup> is to be signed by a representative of the tenderer authorised to sign contracts with third parties.

The **Financial identification**<sup>26</sup> form shall be duly filled in and signed by an authorised representative of the tenderer and his or her banker.

The above forms must be accompanied by the evidence as indicated at the bottom of each form.

Both joint offers and subcontracting are allowed in response to this call for tenders. Offers may even combine both approaches. In any case, the tender documents must specify very clearly by means of the appropriate forms, detailed hereafter, whether each company involved in the tender is acting as a partner in a joint offer or as a subcontractor (this also applies where the various companies involved belong to the same group, or even where one is the parent company of the others).

All *tenderers* must provide their legal entity form as well as the evidence indicated at the bottom of that form.

*Subcontractors* are only obliged to provide the legal entity form without the evidence, and are not required to present the financial identification form.

In case of a *joint offer*, only the co-ordinator must return the financial identification form.

In case of a tenderer submitting a joint offer who has already set up a consortium or similar entity for conducting the project in case a contract will be awarded, the tenderer should mention this fact in the tender, together with any other relevant information in this connection.

In case of tenderers submitting a joint offer who have not yet set up a consortium or similar entity, the tenderers should be aware that, in case the tenderers are awarded the contract, the Agency may require the tenderer to give a formal status to this collaboration before the contract is signed. This can take the form of:

- an entity with legal personality recognised by a Member State; or
- an entity without legal personality but offering sufficient protection of the Agency's contractual interests (depending on the Member State concerned, this may be, for example, a consortium or a temporary association).

In case of tenderers submitting a *joint offer*, the tenderers are asked to fill in and duly sign one of the attached **powers of attorney**<sup>27</sup>, depending on the set up that has been chosen by the tenderers.

If the tenderer envisages *subcontracting*, the tender must include:

- a **document**<sup>28</sup> clearly stating the roles, activities and responsibilities of the proposed subcontractor(s), and the reasons why subcontracting is envisaged;

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<sup>25</sup> This form is available at:

[http://ec.europa.eu/budget/contracts\\_grants/info\\_contracts/legal\\_entities/legal\\_entities\\_en.cfm](http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm)

<sup>26</sup> The form is available at:

[http://ec.europa.eu/budget/contracts\\_grants/info\\_contracts/financial\\_id/financial\\_id\\_en.cfm](http://ec.europa.eu/budget/contracts_grants/info_contracts/financial_id/financial_id_en.cfm)

<sup>27</sup> Section 4.3.3

<sup>28</sup> To be provided in free format

- a **letter of intent**<sup>29</sup> by each proposed subcontractor stating its intention to collaborate with the tender if the tenderer wins the contract and their willingness to accept the tasks and the terms and conditions set out above, in particular article II.17 of the draft Service Contract.

### **Exclusion criteria documentation**

Tenderers or their representatives shall provide a **declaration on their honour**<sup>30</sup>, duly signed and dated in which they:

- state whether or not they are in one or more of the situations referred to in Articles 93 and 94 of the Financial Regulation and detailed in the form;
- undertake to submit to the Agency any additional document relating to the exclusion criteria, that the Agency considers necessary to perform its checks, within seven calendar days following the receipt of the Agency's request.

Where the bid constitutes a *joint offer*, each entity must provide the form. Where the total amount envisaged for *subcontracting* is above 50% of the total contract value, the potential subcontractor(s) must also provide the form (as required from the potential contractor). The same applies regarding the requirement to present evidence of compliance with the exclusion criteria.

By returning the above-mentioned form, duly signed, tenderers confirm that they have been notified of the following points.

Administrative or financial penalties may be imposed by the Agency on tenderers who are in one of the cases of exclusion provided for in Articles 93 and 94 of the Financial Regulation after they have been given the opportunity to present their observations.

These penalties are detailed in Article 96 of the Financial Regulation and Articles 133a and 134b of the Regulation laying down the rules for the implementation of the Financial Regulation.

### **Selection criteria documentation**

#### General

This part of the tender concerns the criteria and evidence relating to the technical and professional capacity and economic and financial capacity of the service provider(s) involved in the bid, It should also contain any other document that the tenderer(s) wish(es) to include by way of clarification. The evidence for the selection criteria shall be assessed in the second stage of the evaluation of the tenders<sup>31</sup>.

An economic operator may rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. In that case, evidence must be provided that it will have at its disposal the resources necessary for performance of the contract, for example by producing a clear undertaking on the part of those entities to place those resources at its disposal.

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<sup>29</sup> See Section 4.3.2

<sup>30</sup> See Section 4.3.4

<sup>31</sup> See Selection criteria, page 29

In addition, all tenderers are informed that they may be asked to prove that they are authorised to perform the contract under national law, as evidenced by inclusion in a professional or trade register or a sworn declaration or certificate, membership of a specific organisation, express authorisation, or entry in the VAT register.

In case of joint offer or sub-contracting, the tenderer(s) must stipulate the role, qualifications and experience of each service provider and, where relevant, the monitoring arrangements that exist between them.

#### Evidence of the economic and financial capacity of the service provider(s)

Evidence for selection criterion 1 is to be provided by submitting the following documents:

This proof is to be provided by submitting the completed Financial and Economic Capacity Overview Form<sup>32</sup>, as well as a full copy of the tenderer's annual accounts (balance sheet, profit and loss account, notes on the accounts and auditors' remarks when applicable) of the last three years, as approved by the general assembly of the company and, where applicable, audited and/or published. These documents must be certified by the tenderer.

If, for some exceptional reason which the Agency considers justified, a tenderer is unable to provide one or other of the above documents, he or she may prove his or her economic and financial capacity by any other document which the Agency considers appropriate. In any case, the Agency must at least be notified of the exceptional reason and its justification in the tender. The Agency reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

All tenderers must provide proof of their economic and financial capacity.

#### Evidence of the technical and professional capacity of the service provider(s)

Evidence of the technical and professional capacity of the providers involved in the tender must be furnished on the basis of the following documents:

Evidence for selection criterion 2.1:

Two CVs duly completed and presented in the appropriate format<sup>33</sup>. The CVs must indicate the contractual link with the staff member.

Evidence for selection criterion 2.2:

A minimum of one relevant project reference<sup>34</sup> with the value, dates and place, as well as a description of the content.

By submitting a tender, each legal entity involved therein accepts the possibility of a check being carried out by the Agency on its technical capacities.

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<sup>32</sup> See Section 4.3.5

<sup>33</sup> <http://europass.cedefop.europa.eu/europass/home/vernav/Europasss+Documents/Europass+CV/navigate.action>

<sup>34</sup> See template in Section 4.4

## ***Section Two: Technical proposal***

### **Qualitative award criteria documentation**

This section is of great importance in the evaluation of the tenders, the award of the contract and the future implementation of any resulting contract. The technical proposal must respond to these technical specifications and provide, as a minimum, all the information needed for the purpose of awarding the contract.

Tenderers should note that, in order to ensure equal treatment, it is not possible to modify tenders after their submission in relation to the technical and financial proposals. As a consequence, incompleteness in this section can only result in a negative impact on the evaluation against the award criteria. They should note also that proposals deviating from the technical specifications may be rejected on the grounds of non-conformity.

The technical specifications and the tender of the successful tenderer shall become integral parts of the contract and will constitute annexes to the contract.

#### Assessment basis for award criterion AW1:

The methodological proposal for the provision of the services under the contract.

The proposal for the scientific methodology as applied to the provision of the services must address the requirements of the technical specifications in general and take into account the following elements in particular:

A description of the approach to be followed to ensure that developed ontologies

- are of high quality and compatible with existing terminology used in the QSAR Toolbox and at international level used for chemical safety assessment
- can be used to further improve the accessibility of experimental data stored in the QSAR Toolbox
- are logically linked

A description of the approach to identify key existing relevant work (for example existing chemical, biological and medical ontologies) which should be taken into account as basis for the project work.

This proposal must demonstrate an understanding of the objectives of the contract and the work to be carried out. The proposal must address types of logical linkages between controlled vocabularies to be developed and how the developed ontologies can be used within the QSAR Toolbox.

The proposal may be presented in free format, but must not exceed 10 A4 pages and must be logically structured.

#### Assessment basis for award criterion AW2:

The methodological proposal illustrated within a case study

The tenderer must provide a solution for a case study whereby the tenderer is required to



- develop and present a number of examples of controlled vocabularies for an endpoint relevant for human health (see also section 1.1.5). The examples can refer for instance to a specific study design, strain, species, route of exposure, biomarker, organ and/or effect
- make reference to any existing relevant and available information used as basis for the case study
- provide examples for define relationships, synonymous, homonymous, and restrictions rules if applicable

The case study shall exemplify the methodological approach and shall also illustrate the level of detail for developed ontologies that is envisaged for the project work. The case study may be presented in free format, but must not exceed 5 A4 pages and must be logically structured.

### ***Section Three: Financial proposal***

#### **Financial award criteria documentation**

Tenderers must use the financial form<sup>35</sup> to formulate their financial bid establishing a maximum price for the expert profile.

The tenderers attention is drawn to the following points:

- Prices must be presented rating a single working day unit and be all-inclusive. Once the framework contract is established the price of the Specific Contracts must be based on the maximum price defined by the tenderers that cannot be exceeded
- Prices must be expressed in euros
- Prices should be quoted free of all duties, taxes and other charges, i.e. also free of VAT, as the Communities are exempt from such charges in the EU under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union of 8 April 1965 (OJEC L 152 of 13 July 1967). Exemption is granted to the Agency by the governments of the Member States, either through refunds upon presentation of documentary evidence or by direct exemption. For those countries where national legislation provides an exemption by means of a reimbursement, the amount of VAT is to be shown separately. In case of doubts about the applicable VAT system, it is the tenderers responsibility to contact his national authorities to clarify the way in which the European Community is exempt from VAT
- Prices shall not be conditional and be directly applicable by following the technical specifications
- Prices shall not be subject to revision, in accordance with Article I.3 of the contract
- Prices shall be applicable for the entire duration of the framework contract

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<sup>35</sup> Section 4.5.1

All tenders must contain all the information and all the supporting documents required by these specifications. In the absence of the required information or documents, the Agency may disqualify the bid. The Agency reserves the right, however, to request additional evidence in relation to the bid submitted for evaluation or verification purposes within a time-limit stipulated in its request.

(c) Form of the tender

The tender must be submitted under double sealed cover.

The outer envelope should bear the address as mentioned below.

The inner envelope should be addressed to the Financial Unit R1 and marked "*Invitation to tender No ECHA/2011/25*" and "*Not to be opened by the internal mail service*". If self-adhesive envelopes are used, they must be sealed with adhesive tape and the sender must sign across the tape. The inner envelope must also contain three sealed envelopes, one containing the administrative proposal, the second the technical proposal and the third the financial bid. Each of these envelopes must clearly indicate the content. The administrative proposal, the technical proposal and the financial bid must be submitted, in duplicate (one set of originals and one set of copies) and a third set in electronic format (on CD ROM).

**3.1.2. *Submission of the tender***

(a) Terms and conditions for submission

Submission of a tender implies that the Contractor accepts all the terms and conditions set out in these specifications (including the annexes) and waives all other terms of business.

Submission of a tender binds the Contractor to whom the contract is awarded during performance of the contract.

The tenderer's bid, in conjunction with the technical specifications, shall be an integral part of the contract and will constitute annexes to the contract.

Once the Agency has accepted the tender, it shall become the property of the Agency and the Agency shall treat it confidentially.

The Agency shall not reimburse expenses incurred in preparing and submitting tenders.

The Protocol on the Privileges and Immunities or, where appropriate, the Vienna Convention of 24 April 1963 on Consular Relations shall apply to this invitation to tender.

The offer must remain valid for a period of 6 months following the final date for submitting tenders (see below). During this period, tenderers must maintain all the conditions of their bids.

The tendering procedure shall not involve the Agency in any obligation to award the contract.

Up to the point of signature, the contracting authority may either abandon the procurement or cancel the award procedure. This decision must be substantiated and the tenderers notified.

No compensation may be claimed by tenderers whose tender has not been accepted, including when the Agency decides not to award the contract.

(b) Requirements for submission

Tenders may be:

- a) either sent by registered mail, posted no later than 8 July 2011, (date as postmark); to the following address:

*European Chemicals Agency (ECHA)  
Invitation to tender No: ECHA/2011/25  
Financial Unit R1  
PO Box 400  
Annankatu 18  
00121 Helsinki  
Finland*

- b) or sent by courier services, no later than 8 July 2011 (date of deposit slip), to the following address:

*European Chemicals Agency (ECHA)  
Invitation to tender No: ECHA/2011/25  
Financial Unit R1  
Annankatu 18  
00120 Helsinki  
Finland*

- c) or delivered by hand, in person or by an authorised representative no later than 16:00 hours Helsinki time on 8 July 2011, (date of acknowledgement of receipt by the Agency) to the address mentioned above.

Tenderers shall observe precisely the above indications in order that tenders are sent to their specified destination in due time.

Evidence of timely submission by post or courier service will be constituted by the date of the postmark or the date of the deposit slip. In the case of hand-delivery, the signed and dated receipt will serve as evidence.

Late submission will lead to the exclusion of the tender from the award procedure for this contract. Offers sent by e-mail or by fax will also be non admissible. Envelopes found open at the opening session will also lead to non admissibility of the tender. Consequently, tenderers must ensure that their bids are packed in such a way as to prevent any accidental opening during its mailing.

### 3.2. CONTACT BETWEEN THE TENDERER AND THE AGENCY

In principle, no contact is permitted between the Agency and the tenderers during the contract award procedure:

However, in exceptional circumstances contact may be made on the tenderers' initiative before the final date for the receipt of bids, in order (and only for this reason) to clarify the nature of the contract.

Such requests for further information may be made only in writing with the subject indication, « ECHA/2011/25 » to the following e-mail address:

*contracts-team@echa.europa.eu*

The Agency is not bound to reply to requests for additional information made less than five working days before the deadline for submission of tenders.

Insofar as it has been requested in good time, the questions raised and the additional information provided by the Agency will be published on the website at:

[http://echa.europa.eu/opportunities/procurement\\_en.asp](http://echa.europa.eu/opportunities/procurement_en.asp)

All tenderers are advised to take note of the fact that no additional information will be sent (neither by post nor by e-mail) regarding new information that has become available. Therefore, all tenderers are kindly requested to visit the above-mentioned website frequently prior to submitting bids.

Similarly, contact may in exceptional circumstances be made on the Agency's initiative:

- before the final date for the receipt of bids, in order to inform interested parties of an error, a lack of precision, an omission or any other material shortcoming in the drawing up of the documents of the invitation to tender;
- or, after the opening of bids, where a bid requires clarification or in order to correct material errors made in drawing up a bid.

Please note that in any event such contact may not result in a modification of the terms of the bid. In case the Agency deems it appropriate to provide additional information it will be published on the website mentioned above.

### 3.3. OPENING OF THE TENDERS

Tenders will be opened at 11:00 on 15 July 2011 at the following location:

*Office address:  
European Chemicals Agency (ECHA)  
Annankatu 18  
00120 Helsinki  
Finland*

A representative of each tenderer may attend the opening of the bids. Tenderers wishing to attend are requested to notify their intention by sending an e-mail at least 2 working days in advance to the above-mentioned e-mail address. This notification must be signed by an authorised representative of the tenderer and specify the name of the person who will attend the opening of the bids on the tenderer's behalf.

### 3.4. EVALUATION OF THE TENDERS

The evaluation will be based on each tenderer's bid. In addition, the Agency reserves the right to use any other information from public or specialist sources.

All the information will be assessed in the light of the criteria set out in these specifications. The procedure for the award of the contract, which will concern only admissible bids, will be carried out in three successive stages.

Only bids meeting the requirements of one stage will be examined in the next stage.

The aim of each of these stages is:

1. to check, in the first stage (exclusion criteria), whether tenderers can take part in the tendering procedure and, where applicable, be awarded the contract;
2. to check, in the second stage (selection criteria), the technical and professional capacity and economic and financial capacity of each tenderer who has passed the exclusion stage;
3. to evaluate on the basis of the award criteria the technical and financial tenders and establish a ranking list, by order of merit, of all tenders having passed the exclusion and selection stages, as well as the quality thresholds set for the evaluation of the award criteria.

#### Stage 1 – application of exclusion criteria

In accordance with Articles 93 and 94 of the Financial Regulation, tenderers shall be excluded from the selection and award procedures if they do not satisfy criteria a) to f) specified in the exclusion criteria form<sup>36</sup>.

Furthermore, contracts may not be awarded to tenderers who, during the procurement procedure are subject to a conflict of interest (criteria g) or are guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the contract procedure or fail to supply this information (criteria h) or fall into one of the situations as specified under criteria a) to f).

#### Stage 2 - application of selection criteria

These criteria will be assessed on the basis of the documents indicated<sup>37</sup>.

<b><u>SELECTION CRITERIA</u></b>
<b>1. FINANCIAL AND ECONOMIC CAPACITY</b>
1.1 Sufficient financial and economic capacity for the implementation of the contract
A minimum average annual turnover of 100,000 EUR over the past 3 financial years.

<sup>36</sup> See section 4.3.4

<sup>37</sup> See section Selection criteria documentation, page 64

## 2. TECHNICAL AND PROFESSIONAL CAPACITY

2.1 Sufficient technical capacity to provide the human resources required for the implementation of the contract.

A minimum of two permanently employed staff members meeting the requirements<sup>38</sup> of the profile.

2.2 Sufficient professional capacity to provide the services

A minimum of one scientific project similar in scope<sup>39</sup> executed in the past 10 calendar years for a minimum total value of 20.000 EUR.

A consolidated assessment shall be made for joint offers (all members of the consortium together) and in case of subcontracting (tenderer plus subcontractor) to the extent that those entities put their resources at the disposal of the tenderer for the performance of the contract, as evidenced by a clear undertaking on the part of those entities.

### Stage 3 - application of award criteria

Framework contracts shall be awarded under the best-value-for-money procedure. The technical evaluation will be made by establishing an overall technical score for the technical proposal that takes into account the score for the award criterion indicated below.

The following award criteria will be applied:

No	Qualitative award criterion	Weighting (maximum points)
1.	<i>Quality of the methodological proposal for the provision of the services under the contract</i>	45
2	<i>Quality of the methodological proposal for the case study</i>	15
<b>Total number of points</b>		60

The selected tender is assessed according to the above qualitative award criteria and the weighting applicable to each criterion.

**Tenders scoring less than 60% in the overall points awarded or less than 50% in the points awarded for a single criterion will be excluded from the rest of the assessment procedure.**

<sup>38</sup> expert in human health toxicology must have knowledge and skills as described in 1.4.1 (Requirements for the Resources).

<sup>39</sup> See section 1

<b>Technical Merit</b>	
TM	$TM = (AW1 + AW2)$

The **Technical Merit (TM)** is evaluated as follows: a maximum of **60 points** are given for all qualitative award criteria. The offers are ranked according to the above mentioned formula, in which:

AW1 = Award Criteria 1

AW2 = Award Criteria 2

60 = Maximum points to be awarded

<b>Price</b>	
P	$P = (Pmin/Po) \times 40$

The **Price criterion (P)** is evaluated as follows: a maximum of 40 points is given to the lowest price offer. The offers are ranked according to the above mentioned formula, in which:

P = Classification of each price offer (points to be awarded)

Po = Price of each offer: total price

Pmin = Minimum price offered among all tenders

40 = Maximum points to be awarded

<b>Final Evaluation</b>	
X	$X = TM + P$

The contracts will be awarded to the most economically advantageous tenders on the basis of the following criteria:

-Technical Merit (TM) (60 points)

- Price (P) (40 points)

### 3.5. AWARD OF THE CONTRACT

The Agency will inform tenderers of decisions reached concerning the award of the contract, including the grounds for any decision not to award a contract or to cancel the procedure.

If a written request is received from any non successful tenderer, the Agency will inform the tenderer of the reasons for their lack of success and of the name of the successful tenderer.

However, certain information may be withheld where its release would impede law enforcement or otherwise be contrary to the public interest, or would prejudice the legitimate commercial interests of economic operators, public or private, or might prejudice fair competition between them.

The procurement procedure may be concluded by a contract signed by the parties. In this case, the General Terms and Conditions applicable to service contracts referred to below shall apply.

After the period of validity of the tender has expired, conclusion of the contract shall be subject to the tenderers' agreement in writing.

The Agency shall not sign the contract or framework contract with the successful tenderers until a standstill period of 14 calendar days has elapsed, running from the day after the simultaneous dispatch of the notification letters to the tenderers informing them of the award decision.

During the standstill period, the Agency will request the tenderers proposed for award to provide the evidence on exclusion criteria defined in Articles 93 and 94 of the Financial Regulation. If this evidence was not provided or proved to be unsatisfactory, the Agency reserves the right to cancel the award procedure or to change the award decision to the benefit of the next best ranked tenderer on condition that he satisfies with the provision of the evidence on exclusion.

The tenderers to whom the contract is to be awarded shall provide, within the 15 days following the receipt of the letter informing him of the proposed award of the contract and preceding the signature of the contract, the following evidence confirming the declaration of honour:

- 1 The Agency shall accept as satisfactory evidence that the tenderer to whom the contract is to be awarded is not in one of the situations described in point (a), (b) or (e) of Article 93(1) of the Financial Regulation, a recent extract from the judicial record or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied;
- 2 The Agency shall accept, as satisfactory evidence that the tenderer is not in the situation described in point (d) of Article 93(1) of the Financial Regulation, a recent certificate issued by the competent authority of the State.
- 3 Where the document or certificate referred to in paragraph 1 and 2 is not issued in the country concerned and for the other cases of exclusion referred to in Article 93 of the Financial Regulation, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.
- 4 Depending on the national legislation of the country in which the tenderer is established, the documents referred to in paragraphs 1, 2, and 3 shall relate to legal persons and/or natural persons including, where necessary, company directors or any person with power of representation, decision-making or control in relation to the tenderer or tenderer. This would be the case when the national legislation concerned gives juridical responsibility of the acts committed by a legal entity (moral persons) to their legal representatives. The tenderer shall provide information on the ownership or on the management, control and power of representation of the legal entity whenever necessary for the proper understanding of the evidence submitted or whenever the Agency requests it.



- 5 Where they have doubts as to whether tenderers are in one of the situations of exclusion, the Agency may itself apply to the competent authorities referred to in paragraph 3 to obtain any information they consider necessary about that situation.
- 6 The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to in paragraphs 1 and 2 if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case, the tenderer shall declare on his honour that the documentary evidence has already been provided to the Agency in a previous procurement procedure and confirm that no changes in his situation have occurred. He shall indicate in its tender all the references necessary to allow the Agency services to check this evidence.

## 4. ANNEXES

### 4.1. TECHNICAL DOCUMENTATION

The technical documentation constitutes an integral part of the technical specifications.

Information related to the Agency: [http://www.echa.europa.eu/home\\_en.asp](http://www.echa.europa.eu/home_en.asp)

Information related to the QSAR Toolbox: [www.qsartoolbox.org](http://www.qsartoolbox.org),  
<http://www.oecd.org/env/existingchemicals/qsar>

Information related to IUCLID: <http://iuclid.eu>

Schema:

- ToxML (Toxicology XML standard: <http://www.leadscope.com/toxml.php>)
- OECD Harmonised Templates: <http://www.oecd.org/ehs/templates>

Existing toxicity data standard

- OBO Foundry: <http://www.obofoundry.org>
- Web Ontology Language (OWL): <http://www.w3.org/TR/owl-ref>

Existing pieces of work related to ontologies:

- OpenTox: <http://www.opentox.org>
- Bio-portal ontology depository: <http://bioportal.bioontology.org>
- Anatomy ontologies: <http://sig.biostr.washington.edu/projects/fm/index.html>
- Pathology ontologies: [http://obi-ontology.org/page/Main\\_Page](http://obi-ontology.org/page/Main_Page)
- Protégé Editor: <http://protege.stanford.edu>
- DevTox: <http://www.devtox.org/infpartner.htm>
- Gene Ontology: <http://www.geneontology.org>

Qverview of relevant endpoints:

[http://echa.europa.eu/doc/publications/practical\\_guides/pg\\_report\\_robust\\_study\\_summaries.pdf](http://echa.europa.eu/doc/publications/practical_guides/pg_report_robust_study_summaries.pdf)

## 4.2. CONTRACTUAL DOCUMENTATION

### 4.2.1. Model Framework Contract



# FRAMEWORK SERVICE CONTRACT

CONTRACT NUMBER – ECHA/2011/25

The European Chemicals Agency (hereinafter referred to as "Agency"), represented for the purposes of the signature of this contract by Mr Jukka Malm, Director of Regulatory Affairs,

of the one part,

and

[official name in full]

[official legal form]<sup>40</sup>

[statutory registration number]<sup>41</sup>

[official address in full]

[VAT registration number]

(hereinafter referred to as "the Contractor"<sup>42</sup>), [represented for the purposes of the signature of this contract by [forename, surname and function,]]

of the other part,

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<sup>40</sup> Delete if contractor is a natural person or a body governed by public law.

<sup>41</sup> Delete if contractor is a body governed by public law. For natural persons, indicate the number of their identity card or, failing that, of their passport or equivalent.

<sup>42</sup> In the case of a joint offer and provided the invitation to tender so specifies, the following clause should be added below the identification of the parties: "The parties identified above and hereinafter collectively referred to as 'the Contractor' shall be jointly and severally liable vis-à-vis the Commission for the performance of this contract".

## HAVE AGREED

the **Special Conditions** and the **General Conditions** below and the following Annexes:

**Annex I** – Tender Specifications (Invitation to Tender ECHA2011/25)

**Annex II** – Contractor's Tender (No [complete] of [complete])

which form an integral part of this contract (hereinafter referred to as “the Contract”).

The terms set out in the Special Conditions shall take precedence over those in the other parts of the Contract. The terms set out in the General Conditions shall take precedence over those in the Annexes. The terms set out in the Tender Specifications (Annex I) shall take precedence over those in the specific contracts, the latter taking precedence over the Tender (Annex II).

Subject to the above, the several instruments forming part of the Contract are to be taken as mutually explanatory. Ambiguities or discrepancies within or between such parts shall be explained or rectified by a written instruction issued by the Agency, subject to the rights of the Contractor under Article I.8 should he dispute any such instruction.

## **I – SPECIAL CONDITIONS**

### **ARTICLE I.1 - SUBJECT**

- I.1.1 The subject of the Contract is the provision of scientific services for the development of ontologies.
- I.1.2 Signature of the Contract imposes no obligation on the Agency to purchase. Only implementation of the Contract through specific contracts is binding on the Agency.
- I.1.3 Once implementation of the Contract has been asked or has commenced, the Contractor shall reply and provide the services in accordance with all terms and conditions of the Contract.
- I.1.4 The Contract does not confer on the Contractor any exclusive right to provide the services described in Annex I to the Agency.

### **ARTICLE I.2 - DURATION**

- I.2.1 The Contract shall enter into force on the date on which it is signed by the last contracting party.
- I.2.2 Under no circumstances may implementation commence before the date on which the Contract enters into force. Execution of the tasks may under no circumstances begin before the date on which the order or Specific Contract enters into force.
- I.2.3 The Contract is concluded for a period of 48 months with effect from the date on which it enters into force. This contractual period and all other periods specified in the Contract are calculated in calendar days unless otherwise indicated.
- I.2.4 The specific contracts shall be returned signed before the Contract to which they refer expires.  
The Contract shall continue to apply to such specific contracts after its expiry, but no longer than 6 months.

### **ARTICLE I.3 –PRICES**

- I.3.1 The prices of the services shall be in accordance with the maximum prices listed in Annex II.
- I.3.2 Prices shall be expressed in EUR.
- I.3.3 Prices shall be fixed and not subject to revision.
- I.3.4. In addition to the total amount specified in each specific contract, travel, subsistence and shipment expenses or any other expenses provided for by the Tender Specifications shall be reimbursed in accordance with Article II.7, if applicable according to the terms and conditions of the Service Request for the specific contract. The rate of the daily subsistence allowance, where applicable, shall be 240 EUR..

## **ARTICLE I.4 – IMPLEMENTATION OF THE CONTRACT**

- I.4.1 The Contract shall be implemented through Specific Contracts on a Fixed Price basis, in accordance with Annex I.
- I.4.2. The Specific Contracts shall be awarded through re-opening of competition among the Contractors. The request of services shall be done in accordance with Annex I.
- I.4.3 Unless indicated otherwise in the Service Request, within 10 working days of any Service Request being sent by the Agency to the Contractor, the Agency shall receive a completed specific tender back, duly signed and dated. In the event of failure to observe these conditions the Contractor shall be considered to waive the participation in the specific competition. The Agency may sign a Specific Contract with the contractor who has submitted the best specific tender on the basis of the award criteria set out in Annex I. The Specific Contract may precise the terms of the present framework contract or modify them unsubstantially, notably as concerns prices.
- I.4.4. Within 10 working days of a Specific Contract being sent by the Agency to the Contractor, the Agency shall receive it back, duly signed and dated.

## **ARTICLE I.5 – PAYMENT PERIODS**

- I.5.1. Payments under the Contract shall be made in accordance with Article II.4 and II.5. Payments shall be executed only if the Contractor has fulfilled all his contractual obligations by the date on which the invoice is submitted. Within thirty days of the date on which the admissible request for payment is received, the Agency shall make the payment corresponding to the relevant invoices and statements of reimbursable expenses.
- I.5.2. The terms of payment shall be specified for each Specific Contract as indicated by the Agency in the Service Request for a Specific Contract.

## **ARTICLE I.6 – BANK ACCOUNT**

Payments shall be made to the Contractor's bank account denominated in euro, identified<sup>43</sup> as follows:

Name of bank: [complete]

Address of branch in full: [complete]

Exact designation of account holder: [complete]

Full account number including codes: [complete]

[IBAN<sup>44</sup> code: [complete]]

## **ARTICLE I.7 – GENERAL ADMINISTRATIVE PROVISIONS**

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<sup>43</sup> By a document issued or certified by the bank.

<sup>44</sup> BIC or SWIFT code for countries with no IBAN code.

Any communication relating to the Contract or to its implementation shall be made in writing and shall bear the Contract and order or Specific Contract numbers. Ordinary mail shall be deemed to have been received by the Agency on the date on which it is registered by the department responsible indicated below. Communications shall be sent to the following addresses<sup>45</sup>:

Agency:

European Chemicals Agency  
Annankatu 18  
00-100 Helsinki  
Finland

Contractor:

Mr/Mrs/Ms [complete]  
[Function]  
[Company name]  
[Official address in full]

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<sup>45</sup> Fax number and e-mail accounts may be added. If an e-mail account is given, incoming e mails should be redirected if the account holder is absent and a clause should be added specifying what is considered to be the reference date of the electronic communication (date of sending, receiving or opening).

## **ARTICLE I.8 – APPLICABLE LAW AND SETTLEMENT OF DISPUTES**

I.8.1 The Contract shall be governed by European Union Law, complemented where necessary by the national substantive law of Finland.

I.8.2 Any dispute between the parties resulting from the interpretation or application of the Contract which cannot be settled amicably shall be brought before the Helsinki District Court.

## **ARTICLE I.9 – DATA PROTECTION**

Any personal data included in or relating to the Contract, including its execution shall be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The data shall be processed solely for the purposes of the performance, management and monitoring of the Contract by the Agency without prejudice to possible transmission to the bodies charged with a monitoring or inspection task in application of Union law. The Contractor shall have the right of access to his/her personal data and the right to rectify any such data. Should the Contractor have any queries concerning the processing of his/her personal data, s/he shall address them to the Agency. The Contractor shall have right of recourse at any time to the European Data Protection Supervisor.

Where the Contract requires the processing of personal data, the Contractor may act only under the supervision of the data controller, in particular with regard to the purposes of the processing, the categories of data which may be processed, the recipients of the data, and the means by which the data subject may exercise his/her rights.

The data shall be confidential within the meaning of Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data. The Contractor shall limit access to the data to the staff strictly necessary for the performance, management and monitoring of the Contract.

The Contractor undertakes to adopt appropriate technical and organisational security measures having regard to the risks inherent in the processing and to the nature of the personal data concerned in order to:

- j) prevent any unauthorised person from having access to computer systems processing personal data, and especially:
- k) unauthorised reading, copying, alteration or removal of storage media;
- l) unauthorised data input as well as any unauthorised disclosure, alteration or erasure of stored personal data;
- m) unauthorised persons from using data-processing systems by means of data transmission facilities;



- n) ensure that authorised users of a data-processing system can access only the personal data to which their access right refers;
- o) record which personal data have been communicated, when and to whom;
- p) ensure that personal data being processed on behalf of third parties can be processed only in the manner prescribed by the Agency;
- q) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or erased without authorisation;
- r) design its organisational structure in such a way that it meets data protection requirements.

#### **ARTICLE I.10 – TERMINATION BY EITHER CONTRACTING PARTY**

Either contracting party may, of its own volition and without being required to pay compensation, terminate the Contract by serving 3 months formal prior notice. Should the Agency terminate the Contract, the Contractor shall only be entitled to payment corresponding to the services ordered and executed before the termination date. On receipt of the letter terminating the Contract, the Contractor shall take all appropriate measures to minimise costs, prevent damage, and cancel or reduce his commitments. He shall draw up the documents required by the Special Conditions for the services rendered up to the date on which termination takes effect, within a period not exceeding sixty days from that date.

#### **ARTICLE I.10a – CONTRACT CONCLUDED DURING STANDSTILL PERIOD**

In case this Contract was signed by both the Agency and the Contractor before the expiry of 14 calendar days from the day after simultaneous dispatch of information about the award decisions and decisions to reject, this Contract shall be null and void.

## **II – GENERAL CONDITIONS**

### **ARTICLE II.1 – PERFORMANCE OF THE CONTRACT**

II.1.1 The Contractor shall perform the Contract to the highest professional standards. The Contractor shall have sole responsibility for complying with any legal obligations incumbent on him, notably those resulting from employment, tax and social legislation.

II.1.2 The Contractor shall have sole responsibility for taking the necessary steps to obtain any permit or licence required for performance of the Contract under the laws and regulations in force at the place where the tasks assigned to him are to be executed.

II.1.3 Without prejudice to Article II.3 any reference made to the Contractor's staff in the Contract shall relate exclusively to individuals involved in the performance of the Contract.

II.1.4 The Contractor must ensure that any staff performing the Contract have the professional qualifications and experience, as well as the knowledge and skills, required for the execution of the tasks assigned to him.

II.1.5 The Contractor shall neither represent the Agency nor behave in any way that would give such an impression. The Contractor shall inform third parties that he does not belong to the European public service.

II.1.6 The Contractor shall have sole responsibility for the staff who execute the tasks assigned to him.

The Contractor shall make provision for the following employment or service relationships with his staff:

- staff executing the tasks assigned to the Contractor may not be given orders direct by the Agency;
- the Agency may not under any circumstances be considered to be the staff's employer and the said staff shall undertake not to invoke in respect of the Agency any right arising from the contractual relationship between the Agency and the Contractor.

II.1.7 In the event of disruption resulting from the action of a member of the Contractor's staff working on Agency premises or in the event of the expertise of a member of the Contractor's staff failing to correspond to the profile required by the Contract, the Contractor shall replace him without delay. The Agency shall have the right to request the replacement of any such member of staff, stating its reasons for so doing. Replacement staff must have the necessary qualifications and be capable of

performing the Contract under the same contractual conditions. The Contractor shall be responsible for any delay in the execution of the tasks assigned to him resulting from the replacement of staff in accordance with this Article.

II.1.8 Should any unforeseen event, action or omission directly or indirectly hamper execution of the tasks, either partially or totally, the Contractor shall immediately and on his own initiative record it and report it to the Agency. The report shall include a description of the problem and an indication of the date on which it started and of the remedial action taken by the Contractor to ensure full compliance with his obligations under the Contract. In such event the Contractor shall give priority to solving the problem rather than determining liability.

II.1.9 Should the Contractor fail to perform his obligations under the Contract in accordance with the provisions laid down therein, the Agency may - without prejudice to its right to terminate the Contract - reduce or recover payments in proportion to the scale of the failure. In addition, the Agency may impose penalties or liquidated damages provided for in Article II.16.

II.1.10 The Agency reserves the right, prior to the signature of a specific contract, to proceed to security screenings of any individual proposed and to refuse those individuals on security grounds, without giving any further explanation. The Agency reserves the right, after the signature of a specific contract, to require any person working on its premises to attend security briefings, follow security-related trainings and/or sign a security statement.

II.1.11 During the performance of the contract, members of the Contractor's staff working on Agency premises must respect the Agency's security policies, as notified by the Agency.

## **ARTICLE II. 2 – LIABILITY**

II.2.1 The Agency shall not be liable for damage sustained by the Contractor in performance of the Contract except in the event of wilful misconduct or gross negligence on the part of the Agency.

II.2.2 The Contractor shall be liable for any loss or damage caused by himself in performance of the Contract, including in the event of subcontracting under Article II.13. The Agency shall not be liable for any act or default on the part of the Contractor in performance of the Contract.

II.2.3 The Contractor shall provide compensation in the event of any action, claim or proceeding brought against the Agency by a third party as a result of damage caused by the Contractor in performance of the Contract.

II.2.4 In the event of any action brought by a third party against the Agency in connection with performance of the Contract, the Contractor shall assist the Agency. Expenditure incurred by the Contractor to this end may be borne by the Agency.

II.2.5 The Contractor shall take out insurance against risks and damage relating to performance of the Contract if required by the relevant applicable legislation. He shall take out supplementary insurance as reasonably required by standard practice in the industry. A copy of all the relevant insurance contracts shall be sent to the Agency should it so request.

### **ARTICLE II. 3 - CONFLICT OF INTERESTS**

II.3.1 The Contractor shall take all necessary measures to prevent any situation that could compromise the impartial and objective performance of the Contract. Such conflict of interests could arise in particular as a result of economic interest, political or national affinity, family or emotional ties, or any other relevant connection or shared interest. Any conflict of interests which could arise during performance of the Contract must be notified to the Agency in writing without delay. In the event of such conflict, the Contractor shall immediately take all necessary steps to resolve it.

The Agency reserves the right to verify that such measures are adequate and may require additional measures to be taken, if necessary, within a time limit which it shall set. The Contractor shall ensure that his staff, board and directors are not placed in a situation which could give rise to conflict of interests. Without prejudice to Article II.1 the Contractor shall replace, immediately and without compensation from the Agency, any member of his staff exposed to such a situation.

II.3.2 The Contractor shall abstain from any contact likely to compromise his independence.

II.3.3 The Contractor declares:

- that he has not made and will not make any offer of any type whatsoever from which an unjustified advantage can be derived under the Contract,
- that he has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept, any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to performance of the Contract.

II.3.4 The Contractor shall pass on all the relevant obligations in writing to his staff, board, and directors as well as to third parties involved in performance of the Contract. A copy of the instructions given and the undertakings made in this respect shall be sent to the Agency should it so request.

### **ARTICLE II. 4 – INVOICING AND PAYMENTS**

II.4.1 Pre-financing:

Where required by Article I.5, the Contractor shall provide a financial guarantee in the form of a bank guarantee or equivalent supplied by a bank or an authorised financial institution (guarantor) equal to the amount indicated in the same Article to cover pre-financing under the Contract. Such guarantee may be replaced by a joint and several guarantee by a third party.

The guarantor shall pay to the Agency at its request an amount corresponding to payments made by it to the Contractor which have not yet been covered by equivalent work on his part.

The guarantor shall stand as first-call guarantor and shall not require the Agency to have recourse against the principal debtor (the Contractor).

The guarantee shall specify that it enters into force at the latest on the date on which the Contractor receives the pre-financing. The Agency shall release the guarantor from its obligations as soon as the Contractor has demonstrated that any pre-financing has been covered by equivalent work. The guarantee shall be retained until the pre-financing has been deducted from interim payments or payment of the balance to the Contractor. It shall be released the following month or, at the latest, three months after the issuance of a recovery order. The cost of providing such guarantee shall be borne by the Contractor.

#### II.4.2 Interim payment:

At the end of each of the periods indicated in the Specific Contract the Contractor shall submit to the Agency a formal request for payment accompanied by those of the following documents which are provided for in the Specific Contract:

- an interim technical report and any deliverable in accordance with the instructions laid down in Annex I of the Specific Contract ;
- the relevant invoices indicating the reference number of the Contract and of the order or Specific Contract to which they refer;
- statements of reimbursable expenses in accordance with Article II.7.

If the report is a condition for payment, on receipt the Agency shall have the period of time indicated in the Special Conditions in which:

- to approve it, with or without comments or reservations, or suspend such period and request additional information; or
- to reject it and request a new report.

If the Agency does not react within this period, the report shall be deemed to have been approved. Approval of the report does not imply recognition either of its regularity or of the authenticity, completeness or correctness of the declarations or information enclosed.

Where the Agency requests a new report because the one previously submitted has been rejected, this shall be submitted within the period of time indicated in the Special Conditions. The new report shall likewise be subject to the above provisions.

#### II.4.3 Payment of the balance:

Within sixty days of completion of the tasks referred to in each order or specific contract, the Contractor shall submit to the Agency a formal request for payment accompanied by those of the following documents, which are provided for in the Special Conditions:

- a final technical report and any deliverable in accordance with the instructions laid down in Annex I to the Specific Contract;
- the relevant invoices indicating the reference number of the Contract and of the order or Specific Contract to which they refer;
- statements of reimbursable expenses in accordance with Article II.7.

If the report is a condition for payment, on receipt the Agency shall have the period of time indicated in the Special Conditions in which:

- to approve it, with or without comments or reservations, or suspend such period and request additional information; or
- to reject it and request a new report.

If the Agency does not react within this period, the report shall be deemed to have been approved. Approval of the report does not imply recognition either of its regularity or of the authenticity, completeness or correctness of the declarations and information enclosed.

Where the Agency requests a new report because the one previously submitted has been rejected, this shall be submitted within the period of time indicated in the Special Conditions. The new report shall likewise be subject to the above provisions.

### **ARTICLE II. 5 – GENERAL PROVISIONS CONCERNING PAYMENTS**

II.5.1 Payments shall be deemed to have been made on the date on which the Agency's account is debited.

II.5.2 The payment periods referred to in Article I.5 may be suspended by the Agency at any time if it informs the Contractor that his payment request is not admissible, either because the amount is not due or because the necessary supporting documents have not been properly produced. In case of doubt on the eligibility of the expenditure indicated in the payment request, the Agency may suspend the time limit for payment for the purpose of further verification, including an on-the-spot check, in order to ascertain, prior to payment, that the expenditure is eligible.

The Agency shall notify the Contractor accordingly and set out the reasons for the suspension by registered letter with acknowledgment of receipt or equivalent. Suspension shall take effect from the date of dispatch of the letter. The remainder of the period referred to in Article I.5 shall begin to run again once the suspension has been lifted.

II.5.3 In the event of late payment the Contractor shall be entitled to interest, provided the calculated interest exceeds EUR 200. In case interest does not exceed EUR 200, the Contractor may claim interest within two months of receiving the payment. Interest shall be calculated at the rate applied by the European Central Bank to its most recent main refinancing operations (“the reference rate”) plus seven percentage points (“the margin”). The reference rate in force on the first day of the month in which the payment is due shall apply. Such interest rate is published in the C series of the Official Journal of the European Union. Interest shall be payable for the period elapsing from the calendar day following expiry of the time limit for payment up to the day of payment. Suspension of payment by the Agency may not be deemed to constitute late payment.

## **ARTICLE II. 6 – RECOVERY**

II.6.1 If total payments made exceed the amount actually due or if recovery is justified in accordance with the terms of the Contract, the Contractor shall reimburse the appropriate amount in euro on receipt of the debit note, in the manner and within the time limits set by the Agency.

II.6.2 In the event of failure to pay by the deadline specified in the request for reimbursement, the sum due shall bear interest at the rate indicated in Article II.5.3. Interest shall be payable from the calendar day following the due date up to the calendar day on which the debt is repaid in full.

## **ARTICLE II. 7 - REIMBURSEMENTS**

II.7.1 Where provided by the Specific Contract, the Agency shall reimburse the expenses that are directly connected with execution of the tasks on production of original supporting documents, including receipts and used tickets.

II.7.2 Travel and subsistence expenses shall be reimbursed, where appropriate, on the basis of the shortest itinerary.

II.7.3 Travel expenses shall be reimbursed as follows:

- a) travel by air shall be reimbursed up to the maximum cost of an economy class ticket at the time of the reservation;
- b) travel by boat or rail shall be reimbursed up to the maximum cost of a first class ticket;
- c) travel by car shall be reimbursed at the rate of one first class rail ticket for the same journey and on the same day;

- d) travel outside Union territory shall be reimbursed under the general conditions stated above provided the Agency has given its prior written agreement.

II.7.4 Subsistence expenses shall be reimbursed on the basis of a daily allowance as follows:

- a) for journeys of less than 200 km (return trip) no subsistence allowance shall be payable;
- b) daily subsistence allowance shall be payable only on receipt of a supporting document proving that the person concerned was present at the place of destination;
- c) daily subsistence allowance shall take the form of a flat rate payment to cover all subsistence expenses, including accommodation, meals, local transport, insurance and sundries;
- d) daily subsistence allowance, where applicable, shall be reimbursed at the rate specified in Article I.3.

II.7.5 The cost of shipment of equipment or unaccompanied luggage shall be reimbursed provided the Agency has given prior written authorisation.

## **ARTICLE II. 8 – OWNERSHIP OF THE RESULTS - INTELLECTUAL AND INDUSTRIAL PROPERTY**

Any results or rights thereon, including copyright and other intellectual or industrial property rights, obtained in performance of the Contract, shall be owned solely by the Agency, which may use, publish, assign or transfer them as it sees fit, without geographical or other limitation, except where industrial or intellectual property rights exist prior to the Contract being entered into.

## **ARTICLE II. 9 – CONFIDENTIALITY**

II.9.1. The Contractor undertakes to treat in the strictest confidence and not make use of or divulge to third parties any information or documents which are linked to performance of the Contract. The Contractor shall continue to be bound by this undertaking after completion of the tasks.

II.9.2. The Contractor shall obtain from each member of his staff, board and directors an undertaking that they will respect the confidentiality of any information which is linked, directly or indirectly, to execution of the tasks and that they will not divulge to third parties or use for their own benefit or that of any third party any document or information not available publicly, even after completion of the tasks.

II.9.3. The Contractor shall ensure that each member of his staff working on Agency premises complies with ECHA Security instructions and policies concerning the access to the building and the information.

## **ARTICLE II.10 - USE, DISTRIBUTION AND PUBLICATION OF INFORMATION**



II.10.1 The Contractor shall authorise the Agency to process, use, distribute and publish, for whatever purpose, by whatever means and on whatever medium, any data contained in or relating to the Contract, in particular the identity of the Contractor, the subject matter, the duration, the amount paid and the reports. Where personal data is concerned, Article I.9 shall apply.

II.10.2 Unless otherwise provided by the Special Conditions, the Agency shall not be required to distribute or publish documents or information supplied in performance of the Contract. If it decides not to publish the documents or information supplied, the Contractor may not have them distributed or published elsewhere without prior written authorisation from the Agency.

II.10.3 Any distribution or publication of information relating to the Contract by the Contractor shall require prior written authorisation from the Agency and shall mention the amount paid by the Union. It shall state that the opinions expressed are those of the Contractor only and do not represent the Agency's official position.

II.10.4 The use of information obtained by the Contractor in the course of the Contract for purposes other than its performance shall be forbidden, unless the Agency has specifically given prior written authorisation to the contrary.

## **ARTICLE II. 11 – TAXATION**

II.11.1 The Contractor shall have sole responsibility for compliance with the tax laws which apply to him. Failure to comply shall make the relevant invoices invalid.

II.11.2 The Contractor recognises that the Agency is, as a rule, exempt from all taxes and duties, including value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union.

II.11.3 The Contractor shall accordingly complete the necessary formalities with the relevant authorities to ensure that the goods and services required for performance of the Contract are exempt from taxes and duties, including VAT.

II.11.4 Invoices presented by the Contractor shall indicate his place of taxation for VAT purposes and shall specify separately the amounts not including VAT and the amounts including VAT.

## **ARTICLE II. 12 – FORCE MAJEURE**

II.12.1 Force majeure shall mean any unforeseeable and exceptional situation or event beyond the control of the contracting parties which prevents either of them from performing any of their obligations under the Contract, was not due to error or negligence on their part or on the part of a subcontractor, and could not have been avoided by the exercise of due diligence. Defects in equipment or material or delays in making it available, labour

disputes, strikes or financial problems cannot be invoked as force majeure unless they stem directly from a relevant case of force majeure.

II.12.2 Without prejudice to the provisions of Article II.1.8, if either contracting party is faced with force majeure, it shall notify the other party without delay by registered letter with acknowledgment of receipt or equivalent, stating the nature, likely duration and foreseeable effects.

II.12.3 Neither contracting party shall be held in breach of its contractual obligations if it has been prevented from performing them by force majeure. Where the Contractor is unable to perform his contractual obligations owing to force majeure, he shall have the right to remuneration only for tasks actually executed.

II.12.4 The contracting parties shall take the necessary measures to reduce damage to a minimum.

### **ARTICLE II. 13 – SUBCONTRACTING**

II.13.1 The Contractor shall not subcontract without prior written authorisation from the Agency nor cause the Contract to be performed in fact by third parties.

II.13.2 Even where the Agency authorises the Contractor to subcontract to third parties, he shall none the less remain bound by his obligations to the Agency under the Contract and shall bear exclusive liability for proper performance of the Contract.

II.13.3 The Contractor shall make sure that the subcontract does not affect rights and guarantees to which the Agency is entitled by virtue of the Contract, notably Article II.17.

### **ARTICLE II. 14 – ASSIGNMENT**

II.14.1 The Contractor shall not assign the rights and obligations arising from the Contract, in whole or in part, without prior written authorisation from the Agency.

II.14.2 In the absence of the authorisation referred to in 1 above, or in the event of failure to observe the terms thereof, assignment by the Contractor shall not be enforceable against and shall have no effect on the Agency.

### **ARTICLE II. 15 – TERMINATION BY THE AGENCY**

II.15.1 The Agency may terminate the Contract or a Specific Contract in the following circumstances:

- a) where the Contractor is being wound up, is having his affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any

analogous situation arising from a similar procedure provided for in national legislation or regulations;

- b) where the Contractor has not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which he is established or with those of the country applicable to the Contract or those of the country where the Contract is to be performed;
- c) where the Agency has evidence or seriously suspects the Contractor or any related entity or person, of professional misconduct;
- d) where the Agency has evidence or seriously suspects the Contractor or any related entity or person, of fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Union's financial interests;
- e) where the Agency has evidence or seriously suspects the Contractor or any related entity or person, of substantial errors, irregularities or fraud in the award procedure or the performance of the Contract;
- f) where the Contractor is in breach of his obligations under Article II.3;
- g) where the Contractor was guilty of misrepresentation in supplying the information required by the Agency as a condition of participation in the Contract procedure or failed to supply this information;
- h) where a change in the Contractor's legal, financial, technical or organisational situation could, in the Agency's opinion, have a significant effect on the performance of the Contract;
- i) where execution of the tasks under a pending order or a Specific Contract has not actually commenced within fifteen days of the date foreseen, and the new date proposed, if any, is considered unacceptable by the Agency;
- j) where the Contractor is unable, through his own fault, to obtain any permit or licence required for performance of the Contract;
- k) where the Contractor, after receiving formal notice in writing to comply, specifying the nature of the alleged failure, and after being given the opportunity to remedy the failure within a reasonable period following receipt of the formal notice, remains in serious breach of his contractual obligations;
- l) when due to the termination of the contract with one or more of the contractors there is no minimum required competition within the multiple framework contract with reopening of competition.

II.15.2 In case of force majeure, notified in accordance with Article II.12, either contracting party may terminate the Contract, where performance thereof cannot be ensured for a period corresponding to at least to one fifth of the period laid down in Article I.2.3.

II.15.3 Prior to termination under point c), d), e), h) or k), the Contractor shall be given the opportunity to submit his observations.

Termination shall take effect on the date on which a registered letter with acknowledgment of receipt terminating the Contract is received by the Contractor, or on any other date indicated in the letter of termination.

II.15.4 Consequences of termination:

In the event of the Agency terminating the Contract or Specific Contract in accordance with this Article and without prejudice to any other measures provided for in the Contract, the Contractor shall waive any claim for consequential damages, including any loss of anticipated profits for uncompleted work. On receipt of the letter terminating the Contract, the Contractor shall take all appropriate measures to minimise costs, prevent damage, and cancel or reduce his commitments. He shall draw up the documents required by the Special Conditions for the tasks executed up to the date on which termination takes effect, within a period not exceeding sixty days from that date.

The Agency may claim compensation for any damage suffered and recover any sums paid to the Contractor under the Contract.

On termination the Agency may engage any other contractor to execute or complete the services. The Agency shall be entitled to claim from the Contractor all extra costs incurred in doing so, without prejudice to any other rights or guarantees enforceable under the Contract.

#### **ARTICLE II.15a – SUBSTANTIAL ERRORS, IRREGULARITIES AND FRAUD ATTRIBUTABLE TO THE CONTRACTOR**

Where, after the award of the Contract or a Specific Contract, the award procedure or the performance of the Contract prove to have been subject to substantial errors, irregularities or fraud, and where such errors, irregularities or fraud are attributable to the Contractor, the Agency may refuse to make payments, may recover amounts already paid or may terminate all the contracts concluded with the Contractor, in proportion to the seriousness of the errors, irregularities or fraud.

#### **ARTICLE II. 16 – LIQUIDATED DAMAGES**

Should the Contractor fail to perform his obligations under the Contract within the time limits set by the Contract, then, without prejudice to the Contractor's actual or potential liability incurred in relation to the Contract or to the Agency's right to terminate the Contract, the Agency may decide to impose liquidated damages of 0.2% of the amount of the relevant purchase per

calendar day of delay. The Contractor may submit arguments against this decision within thirty days of notification by registered letter with acknowledgement of receipt or equivalent. In the absence of reaction on his part or of written withdrawal by the Agency within thirty days of the receipt of such arguments, the decision imposing the liquidated damages shall become enforceable. These liquidated damages shall not be imposed where there is provision for interest for late completion. The Agency and the Contractor expressly acknowledge and agree that any sums payable under this Article are in the nature of liquidated damages and not penalties, and represent a reasonable estimate of fair compensation for the losses that may be reasonably anticipated from such failure to perform obligations.

## **ARTICLE II. 17 – CHECKS AND AUDITS**

II.17.1 Pursuant to Article 142 of the Financial Regulation applicable to the general budget of the European Communities, the Court of Auditors shall be empowered to audit the documents held by the natural or legal persons receiving payments from the budget of the Union from signature of the Contract up to five years after payment of the balance of the last implementation.

II.17.2 The Agency or an outside body of its choice shall have the same rights as the Court of Auditors for the purpose of checks and audits limited to compliance with contractual obligations from signature of the Contract up to five years after payment of the balance of the last implementation.

II.17.3 In addition, the European Anti-Fraud Office may carry out on-the-spot checks and inspections in accordance with Council Regulation (Euratom, EC) No 2185/96 and Parliament and Council Regulation (EC) No 1073/1999 from signature of the Contract up to five years after payment of the balance of the last implementation.

## **ARTICLE II. 18 – AMENDMENTS**

Any amendment to the Contract shall be the subject of a written agreement concluded by the contracting parties. An oral agreement shall not be binding on the contracting parties. An order or a Specific Contract may not be deemed to constitute an amendment to the Contract.

## **ARTICLE II. 19 – SUSPENSION OF THE CONTRACT**

Without prejudice to the Agency's right to terminate the Contract, the Agency may at any time and for any reason suspend execution of the Contract, pending orders or specific contracts or any part thereof. Suspension shall take effect on the day the Contractor receives notification by registered letter with acknowledgment of receipt or equivalent, or at a later date where the notification so provides. The Agency may at any time following suspension give notice to the Contractor to resume the work suspended. The Contractor shall not be entitled to claim compensation on account of suspension of the Contract, of the orders or specific contracts, or of part thereof.

SIGNATURES

For the Contractor, [Company name/forename/surname/function]	For the Agency Mr Jukka Malm Director of Regulatory Affairs
signature[s]:  _____	signature[s]:  _____
Done at [place], [date]	Done at Helsinki, [date]

In duplicate in English.

ANNEX I  
SPECIFICATIONS

ANNEX II  
CONTRACTOR'S OFFER

#### 4.2.2. Model Specific Contracts

### FIXED PRICE

**SPECIFIC CONTRACT No** [complete]<sup>46</sup>  
implementing Framework Contract No ECHA/2011/25

The European Chemicals Agency (hereinafter referred to as "the Agency"), which is represented for the purposes of the signature of this contract by [official name in full],

of the one part,

and

[official name in full]

[official legal form]

[statutory registration number]

[official address in full]

[VAT registration number]

(hereinafter referred to as "the Contractor"), [represented for the purposes of the signature of this contract by [name in full and function,]]

of the other part,

HAVE AGREED

#### **ARTICLE 1: SUBJECT**

- 1.1 This Specific Contract implements Framework Contract No ECHA/2011/25 signed by the Agency and the Contractor on [complete date] [*and renewed on complete date*].
- 1.2 The subject of this Specific Contract is [short description of subject].
- 1.3 The Contractor undertakes, on the terms set out in the Framework Contract and in this Specific Contract and the annex[es] thereto, which form an integral part thereof, to perform the tasks as specified in Annex A of the Specific Contract.

---

<sup>46</sup> Options [in italics] to be deleted where not applicable.  
Options [in roman] to be completed.



## **ARTICLE 2: DURATION**

- 2.1 This Specific Contract shall enter into force on the date on which it is signed by the last contracting Party.
- 2.2 The duration of the tasks shall not exceed [*days/months*]. Execution of the tasks shall start from the [*date of entry into force of this Specific Contract*] or [*indicate date*]. The period of execution of the tasks may be extended only with the express written agreement of the parties before such period elapses.

## **ARTICLE 3: PRICE**

- 3.1 The total amount to be paid by the Agency under this Specific Contract for the provision of the deliverables specified in Annex A shall be EUR [amount in figures and in words].
- [3.2. *This amount shall cover all expenditure incurred by the Contractor in performing this Specific Contract.*]
- [3.2 *In addition to the amount specified in Article 3.1, travel and subsistence expenses up to a maximum amount of EUR [amount in figures and in words] shall be reimbursed according to the provisions of the Framework Contract.*]

## **ARTICLE 4: PAYMENTS**

Payments under this Specific Contract shall be made in accordance with Article II.4 of the Framework Contract. [*A performance guarantee shall be made in accordance with Article I.5.3 of the Framework Contract.*]

- 4.1 Pre-financing:

*If a pre-financing shall apply, the following clauses are to be inserted, otherwise it will be stated "not applicable".*

A pre-financing of XX %<sup>47</sup> equal to the amount of the Specific Contract shall be made.

Within 30 days of Specific Contract signature by the last contracting Party and the receipt by the Agency of a request for pre-financing with a relevant invoice a pre-financing payment equal to XX% of the total amount referred to in the Specific Contract shall be made.

*In case a pre-financing guarantee is required the above paragraph is to be replaced with.*

*Within 30 days of the latest of the following dates:*

---

<sup>47</sup> A pre-financing may not exceed 30% of the total amount as specified in Article 3.1.

- *signature of the Specific Contract by the last contracting part and the receipt by the Agency of a request for pre-financing with a relevant invoice*
- *the receipt by the Agency of a duly constituted financial guarantee equal to at least XX % of the amount of the Specific Contract*

*a pre-financing payment of XX% of the total amount referred to in the Specific Contract shall be made.*

#### 4.2 Interim payment:

*If an interim-payment shall apply, the following clauses are to be inserted, otherwise it will be stated “not applicable”.*

The request for an interim payment of EUR [amount in figures and in words] which represents XX % of the total value of the amount specified in Article 3.1 of the Specific Contract shall be valid if accompanied by:

- the technical report(s) and/or Deliverable(s) in another format in accordance with Annex A of the Specific Contract;
- statements of reimbursable expenses in accordance with Article II.7 of the Framework Contract;
- the relevant invoices, indicating the reference number of the Framework Contract and the Specific Contract to which they refer

provided the above report and/or deliverable has been approved by the Agency by means of a certificate of provisional acceptance.

If not specified otherwise in Annex A to the Specific Contract, the approval of the report and/or Deliverable by the Agency will be given according to the acceptance procedure as laid out in Annex I to the Framework Contract. [Depending on the complexity of the project, the Agency may foresee a longer period for approval or rejection of reports and/or deliverables. However, this will be specified in the Service Request].

Within 30 days of the date on which the report and/or Deliverable is approved by the Agency, an interim payment corresponding to the relevant invoice shall be made.

#### 4.3 Payment of the balance:

The request for payment of the balance of the Contractor shall be valid if accompanied by:

- the technical report(s) and/or Deliverable(s) in another format in accordance with Annex A of the Specific Contract;
- statements of reimbursable expenses in accordance with Article II.7 of the Framework Contract, where applicable;
- the relevant invoices, indicating the reference number of the Framework Contract and the Specific Contract to which they refer

provided the above reports and/or Deliverables has been approved by the Agency by means of a certificate of final acceptance.

If not specified otherwise in Annex A to the Specific Contract, the approval of the report and/or deliverable by the Agency will be given according to the acceptance procedure as laid out in Annex I to the Framework Contract. *[Depending on the complexity of the project, the Agency may foresee a longer period for approval or rejection of reports and/or deliverables. However, this will be specified in the Service Request].*

Within thirty days of the date on which the report and/or Deliverable is approved by the Agency, payment of the balance corresponding to the relevant invoice shall be made.

## **ARTICLE 5: GENERAL ADMINISTRATIVE PROVISIONS**

5.1 Any communication under this Specific Contract shall be made in accordance with Article I.7 of the Framework Contract.

5.2 The persons responsible for the implementation of this Specific Contract are:

For the Agency: European Chemicals Agency  
P.O. Box 400,  
00121 HELSINKI, Finland  
Fax: +358 9 68618210  
*[Name & Office address of the contract manager]*  
Email: [to be completed]

For the Contractor: Mr/Mrs  
*[Function]*  
*[Company name]*  
*[Official address in full]*

## **ARTICLE 6: PLACE OF PERFORMANCE**

The tasks shall be executed at the premises of the Contractor.

## **ARTICLE 7: ANNEXES**

The following annexes form an integral part of this Specific Contract:

Annex A: Technical Specifications

Annex B: Contractor's offer dated [...] and accepted by the Agency

SIGNATURES

For the Contractor, [Company name/forename/surname/function]	For the Agency Mr Jukka Malm Director of Regulatory Affairs
signature[s]:  _____	signature[s]:  _____
Done at [place], [date]	Done at Helsinki, [date]

In duplicate in [English].

**Specific Contract N° XXXX**

**Annex A**

**Technical Specifications**

**Annex B**

**Contractor's Offer**

### 4.2.3. *Technical Specifications template*

#### **Technical Specifications**

##### I. Services

###### I.1 Tasks

Description of tasks/activities

Organisation of tasks

Meetings

###### I.2 Deliverables

Description of deliverables

The specific deliverables, which are all the subject of acceptance unless specified otherwise, are:

[list of all requested deliverables as outlined in the request for offer by the Agency]

Delivery schedule

The delivery schedule is as follows:

- T0 being the date of signature of this agreement;
- [list of all requested deliverables with timetable]

##### II Resources

[Requirements for the profiles]

#### 4.2.4. Invitation to tender template



**Subject: ECHA/2011/25 – SC [...]: invitation to tender**

**The Agency hereby invites you to submit an offer for a specific contract under our above-mentioned framework contract.**

**In addition to the general information contained in the specifications of the framework contract, information specific to this re-opening of competition is provided in the model contract and the technical specifications, here enclosed, as well as in the provisions hereafter.**

**The technical proposal must [...].**

**The financial proposal must not exceed the maximum budget of [...]€.**

**The final date for the submission of your offer is [...].**

**The Agency looks forward to receiving your offer.**

**Yours sincerely,**

**[Name]**

**[Function]**

**Enclosures: Model contract  
Technical Specifications**



### **4.3. PROCUREMENT DOCUMENTATION**

#### **4.3.1. *Eligibility documentation***

## **Identification of the Tenderer**

(to be completed by the tenderer)



**LEGAL ENTITIES**  
**PRIVATE COMPANIES**

<b>TYPE OF COMPANY</b>			
<b>NGO</b>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	(Non Gouvernemental Organisation)
<b>NAME(S)</b>			
<b>ABBREVIATION</b>			
<b>ADDRESS OF THE HEAD OFFICE</b>			
<b>POSTAL CODE</b>		<b>P.O. BOX</b>	
<b>CITY</b>			
<b>COUNTRY</b>			
<b>VAT</b>			
<b>PLACE OF REGISTRATION</b>			
<b>DATE OF REGISTRATION</b>	D	M	Y Y Y Y
<b>REGISTRATION NR</b>			
<b>PHONE</b>		<b>FAX</b>	
<b>E-MAIL</b>			
<b>CONTACT PERSON</b>			

**THIS "LEGAL ENTITY" FORM SHOULD BE FILLED IN AND RETURNED TOGETHER WITH:**

- \* A COPY OF ANY OFFICIAL DOCUMENT (E.G. OFFICIAL GAZETTE, REGISTER OF COMPANIES, ETC.) SHOWING THE CONTRACTOR'S NAME AND ADDRESS AND THE REGISTRATION NUMBER GIVEN TO IT BY THE NATIONAL AUTHORITIES;
- \* A COPY OF THE VAT REGISTRATION DOCUMENT IF APPLICABLE AND IF THE VAT NUMBER DOES NOT APPEAR ON THE OFFICIAL DOCUMENT REFERRED TO ABOVE.

**DATE AND SIGNATURE**

# LEGAL ENTITIES

This information is to be stored in the Commission's accounting records for use in its payment procedures.  
Commission staff carrying out such procedures will be able to consult it for this purpose.

## INDIVIDUAL

TITLE	<input type="text"/>
NAME	<input type="text"/>
FIRST NAME	<input type="text"/>
(NAME 2)	<input type="text"/>
(NAME 3)	<input type="text"/>
OFFICIAL ADDRESS	<input type="text"/> <input type="text"/>
<small>(OFFICIAL Address = Your PERMANENT address; generally the one which is registered on your identity card)</small>	
POSTAL CODE	<input type="text"/>
P.O. BOX	<input type="text"/>
TOWN/ CITY	<input type="text"/>
COUNTRY	<input type="text"/>
VAT NR	<input type="text"/>
IDENTITY CARD NUMBER	<input type="radio"/> <input type="text"/>
PASSPORT NUMBER	<input type="radio"/> <input type="text"/>
DATE OF BIRTH	<input type="text"/> <sup>D</sup> <input type="text"/> <sup>D</sup> <input type="text"/> <sup>M</sup> <input type="text"/> <sup>M</sup> <input type="text"/> <sup>Y</sup> <input type="text"/> <sup>Y</sup> <input type="text"/> <sup>Y</sup> <input type="text"/> <sup>Y</sup> PLACE OF BIRTH <input type="text"/>
COUNTRY OF BIRTH	<input type="text"/>
PHONE	<input type="text"/>
FAX	<input type="text"/>
E-MAIL	<input type="text"/>

**THIS "LEGAL ENTITY" FORM SHOULD BE FILLED IN AND RETURNED WITH A LEGIBLE PHOTOCOPY OF YOUR ID CARD OR PASSPORT.**

DATE AND SIGNATURE

**LEGAL ENTITIES**

**PUBLIC ENTITIES**

TYPE OF COMPANY	<input type="text"/>																									
NGO	YES <input type="checkbox"/>	NO <input type="checkbox"/>	(Non Gouvernemental Organisation)																							
NAME(S)	<input type="text"/>																									
	<input type="text"/>																									
	<input type="text"/>																									
	<input type="text"/>																									
ABBREVIATION	<input type="text"/>																									
OFFICIAL ADDRESS	<input type="text"/>																									
	<input type="text"/>																									
	<input type="text"/>																									
POSTAL CODE	<input type="text"/>										P.O. BOX	<input type="text"/>														
CITY	<input type="text"/>																									
COUNTRY	<input type="text"/>																									
VAT	<input type="text"/>																									
PLACE OF REGISTRATION	<input type="text"/>																									
DATE OF REGISTRATION	<input type="text"/> <small>D D</small>		<input type="text"/> <small>M M</small>		<input type="text"/> <small>Y Y Y Y</small>																					
REGISTRATION NR	<input type="text"/>																									
PHONE	<input type="text"/>															FAX	<input type="text"/>									
E-MAIL	<input type="text"/>																									
CONTACT PERSON	<input type="text"/>																									

***This "Legal entity" form should be filled in and returned together with:  
\* a copy of the resolution, law, decree or decision establishing the entity in question;  
\* or, failing that, any other official document attesting to the establishment of the entity.***

DATE :

NAME AND FUNCTION OF THE AUTHORISED REPRESENTATIVE

SIGNATURE

STAMP

**Model financial identification form**  
(to be completed by the tenderer and his or her financial institution)

**The tenderer's attention is drawn to the fact that this document is a model, and a specific form for each Member State is available at the following Internet address:  
[http://ec.europa.eu/budget/execution/ftiers\\_en.htm](http://ec.europa.eu/budget/execution/ftiers_en.htm)**

**SIGNALETIQUE FINANCIER**

<b>TITULAIRE DU COMPTE BANCAIRE</b>	
<b>NOM</b>	<input type="text"/>
<b>ADRESSE</b>	<input type="text"/>
<b>COMMUNE/VILLE</b>	<input type="text"/>
<b>CODE POSTAL</b>	<input type="text"/>
<b>PAYS</b>	<input type="text"/>
<b>NUMERO TVA</b>	<input type="text"/>
<b>CONTACT</b>	<input type="text"/>
<b>TELEPHONE</b>	<input type="text"/>
<b>TELEFAX</b>	<input type="text"/>
<b>E - MAIL</b>	<input type="text"/>

<b>BANQUE</b>	
<b>NOM DE LA BANQUE</b>	<input type="text"/>
<b>ADRESSE (DE L'AGENCE)</b>	<input type="text"/>
<b>COMMUNE/VILLE</b>	<input type="text"/>
<b>CODE POSTAL</b>	<input type="text"/>
<b>PAYS</b>	<input type="text"/>
<b>NUMERO DE COMPTE</b>	<input type="text"/>
<b>IBAN (optionnel)</b>	<input type="text"/>

**REMARQUES:**

<p><b>CACHET de la BANQUE + SIGNATURE du REPRESENTANT DE LA BANQUE</b> (Les deux obligatoires)</p>
--

<p><b>DATE + SIGNATURE DU TITULAIRE DU COMPTE :</b> (Obligatoire)</p>
---

**4.3.2. Subcontractor / Letter of Intent**

**Subcontractor / Letter of Intent**

*Insert reference of this call*

The undersigned: .....

Name of the company/organisation: .....

Address: .....

Declares hereby the intention to collaborate in the execution of the tasks subject to the above call for tender, in accordance with the terms of the offer to which the present form is annexed, if the contract is awarded to ... .... *[name of the tenderer]*.

Declares hereby accepting the general conditions attached to the tendering specifications for this call for tender, and in particular art. II.17 in relation with checks and audits.

**Full name**

**Date**

**Signature**

.....

### **4.3.3. *Power of Attorney documentation***

## POWER OF ATTORNEY – MODEL 1

# Agreement / Power of Attorney

### (DESIGNATING ONE OF THE COMPANIES OF THE GROUP AS LEADER AND GIVING A MANDATE TO IT)

We the undersigned:

- Signatory 1 (Name, Function, Company, Registered address, VAT Number)
- Signatory 2 (Name, Function, Company, Registered address, VAT Number)
- .....
- Signatory N (Name, Function, Company, Registered address, VAT Number),

Each of them having the legal capacity required to act on behalf of his/her company, HEREBY AGREE AS FOLLOWS:

(1) In case the European Chemicals Agency awards Contract .... (« **the Contract** ») to Company 1, Company 2, ..., Company N (« **the Group Members** »), based on the joint offer submitted by them on ... .. for the supply of ..... and/or the provision of services for ... (« **the Supplies and/or the Services** »).

(2) As co-signatories of the Contract, all the Group Members:

- (a) Shall be jointly and severally liable towards the Agency for the performance of the Contract.
- (b) Shall comply with the terms and conditions of the Contract and ensure the proper execution of their respective share of the Supplies and/or the Services.

(3) To this effect, the Group Members designate Company X as **Group Leader**. [*N.B.: The Group Leader has to be one of the Group Members*]

(4) Payments by the Agency related to the Supplies or the Services shall be made through the Group Leader's bank account .[*Provide details on bank, address, account number, etc.*].

(5) The Group Members grant to the Group Leader all the necessary powers to act on their behalf in connection with the Supplies and/or the Services. This mandate involves in particular the following tasks:

- (a) The Group Leader shall sign any contractual documents—including the Contract, and Amendments thereto—and issue any invoices related to the Supplies or the Services on behalf of the Group Members.
- (b) The Group Leader shall act as single point of contact for the Agency in connection with the Supplies and/or the Services to be provided under the Contract. It shall co-ordinate the provision of the Supplies and/or the Services by the Group Members to the Agency, and shall see to a proper administration of the Contract.

Any modification to the present agreement / power of attorney shall be subject to the Agency's express approval.

This agreement / power of attorney shall expire when all the contractual obligations of the Group Members towards the Agency in connection with the Supplies and/or the Services to be provided under the Contract have ceased to exist. The parties cannot terminate it before that date without the Agency's consent.

Signed in ..... on .....

Name  
Function  
Company

Name  
Function  
Company

Name  
Function  
Company

Name  
Function  
Company



## POWER OF ATTORNEY – MODEL 2

# Agreement / Power of Attorney

### (CREATING THE GROUP AS SEPARATE ENTITY, APPOINTING A GROUP MANAGER AND GIVING A MANDATE TO HIM/HER)

We the undersigned:

- Signatory 1 (Name, Function, Company, Registered address, VAT Number)
- Signatory 2 (Name, Function, Company, Registered address, VAT Number)
- .....
- Signatory N (Name, Function, Company, Registered address, VAT Number),

Each of them having the legal capacity required to act on behalf of his/her company, HEREBY AGREE AS FOLLOWS:

(1) In case the European Chemicals Agency awards Contract .... (« **the Contract** ») to Company 1, Company 2, ..., Company N (« **the Group Members** »), based on the joint offer submitted by them on ... .. for the supply of ..... and/or the provision of services for ... (« **the Supplies and/or the Services** »).

(2) As co-signatories of the Contract, all the Group Members:

- (a) Shall be jointly and severally liable towards the Agency for the performance of the Contract.
- (b) Shall comply with the terms and conditions of the Contract and ensure the proper execution of their respective share of the Supplies and/or the Services.

(3) To this effect, the Group Members have set up under the laws of ..... the Group ..... (« **the Group** »). The Group has the legal form of a ..... [*Provide details on registration of the Group: VAT Number, Trade Register, etc.*].

(4) Payments by the Agency related to the Supplies or the Services shall be made through the Group's bank account. [*Provide details on bank, address, account number, etc.*].

(5) The Group Members appoint Mr/Ms ..... as **Group Manager**.

(6) The Group Members grant to the Group Manager all the necessary powers to act alone on their behalf in connection with the Supplies and/or the Services. This mandate involves in particular the following tasks:

- (a) The Group Manager shall sign any contractual documents—including the Contract, and Amendments thereto—and issue any invoices related to the Supplies or the Services on behalf of the Group Members.
- (b) The Group Manager shall act as single point of contact for the Agency in connection with the Supplies and/or the Services to be provided under the Contract. He/she shall co-ordinate the provision of the Supplies and/or the Services by the Group Members to the Agency, and shall see to a proper administration of the Contract.

Any modification to the present agreement / power of attorney shall be subject to the Agency's express approval.

This agreement / power of attorney shall expire when all the contractual obligations of the Group Members towards the Agency in connection with the Supplies and/or the Services to be provided under the Contract have ceased to exist. The parties cannot terminate it before that date without the Agency's consent.

Signed in ..... on .....

Name  
Function  
Company

Name  
Function  
Company

Name  
Function  
Company

Name  
Function  
Company

#### **4.3.4.** *Exclusion criteria documentation*

## Exclusion Criteria Form

The undersigned [*name of the signatory of this form, to be completed*]:

- in his/her own name (*if the economic operator is a natural person or in case of own declaration of a director or person with powers of representation, decision making or control over the economic operator<sup>48</sup>*)
- or
- representing (*if the economic operator is a legal person*)

official name in full (*only for legal person*):

official legal form (*only for legal person*):

official address in full:

VAT registration number:

declares that the company or organisation that he/she represents / he/she:

- a) is not bankrupt or being wound up, is not having its affairs administered by the courts, has not entered into an arrangement with creditors, has not suspended business activities, is not the subject of proceedings concerning those matters, and is not in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- b) has not been convicted of an offence concerning professional conduct by a judgment which has the force of *res judicata*;
- c) has not been guilty of grave professional misconduct proven by any means which the contracting authorities can justify;
- d) has fulfilled all its obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which it is established, with those of the country of the contracting authority and those of the country where the contract is to be carried out;
- e) has not been the subject of a judgement which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;
- f) is not a subject of the administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the procurement procedure or failing to supply an information, or being declared to be in serious breach of his obligation under contract covered by the budget.

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<sup>48</sup> To be used depending on the national legislation of the country in which the candidate or tenderer is established and where considered necessary by the contracting authority (see art. 134(4) of the Implementing Rules).

In addition, the undersigned declares on their honour:

- g) they have no conflict of interest in connection with the contract; a conflict of interest could arise in particular as a result of economic interests, political or national affinities, family or emotional ties or any other relevant connection or shared interest;
- h) they will inform the contracting authority, without delay, of any situation considered a conflict of interest or which could give rise to a conflict of interest;
- i) they have not made and will not make any offer of any type whatsoever from which an advantage can be derived under the contract;
- j) they have not granted and will not grant, have not sought and will not seek, have not attempted and will not attempt to obtain, and have not accepted and will not accept any advantage, financial or in kind, to or from any party whatsoever, constituting an illegal practice or involving corruption, either directly or indirectly, as an incentive or reward relating to award of the contract.
- k) that the information provided to the Agency within the context of this invitation to tender is accurate, sincere and complete.
- l) that in case of award of contract, they shall provide the evidence that they are not in any of the situations described in points a, b, d, e above<sup>49</sup>.

For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the Tenderer is a legal person and the national legislation of the country in which the Tenderer is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the Tenderer.

For the situation described in point (d) above, recent certificates or letters 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 Tenderer is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in two paragraphs above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.]

By signing this form, the undersigned acknowledges that they have been acquainted with the administrative and financial penalties described under art 133 and 134 b of the Implementing Rules (Commission Regulation 2342/2002 of 23/12/02), which may be applied if any of the declarations or information provided prove to be false.

Full name

Date

Signature

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<sup>49</sup> Mandatory for contracts of value above €133 000 only (see art. 134(2) of the Implementing Rules). The contracting authority can nevertheless request such evidence for contracts with a lower value.

**4.3.5. *Financial and Economic Capacity Overview Form***

<b>Financial and Economic Capacity Overview</b>			
<b>Currency : EURO</b>	<b>Figures (000)</b>		
	<b>N*</b> (* most recent figures available)	<b>N-1</b>	<b>N-2</b>
<b>Total Balance Sheet</b>			
TRADE DEBTORS <i>Amounts due by commercial customers</i>			
CAPITAL and RESERVES (Equity) <i>Amounts owned by the company</i>			
TRADE CREDITORS <i>Amounts due to commercial suppliers</i>			
SHORT TERM DEBT			
LONG TERM DEBT			
LIQUIDITY <i>Bank accounts, cash at hand</i>			
<b><u>About PROFIT &amp; LOSS</u></b>			
TURNOVER			
ORDINARY RESULT			
EXTRAORDINARY RESULT			
INCOME TAX			
NET RESULT			

**You may add any data that you would consider of vital relevance for your organisation and for the understanding of the above figures.**

Comments: Please explain BRIEFLY important variations from one year to another if appropriate. In case of negative equity or repeated losses, please explain how the future of the organisation will be ensured.

#### **4.4. PROJECT REFERENCE FORM**

The Project Reference Form must be used to give details about relevant projects the tenderer wants to present as proof of experience.

The Project Reference Form consists of two pages:

- Front page
- Description page

Both pages must be used to form a complete Project Reference Form

A new Project Reference Form must be completed for each project.



**Project Reference Form (page 1 of 2)**

**Project reference n°** \_\_\_\_\_

**Project reference front page**

**Project name:**

**Start date** (mm/yy):

**Finish date** (mm/yy):

**Client name:**

**Contact person:**

**Phone:**

**Project type** (development, maintenance, etc.):

**Principal contractor for this project** (check the appropriate):

Tenderer

Other

**Principal location for this project:**

Tenderer premises

Client's premises

Other

**Number of tenderer's own technical staff involved** in man-days, by profile

1.

2.

3.

4.

5.

...

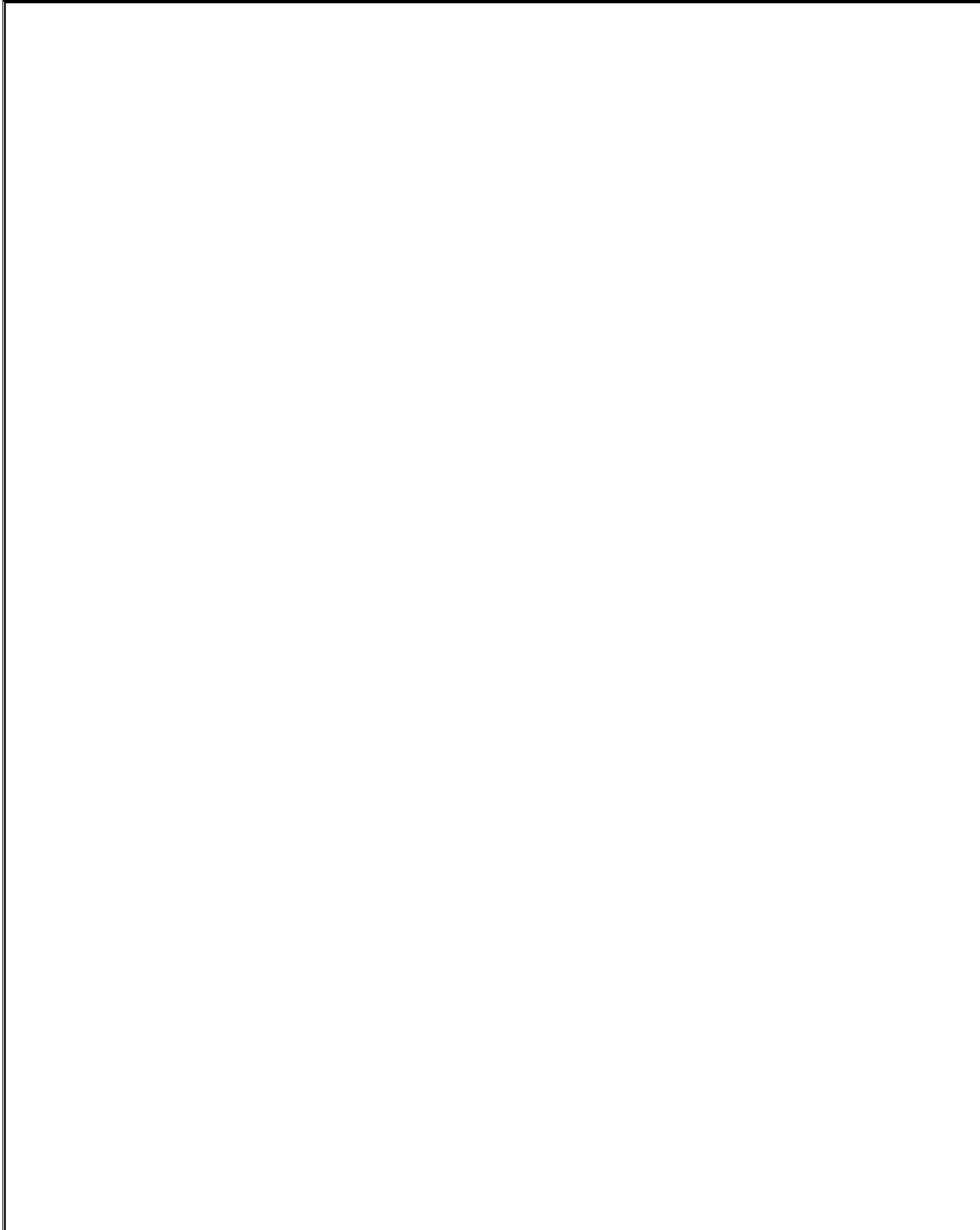
**Total:**

**Methodologies involved:**

**Project Reference Form (page 2 of 2)**

**Project reference n° \_\_\_\_\_**

**Project description page**

A large, empty rectangular box with a thin black border, intended for the project description. It occupies the majority of the page's vertical space below the header and title.

#### **4.5. EUROPEAN CURRICULUM VITAE FORMAT**

**EUROPEAN  
CURRICULUM  
VITAE  
FORMAT**



**PERSONAL INFORMATION**

Name [ **SURNAME, other name(s)** ]  
Address [ **House number, street name, postcode, city, country** ]  
Telephone  
Fax  
E-mail  
  
Nationality  
Date of birth [ Day, month, year ]

**WORK EXPERIENCE**

- Dates (from – to) [ Add separate entries for each relevant post occupied, starting with the most recent. ]
- Name and address of employer
  - Type of business or sector
  - Occupation or position held
  - Main activities and responsibilities

**EDUCATION AND TRAINING**

- Dates (from – to) [ Add separate entries for each relevant course you have completed, starting with the most recent. ]
- Name and type of organisation providing education and training
- Principal subjects/occupational skills covered
  - Title of qualification awarded
  - Level in national classification (if appropriate)

**PERSONAL SKILLS  
AND COMPETENCES**  
*Acquired in the course of life and  
career but not necessarily covered by  
formal certificates and diplomas.*

MOTHER TONGUE

[ Specify mother tongue ]

OTHER LANGUAGES

- Reading skills
- Writing skills
- Verbal skills

[ Specify language ]

[ Indicate level: excellent, good, basic. ]

[ Indicate level: excellent, good, basic. ]

[ Indicate level: excellent, good, basic. ]

**SOCIAL SKILLS  
AND COMPETENCES**  
*Living and working with other  
people, in multicultural  
environments, in positions where  
communication is important and  
situations where teamwork is  
essential (for example culture and  
sports), etc.*

[ Describe these competences and indicate where they were acquired. ]

**ORGANISATIONAL SKILLS  
AND COMPETENCES**  
*Coordination and administration of  
people, projects and budgets; at  
work, in voluntary work (for example  
culture and sports) and at home, etc.*

[ Describe these competences and indicate where they were acquired. ]

**TECHNICAL SKILLS  
AND COMPETENCES**  
*With computers, specific kinds of  
equipment, machinery, etc.*

[ Describe these competences and indicate where they were acquired. ]

**ARTISTIC SKILLS  
AND COMPETENCES**  
*Music, writing, design, etc.*

[ Describe these competences and indicate where they were acquired. ]

**OTHER SKILLS  
AND COMPETENCES**  
*Competences not mentioned above.*

[ Describe these competences and indicate where they were acquired. ]

**DRIVING LICENCE(S)**

**ADDITIONAL  
INFORMATION**

[ Include here any other information that may be relevant, for example contact persons,  
references, etc. ]

**ANNEXES**

[ List any attached annexes. ]

#### 4.5.1. Award criteria documentation

##### FINANCIAL FORM

ECHA/2011/25	FINANCIAL PROPOSAL
PROFILE	MAXIMUM PRICE PER PERSON-DAY
Expert in human health toxicology	[...] EUR