

ECHA/2011/172

Service Contract

**Characterisation, chemical representation and modelling of
UVCB substances**

Open procurement procedure

Contract notice: OJ 2011/S 231-373777

Invitation to Tender

Specifications

Model Contract

CONTENTS

1	THE SERVICES (TECHNICAL SPECIFICATIONS)	3
1.1	BACKGROUND	3
1.1.1	<i>The European Chemicals Agency and REACH</i>	3
1.1.2	<i>The regulatory challenges of UVCB substances</i>	3
1.1.3	<i>Use of non-testing methods under REACH</i>	4
1.2	DESCRIPTION OF RESOURCES	5
1.3	DESCRIPTION OF TASKS	5
1.3.1	<i>Generic nature of the tasks</i>	5
1.3.2	<i>UVCB types covered in this Contract</i>	7
1.3.3	<i>Modelling of physicochemical, fate and (eco)toxicological properties of UVCB constituents</i>	8
1.3.4	<i>Implementation requirements</i>	9
1.3.5	<i>Existing approaches for the chemical representation of UVCB substances and the generation of representative structures</i>	11
1.3.6	<i>Organisation of the tasks</i>	12
1.4	DESCRIPTION OF DELIVERABLES.....	14
2	THE CONTRACT	17
2.1	THE NATURE OF THE CONTRACT	17
2.2	STARTING DATE OF THE CONTRACT AND DURATION OF THE TASKS	17
2.3	PLACE OF PERFORMANCE.....	17
2.4	TERMS OF PAYMENT	17
2.5	GUARANTEES	17
2.6	LIABILITY	17
2.6.1	<i>Joint Offers</i>	17
2.6.2	<i>Subcontracting</i>	18
2.7	DATA PROTECTION.....	18
3	THE PROCUREMENT PROCEDURE	20
3.1	PREPARATION AND SUBMISSION OF THE TENDER	20
3.1.1	<i>Preparation of the tender</i>	20
3.2	CONTACT BETWEEN THE TENDERER AND THE AGENCY	27
3.3	OPENING OF THE TENDERS.....	28
3.4	EVALUATION OF THE TENDERS	28
3.5	AWARD OF THE CONTRACT	30
4	ANNEXES	33
4.1	TECHNICAL DOCUMENTATION	33
4.2	CONTRACTUAL DOCUMENTATION (DRAFT SERVICE CONTRACT)	34
4.3	PROCUREMENT DOCUMENTATION	51
4.3.1	<i>Eligibility documentation</i>	51
4.3.2	<i>Exclusion criteria documentation</i>	61
4.3.3	<i>Selection criteria documentation</i>	63
4.4	PROJECT REFERENCE FORM.....	64
4.5	EUROPEAN CURRICULUM VITAE FORMAT	67
4.5.1	<i>Award criteria documentation</i>	70

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) carries out or co-ordinates the necessary activities under the REACH Regulation (REACH)¹ and the Regulation on the Classification, Labelling and Packaging of substances and mixtures (CLP)². The REACH processes are designed to provide information on properties and effects of chemicals on environment and human health, to ensure their safe use, and to ensure competitiveness of the European industry. Manufacturers and importers are required to gather information on the properties of their substances, to carry out a safety assessment and to register the information in a central database run by the Agency. More information about the Agency, its structure and activities can be found on the Agency website³.

Substances of unknown or variable composition, complex reaction products or biological materials, collectively called UVCB⁴ under REACH, pose the greatest challenge in a number of REACH processes, in particular in the context of dossier and substance evaluation but also priority setting activities of the Agency. The purpose of this Contract is to develop a computational methodology for generating representative structures likely to be present in the UVCB and to perform a preliminary screening of their hazardous properties using non-testing methods. The outcome of the project will assist in assessing the homogeneity of UVCBs as far as the likely presence or absence of hazardous constituents is concerned, which can be subsequently applied in dossier and substance evaluation processes but also used by Industry in designing a comprehensive testing strategy of UVCB substances.

1.1.2 *The regulatory challenges of UVCB substances*

Under REACH, substances are defined as much as possible by the chemical composition and the identification of constituents. UVCB substances differ from mono or multi-constituent substances that are fully definable by chemical composition alone. This is because the number of constituents is large and/or the composition is, to a significant part unknown, and/or the variability in composition is large or poorly predictable. In principle, the information requirements for the registration of UVCB substances can be based on tests with a suitable sample within the specification of the UVCB, from testing on identified constituents and from read-across/category or quantitative structure activity relationships. The application of read-across and categories for fulfilling the information needs in registration dossiers is another challenge, as the compositional differences between the registered substance and the analogue may or may not be of concern, depending on whether the toxicological effect arises from constituents at significantly different concentrations. Pragmatic options are to assess the main constituents in terms of quantity or the most hazardous constituents from those which could be identified, provided that the

¹ Regulation (EC) No. 1907/2006

² Regulation (EC) No. 1272/2008

³ http://www.echa.europa.eu/home_en.asp

⁴ For definitions and identifiers used to characterise UVCBs under REACH see the guidance for identification and naming of substances under REACH in http://guidance.echa.europa.eu/guidance_en.htm.

toxicologically unaccounted for mass fraction of the UVCB is unlikely to possess significant hazardous properties and provided that sufficient justification and documentation for any assumption is provided.

From this perspective, the Agency supports the development of computational methodologies that will use analytical and physicochemical characterisation data of UVCB substances for generating representative structures within the domain of the UVCB, and for assessing their fate and (eco)toxicological profile by using non-testing methods in a systematic fashion. This information can be used for refining the analytical characterisation focusing on critical constituents. The outcomes may also assist in building a stronger argumentation in read-across and category justifications in dossiers submitted by companies.

The Contract shall cover UVCB substances in general, including substances presenting poorly predictable, complex and/or variable composition. Both biological and chemical sources that have been modified via refinement or chemical processes will be considered. The Contract shall refer specifically to substances derived from fossil fuels (including petroleum substances) and from other natural extracts (such as vegetable and animal oils and fats derivatives, natural fragrances, natural dyes, natural pigments, resins/rosins and their modified derivatives) as well as oligomers. Inorganic and organometallic UVCB substances are however excluded from the scope of the contract due to the scarcity of computational models for predicting their fate and (eco)toxicological properties.

The volume of the contract over its entire duration shall be a maximum of 200.000 EUR including all expenses.

The chemical representation and modelling of UVCB substances is inherently linked to the source, the manufacturing process and other identifiers, including analytical techniques and industry-specific identifiers and end-product quality indices, which can provide boundaries of the chemical space. Hence, the project requires expertise in both physico-chemical substance characterisation and computational chemistry/toxicology in a regulatory context.

1.1.3 Use of non-testing methods under REACH

REACH foresees⁵ the use of qualitative and quantitative structure-activity relationships ((Q)SAR) to indicate the presence or absence of a certain dangerous property, if the model used is scientifically valid, the predicted substance falls within the applicability domain, the results are adequate for classification and labelling and/or risk assessment, and that adequate and reliable documentation is provided. Similarly, REACH foresees the use of category and read-across methodologies for filling data gaps, if the results are adequate for classification and labelling, the data on the analogues cover reliably and adequately the key parameters of the test required, the existing data refer to exposure durations comparable or longer than the exposure duration in the test required and adequate and reliable documentation is provided. The application of such non-testing methods is part of this Contract for evaluating the hazard profile of UVCB representative structures.

⁵ The alternative ways of fulfilling the information requirements are laid down in Annex XI of the Regulation and include read-across, (Q)SAR and grouping, Regulation (EC) No. 1907/2006; OECD has published principles for assessing the validity of (Q)SAR models at http://www.oecd.org/document/4/0,3746,en_2649_34379_42926724_1_1_1_1,00.html

More details on the endpoints to be modeled, and suggestions for available models are given in Section 1.3.3.

1.2 Description of resources

The required minimum knowledge and skills are outlined below. This expertise should be collectively exhibited in the CVs submitted by the tenderer. Expertise could have been gained by formal education, training or relevant professional experience.

Education:

- university degree in a relevant subject such as chemistry, pharmacology, toxicology, environmental sciences, (chemo)-informatics.

Knowledge and skills:

- good knowledge on the use of computational methods for predicting physicochemical, fate and (eco)toxicological properties of chemicals,
- understanding of analytical and physicochemical methods for the characterisation of substances and in particular UVCB substances,
- understanding of chemical safety assessment of UVCBs, and
- proficiency level of B1 in English⁶.

Experience:

- minimum of 5 years of experience in a relevant field.

1.3 Description of tasks

1.3.1 Generic nature of the tasks

The purpose of this Contract is the development of a generic and flexible methodology for generating a computationally manageable number of representative structures that span the chemical space defined by the UVCB identifiers and their computational assessment with respect to physicochemical, fate and (eco)toxicological properties. UVCB substances are generally not fully definable by chemical composition, and, hence, a set of identifiers is needed in addition to what is known about their chemical composition. The identifiers used under REACH are related to the source of the substance and the process used for manufacturing. In addition, other identifiers, such as chromatographic and spectral fingerprints and physicochemical properties or conditions of the manufacturing process can be useful parameters. The combination of all these identifiers defines the chemical space of the UVCB, which may encompass a large number of individual constituents that often prevents their full enumeration. The ability to generate representative structures and predict their hazardous properties can be used in hazard and risk assessment of UVCB substances by pointing out the regions of chemical space of greatest concern. Moreover, it can point to the targeted analytical characterisation of constituents, as representative structures predicted to be hazardous should be analytically

⁶ <http://europass.cedefop.europa.eu/europass/home/vernav/Europass+Documents/Europass+CV/navigate.action>

determined, because knowledge of their concentration may be needed for correct classification and labelling and PBT assessment, and when UVCB substances are involved in read-across and category justifications.

What follows are the activities planned for the required services. The indicative percentage of the total workload anticipated for each work package is given in brackets.

Work package A (estimated 15 % of total work volume): compilation of background information (literature review)

- review of background information with respect to the characterisation of the UVCB substances in the test cases (work package C) in regulatory contexts, and in particular under REACH,⁷
- list and description of UVCB identifiers that can be used for narrowing down the computational generation of representative structures in the test cases (work package C), such as molecular weight distribution, chromatographic and spectral fingerprints, range of carbon atoms, iodine value, degree of conjugation, references to standards, boiling point cut-offs in fractional distillations, and viscosity ranges of the final product, and
- list and description of computational models that can be employed for predicting the measured UVCB identifiers on the basis of the molecular structure of constituents and their properties present in the UVCB. This includes, for example, the use of quantitative structure activity relationships, equations of state or molecular modelling techniques, to predict the boiling point or viscosity of individual constituents or their mixtures, and
- list and review of applicability of computational models that can be used to predict fate and (eco)toxicological properties of the UVCB substances as described in work package C.

Work package B (estimated 55 % of total work volume): methodological developments

- development of a computational representation of UVCB substances, called **UVCB description format**⁸ hereafter, that includes the constraints imposed by the UVCB identifiers and a visualisation scheme for UVCB substances,
- development of a methodology for the generation of representative structures by using the computational representation of the UVCB as input, and for subsequently predicting their physicochemical, fate and (eco)toxicological properties,
- development of a methodology for using predicted physicochemical, fate and (eco)toxicological properties of representative structures of UVCB substances to identify the representative structures of greatest concern; this step may need to be executed iteratively with the previous step, so that generating further representative structures do not lead to new toxicity alerts or changes in the range of toxicity or fate values for quantitative endpoints. Existing

⁷ Regulation (EC) No. 1907/2006, Guidance for identification and naming of substances under REACH in http://guidance.echa.europa.eu/guidance_en.htm

⁸ SMARTS is an example language to describe UVCBs, <http://www.daylight.com/dayhtml/doc/theory/theory.smarts.html>

(Q)SAR models, other non-test methods such as read-across and/or existing experimental data can be used, taking into account their applicability for generated structures, and

- development of a reporting format and visualisation tool for grouping the generated structures in terms of similarity in the predicted endpoints.

Work package C (estimated 30 % of total work volume): application in selected cases and dissemination

- application of the developed methodologies on selected cases specified by the Agency in the kick-off meeting, belonging to one of the UVCB types detailed in section 1.3.2, and
- a proposal for the integration of the developed methodologies in the QSAR Toolbox⁹ for category building involving UVCB substances (and also multi-constituent substances, i.e. substances comprising more than one chemical structure) and for the development of a reporting format tailored to UVCB.

Although the Work Packages B and C make use of non-testing methods, the emphasis of the Contract is on the generation of representative structures for UVCB substances. The Contractor is requested to make use of existing structure-activity relationship models or read-across/category software tools and also collaborate with ECHA, that will also perform fate and (eco)toxicity predictions on the representative structures generated by the Contractor.

1.3.2 UVCB types covered in this Contract

The type of UVCB substances addressed in this Contract are typically manufactured from crude oil or other sources, such as natural fats, after refinement and/or chemical processing.

The common structural feature of these UVCB substances is that all constituents contain one or more long-chain alkyl group that is possibly attached to none, one or more functional groups. The functional group(s), if present, may be neutral, such as a carboxylic acid group, or charged such as carboxylate or ammonium ions with the corresponding organic or inorganic counterions. The position of the functional group may be defined according to the hybridisation state of the carbon atom that is connected to, or the branching, for example in primary, secondary or tertiary amines. Heteroatoms, such as nitrogen, oxygen and sulphur may also be present in defined functional groups.

The alkyl chain may differ in the length, the number of (conjugated) double and triple bonds, the degree of branching, the presence of aromatic and non aromatic rings, and the position of the functional group(s). The position of unsaturated bonds may be limited to certain parts of the chain, as in alpha-olefins. Branching may also be limited to certain positions of the chain with respect to the unsaturated bond, such as the vinyl, allylic or at carbon atoms further from the unsaturated bond. The alkyl branches may have odd, even or arbitrary number of carbons, depending on the

⁹ The Toolbox is a freely available software application to identify and fill (eco)toxicological data gaps for chemicals hazard assessment; for further information please see section 1.3.3.

source of the starting material, i.e. of natural or synthetic origin, and the process. The alkyl chain may be defined with a generic description, such as tallow or coco.¹⁰

There can be constraints arising from the manufacturing process, e.g. that the substance only contains distillates in a specified temperature range (cut-offs) or from performance indicators of the final product, such as a viscosity specification. Other physicochemical identifiers, such as vapour pressure, flash point and self-ignition temperature may also be available and should be used, to the extent possible, for narrowing down the UVCB chemical boundaries.

Implicit constraints on the chemical structure of the constituents may also arise from the process involved, such as chemical structure modifications during catalytic cracking, isomerisation or hydrogenation. Oligomerisation reactions, such as reactions between a set of alkenes, would also need to be covered, up to a specified oligomerisation number.

1.3.3 *Modelling of physicochemical, fate and (eco)toxicological properties of UVCB constituents*

The list of physicochemical, fate and (eco)toxicological properties that are of interest in REACH can be found in the Annexes of the REACH Regulation and in the practical guide for reporting robust study summaries in IUCLID.¹¹ Water solubility, octanol/water partition coefficient, vapour pressure and Henry's constant are key physicochemical properties in hazard and risk assessment. The potential for mutagenicity, carcinogenicity, skin sensitisation, reproductive toxicity (pre-natal developmental toxicity and effects on fertility) and repeated dose toxicity will be the focus of human health hazard assessment of the UVCB constituents. An indicative, qualitative assessment on how mitigating factors of the UVCB constituents may affect toxicological outcome will be needed, for example by grouping constituents that are unlikely to be absorbed due to unfavourable molecular weight, water solubility, or octanol/water partition coefficient.

For the environmental hazard assessment, the focus will be on short and long term toxicity to aquatic species, abiotic and biotic degradation and bioaccumulation in fish. This assessment may include the computational prediction of stable degradation products for some of the test cases in work package C, including their bioaccumulation, persistence and toxicological properties. The UVCB constituents should be grouped in terms of their overall PBT or vPvB properties¹² but also their relative partitioning into the different environmental compartments. Relative partitioning can, for example, be assessed with a fugacity model,¹³ based on the overall half-lives in air, water, soil and sediment due to relevant hydrolysis, photolysis and biodegradation properties, and physicochemical properties including

¹⁰ More information can be obtained from industrial chemistry and chemical technology texts, such as Ullmann's Encyclopedia of Industrial Chemistry, <http://onlinelibrary.wiley.com/book/10.1002/14356007>

¹¹ Regulation (EC) No. 1907/2006, Guidance for identification and naming of substances under REACH in http://guidance.echa.europa.eu/guidance_en.htm and Practical Guide for reporting robust study summaries in REACH http://echa.europa.eu/doc/publications/practical_guides/pg_report_robust_study_summaries.pdf

¹² See Guidance for PBT assessment at http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_c_en.pdf?vers=20_08_08 for PBT and vPvB criteria

¹³ See D. Mackay et al., Assessing the fate of new and existing chemicals: a five-stage process. Environ. Toxicol. Chem. 15:1618-1626, 2006, D. Mackay et al., Evaluating the environmental fate of a variety of types of chemicals using the EQC model. Environ. Toxicol. Chem. 15:1627-1637, 1996 and the implementation of the model in the US-EPA physicochemical and environmental fate estimation program EPISUITE at <http://www.epa.gov/opptintr/exposure/pubs/episuite.htm>

Henry's law constant, soil absorption coefficient, octanol/water partition coefficient and vapour pressure.

A suggestive list of software packages for predicting the endpoints above is given in the REACH Guidance for Information Requirements, Chapter R.7 and the in depth guidance on non-testing approaches, Chapter R.6. Guidance documents can be found at

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1314181643. ECHA will also run predictions on the generated representative structures generated by the Contractor, using a collection of freely available and commercial tools used by the Agency in Evaluation and Risk Management processes. Hence, the methodology for generating representative structures and running predictions should be modular, by allowing exporting the generated structures in widely acceptable formats, such as SMARTS, SMILES and MDL Molfile formats.

The non-test methods that can be used to predict the physicochemical, fate and (eco)toxicity endpoints of interest can be both, quantitative structure activity relationships and analogue identification¹⁴/category building tools and methodologies. Notably, the QSAR Toolbox¹⁵ is an application for the:

- 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, and the
- use of existing experimental data to fill the data gap(s).

The way(s) of data gap filling techniques for predicting the endpoints in Section 1.3.3 and the methodology for examining whether the proposed techniques satisfy the REACH acceptability criteria in Section 1.1.3, should be established. In particular, the developed methodology should include an assessment on whether UVCB representative structures fall within the applicability domain of the chosen models, including the descriptor domain, the structural fragment domain and if applicable the mechanistic and metabolism domain.

The list of non-testing methods used to predict the properties of generated representative structures will be discussed in the kick-off meeting, within 2 weeks from the start of the project.

1.3.4 Implementation requirements

The developed methodology should facilitate the grouping of the representative structures into groups of constituents of similar fate or toxicological concern, e.g. constituents that activate the same set of alerts, or are predicted to have effect levels or concentrations in the same range. The methodology should also allow both the identification of worst case representative structure, e.g. in the context of PBT assessments, or the calculation of the average and the range for quantitative endpoints. Constituents with outlying properties should be identified. Overall, the methodology is intended to assist Industry and Authorities in defining the relevant

¹⁴ See the US-EPA Analog Identification Methodology (AIM) for an example at <http://www.epa.gov/oppt/sf/tools/aim.htm>

¹⁵ The QSAR Toolbox can be downloaded for free via the website www.qsartoolbox.org.

(groups of) constituents within a composition. Hence, in the context of PBT/vPvB assessment, in particular, it would be beneficial to categorise and visualise the UVCB constituents on the basis of their predicted PBT properties. This knowledge of the variability of PBT/vPvB potential within the space of the UVCB can assist in proposing chemical constituents that need to be chemically identified as relevant for the classification and/or PBT assessment of the substance. Similarly, chemical similarity in read-across can also be examined on the basis of comparisons of the composition information for the groups of identified constituents that are of toxicological concern for the endpoint of interest.

Prior to the generation of representative structures, the total number of distinct representative structures covered by the UVCB description format should be estimated. The methodology should also provide an estimation of the time required to generate the representative structures. The algorithm for the generation of representative structures may depend on the estimated total number of possible representative structures. In case full enumeration is not possible, the algorithm may randomly generate representative structures so that the chemical space of the UVCB is covered as uniformly as possible, based on structural (e.g. degree of branching) or descriptor ranges, with the descriptors selected depending on the endpoint modeled (e.g. octanol/water partition coefficient in the case of aquatic toxicity modelling). The project aim is that the applied methodology for generating representative structures of a UVCB is done in a computationally manageable manner. An estimate for the coverage of the UVCB space by the selected representative structures will be needed, which is ideally endpoint specific. For example, if hazard prediction of a given endpoint is based on a set of substructure searches (alerts), it would be expected that the generation of representative structures can be considered complete when all possible alerts within the space of the UVCB have been activated at least once.

Representative structures that can have (stereo) isomers, such as chiral centres (unless for meso compounds), double bonds or rings that can give rise to cis/trans isomerism should be identified, even if fate and (eco)toxicological predictions are only based on two-dimensional structural information. This is in line with the REACH Annex VI, 2.2.2 that requires information on the typical ratio of (stereo) isomers to be given if applicable and appropriate.¹⁶ The generation of representative structures may account for the relative energy of isomers to eliminate certain chemical structures that are unlikely to be present in UVCB substances, such as alkenes with significant angle strain because of the presence of a double bond at a bridgehead position (Bredt's rule).

The focus of development should be given on computational efficiency given the complexity of many UVCBs. For example, structural activity methods could be applied directly to the UVCB description format, without prior enumeration of the UVCB constituents. This is possible if the toxicity alerts only depend on substructure searching. For example, the presence of a functional group can be checked directly in a SMARTS representation and not after the generation of representative structures. Similarly, group contribution predictive models, i.e models whose independent variables only include the number of groups present and not the exact connectivity, may also be applied without full enumeration of the UVCB constituents. This approach is not applicable in the case of models that require information on the

¹⁶ Regulation (EC) No. 1907/2006

three-dimensional properties of the molecule, such as the use of size or diameter of a constituent as a descriptor in models for the prediction of bioaccumulation potential.

1.3.5 Existing approaches for the chemical representation of UVCB substances and the generation of representative structures

Work package B includes the development of a UVCB description format, for the succinct notation of the chemical space covered by the UVCB. Such notation is needed, when UVCB substances are handled in databases capable of storing and processing chemical structures, and are needed when chemical queries need to include information on the chemical structure of the UVCB. There have been considerable developments on how molecular patterns can be digitally represented. This section provides a non-exhaustive list of methods that can provide a starting point for the development of a UVCB description format.

SMARTS has been proposed as a flexible language for describing molecular patterns. It is a straightforward extension of the SMILES (Simplified Molecular Input Line Entry System) notation for representing fully defined molecules (SMILES)¹⁷ and reactions. SMARTS¹⁸ uses the same atom and bond symbols as in SMILES to depict the molecule's graph, but adds special (primitive) symbols and logical operators so that the notation allows flexibility. With these extra primitive symbols and logical operators it is possible to depict features like variable connectivity or the presence, for instance, of predefined substituents at the ortho position of a given atom in an aromatic ring. Several SMARTS parsers have been developed, such as PerlMol¹⁹, and are supported by leading computational chemistry developers, such as Schrödinger²⁰ and ChemAxon.²¹

Markush structures are an alternative chemical representation of a class of constituents using a generic notation. All constituents in the class contain a common structural feature, the root structure, and differ in the substitution at defined positions on the root structure. ChemAxon's MarvinSketch²² is one of the implementations, which allows good flexibility for the representation of UVCB substances using R-groups, link nodes, atom lists, position variation, repeating units, homology series, the application of logical conditions (R-logic), and an intuitive visualisation environment. MarvinSketch also allows the export of generated Markush structures in several formats, including SMARTS, and the more succinct ChemAxon's extended SMILES format that can be potentially used as a starting point for the UVCB description format.

OASIS CMP tools, included within the OASIS basic tools package²³ is an alternative computational approach that includes an advanced graphical editor for entering UVCB substances, that are automatically represented in a proprietary string format. The generation capabilities of CMP allow the enumeration of fragments, generation

¹⁷ Full details on the SMILES and encoding rules can be found at <http://www.daylight.com/dayhtml/doc/theory/theory.smiles.html> and at "SMILES 1. Introduction and Encoding Rules", D.J. Weininger, *J.Chem. Inf. Comput. Sci.*, **1988**, 28,31.

¹⁸ Full details on the SMILES notation can be found at <http://www.daylight.com/dayhtml/doc/theory/theory.smarts.html>

¹⁹ See <http://www.perlmol.org/features.html> for more information.

²⁰ <http://www.schrodinger.com/>

²¹ <http://www.chemaxon.com/>

²² More details can be found at <http://www.chemaxon.com/products/marvin/marvinsketch/>

²³ Available at <http://oasis-lmc.org/?section=software&swid=12>

of alkyl chains, positional isomers and the inclusion of heteroatoms in rings, whilst additional fragment functionality is allowed for performing queries.

1.3.6 Organisation of the tasks

(a) Administrative Project Manager and Project Team at the Agency

A Project Team will be put in place, comprising staff from the Agency. The ECHA Project Team will encompass scientific and technical expertise with members having experience with analytical, physical and computational chemistry, substance identification and predictive toxicology using quantitative structure activity relationships and read-across/category methodologies in regulatory processes. This team will be responsible for running physicochemical, fate and (eco)toxicological property predictions on the generated representative structures in collaboration with the Contractor.

The project will be formally managed by an Agency Project Manager nominated by the Agency. The Agency project manager will represent the Agency in contacts with the Contractor and external stakeholders 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. The Agency Project Manager shall ensure that a Certificate of Acceptance is delivered in the case the deliverables have been satisfactory, which shows the acceptance date and mentions any reservations it may have regarding the services. The Certificate is needed in order to receive the payments from the Agency as explained in the section 4.2.

(b) Meetings and deliverables presentations

The Contractor is expected to work in close cooperation with the ECHA Project Team.

The Contractor shall attend and/or organise meetings with the ECHA Project Team and other relevant parties to discuss methodological and organisational issues related to the Contract implementation. The Contractor shall be prepared to participate in two face-to-face meetings in ECHA's premises in Helsinki, Finland.

Within two weeks after entry into force of the Contract, the Agency Project Manager will organise a half-day kick-off meeting at the Agency with the Contractor to officially discuss in detail the planning and other organisational aspects of the project. This meeting will officially start the work. Members of the ECHA Project Team will attend. During this meeting the Agency will provide a set of UVCB test cases (work package C) that fall under the general description in Section 1.3.2. The indicative number of these test cases is five to ten. During this meeting, the Agency and the Contractor will fine-tune the implementation requirements for the development of the UVCB description format and the methodology for generating representative structures. All dates for report deliverables and meeting arrangements refer to the kick-off meeting as time zero.

The Contractor will be asked to base the literature review in work package A, the development of the methodology in work package B and the practical demonstration in work package C on these test cases. On the basis of these test cases, the Contractor shall draft a detailed Work Plan to describe the activities planned by month and by resource. The Work Plan should be delivered one month after the kick-off meeting.

The ECHA Project Team will provide feedback on the Work Plan within 2 weeks from its delivery.

Bimonthly telephone or video conferences between the ECHA Project Team and the Contractor will be organised according to Table 1 to discuss the project status, the activities for the subsequent months, technical issues and present deliverables at the project milestones as shown in Section 1.4.

A member of the Project Team will visit the Contractor’s site after 4 months from the start of the project to have a one-day hands-on demonstration of the under-development methodology and associate software tools and infrastructure. The member of the ECHA Project Team will provide feedback to the Contractor and inform the Project Team on progress.

A one-day review meeting between the ECHA Project Team and the Contractor will be organised at the Agency at month 10 of the Contract to review progress towards the final deliverables. The Contractor will be asked to present the under-development methodology and the draft results on the test cases. During this meeting, the Contractor will deliver a half-day training at the Agency on any software tools and calculation procedures used or developed as part of the methodology, using the test cases in work package C as working examples.

A final tele- or video-conference will take place at month 12 of the Contract to discuss the end results and lessons learned from the test cases.

The frequency of tele- or video-conferences can be adapted as necessary in agreement with both parties. Finally, there will be phone calls every two weeks to discuss progress, unless these phone calls overlap with planned meetings or tele-/video-conferences.

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 5 working days after the meeting. Within 5 days the ECHA Project Team shall provide its comments and the Contractor shall submit the finalised minutes to the ECHA Project manager.

Table 1 Meetings during the Contract period

Meeting	Time after kick-off meeting	Purpose	Venue	Attendees from the Contractor
1. Kick-off meeting (face to face)	Month 0 (about 2 weeks after Contract signature)	Introduction and discussion of the test cases by the Agency described in Work Package C. Discussion of organisational aspects and expected deliverables.	Agency, Helsinki (half-day meeting)	Contractor’s project team representatives and key subcontractors or partners (if applicable)
2. Tele- or video-conference	Month 2	Review status, activities for subsequent months, technical issues, and discuss any outstanding issues on the Work Plan.	-	

3. Visit of ECHA Project Team member to the Contractor's site	Month 4	Presentation of preliminary methodology and results by the Contractor. Hands-on demonstration of under-development methodology and tools for generating representative structures. Discussion of the report summarising the work under Work Package A.	Contractor's site (1-day meeting)	Contractor's project team
4. Tele- or video-conference	Month 6	Review status, activities for subsequent months, technical issues.	-	Contractor's project team
5. Tele- or video-conference	Month 8	Review status, activities for subsequent months, technical issues.	-	Contractor's project team
6. Review meeting	Month 10	Review progress towards final deliverables. Half-day training on any software tools and calculation procedures developed as part of the methodology.	Agency, Helsinki (1-day meeting)	Contractor's project team and key subcontractors or partners (if applicable)
5. Final tele- or video-conference	Month 12	Presentation of end-results and discussion on lessons learned.	-	Contractor's project team

During each tele- or video-conference or review meeting in Table 1, the Contractor is requested to provide a short summary of progress made and the resources spent in the last two months of the project.

1.4 Description of deliverables

The Contractor is required to meet the following milestones and submit the following material to the Agency:

1. Work Plan at month 1 from kick-off meeting

The Work Plan should describe in detail the activities planned by month and by resource for the duration of the Contract. ECHA Project Team will provide feedback on the Work Plan within 2 weeks of its delivery. Outstanding issues will be discussed in the tele- or video-conference within the first 2 months of the Contract.

2. Literature review (WP A) at month 2 from kick-off meeting

The Contractor should deliver a report with the outcomes of Work Package A at month 2 of the Contract. The report should be tailored to the needs of the test cases delivered by the Agency to the Contractor at the kick-off meeting.

3. UVCB description format and specifications

A first draft of the specifications for the UVCB description format should be finalised within 3 ½ months from the start of the Contract. The Contractor should prepare a document with the specifications of the developed format to the Agency.

The specifications should include examples, preferably based on the test cases under Work Package C, so that ECHA Project Team is familiarised with its use.

4. Hands-on on preliminary methodology

The Contractor should prepare presentation material for the visit of the ECHA Project Team representative in his/her site at month 4 of the Contract.

5. First set of representative structures sent to ECHA

The Contractor should send a first set of representative structures generated for the test cases in Work Package C to the Agency within 5 ½ months of the start of the Contract. These structures will be discussed in the tele- or video-conference at month 6, including the possible use of Agency's software on these representative structures for predicting the endpoints in Section 1.3.3.

6. Review meeting and training

With the training at month 10, the Agency shall be able to independently use the developed methodology for generating representative structures and assessing their hazard profile. Training material shall be developed and provided a week in advance to the training.

7. Presentation of end results

Final report at month 12 from kick-off meeting

Based on the comments on draft final report by the ECHA Project Team, the contractor shall prepare the final report within 1 week after receiving the comments. The Agency shall have 30 days from receipt to approve or reject the final report, and the Contractor shall have 15 days in which to submit additional information or a new report.

A Gantt chart with milestones and an indicative scheduling of the three Work Packages is shown in Figure 1.

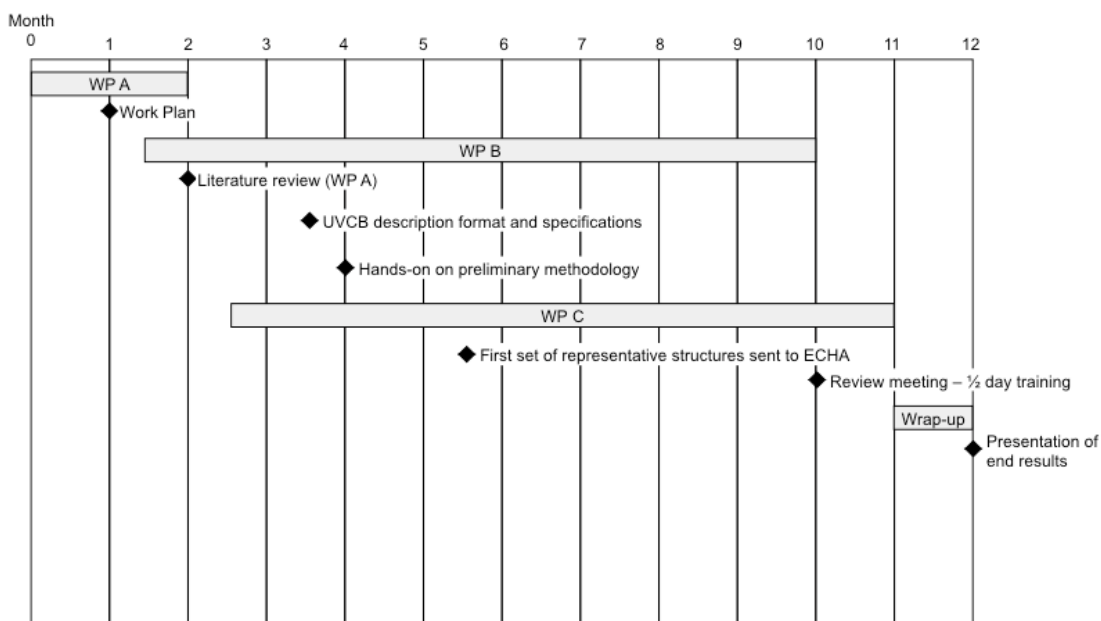


Figure 1 Milestones and indicative Gantt chart. Time zero refers to the kick-off meeting.

2 THE CONTRACT

2.1 The nature of the contract

Service Contract

2.2 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.

It is expected to be signed in February 2012.

The duration of the tasks shall not exceed 12 months from the time of the kick-off meeting, which should be organised after ca two weeks from the starting date of the contract.

The execution of the tasks may not start before the contract has entered into force. 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.

2.3 Place of performance

The place of performance of the tasks shall be the Contractor's premises or any other place indicated in the tender, with the exception of the Agency's premises, unless agreed otherwise in writing by the parties.

2.4 Terms of payment

Payments shall be made in accordance with Articles I.3, I.4, II.4 & II.5 of the draft service contract (Section 4.2).

The payment scheme will consist of two interim payments of 20% and 40 % and the payment of the balance. The first interim payment of 20 % will be paid upon completion of Work Package A (see Figure 1). The second interim payment of 40 % will be paid upon successful completion of milestone "First set of representative structures sent to ECHA" (see Figure 1). The balance will be paid upon acceptance of the project deliverables at the end of the project.

The schedule and the procedure for the approval of payments and the documents to be submitted are described in Articles I.4, II.4, II.5 and in Annex I to the draft service contract referred to above.

2.5 Guarantees

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

2.6 Liability

2.6.1 Joint Offers

Partners in a joint offer assume joint and several liability 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.

2.6.2 *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, and
- 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.

2.7 **Data Protection**

Any response to the invitation to tender will require the recording and further processing of personal data (name, address, CV, for example). This data will be processed in accordance with the requirements of Regulation (EC) 45/2001 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. Except if mentioned otherwise, replies to questions and personal data are necessary for the purpose of assessing a tender according to the specifications of the invitation to tender and will only be processed by the Agency's Data Controller for this purpose. A tenderer may, upon request, obtain the communication of personal data and rectify any inaccurate or incomplete personal data. Any queries concerning the processing of personal data should be addressed to by the Agency's Data Controller. As regards to the processing of personal data, a tenderer has the right to 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, and
- i) design its organisational structure in such a way that it meets data protection requirements.

3 THE PROCUREMENT PROCEDURE

3.1 Preparation and submission of the tender

3.1.1 Preparation of the tender

3.1.1.1 General

Tenders must be clear and concise, with continuous page numbering, and assembled in a coherent fashion (e.g. bound or stapled, etc.). 3.1.1

Tender documents can be submitted in any of the official languages of the European Union. However, since the working language of the agency is English, ECHA would appreciate to receive the Tenders written in English language.

Tenders must include the following information:

- all the information and documents requested by the Agency in order to assess the tender,
- the price in euro, filled in the form of the Financial offer (section 4.5.1);
- one specimen signature of an authorised agent (preferably in blue ink) on the legal entity form²⁴, and a statement from the same agent confirming the validity of the tender, and
- 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.

3.1.1.2 Content of the tender

3.1.1.2.1 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 Communities 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 Communities 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 (see section 4.3):

²⁴ See section 4.3

All tenderers must provide their legal entity form as well as the evidence indicated at the bottom of that form. The **Legal Entity Form**²⁵ is to be signed by a representative of the tenderer authorised to sign contracts with third parties.

The **Financial identification**²⁶ 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).

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**²⁷, depending on the set up that has been chosen by the tenderers.

If the tenderer envisages subcontracting, the tender must include:

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

²⁵ This form is available at:

http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

²⁶ The form is available at:

http://ec.europa.eu/budget/contracts_grants/info_contracts/financial_id/financial_id_en.cfm.

²⁷ See section 4.3

²⁸ To be provided in free format

- a **letter of intent**²⁹ 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**³⁰, 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, and
- 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 tenders³¹.

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

²⁹ See section 4.3

³⁰ See Section 4.3.2

³¹ See Section 3.4

the contract, for example by producing a clear undertaking on the part of those entities to place those resources at its disposal.

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:

The tenderer shall submit the completed Financial and Economic Capacity Overview Form³², 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)

The ability of service providers to perform services will be assessed in particular with regard to their know-how, efficiency, experience and reliability.

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

a) Evidence for selection criterion 2.1:

A minimum of five CVs duly completed and presented in the appropriate format³³. The submitted CVs must indicate the professional relation with the tenderer.

b) Evidence for selection criterion 2.2:

³² See Section 4.3.3

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

A minimum of one relevant project reference with the value, dates and place, as well as a description of the content as stated in section 3.4.

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.

3.1.1.2.2. Section Two: Technical proposal

Qualitative award criteria documentation

This section is of great importance in the assessment of the bids, the award of the contract and the future execution of any resulting contract. Some guidelines are given below, but attention is also drawn to the award criteria, which define those parts of the technical proposal to which the tenderers should pay particular attention. The technical proposal should address all matters laid down in the technical specifications as described³⁴ and should include models, examples and technical solutions to problems raised in these specifications giving an answer to each of the points mentioned with regard to the methodology, deadlines and organisation. The level of practical details provided in the tender will be extremely important for the evaluation of the tender. 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.

Please note that, to grant equal treatment of all tenders, it is not possible to modify offers after their submission in relation to the technical and financial proposals. As a consequence, incompleteness in this section can only result in negative impact for the evaluation of award criteria. Please note also, that proposals deviating from the technical specifications may be rejected for 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.

Tenders should elaborate on all points addressed by these specifications in order to score as many points as possible. The mere repetition of mandatory requirements set out in these specifications, without going into details or without giving any added value, will only result in a very low score. In addition, if certain essential points of these specifications are not expressively covered by the tender, the Agency may decide to give a zero mark for the relevant qualitative award criteria.

Assessment basis for award criterion AW1:

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

The proposal for the scientific methodology, including the use or development of necessary software tools, as applied to the provision of the services must address the requirements of the technical specifications.

The description of the approach to be followed will be used to assess whether the Contract's scope is understood and that the tenderer's overall scientific approach and proposed methodology for carrying out the activities/tasks in Section 1.3 are appropriate for the nature of the tasks and the duration of the Contract.

³⁴ See Section 1

The tenderer is requested to address in the tender all technical points in 1.3. However, the following points are of greatest importance:

- the approach to be followed for defining the UVCB description format including the UVCB boundaries, the starting point if an existing format is to be used and the reasons for its selection and any extensions,
- an outline of the approach for generating representative structures that the tenderer intends to follow given the often very large number of possible representative structures within the space of the UVCB definition. Particular emphasis should be placed on ways to estimate the total number of representative structures,
- how the tenderer plans to keep the computational time manageable for generating representative structures and running predictions on them,
- the way the tenderer plans to ensure that generated structures can be transferred and used for running predictions with external tools and the way to automatically assess the reliability of these predictions for each generated structure, and
- the way the tenderer plans to group and visualise the generated structures in terms of similarity in their physicochemical, fate and (eco)toxicological properties.

The proposal may be presented in free format, but should preferably not exceed 15 A4 pages and must be logically structured.

Assessment basis for award criterion AW2:

Organisational set-up, technical expertise and experience of the work team members assigned to each task.

The tenderer should describe his approach towards the composition of the project team to ensure that project deliverables can be met within the time frame and budget provided. The tender should clearly identify the key individuals assigned to work on each part of the project, how they will be set up in teams to address the work. The tenderer should also propose a project management plan with a task description, timetable, efforts and allocation of resources.

- Work teams. The tenderer should clearly identify the team members. Key personnel should be named and appropriateness for the role in the project should be justified with reference to the personnel CVs and project role requirements. Previous experience of key individuals in similar or related projects should be explicitly mentioned in the tender. The appropriateness of the work team will be assessed on a basis of the qualifications of the team members and the reasoning in their selection for performing the tasks described in Section 1.3.
- Coordination of work. The quality of the coordination work planned will be assessed by the management plan. It should ensure that all the tasks will be performed and deliverables produced within the foreseen timeframe.

- Resource allocation. The resource allocation will be assessed based on rational and realistic distribution between the Work packages as described in Section 1.3, and human resource profiles that will be involved in the project.

3.1.1.2.3. Section Three: Financial proposal

Financial award criteria documentation

Tenderers must use the financial form³⁵ to formulate their financial proposal.

The tenderers attention is drawn to the following points:

- 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 Communities 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, and
 - prices shall be fixed and not subject to revision.
- the reference price for the award of the contract shall consist of the amount in payment of the tasks executed, as stated in Article I.3.1 of the contract.

For each category of staff to be involved in the project, the tenderer must specify:

- the total labour costs,
- the daily rates and total number of days (man-days) each member of staff will contribute to the project, and
- other categories of costs, (including travel costs, accommodation costs, ...) indicating the nature of the cost, the total amount, the unit price and the quantity. Flat-rate amounts should be avoided. If, exceptionally, they are used, specimen quotations for the flat-rate amounts must be provided.

³⁵ See section 4.5.1

Bids involving more than one legal entity must specify the amounts for each legal entity.

Bids involving more than one service provider must specify the amounts for each provider.

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.

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/2011/172 » to the following e-mail address:

<i>opencalls@echa.europa.eu</i>

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

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 on 23/01/2012 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 to:

1. check, in the first stage (exclusion criteria), whether tenderers can take part in the tendering procedure and, where applicable, be awarded the contract,
2. 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, and
3. 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 form³⁶.

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).

³⁶ See section 4.3.2

Stage 2 - application of selection criteria

These criteria will be assessed on the basis of the documents indicated³⁷.

<u>SELECTION CRITERIA</u>
1. FINANCIAL AND ECONOMIC CAPACITY
1.1 Sufficient financial and economic capacity for the implementation of the contract A minimum average annual turnover of 400,000 EUR over the past 3 financial years.
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 five key personnel who will participate in the project and collectively possess the knowledge and skills as described in Section 1.2. All shall have a proficiency level of B1 in English, and at least two of them a minimum of five years of experience in a relevant field.
2.2 Sufficient professional capacity to provide the services A minimum of one scientific project similar in scope ³⁸ executed in the past five calendar years for a minimum total value of 50.000 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

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.

³⁷ See section 3.1.1

³⁸ See section 1

No	Qualitative award criteria	Weighting (maximum points)
1.	<i>Understanding of the objectives of the project and quality of the methodological proposal for the provision of the services under the contract</i>	75
2.	<i>Quality of the composition of the project team and distribution of tasks</i>	25
Total quality points		100

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.

Tenders presenting a total price superior to the maximum amount of 200.000 € will be excluded from the rest of the assessment procedure.

The contract will be awarded to the tender which is the most cost-effective (offers the best value for money) on the basis of the highest ratio between the total points scored and the price.

Final Evaluation	
	1000 * (Total Quality Points / Price)

Tenders should elaborate on all points addressed by these specifications in order to score as many points as possible. The mere repetition of mandatory requirements set out in these specifications, without going into details or without giving any added value, will only result in a very low score. In addition, if certain essential points of these specifications are not expressively covered by the tender, the Agency may decide to give a zero mark for the relevant qualitative award criteria.

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 tenderer's agreement in writing.

The Agency shall not sign the contract or framework 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.

During the standstill period, the Agency will request the tenderer 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 tenderer 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, and
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.

4.1 TECHNICAL DOCUMENTATION

The technical documentation constitutes an integral part of the technical specifications and consists of the following documents:

1. Information related to the Agency, http://www.echa.europa.eu/home_en.asp
2. Information related to the QSAR Toolbox: www.qsartoolbox.org,
<http://www.oecd.org/env/existingchemicals/qsar>
3. Information related to IUCLID, <http://iuclid.eu>
4. Overview of relevant endpoints for registrations under REACH,
http://echa.europa.eu/doc/publications/practical_guides/pg_report_robust_study_summaries.pdf
5. Guidance for identification and naming of substances under REACH, and guidance on information requirements and chemical safety assessment, chapter R.6: QSARs and grouping of chemicals,
http://guidance.echa.europa.eu/guidance_en.htm
6. Ullmann's Encyclopedia of Industrial Chemistry,
[HTTP://ONLINELIBRARY.WILEY.COM/BOOK/10.1002/14356007](http://ONLINELIBRARY.WILEY.COM/BOOK/10.1002/14356007)
7. Kirk-Othmer Encyclopedia of Chemical Technology,
[HTTP://ONLINELIBRARY.WILEY.COM/BOOK/10.1002/0471238961](http://ONLINELIBRARY.WILEY.COM/BOOK/10.1002/0471238961)
8. Petrotox and Petrorisk models,
<http://www.concawe.be/content/default.asp?PageID=778> and
<http://www.concawe.be/content/default.asp?PageID=777>. Information on physicochemical properties of petroleum substances can be found at
http://www.concawe.be/DocShareNoFrame/docs/5/PGEKDBCCEFIJFFMDDO_NMNNNMVEVCWD9N9YBYB3B1WK23/CEnet/docs/DLS/Rpt_10-6-2010-05145-01-E.pdf.
9. SMARTS, a language for describing molecular patterns,
<http://www.daylight.com/dayhtml/doc/theory/theory.smarts.html>

4.2 Contractual Documentation (Draft Service Contract)



Model

SERVICE CONTRACT No. – ECHA/2011/172

The European Chemicals Agency (hereinafter referred to as "the Agency"), which is represented for the purposes of the signature of this Contract by [forename, surname, function, Directorate],

of the one part,

and

[official name in full]

[official legal form]³⁹

[statutory registration number]⁴⁰

[official address in full]

[VAT registration number]

(hereinafter referred to as "the Contractor"⁴¹), [represented for the purposes of the signature of this contract by [forename, surname and function,]]

of the other part,

HAVE AGREED

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

Annex I – Tender Specifications (Invitation to Tender No [complete] of [complete]) and Monitoring

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

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

³⁹ Delete if contractor is a natural person or a body governed by public law.

⁴⁰ 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.

⁴¹ 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 Agency for the performance of this 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 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.7 should he dispute any such instruction.

I – SPECIAL CONDITIONS

ARTICLE I.1 - SUBJECT

- I.1.1.** The subject of the Contract is [short description of subject].
- I.1.2.** The Contractor shall provide the services as requested in accordance with the Tender Specifications annexed to the Contract (Annex I).

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 party⁴².
- I.2.2.** Provision of the services may under no circumstances begin before the date on which the Contract enters into force.
- I.2.3.** The duration to provide the services shall not exceed 12 months. This period and all other periods specified in the Contract are calculated in calendar days. Provision of the services shall start from the kick-off meeting. The period of provision of the services may be extended only with the express written agreement of the parties before such period elapses.

ARTICLE I.3 – CONTRACT PRICE

- I.3.1.** The maximum total amount to be paid by the Agency under the Contract shall be EUR [amount in figures and in words] covering all services provided.

ARTICLE I.4 – PAYMENT PERIODS AND FORMALITIES⁴³

Payments under the Contract shall be made in accordance with Article II.4. Payments shall be executed only if the Contractor has fulfilled all his contractual obligations by the date on which the invoice is submitted. Payment requests may not be made if payments for previous periods have not been executed as a result of default or negligence on the part of the Contractor.

I.4.1. Pre-financing:

Not applicable

I.4.2 Interim payments:

Requests for the 1st interim payment by the Contractor shall be admissible if accompanied by:

⁴² As a rule the Agency signs last. In this case, the Contractor should be duly informed of the date on which the Contract enters into force.

⁴³ The insertion of pre-financing and interim payment clauses is optional but there must always be provision for payment of the balance.

- the Certificate of Acceptance by the ECHA of the deliverables related to the milestone, as specified in section 2.4 Terms of Payment.
- the relevant invoices

provided the report has been approved by the Agency.

The Agency shall have twenty working days from receipt to approve or reject the report and to pay the 1st interim payment corresponding to the relevant invoices [EUR complete amount in figures and in words] equal to 20 % of the total amount referred to in Article I.3.1. The Contractor shall have twenty days in which to submit additional information or a new report.

Requests for the 2nd interim payment by the Contractor shall be admissible if accompanied by:

- the Certificate of Acceptance by the ECHA of the deliverables related to the milestone, as specified in section 2.4 Terms of Payment.
- the relevant invoices

provided the report has been approved by the Agency.

The Agency shall have twenty working days from receipt to approve or reject the report and to pay the 1st interim payment corresponding to the relevant invoices [EUR complete amount in figures and in words] equal to 40 % of the total amount referred to in Article I.3.1. The Contractor shall have twenty days in which to submit additional information or a new report.

I.4.3. Payment of the balance:

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

- the Certificate of Acceptance by the ECHA of the deliverables related to the milestone, as specified in section 2.4 Terms of payment
- the relevant invoices

provided the deliverables has been approved by the Agency.

The Agency shall have 20 days from receipt to approve or reject the deliverables, and the Contractor shall have 20 days in which to submit additional or new information.

Within 30 days of the date on which the report is approved by the Agency, payment of the balance corresponding to the relevant invoice [EUR complete amount in figures and in words] equal to 40 % of the total amount referred to in Article I.3.1 shall be made.

[For Contractors established in Belgium, the provisions of the Contract constitute a request for VAT exemption No 450, provided the Contractor includes the following statement in his invoice(s): “Exonération de la TVA, article 42, paragraphe 3.3 du code de la TVA” or an equivalent statement in the Dutch or German language.]

ARTICLE I.5 – BANK ACCOUNT

Payments shall be made to the Contractor’s bank account denominated in euro⁴⁴, identified⁴⁵ as follows:

⁴⁴ Or local currency where the receiving country does not allow transactions in EUR.

Name of bank: [complete]
Address of branch in full: [complete]
Exact designation of account holder: [complete]
Full account number including codes: [complete]
[IBAN⁴⁶ code: [complete]]

ARTICLE I.6 – GENERAL ADMINISTRATIVE PROVISIONS

Any communication relating to the Contract shall be made in writing and shall bear the Contract number. 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 addresses⁴⁷:

The Agency:

European Chemicals Agency (ECHA)
[Directorate [complete]]
[Unit [complete]]
[Postcode and city]

Contractor:

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

ARTICLE I.7– APPLICABLE LAW AND SETTLEMENT OF DISPUTES

1.7.1. The Contract shall be governed by Union law, complemented, where necessary, by the Finnish law.

1.7.1a. Without prejudice to Article 1.7.2., in the event that any dispute arises between the parties resulting from the interpretation or application of the Contract and the dispute is not resolved by negotiation, the parties may agree to submit the dispute to mediation.

If any party to the dispute gives written notice to the other party of its desire to commence mediation, and the other party agrees in writing, the parties shall jointly appoint a mutually acceptable mediator within two weeks of the date of the said written agreement. If the parties are unable to agree upon the appointment of a mediator within that time period, any party may apply to [court, organisation or person agreed to by the parties when signing the Contract], for the appointment of a mediator.

The mediator's written proposal or his written conclusion stating that no proposal can be made, shall be produced within two months of the date of the written agreement by the second party to commence mediation. The mediator's proposal or conclusion shall not be binding for the parties, who reserve the right to bring the dispute before the courts, as per Art. 1.7.2.

⁴⁵ By a document issued or certified by the bank.

⁴⁶ BIC or SWIFT code for countries with no IBAN code.

⁴⁷ 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).

Within two weeks of the date of notification of the proposal by the mediator, the parties can conclude a written agreement, duly signed by all parties, based on the proposal.

The parties further agree to share equally the costs of mediation by the mediator, which costs will not include any other costs incurred by a party in connection with the mediation.⁴⁸

- I.7.2.** Any dispute between the parties resulting from the interpretation or application of the Contract which cannot be settled amicably shall be brought before the courts of Helsinki.

ARTICLE I.8 – DATA PROTECTION

Any personal data included in the Contract 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 EU 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 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, she/he shall address them to the Data Protection Officer of ECHA. 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:
 - aa) unauthorised reading, copying, alteration or removal of storage media;
 - ab) unauthorised data input as well as any unauthorised disclosure, alteration or erasure of stored personal data;
 - ac) unauthorised persons from using data-processing systems by means of data transmission facilities;
- b) ensure that authorised users of a data-processing system can access only the personal data to which their access right refers;
- c) record which personal data have been communicated, when and to whom;
- d) ensure that personal data being processed on behalf of third parties can be processed only in the manner prescribed by the contracting institution or body;
- e) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or erased without authorisation;
- f) design its organisational structure in such a way that it meets data protection requirements.

⁴⁸ Optional clause.

ARTICLE I.9 – 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 14 days formal prior notice. Should the Agency terminate the Contract, the Contractor shall only be entitled to payment corresponding to part-performance of the Contract. 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 provided up to the date on which termination takes effect, within a period not exceeding sixty days from that date.

ARTICLE I.9a – 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.

This article is not applicable for contracts not covered by Directive 2004/18/EC and in cases indicated in Article 158a(2) of the rules for the implementation of the Financial Regulation (Regulation No 2342/2002).

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 services requested 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 required for the provision of the services 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 conduct the services requested.

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

- staff providing the service requested from the Contractor may not be given orders direct by the Commission;
 - 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 the 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 provision of the services 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 provision of the services, 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 claim compensation or impose liquidated damages provided for in Article II.16.

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 – PAYMENTS

II.4.1. Pre-financing:

Where required by Article I.4.1, 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 Annex I 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:

- an interim technical report in accordance with the instructions laid down in Annex I;
- the relevant invoices indicating the reference number of the 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 requested services referred to in Annex I 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 in accordance with the instructions laid down in Annex I;
- the relevant invoices indicating the reference number of the 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.

II.4.4. Payment currency and costs:

Payments are executed in the currency of the contract.

Costs of the transfer are borne in the following way:

- costs of dispatch charged by the bank of the Agency are borne by the Agency,
- cost of receipt charged by the bank of the Contractor are borne by the Contractor,
- all costs of repeated transfer caused by one of the parties are borne by the party who caused repetition of the transfer.

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.4 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.4 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 under the Contract 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.
- II.6.3.** The Agency may, after informing the Contractor, recover amounts established as certain, of a fixed amount and due by offsetting, in cases where the Contractor also has a claim on the Agency that is certain, of a fixed amount and due. The Agency may also claim against the guarantee, where provided for.

ARTICLE II.7 - REIMBURSEMENTS

- II.7.1.** Where provided by the Special Conditions or by Annex I, the Agency shall reimburse the expenses which are directly connected with provision of the services 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.3.3.

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 Union, 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 provision of the requested services.

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 provision of the services 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 provision of the services.

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.8 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 services actually provided.
- 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 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 provision of the services has not actually commenced within three months⁴⁹ 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

⁴⁹ This period can be modified in the Special Conditions depending on the nature of the contract.

within a reasonable period following receipt of the formal notice, remains in serious breach of his contractual obligations.

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 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 services provided 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 complete the services. The Agency shall be entitled to claim from the Contractor all extra costs incurred in making good and completing the services, without prejudice to any other rights or guarantees it has under the Contract.

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

Where, after the award of the 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%⁵⁰ of the amount specified in Article I.3.1 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

⁵⁰ The daily rate for liquidated damages may be modified in the Special Conditions where the subject of the contract so justifies.

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.
- 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.
- 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.

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.

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 provision of the services under the Contract 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 or of part thereof.

SIGNATURES

For the Contractor,
[Company name/forename/surname/function]

For the Agency,
[forename/surname/function]

signature[s]: _____

signature[s]: _____

Done at [], [date]

Done at [Helsinki], [date]

In duplicate in English.

4.3 Procurement documentation

4.3.1 Eligibility documentation

Identification of the Tenderer

(to be completed by the tenderer)

LEGAL ENTITIES
PRIVATE COMPANIES

TYPE OF COMPANY	<table border="1" style="width: 100%; height: 15px;"> <tr> <td style="width: 25%;"> </td> <td style="width: 25%;"> </td> <td style="width: 25%;"> </td> <td style="width: 25%;"> </td> </tr> </table>														
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ADDRESS OF THE HEAD OFFICE	<table border="1" style="width: 100%; height: 30px;"> <tr><td> </td></tr> <tr><td> </td></tr> </table>														
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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

PRIVATE COMPANIES

TYPE OF COMPANY	<input type="text"/>																																	
NGO	YES <input type="checkbox"/>	NO <input type="checkbox"/>	(Non Gouvernemental Organisation)																															
NAME(S)	<input type="text"/>																																	
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COUNTRY	<input type="text"/>																																	
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CONTACT PERSON	<input type="text"/>																																	

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- * 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"/> ^D <input type="text"/> ^D <input type="text"/> ^M <input type="text"/> ^M <input type="text"/> ^Y <input type="text"/> ^Y <input type="text"/> ^Y <input type="text"/> ^Y 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 :	STAMP
NAME AND FUNCTION OF THE AUTHORISED REPRESENTATIVE	
SIGNATURE	

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

SIGNALETIQUE FINANCIER

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

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

REMARQUES:

CACHET de la BANQUE + SIGNATURE du REPRESENTANT DE LA BANQUE (Les deux obligatoires)

DATE + SIGNATURE DU TITULAIRE DU COMPTE : (Obligatoire)

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
.....		

POWER OF ATTORNEY

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

4.3.2 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 operator⁵¹*)

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;

⁵¹ 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).

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.

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 above⁵².

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

⁵² 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.

4.3.3 Selection criteria documentation

Financial and Economic Capacity Overview Form

Financial and Economic Capacity Overview			
Currency : EURO	Figures (000)		
	N* (* most recent figures available)	N-1	N-2
Total Balance Sheet			
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>			
<u>About PROFIT & LOSS</u>			
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 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 most of the page below the header.

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)
- Name and address of employer
 - Type of business or sector
 - Occupation or position held
- Main activities and responsibilities

[Add separate entries for each relevant post occupied, starting with the most recent.]

EDUCATION AND TRAINING

- Dates (from – to)
- Name and type of organisation providing education and training
- Principal subjects/occupational skills covered
 - Title of qualification awarded
- Level in national classification (if appropriate)

[Add separate entries for each relevant course you have completed, starting with the most recent.]

**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

[Specify language]

• Reading skills

[Indicate level: excellent, good, basic.]

• Writing skills

[Indicate level: excellent, good, basic.]

• Verbal skills

[Indicate level: excellent, good, basic.]

SOCIAL SKILLS

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

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.*

ORGANISATIONAL SKILLS

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

AND COMPETENCES

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

TECHNICAL SKILLS

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

AND COMPETENCES

*With computers, specific kinds of
equipment, machinery, etc.*

ARTISTIC SKILLS

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

AND COMPETENCES

Music, writing, design, etc.

OTHER SKILLS

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

AND COMPETENCES

Competences not mentioned above.

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

<i>Price component</i>	<i>Unit price</i>	<i>Quantity (number of days required)</i>	<i>Total</i>
Work Package A (WP A)			
Human resources			
Person X (role)			
Person Y (role)			
.....			
Subtotal (1)			
Other			
Item X			
Item Y			
.....			
Subtotal (2)			
TOTAL WP A			
Work Package B (WP B)			
Human resources			
Person X (role)			
Person Y (role)			
.....			
Subtotal (1)			
Other			
Item X			
Item Y			
.....			
Subtotal (2)			
TOTAL WP B			
...			

Please make sure that all travel and subsistence expenses related to the implementation of the contract are included in your offer (please refer to section 1.3.6 for the provisional meeting schedule).