

ECHA/2011/01

Multiple Framework Contract with re-opening of competition for scientific services for ECHA

Open procurement procedure Specifications and model contract

Contract notice: OJEU 2011/S 77-125413

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1. THE SERVICES (TECHNICAL SPECIFICATIONS)

1.1. BACKGROUND

The European Chemicals Agency (ECHA), located in Helsinki, Finland manages the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the European Union. These REACH processes are designed to provide additional information on chemicals, to ensure their safe use, and to ensure competitiveness of the European industry.

In its decision-making the Agency will take the best available scientific and technical data and socio-economic information into account. It will also provide information on chemicals and technical and scientific advice. By assessing and approving testing proposals, the Agency will minimize animal testing.

An important element of ECHA's work is to carry out effectively different tasks related to the implementation of the REACH and CLP Regulations. It is foreseen that ECHA will also be responsible for implementation of scientific and technical tasks under the proposed Regulation concerning the placing on the market and use of biocidal products, so called Biocides Regulation (currently under preparation) and under the Regulation concerning the export and import of dangerous chemicals, so called PIC Regulation (recast of Regulation (EC) No 689/2008 under preparation).

The Framework Contract is expected to cover the following services:

- a) Assisting the Agency in the scientific and technical implementation of the REACH Regulation concerning health, environmental and socio-economic issues, CLP Regulation, the Biocides Regulation and PIC Regulation. This assistance concerns registration (including Product and Process Orientated Research and Development (PPORD) and substance identification tasks), evaluation (testing proposals, compliance checking and substance evaluation), restriction, harmonised classification and labelling, authorisation, evaluation of biocidal active substances and authorisation applications of biocidal products. This should also include undertaking hazard, exposure, risk and socio-economic assessments.
- b) Evaluating the latest scientific findings related to the health and environmental impacts of chemicals and assessing the possible implications of these findings for implementing the REACH Regulation, CLP Regulation, the Biocides Regulation and PIC Regulation;
- c) Developing and improving methodologies supporting the implementation of REACH Regulation, CLP Regulation, Biocides Regulation and PIC Regulation, including methodologies for identifying substances, for the hazard, exposure and risk assessment of chemicals, testing strategies (including the development of computational methodologies) and for the socio-economic assessment of the impacts of changes in the regulatory management of chemicals, taking due account of the economic cost/benefits as well the health and environmental benefits of the proposed restriction or authorisation measures; and

d) Monitoring the effectiveness of current Community and Member States' policies to reduce the impacts of chemicals particularly with respect to the achievement the objectives of the REACH Regulation, CLP Regulation, the Biocides Regulation and PIC Regulation.

1.2. DESCRIPTION OF RESOURCES

For the implementation of the framework contract, highly qualified and experienced experts will be needed. The requirements for the profiles indicated below shall be applicable to all resources involved in the implementation of the framework contract. These requirements will be further defined in the service request for the specific contracts. Justified by the specific nature of the tasks to be performed by the experts, the Agency will stipulate at the level of specific contracts further required knowledge and skills within the relevant areas of expertise.

Category of expert	1) Educational background	2) Professional experience ¹	3) Additional requirements
Senior expert	At least a Master's degree in a subject relevant to the "Areas of expertise" listed below	Experience of at least 12 years in at least one of the "Areas of expertise" listed below	Knowledge of written and spoken English at C1 level in the Common European Framework of Reference for languages ² and
			Experience in drafting reports and presentations in English
Expert	At least a Master's degree in a subject relevant to the "Areas of expertise" listed below	Experience of at least 6 years in at least one of the "Areas of expertise" listed below	Knowledge of written and spoken English at C1 level in the Common European Framework of Reference for languages ² and
			Experience in drafting reports and presentations in English
Junior expert	At least a Master's degree in a subject relevant to the "Areas of expertise" listed below	Experience of at least 2 years in at least one of the "Areas of expertise" listed below	Knowledge of written and spoken English at C1 level in the Common European Framework of Reference for languages ² and
			Experience in drafting reports and presentations in English

¹ Only relevant professional experience acquired **after achieving** the minimum qualification stated in point 1

[&]quot;Educational background" shall be considered

² See Section 4.3.3 "European levels- self assessment grid"

Areas of expertise:

1) Chemistry (organic, inorganic, analytical, etc), chemical and process engineering, substance identification including the application of the guidance for identifying and naming of substances under REACH, the chemical nomenclature (i.e. IUPAC rules), IUCLID and various chemical databases;

2) Toxicology and ecotoxicology: including experimental testing, alternative testing methods, computational and other predictive methods;

3) Environmental and industrial economics, socio-economic assessment relevant for the regulatory management of chemicals;

4) Hazard assessment, exposure assessment, risk assessment and risk management related to industrial chemicals and biocides;

5) Chemical safety assessment (CSA) and its implementation including tools such as, IUCLID, and Chesar, and tools supporting exposure estimation such as ECETOC TRA, Stoffenmanager, ART, Consexpo;

6) ChemoInformatics including: generation and use of different notations for chemical structure, quantitative structure-activity relationships (QSAR), (eco)toxicological information and fate modelling and reviewing highly specialised literature and extracting meaningful information on the subject.

Confidentiality and conflict of interest:

Pursuant to Article II.3.1 of the Framework Contract, the Agency may request a "Declaration of confidentiality and absence of conflict of interest" from each member of the team/each expert involved in the implementation of the specific contracts.

1.3. DESCRIPTION OF TASKS

1.3.1. Tasks

Different types of tasks need to be performed by the contractors under the Framework Contract in order to assist the Agency in a range of activities. For information purposes only and in order to aid potential bidders, examples of such tasks are presented below. This description is neither exhaustive nor exclusive nor is the distribution of tasks between the various areas below necessarily an illustration of the final distribution of tasks that will be undertaken via the conclusion of specific contracts.

1. Assistance in substance identification and review of available databases and inventories

The contractor may be asked to contribute to resolve issues related to substance identification, providing scientific support and high level specific expertise in various relevant chemical fields, and retrieving information from literature and databases. This task can include the development of case studies for specific substances and specific groups of substances or for specific issues to be investigated.

The contractor may be required to provide support in the assessment and revision (e.g. identification of errors and overlapping entries) of available databases and inventories for the REACH Regulation, including EC- EINECS-ELINCS-NLP, Annex XVII of REACH, etc, and to analyse and propose consistent revision and cleaning up of the CLP Inventory due to the revision of the EC inventory as well as of Annex VI of CLP (the harmonised classifications) due to the revision of the EC inventory, or to carry out corresponding tasks related to active substances in biocidal products.

The contractor may also be asked to perform analysis, development and implementation, needed for extending existing classical structural lists to chemically intelligent databases in order to expand the searching functionality by chemical structures/substructures, chemical/toxicological categories, etc. Additionally, support with engine updates and data migration from/to chemical databases might be needed.

In relation to the same subjects the contractor may be also asked to provide scientific and technical support guidelines and manuals for internal and external use.

2. Market intelligence

The contractor may assist the Agency in setting up (industry) surveys to answer specific questions, such as the expected dossier submission for REACH deadlines. Such surveys can be used to improve ECHA services, e.g. by analyses of the market. The task will require the contractor to conduct surveys on a large scale and compile and process the results.

3. PPORD

The Agency may require assistance for the prioritisation/identification of the PPORD notification dossiers submitted in accordance with Article 9 of REACH and for which the need to impose conditions needs to be considered (Article 9(4)) or for which an extension for the five years exemption period might be granted (Article 9(7)).

The contractor may be asked to provide assistance to develop the workflow for the implementation of the PPORD assessment task, to develop criteria and methodologies for screening/selecting PPORD notifications to be assessed (use of databases and IT tools), for identifying additional information to be requested to the PPORD notifier and finally for defining which conditions should be imposed in order to ensure that the conditions specified in Article 9(4) are respected.

This task will require an assessment of the scientific and technical aspects of the dossier, coordination of any further dossier assessment with experts within the Agency, documenting the need to impose conditions for the PPORD and drafting the conditions to be imposed.

4. Assistance in dossier evaluation

The Agency may require assistance in the resolution of issues related to Dossier Evaluation under REACH. In particular in cases where detailed, scientifically reasoned reports are required to facilitate efficient and effective dossier evaluation in the context of compliance checks and testing proposals. The Agency may require assistance in the form of contributions to discussions at Seminars/Workshops related to dossier evaluation issues be they internal or with Member State Competent Authorities, Member State Committee of ECHA and/or industry. Assistance in the development/preparation of scientific reports such as REACH Article 117(3) reports may be required. Furthermore, assistance may be required in order to build scientific capacity within ECHA in terms of emerging fields of scientific research e.g. nanomaterials and alternative test methods.

5. Assistance in processes relating to substance evaluation

The Agency may request assistance in developing the criteria to prioritise substances for substance evaluation as well as during the development of the Community Rolling Action Plan.

6. Assessment of computational methods for hazard and risk characterisation, and risk management

The Agency may require assistance with reviewing and comparing commercially or freely available models and software for predicting the physico-chemical, environmental fate, ecotoxicological and toxicological properties of chemicals. The review may encompass: the appropriateness and scientific validity of the underlying modelling approach; the quality of the experimental data used to train, validate or fine tune the model; the accuracy of the predictions; the construction of test cases

and critical evaluation of the results; the relevance of the predictions for regulatory applications; the user-interface; the ability to modify, extend an; generally customise the software features; the availability of adequate documentation, training on its use and provision of support; the usability of the software within the existing software and hardware infrastructure in the Agency. The contractor may be asked to review modelling methodologies reported in the open literature, including QMRFs.

7. Data assessment, analysis and data management

In order to extract, collate and analyze the data from different sources additionally support can be needed for: data pre-processing, feature extraction, clustering and feature clustering, data classification and regression types of data analyses. The Agency may require methodological support in the development of models and tools, as well as integration of non-testing methods in the workflows of the Agency and its procedures. This may include development of new models, structural alerts, and clusters of substances; implementation of those models in software; implementation of other models and predictive approaches in software (e.g. alerts or transformations found in literature, or models published but not implemented in an specific software tool); assessment of the models/tools developed and generation of proper documentation about them; integration of those new models/tools in the workflows and processes of the Agency.

8. Assistance for development of technical and scientific specifications for new or existing tools, including information and communication technologies

The Agency may request the contractor to provide different kinds of scientific complementary services to further develop the tools used by the Agency. Examples of scientific services that could be provided include capture of stakeholder requirements, preparation of system specifications, evaluation of specific software (e.g. modelling tools), development of scientific criteria and algorithms for the implementation and customization of the existing data integration platforms, for data migration and other integration work, specifications for improvement of user interface e.g. offering search functionality on chemical identities and on the properties of chemicals, possibility to display results in a web interface and link with similar databases from other institutions, as well as the possibility of user registration and provision of other functionalities (such as FAQs in form of a searchable database).

9. Scientific support to Chemical Safety Assessment related activities, including for the supply chain mechanisms

The Agency may require assistance for activities carried out by the Agency related to Chemical Safety Assessment (CSA). This could relate to the analysis of the information received in Chemical Safety Reports (CSR) (e.g. comparative analysis of exposure estimation tools used for the CSA or analysis of the relevancy of the

regional concentrations in CSRs when several CSRs are submitted for a given substance). It could also relate to development work on methodology for the preparation of CSA/CSRs (e.g. working out solutions for issues related to CSA for multi-constituent substance, for substance reacting on use or for polymers), including specifications for Chesar development (e.g. scientific analysis for the plugging possibilities of existing exposure estimation tools to Chesar or further development of Chesar for substance evaluation or any related topic) or working out solutions for guidance related to existing gaps in the current guidance on CSA. CSA related activities of the Agency could also consist in comparative analysis of CSA under REACH and risk assessment under the Biocides Regulation or other chemical legislation. In addition chemical safety assessment related activities for and by downstream users (DU) are also to be covered, e.g. development of method for the processing of Exposure Scenarios by formulators, methodology for DU CSA preparation (including potentiality for the further development of Chesar for DU).

10. Data sharing

There are different issues to be solved on how to efficiently share data that have been submitted by stakeholders to the Agency. The contractor may be asked to develop specific data sharing procedures (both for the Agency and stakeholders) or tools (including IT tools), including the organisation and inclusion of possible stakeholder input when these tools are used in particular in the context of the inquiry process and Substance Information Exchange Forum (SIEF). The contractor may also be asked to contribute to the resolution of issues related to the extraction of endpoint data from dossiers among several which are empty.

The contractor may also be asked to assist in identifying and listing pre-registrants in case activities defined by ECHA (e.g. removing pre-registrations entries) require getting in contact with the pre-registrant(s).

In case of a high number of submission of data sharing dispute claims, the contractor may also be requested to assist in the preparation of the reports which allow for the assessment of the information (whether complete) submitted to ECHA by the claiming parties. The contractor may be called to contribute to the ECHA strategies to deliver communication tools/ approaches to defined industry targets (e.g. SMEs, national trade associations) in relation to technical contents (e.g. by developing targeted newsletters, other supporting media, etc.).

11. Assistance in the development of dissemination of information

Dissemination of information in a timely and relevant manner is one of the main goals of the Agency. The dissemination will take place i.a. by giving access to different databases and by disseminating information on the web. The contractor may be requested to prepare and keep up to date specific IT services, including web-based services (discussion, forums, blogs, surveys, etc.). The contractor may also be requested to handle review requests and assist in the dissemination of data.

12. Service on biocides

The current Biocidal Products Directive (BPD) will be replaced by a Regulation. The Commission launched a proposal in 2009 which is currently going through the legislative process. The foreseen entry into force is 2012. ECHA will provide technical and scientific support under the Biocides Regulation. Preparations within ECHA have started in the beginning of 2011. Assistance may be needed in these activities. This may vary from contributing to the development of several "submission pipelines" (approval of active substances, national authorisation, Union authorisation, data sharing and technical equivalence for example) to the development of technical guidance. Once the Biocides Regulation has entered into force, assistance may be needed in the scientific and technical tasks of ECHA. This may include assistance in the activities of the future Biocidal Products Committee and/or Coordination Group.

13. Identification of substances for which further risk management actions by the authorities may be required

Assistance in the collation of information (including retrieval from registration dossiers) relevant for taking decisions as to whether the use(s) of a substance potentially exert risks that would need to be addressed by the authorities and what the best management options for risk prevention and controlling would be.

Identification of potential SVHC (substances of very high concern): Assistance in the collation of relevant information and in the evaluation of data, in particular with regard to assessing PBT or vPvB properties of substances or whether they may fulfil the "equivalent level of concern" definition set out in Article 57(f) of REACH.

14. Preparation of dossiers of substances of very high concern

The Agency may be asked to prepare Annex XV dossiers under REACH for the identification of substances of very high concern (SVHC). The Agency might consider contracting (parts of) the preparation of such dossiers out.

15. Assessment and prioritisation of substances of very high concern

The Agency needs to submit to the European Commission at least every second year a recommendation of SVHC from the Candidate List to be placed on Annex XIV of the REACH Regulation. Substances included in Annex XIV require authorisation before they can be used. In the context of developing this recommendation, the Agency may request contractors to acquire additional information (including retrieval from registration dossiers) relevant for prioritising substances from the Candidate List and for developing draft Annex XIV entries in accordance with Article 58.

16. Assessment of Annex VI Harmonised Classification and Labelling dossiers (CLH dossiers)

The Agency may need assistance during the assessment of proposals submitted by Member States or Industry for a harmonised classification and labelling of a substance in accordance with Article 37 of Regulation (EC) No 1272/2008 (the CLP Regulation). This would in particular require assistance in analysing the scientific data presented in the CLH dossier to justify a classification of a substance in accordance with the criteria set out in the CLP Regulation as carcinogenic, mutagenic or toxic to reproduction category 1 or 2, or as a respiratory sensitizer. In specific cases, assistance might also be required for the analysis of the scientific data presented in the CLH dossier to justify the classification of a substance for other adverse effects on human health.

17. C&L inventory

The Agency may need support for the maintenance, quality assessment as well as technical and scientific analysis of the content of the inventory. This would require assistance in substance identity (as detailed in task 1), as well as assistance in monitoring compliance with harmonised classification as stipulated in Annex VI of the CLP Regulation. This task can include the development of case studies for specific substances and specific groups of substances or for specific issues to be investigated, particularly focused on substances classified as carcinogenic, mutagenic or toxic to reproduction category 1 or 2, or as respiratory sensitizers.

18. Preparation of restriction proposals

The European Commission may request the Agency to prepare an Annex XV dossier under REACH for restricting a substance. In such case the Agency may require external assistance in the preparation of the dossier. The services required comprise potentially any aspect of dossier preparation, e.g., hazard and exposure assessments, analysis of the risks as well as technical and economic feasibility of alternatives, costs if the substance is no longer available, human health and environmental impacts of restrictions and related quantified/monetised benefits.

19. Development of the capabilities in health and environmental impact assessment as well as socio-economic analysis

In order to carry out socio-economic analysis, there may be a need to further develop the methodologies and empirical application of assessing the health and environmental impacts of the regulation of chemicals (including problem assessment, development of options, assessment of economic, social and environmental costs and benefits of alternative options). Such work may also include the assessment of disability or quality adjusted life years as well as the morbidity or mortality related to chemicals. Furthermore, the Agency may request assistance in the linking of latest health and environmental assessment to socioeconomic analysis with a focus on chemicals.

20. Development of guidance and providing other support

The Agency envisages that further development and revision of existing technical guidance documents (TGD) may be needed. The contractor may be requested to provide various scientific and technical services in the further development of methods and approaches to be included in the guidance documents or applied by the secretariat. These services can range from setting up and contributing to the process of developing the documents, to giving substantial input to or coordinate the development of specific sections of the document as well as organising the stakeholder consultation process. Furthermore the contractor may be asked to assist in the development of user manuals for the IT system and adapt them to the latest standards and IT versions.

21. Training and awareness raising

The Agency may need assistance in the development of training materials and/or training modules in many of the above identified subject areas, including on the use of specific tools such as IUCLID and Chesar, as well as in carrying out the training programmes. These training programmes may be directed towards the Agency staff, staff from Member States, industry and/or NGOs. Such training courses may be short (e.g. 1 day) and focussed to a specific subject and thus, given to a relatively small group. However, they could also be longer (e.g. 1 week) and more general in scope.

There may also be a need for support to awareness raising activities for industry via webinars, workshops preparation, tutorials, web tutorials and other means on specific topics, e.g. to their obligations related to authorisation or substance in articles, registration deadline of 2013, Biocides regulation, PIC Regulation, etc.

22. Services on other scientific and technical issues

The Agency may need assistance in other scientific and technical questions that have not been mentioned above. These could be of cross cutting nature, e.g. interlinks between legal and technical issues, *ad hoc* needs on organising scientific or technical workshops, assisting in summarising comments received during a consultation, assisting in specific issues in relation to Committees etc. The Agency may also request experts/specialists to work in *ad hoc* or other working groups of the Committees or the Forum, being nominated *ad personam*.

1.4. DESCRIPTION OF DELIVERABLES

The Contractor is to provide the required reports, documents and/or other deliverables in accordance with the conditions of the specific contract appended in Annex 4.2. The

deliverables will vary in nature from request to request and may for instance in terms of the size of the reports range from a few pages on specific questions to a comprehensive analysis on a particular issue or series of issues. Thus, a request for services is likely to vary between one consulting day to several months, depending on the nature of the request.

The main deliverables will be established as part of the specific contracts undertaken in the context of the framework contract. As examples, the deliverables could be:

- in the form of a draft report followed, after account has been taken of the Agency's comments, by a final report;
- in the form of progress reporting if necessary. The contractor could be asked to provide regular reports to the Contract manager at the Agency. The frequency of reporting may differ depending on the size and complexity of the services and will be stipulated in the specific contract.
- in the form of workshops or training sessions accompanied by appropriate written material and presentations;
- in the form of technical analysis, evaluation, specifications or other scientific methodology development.

All communication during the execution of the contract will be made in English. Reports have to be provided electronically in appropriate format (e.g. Word, Excel, Oracle, html, pdf etc) and written in clear English. The final report needs to be provided within the deadline stated in the specific contract.

2 THE CONTRACT

2.1 THE NATURE OF THE CONTRACT

The Contracts are multiple framework service contracts with reopening of competition³.

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

The Agency intends to establish Framework Contracts with a minimum of 3 (three) (provided that a sufficient number of admissible tenders meet the award criteria) and a maximum of 15 (fifteen) contractors.

There will be reopening of competition for each Specific Contract, which can be either a "Fixed Price" or a "Time and Means" Specific 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. The indicative intended date for signing the Framework Contracts is the <u>third quarter of 2011</u>.

The Framework Contracts will run for a period of 24 months and will be automatically renewed up to two times by 12 months, unless written notification to the contrary is sent by one of the contracting parties and received by the other 3 months before expiry of the contract.

The execution of the tasks may not start before the Contract has been signed. The period of execution of the tasks may be extended, only with the written agreement of the contracting parties, before the end of the period originally stated in the Contract.

³ Article 88 of the Financial Regulation and Art. 117 of the Implementing Rules of the Financial Regulation.

2.3 PLACE OF PERFORMANCE

The place of performance of the tasks shall be either the Contractor's premises (for Fixed Price specific contracts) or the Agency's premises (for Time and Means specific contracts), as will be stipulated in the Specific Contracts. In exceptional cases, travel outside the normal location may be required, at the request of the Agency.

2.4 TERMS OF PAYMENT

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

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

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

Pre-financing: For Fixed Price specific contracts with a total value below 200.000 EUR and for all Time and Means specific contracts pre-financing is excluded. Pre-financing, with a maximum of 30% of the value of the contract, is valid for specific contracts (FP) with the total value equal to or above 200,000 EUR unless one or more interim payments are foreseen. The Agency may require a guarantee to cover the pre-financing. The pre-financing is set out in Article I.5 and II.4 of the Framework Contract and in Article 4 of the model Specific Contracts.

2.5 GUARANTEES

Pre-financing guarantee

Where required by the Specific Contract, 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 Party⁴.

Performance guarantee

The Contractor may be required to provide a performance guarantee⁵ for an amount of 10% of the value of a Specific Contract and for its whole duration, which shall cover performance of the Specific Contract in accordance with the terms set out in Annex A to the Specific Contract. It shall be released six (6) months after complete execution and the last payment under the Specific Contract.

For Specific Contracts with a value equal to or above 500 000 EUR, the Contractor shall be required to provide a guarantee. The guarantee shall be issued by a bank, an authorised financial institution or a Third Party in favour of the Agency.

⁴ Guarantees shall be provided in accordance with the model available in section 4.2.3.

⁵ Guarantees shall be provided in accordance with the model available in section 4.2.4

For Specific Contracts with a value below 500 000 EUR, the Contractor may be required to provide a guarantee. The guarantee may also be constituted by deductions from payments as and when they are made.

Model guarantees are provided in Section 4.2.3 and 4.2.4 of these tender specifications.

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 no comply with the tender 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;
- 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.

2.8 IMPLEMENTATION OF THE CONTRACT

The Contract shall be implemented through Specific Contracts, either on a Fixed Price or a Time and Means basis, in accordance with the provisions related to these types, of contracts as specified hereafter.

The Agency estimates that about 90% of the service requests will be Fixed Price and only 10% will be Time and Means.

2.8.1. Contracting mode

Services shall be provided on the basis of two different kinds of specific contracts:

- Fixed Price specific contracts, which correspond to the provision of a defined work; or
- Time & Means specific contracts, which correspond to the performance of a maximum number of man-days at the Agency's premises.

Fixed Price Specific contracts

Fixed Price (FP) specific contracts are assignments of work executed outside the Agency's premises (i.e. off-site or extra-muros) or of work executed both outside and inside the Agency's premises.

The following conditions relating to fixed price specific contracts apply:

- In a Fixed Price Service Request the Agency specifies the deliverables corresponding to the work to be delivered as well as the delivery schedule.
- The Contractor must present an offer meeting the requirements as specified in the Service Requests and associated annexes (specifications, work packages, deliverables, deadlines etc.). The technical offer must include a project plan. It has to indicate the proposed activities, the team structure, where applicable, profiles, roles, responsibilities and workload (man-days) of the consultant(s).
- The technical offer must also contain the CVs of the proposed experts. Predefined CV forms must be used. All information indicated in the CV has to be correct and validated. Contractor's staff proposed must match the required profile description mentioned under Section 1.2 and the specific needs indicated in the Service Request⁶.
- The financial offer must include the price and the reimbursables, where applicable. The total price must be based on the estimation of the number of days for each profile and on prices per man-day equal or below the maximum off site price per man-day indicated in the financial offer for the Framework Contract. The prices must be all-inclusive. However, travel expenses and reimbursables shall be reimbursed, but only in case of work performed at a location other than the Contractor's premises, as indicated in the request for services and in line with the annex to the contract.
- Work is performed typically off-site, on the Contractor's premises. However, some assignment may be for work to be executed on both the Agency's and the Contractor's premises. The Contractor shall provide all necessary infrastructure on his premises for the successful execution of the work.
- For activities performed in the Agency, the performance will take place during ECHA working hours, and not during ECHA public holidays⁷.
- The deliverables must be on time, and conform to the specifications as described in the Specific Contract.
- The invoicing is based on the acceptance of the deliverables by the Agency, independently of the real workload.

Time & Means Specific contracts

Time & Means (TM) specific contracts are used for medium-long to long term assignments of work that is executed inside the Agency's premises (i.e. on-site, intra-muros). One full year corresponds normally to an effective workload of 220 days.

The following conditions relating to Time & Means specific contracts apply:

In a Time & Means Service Request the Agency specifies the workload (by indicating the maximum total number of man-days) and its specific needs for the requested profiles. The Service Request can combine different profiles, with the requested quantity for each profile and the individual workload and the preferred start date.

⁶ See Section 1

⁷ For 2011: <u>http://echa.europa.eu/about/hours_en.asp</u>

- The Contractor must present an offer meeting the requirements as specified in the Service Requests and associated documents.
- The technical offer must also contain the CV's of the proposed experts. Predefined CV forms must be used. All information indicated in the CV has to be correct and validated by the Contractor. Contractor's staff proposed must match the required profile description mentioned under Section 1.2 and the specific needs indicated in the Service Request⁸.
- The financial offer must include the price and the reimbursables, where applicable. The price must be based on prices per man-day equal or below the maximum on site prices per man-day indicated in the financial offer for the Framework Contract. The prices must be all-inclusive. However, travel expenses and reimbursables shall be reimbursed, but only in case of work performed at a location other than the Agency's premises, as indicated in the request for services. Work is normally performed on the Agency's premises. In some cases, on the Agency's request travels outside the normal location can be required.
- Persons proposed must be available for interviews during 10 working days as from the submission deadline.
- Persons proposed must be available at the start of the project.
- When a person is no longer available before the start of a new Contract, the Contractor is obliged to inform the Agency immediately. If the Specific Contract is not yet signed by both parties, the Contractor shall propose new candidates with the equivalent qualifications and experience to the replaced candidate and as required for the profile. If the Specific Contract is signed, the Agency can either ask for a replacement with the performance of 10 working days free of charge or exercise its rights under Article II.1.9 to the Framework Contract.
- On the Agency's demand, during holidays or other periods of planned absence by the person employed, the Contractor will be required to provide an adequate replacement. The replacement person will be given sufficient training and provided with all information necessary to guarantee continuity of the service provided to the Agency. All such training and handover work will be carried out at the Contractor's expense.
- On the Agency's demand, the Contractor must replace personnel who prove incapable of carrying out the specified tasks to the required standards. The replacement candidate will be given sufficient training during an adequate handover period, so that he/she may be immediately operational when the original candidate is withdrawn. Any such replacement and training, if required, will be carried out at no additional cost to the Agency.
- The Contractor shall give a month notice to the Agency of any personnel changes in the team. The prior agreement of the Agency must be obtained.
- In case of replacement, the handover period must be at least 10 working days, free of charge of the Agency. If no handover is possible and additional training is needed for the replacement person, at least 15 working days (free of charge for the Agency) must be performed by the replacement person.
- In case of 'force majeure', if the original person is no longer able to carry out the work, the Contractor is obliged to inform the Agency, immediately provide a competent replacement person and arrange sufficient training (during an

⁸ See section 1

adequate handover period where possible) to guarantee continuity of the service provided to the Agency. Any such replacement will be effected at no additional cost to the Agency.

- In case of replacement, the Contractor must propose a minimum of one replacement person with the equivalent qualifications and experience and as required for the profile. If the Contractor does not propose suitable replacement staff, the Agency may immediately terminate the Contract.
- The invoicing is based on the number of days of actual services rendered and on the acceptance of the deliverables by the Agency.
- For activities performed in the Agency, the performance will take place during ECHA working hours, and not during ECHA public holidays⁹.

2.8.2. Roadmaps

The following paragraphs detail the processes for:

- Fixed Price specific contracts
- Time & Means specific contracts

The involved actors are the Contractor and the Agency.

⁹ For 2011: <u>http://echa.europa.eu/about/hours_en.asp</u>

Roadmaps for Fixed Price specific contracts

Step 1: Need identification

Step 1 Fixed Price	What	 The need for services is identified by the Agency. The Agency prepares the requirements/specifications. The Agency specifies how much time it wants to allow the Contractors to prepare their offer. The time allowed to the Contractors must be at least 10 working days as from the Request Date (Service request dispatch). "The date, by which the Contractors must submit their offer is referred to as the "Submission deadline".
	Parties involved	The Agency
	Result	Requirements"Submission deadline" is fixed

Step 2: Service Request Dispatch

Step 2	What	• The Agency prepares the Service Request which indicates the "Submission deadline".
Fixed Price		• The Agency specifies in the Service Request the modalities regarding the submission of the offer: paper submission or electronic submission.
		• The Agency sends the Service Request by e-mail to the Contractors. The date on which the Agency sends the Service Request is referred to as the "Request date".
	Parties involved	The Agency
	Result	"Request date" is fixed.
		 "Submission deadline" is fixed.
		 Service Request and requirements are dispatched.

Step 3: Presentation of the Offer

Step 3 Fixed Price	What	 The Contractors submit an offer, including the technical offer and the financial offer, by the "Submission deadline", according to the modalities mentioned in the service request (paper submission or electronic submission) If the offer has not been submitted by the "Submission deadline", the Agency will consider this as not respecting the requirements.
	Parties involved	ContractorsThe Agency
	Result	Offers presented.

Step 4: Evaluation of the Offers

Step 4	What	• The period after the "Submission deadline" will be used by the Agency to evaluate the received offers
	Parties involved	ContractorsThe Agency
	Result	The Agency selects the winning offer and informs by email the Contractors who have submitted an offer.

Step 5: Establishment of the Specific Contract

Step 5 Fixed Price	What	• The Specific Contract is established based on the accepted offer. The Specific Contract will include details of the work to be carried out, the start date, the duration in days and any other relevant information including the offer of the Contractor.
	Parties involved	ContractorsThe Agency

Step 6: Execution of the Specific Contract

	14/1 1	The Contractor everytee the Contract in line with the
Step 6	What	The Contractor executes the Contract in line with the requirements set out in the Specific Contract.
Fixed Price		• The Agency is informed on a regular basis about the intermediate results achieved.
		• The final deliverables are provided to the Agency (and if agreed, presented in a deliverables meeting).
	Parties involved	Contractor
		The Agency
	Result	All tasks outlined in the Specific Contract are executed.

Roadmaps for Time and Means Projects

Step 1: Need Identification

	-	
	What	The need for services is identified by the Agency.
		The Agency prepares the requirements/specifications.
I		• The Agency specifies how much time it wants to allow the Contractors to prepare their offer with a list of the qualified persons they propose. The time allowed to the Contractors must be at least 10 working days as from the" Request Date". The date, by which the Contractors must present their offer, is referred to as the "Submission deadline".
	Parties involved	The Agency
	Result	Requirements
		 "Submission deadline" deadline is fixed.

Step 2: Service Request Dispatch

the



	• The Agency specifies in the Service Request the modalities regarding the submission of the offer: paper submission or electronic submission.
	• The Agency sends the Service Request by e-mail to the Contractors. The date on which the Agency sends the Service Request is referred to as the "Request date".
Parties involved	The Agency
Result	"Request date" is fixed.
	"Submission deadline" is fixed.
	Service Request is sent.

Step 3: Preparation and Submission of the Offers

Step 3 TM	What	 The Contractors submit an offer, including the technical offer and the financial offer, by the "Submission deadline", according to the modalities mentioned in the service request (paper submission or electronic submission) If the offer has not been submitted by the "Submission deadline", the Agency will consider this as not respecting the requirements.
	Parties involved	Contractors
		The Agency
	Result	Offers presented

Step 4: Evaluation of the Offers

Step 4	What	The period after the "Submission deadline" will be used by the Agency to evaluate the received offers
	Parties involved	Contractors
		The Agency
	Result	The Agency selects the winning offer and informs by email the Contractors who have submitted an offer.

Step 5: Establishment of the Specific Contract

Step 5	What	he Specific Contract is established on the basis of the ccepted offer. The Specific Contract will include details
Men		
TM		Page 24 of 128

	of the work to be carried out, the start date, the duration in days and any other relevant information, including the offer of the Contractor.
Parties involved	Contractors
	The Agency
Result	Specific Contract is signed.

Step 6: Execution of the Specific Contract

Step 6	What	 The Contractor executes the Contract in line with the requirements set out in the Specific Contract. The Agency is informed on a regular basis about the intermediate results achieved through progess reporting and time-sheets. The final deliverables are provided to the Agency (and if agreed, presented in a deliverables meeting.
	Parties involved	ContractorThe Agency
	Result	All tasks outlined in the Specific Contract are executed.

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.).

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

Tenders must include the following information:

- all the information and documents requested by the Agency in order to assess the tender;
- o the price in euros;
- one specimen signature of an authorised agent (preferably in blue ink) on the legal entity form¹⁰, and a statement from the same agent confirming the validity of the tender;
- the name and contact details of a contact person in relation to the submission of the offer.

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 offer, 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 offer

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 EU 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 EU 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:

¹⁰ See section 4.3.1

The **Legal Entity Form**¹¹ is to be signed by a representative of the tenderer authorised to sign contracts with third parties.

The **Financial identification**¹² form shall be duly filled in and signed by an authorised representative of the tenderer and his or her banker.

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

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

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

<u>Subcontractors</u> 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 will require the tenderer to give a formal status to this collaboration before the contract is signed. This can take the form of:

- o an entity with legal personality recognized 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**¹³, depending on the set up that has been chosen by the tenderers.

¹¹ This form is available at:

http://europa.eu/comm/budget/execution/legal entities en.htm ¹² The form is available at: http://europa.eu/comm/budget/execution/ftiers en.htm.

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

- a document¹⁴ clearly stating the roles, activities and responsibilities of the proposed subcontractor(s), and the reasons why subcontracting is envisaged;
- a letter of intent¹⁵ 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 Framework contract.

Exclusion criteria documentation

Tenderers or their representatives shall provide a **declaration on their honour**¹⁶, 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 Regulation¹⁷ and detailed in the form;
- undertake to submit to the Agency any additional document relating to the exclusion criteria, that the Agency considers necessary to perform its checks, within seven calendar days following the receipt of the Agency's request.

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

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

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

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

Selection criteria documentation

<u>General</u>

¹³ Section 4.3.1

¹⁴ To be provided in free format

¹⁵ See Section 4.3.1

¹⁶ See Section 4.3.2.

¹⁷ Council Regulation (EC Euratom) No 1605/2002 of 25 June 2002, Part One, Title V (Procurement)

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 offer. 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 (as specified in Section 3.4) of the evaluation of the tenders¹⁸.

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

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.

In case of joint offer, or sub-contracting for which the total amount envisaged is above 30% of the total contract value, evidence of the ability of the entity involved in the joint offer or the potential subcontractor(s) to perform the tasks entrusted to him/them shall be included in the offer. Such evidence is the same as that also required from the tenderer, as described and identified above.

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

This proof is to be provided by submitting the completed Financial and Economic Capacity Overview Form¹⁹, 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. If several service providers are involved in the bid, each of them, in principle, must have and show that they have the necessary economic and financial capacity to

¹⁸ See Section 4.3.3.

¹⁹ See Section 4.3.3

perform the tasks assigned to them in the tender. The same applies to subcontractors whose tasks are equal to or exceed 30% of the contract.

Conversely, tenderers should note that the Agency will consider intended subcontracting below 30% of the contract value as an indication that the potential contractor has the resources to complete the tasks under the contract, as well as a factor potentially enhancing the quality of the proposed team organisation.

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:
 - i. The CV's (in Europass format see Section 4.3.3) of the 6 experts and 6 senior experts;
 - ii. The University diplomas for all 12 experts;
 - iii. The relevant sections of the CV's mentioned above (the language skills and the listed working experience in English).
- b) Evidence for selection criterion 2.2:

A list of at least five relevant (in terms of subject²⁰ and value²¹) reference projects executed in the last three years, with the value, dates and places. For each reference project it is mandatory to fill in one project reference form²². The Agency shall be authorised to contact the indicated person to verify the reference.

3.1.1.2.2.Section Two: Technical offer

Qualitative award criteria documentation

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 offers. As a consequence, incompleteness in this section can only result in negative impact for the evaluation of award criteria. Please note also, that offers deviating from the technical specifications may be rejected for non-conformity.

The technical specifications and the tenderer's offer shall be integral parts of the contract and will constitute annexes to the contract.

²⁰ Relevance in terms of subject is coverage of the task(s) mentioned under Section1.3

²¹ Relevance in terms of value is a value of minimum € 30.000 per project

²² Project reference form to be used (see section 4.3.3.)

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.

The assessment will be performed by applying the award criteria mentioned below. These award criteria will be assessed on the basis of the Questionnaire and the Case studies given in Section 4.3.4 "Award criteria documentation".

A) Assessment of the award criteria under the Framework contract:

Assessment basis for award criterion AW1

Criterion 1 – Understanding of the tasks and quality of the proposed services

The assessment basis for this award criterion is the reply provided to the Questionnaire under Section 4.3.4.1.1 (35 points)

Assessment basis for award criterion AW2:

Criterion 2 – Efficiency and project management

The assessment basis for this award criterion is the reply provided to the two case studies developed under Section 4.3.4.1.2 (25 points)

B) Assessment of the award criteria under the Specific contracts:

Assessment basis for award criteria for Fixed Price Specific Contracts

Assessment basis for award criterion AW1

Criterion 1 - Quality and relevance of the methodology

The assessment basis for this award criterion is the Contractor's offer (30 points).

Assessment basis for award criterion AW2

Criterion 2 – Composition and organisation of the proposed team

The assessment basis for this award criterion is the Contractor's offer (30 points).

Assessment basis for award criteria for Time and Means Specific Contracts

Assessment basis for award criterion AW1

Criterion 1- Quality of the proposed services

The assessment basis for this award criterion is the technical offer (15 points).

Assessment basis for award criterion AW2

Criterion 2 - Suitability of the experts' CVs

The assessment basis for this award criterion is the CV(s) of the proposed experts (45 points).

3.1.1.2.3.Section Three: Financial offer

Financial award criteria documentation

Tenderers must use the financial form²³ to formulate their financial offer.

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

²³ See section 4.3.4.2

documentary evidence or by direct exemption. For those countries where national legislation provides an exemption by means of a reimbursement, the amount of VAT is to be shown separately. In case of doubts about the applicable VAT system, it is the tenderers responsibility to contact his national authorities to clarify the way in which the European Community is exempt from VAT;

- Prices shall not be conditional and be directly applicable by following the technical specifications.
- Prices shall be **maximum prices**, within which limit the successful tenderers will compete at the level of the service requests. The maximum prices are subject to price revision at the beginning of the third year in case the contract is renewed.

At the beginning of the third year of the Contract, 80% of each price may be revised upwards or downwards, if such revision is requested by one of the contracting parties by registered letter no later than three months before the second anniversary of the date on which it was signed. The Agency shall purchase on the basis of the prices in force on the date on which specific contracts are signed. Such prices shall not be subject to revision.

The revision shall be determined by the trend in the harmonised consumer price index (MUICP) published for the first time by the Publications Office of the European Union in the Eurostat monthly 'Data in Focus' publication at http://www.ec.europa.eu/eurostat/

Revision shall be calculated in accordance with the following formula:

Pr = Po (0,2+0,8 lr/lo)

Pr - revised price

Po - price in the original tender

Io - monthly index of the final date for submitting tenders

Ir - monthly index of the date on which the request for price revision was received

- The reference price for the award of the **Framework Contracts** shall be based on the maximum prices for the three categories of experts according to the weighting mentioned in the price reference table (4.3.4.2. Financial Offer) in light of the estimated use of each of the different categories of experts (respectively 50%, 35% and 15 % and the type of specific contract (90 % Fixed Price and 10% Time and Means)
- The reference price for the award of the **specific contracts** shall consist of (i) the total (maximum) amount in payment of the tasks

executed and, where applicable, (ii) the amount corresponding to the reimbursable expenses. The reimbursables, referred to in Article I.3.4 of the Framework Contract referred to above, corresponds to the expenses directly connected with the execution of the tasks under the contract which are incurred by the Contractor. In any event, this amount is the maximum amount that can be reimbursed for the expenses incurred. Reimbursable expenses are travel, subsistence and shipment expenses in accordance with the rules on reimbursement set out in Article II.7 of the framework contract referred to above. The daily scales applicable to subsistence expenses are set out in Annex IV of the Framework Contract above. In the bid it must be indicated separately from the amount stipulated in (i).

• Price quoted for man days must be all-inclusive, thus no additional costs may be charged for work executed at the normal place of performance (for Fixed price contracts, the Contractor's premises and for Time and Means contracts, ECHA's premises).

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.

3.1.1.3 Form of the tender

The tender must be submitted under double sealed cover.

The outer envelope should bear the address as mentioned below.

The inner envelope should be addressed to the Finance Unit R1 and marked "*Invitation to tender No ECHA/2011/01*" and "*Not to be opened by the internal mail service*". If self-adhesive envelopes are used, they must be sealed with adhesive tape and the sender must sign across the tape. The inner envelope must also contain three sealed envelopes, one containing the administrative offer, the second the technical offer and the third the financial offer. Each of these envelopes must clearly indicate the content. The administrative, the technical and the financial offer must be submitted, in duplicate (one set of originals and one set of copies) and a third set in electronic format (on CD ROM).

3.1.2 Submission of the tender

3.1.2.1 General terms and conditions for submission

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

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

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

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

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

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

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

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

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

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

3.1.2.2 Requirements for submission

Tenders must be:

a) either sent by registered mail, posted no later than 31 May 2011 (date as postmark) to the following address:

European Chemicals Agency (ECHA)	
Invitation to tender No: ECHA/2011/01	
Finance Unit R1	
PO Box 400	
Annankatu 18	
00121 Helsinki	
Finland	

b) or sent by courier services, no later than 31 May 2011 (date of deposit slip) to the following address:

European Chemicals Agency (ECHA)
Invitation to tender No: ECHA/2011/01
Finance Unit R1
Annankatu 18
00120 Helsinki
Finland

c) or delivered by hand, in person or by an authorised representative no later than 16:00 hours Helsinki time on 31 May 2011 (date of acknowledgement of receipt by the Agency) to the address mentioned above.

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

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

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

3.2 CONTACT BETWEEN THE TENDERER AND THE AGENCY

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

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

Such requests for further information may be made only in writing with the subject indication, *« ECHA/2011/01 »* to the following e-mail address:

procurement@echa.europa.eu

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

Insofar as it has been requested in good time, the questions raised and the additional information will be sent simultaneously to all tenderers who have requested the specifications and will be published on the website at:

http://echa.europa.eu/opportunities/procurement_en.asp

All tenderers are advised to visit the above-mentioned website frequently prior to submitting an offer.

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

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

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

3.3 OPENING OF THE TENDERS

Tenders will be opened at 10:00 am on <u>10 June 2011</u> 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 offers on the tenderer's behalf.

3.4 EVALUATION OF THE TENDERS

The evaluation will be based on each tenderer's offer. 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 offers, will be carried out in three successive stages.

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

The aim of each of these stages is:

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

Stage 1 – application of exclusion criteria

In accordance with Articles 93 and 94 of the Financial Regulation, tenderers shall be excluded from the selection and award procedures if they do not satisfy criteria a) to f) specified in the exclusion criteria form²⁴.

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

Stage 2 - application of selection criteria

These criteria will be assessed on the basis of the documents indicated above²⁵.

SELECTION CRITERIA

1. FINANCIAL AND ECONOMIC CAPACITY

1.1 Sufficient economic and financial capacity to guarantee continuous and satisfactory performance throughout the envisaged lifetime of the contract, in terms of a minimum average annual turnover (or expenditure for public institutions) of at least \in 2.000.000 over the last three years.

2. TECHNICAL AND PROFESSIONAL CAPACITY

2.1 The ability to provide the necessary human resources to carry out the tasks in terms of at least 6 senior experts and 6 experts according to the profiles mentioned under Section 1.2. covering all together at least three of the following areas of expertise:

1) Chemistry (organic, inorganic, analytical, etc), chemical and process

²⁴ See Section 4.3.2

²⁵ See Section 4.3.3

engineering, substance identification including the application of the guidance for identifying and naming of substances under REACH, the chemical nomenclature (i.e. IUPAC rules), IUCLID and various chemical databases;

2) Toxicology and ecotoxicology: including experimental testing, alternative testing methods, computational and other predictive methods;

3) Environmental and industrial economics, socio-economic assessment relevant for the regulatory management of chemicals;

4) Hazard assessment, exposure assessment, risk assessment and risk management related to industrial chemicals and biocides;

5) Chemical safety assessment (CSA) and its implementation including tools such as, IUCLID, and Chesar, and tools supporting exposure estimation such as ECETOC TRA, Stoffenmanager, ART, Consexpo;

6) ChemoInformatics including: generation and use of different notations for chemical structure, quantitative structure-activity relationships (QSAR), (eco)toxicological information and fate modelling and reviewing highly specialised literature and extracting meaningful information on the subject.

2.2. At least five relevant (in terms of $subject^{26}$ and $value^{27}$) reference projects in the past three years covering all together at least three of the abovementioned areas of expertise.

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

The framework contracts will be awarded to the most cost-effective tender. The following award criteria will be applied:

²⁶ Relevance in terms of subject is coverage of the task(s) mentioned under Section1.3

²⁷ Relevance in terms of value is a value of minimum € 30.000 per project

No	Qualitative award criteria	Weighting (maximum points)
AW1	Understanding of the tasks and quality of the proposed services	35
	This criterion serves to assess the tenderer's understanding of the tasks (Section 1.3) and the degree to which the tender shows how carrying out the tasks of the contract would help in the implementation of the REACH Regulation, CLP Regulation, the Biocides Regulation or the PIC Regulation. This criterion also assesses how the tenderer intends to deliver the multidisciplinary services covering the different tasks (in depth ²⁸ and breadth ²⁹).	
AW2	Efficiency and project management	25
	This criterion relates to the quality of methods and approaches, project planning, team organisation, communication/interaction methods, project management and quality assurance methods with a view to execute multidisciplinary projects well.	
	Total number of points	60

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

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

Price criterion

The reference price for the award of the **Framework Contracts** is based on the maximum prices for the three categories of experts according to the weighting mentioned in the price reference table (4.3.4.2. Financial Offer) in light of the estimated use of each of the different categories of experts (respectively 50%,

²⁸ In terms of specific expertise related to a given task

²⁹ In terms of coverage of different tasks

35% and 15%) and the type of specific contract (90% Fixed Price and 10% Time and Means).

The price criterion (P) is evaluated as follows: a maximum of 40 points is given to the lowest price offer. The other offers are ranked according to the following formula:

where:

P = Classification of the evaluated offer (points to be awarded)		
Pmin	 Minimum price offered among all tenders 	
Ро	= Price of the evaluated offer	
40	 Maximum points to be awarded 	

A framework contract will be awarded to (maximum 15) tenders which are the most cost-effective (offer the best value for money) on the basis of the following:

Final Evaluation	
Total points	= Total Quality Points +Total Price Points

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.

Award of specific contracts under the framework contract

When tendering for specific contracts, the contractors should compete within the maximum limit of the price offered in their tender for the Framework contract, as specified in Section 4.3.4.2.

The price offer (Po) shall assume the form of a Fixed price for the whole duration of the specific contract (including reimbursable costs, where applicable) or an offer for a Time and Means contract (including reimbursable costs, where applicable). Maximum unit prices of the Framework contract, possibly revised when the Framework contract is renewed at the beginning of the third year, will apply. The price without VAT is going to be used as the basis for the award of the contract.

For every specific contract to be awarded, the Agency shall request an offer (see above).

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

Award of Fixed Price Specific Contracts

Νο	Qualitative award criteria	Weighting (maximum points)
AW1	Quality and relevance of the methodology This criterion refers to the methodology that the tenderer intends to use to complete the tasks requested in the tender for a specific contract.	30
AW2	Composition and organisation of the proposed team This criterion relates to the professional skills and quality of the proposed team providing the service. Organisation of the team facilitating the efficient delivery of the requested services is also covered by this criterion.	30
	Total number of points	60

Award of Time and Means Specific Contracts

No	Qualitative award criteria	Weighting (maximum points)
AW1	Quality of the proposed services	15
	Quality of the proposed services in terms of methodology, planning and/or organisation, in light of the requirements stated in the service request	
AW2	Suitability of the experts' CVs	45
	Suitability of the experts' CV(s) in light of the requirements stated in the service request.	
	Total number of points	60

Tenders (for both FP and T&M specific contracts) scoring less than 70% in the overall points total or less than 50% in the points awarded for a single criterion will be excluded from the rest of the assessment procedure.

The price criterion (P) is evaluated as follows: a maximum of 40 points is given to the lowest price offer. The other offers are ranked according to the following formula:

$P = (Pmin/Po) \times 40$

where:

P = Classification of the evaluated offer (points to be awarded)

Pmin = Minimum price offered among all tenders

- Po = Price of the evaluated offer
- 40 = Maximum points to be awarded

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 following:

Final Evaluation	
Total points	=Total Quality Points +Total Price Points

3.5 AWARD OF THE CONTRACT

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

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

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

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

After the period of validity of the tender has expired, conclusion of the contract shall be subject to the 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.
- 6 The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to in paragraphs 1 and 2 if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case, the tenderer shall declare on his honour that the documentary evidence has already been provided to the Agency in a previous procurement procedure and confirm that no changes in his situation have occurred. He shall indicate in its tender all the references necessary to allow the Agency services to check this evidence.

4 ANNEXES

4.1 TECHNICAL DOCUMENTATION

Not applicable

4.2 CONTRACTUAL DOCUMENTATION

4.2.1. Model Framework Contract



FRAMEWORK SERVICE CONTRACT

CONTRACT NUMBER – ECHA/2011/01

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

of the one part,

and

[official name in full] [official legal form]³⁰ [statutory registration number]³¹ [official address in full] [VAT registration number]

(hereinafter referred to as "the Contractor"³²), [represented for the purposes of the signature of this contract by [forename, surname and function,]]

of the other part,

³⁰ Delete if contractor is a natural person or a body governed by public law.

³¹ 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.

³² In the case of a joint offer and provided the invitation to tender so specifies, the following clause should be added below the identification of the parties: "The parties identified above and hereinafter collectively referred to as 'the Contractor' shall be jointly and severally liable vis-à-vis the Commission for the performance of this contract".

HAVE AGREED

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

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

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

Annex III – Specific Contracts

Annex IV- Reimbursement of daily subsistence allowances

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

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

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

I – SPECIAL CONDITIONS

ARTICLE I.1 - SUBJECT

- I.1.1 The subject of the Contract is to assist the Agency in carrying out its tasks related to the implementation of the Regulations it is responsible for (REACH, CLP, Biocides and PIC).
- I.1.2 Signature of the Contract imposes no obligation on the Agency to purchase. Only implementation of the Contract through specific contracts is binding on the Agency.
- I.1.3 Once implementation of the Contract has been asked or has commenced, the Contractor shall reply and provide the services in accordance with all terms and conditions of the Contract.
- I.1.4 The Contract does not confer on the Contractor any exclusive right to provide the services described in Annex I to the Agency.

ARTICLE I.2 - DURATION

- I.2.1 The Contract shall enter into force on the date on which it is signed by the last contracting party.
- I.2.2 Under no circumstances may implementation commence before the date on which the Contract enters into force. Execution of the tasks may under no circumstances begin before the date on which the specific contract enters into force.
- 1.2.3 The Contract is concluded for a period of 24 months with effect from the date on which it enters into force. This contractual period and all other periods specified in the Contract are calculated in calendar days unless otherwise indicated.
- 1.2.4 The specific contracts shall be returned signed before the Contract to which they refer expires.

The Contract shall continue to apply to such specific contracts after its expiry, but no longer than 6 months.

1.2.5 The Contract shall be renewed automatically up to 2 times for 12 months under the same conditions, unless written notification to the contrary is sent by one of the contracting parties and received by the other 3 months before expiry of the Contract. Renewal does not imply any modification or deferment of existing obligations.

ARTICLE I.3 – PRICES

I.3.1 The prices of the services shall be in accordance with the following maximum prices:

	OFF-SITE (FP)	ON-SITE (TM)
	Maximum price per man- day (in EUR)	Maximum price per man- day (in EUR)
Senior Expert		
Expert		
Junior Expert		

- I.3.2 Prices shall be expressed in EUR.
- I.3.3 The maximum prices shall be fixed and not subject to revision for implementation during the first two years of duration of the Contract.

At the beginning of the third year of the Contract, 80% of each price may be revised upwards or downwards, if such revision is requested by one of the contracting parties by registered letter no later than three months before the second anniversary of the date on which it was signed. The Agency shall purchase on the basis of the prices in force on the date on which specific contracts are signed. Such prices shall not be subject to revision.

The revision shall be determined by the trend in the harmonised consumer price index (MUICP) published for the first time by the Publications Office of the European Union in the Eurostat monthly 'Data in Focus' publication at http://www.ec.europa.eu/eurostat/.

Revision shall be calculated in accordance with the following formula:

Pr = Po (0,2+0,8 Ir/lo)

Pr - revised price

Po - price in the original tender

Io - monthly index of the final date for submitting tenders

Ir - monthly index of the date on which the request for price revision was received

I.3.4. In addition to the total amount specified in each specific contract, travel, subsistence and shipment expenses shall be reimbursed in accordance with Article II.7, if applicable according to the terms and conditions of the Service Request for the specific contract. The daily subsistence allowance (including accommodation, daily expenses and local travel) referred to in Article II.7.4 (d) shall be determined in accordance with Annex IV.

ARTICLE I.4 – IMPLEMENTATION OF THE CONTRACT

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

ARTICLE I.5 – PAYMENT PERIODS

- I.5.1. Payments under the Contract shall be made in accordance with Article II.4. Payments shall be executed only if the Contractor has fulfilled all his contractual obligations by the date on which the invoice is submitted. Within thirty days of the date on which the admissible request for payment is received, the Agency shall make the payment corresponding to the relevant invoices and statements of reimbursable expenses.
- I.5.2. The terms of payment shall be specified for each Specific Contract as indicated by the Agency in the Service Request for a Specific Contract.
- I.5.3 The Contractor may be required to provide a performance guarantee for an amount of 10% of the value of a Specific Contract and for its whole duration, which shall cover performance of the Specific Contract in accordance with the terms set out in Annex A to the Specific Contract. It shall be released six (6) months after complete execution and the last payment under the Specific Contract.

For Specific Contracts with a value equal to or above 500 000 EUR, the Contractor shall be required to provide a guarantee. The guarantee shall be issued by a bank, an authorised financial institution or a Third Party in favour of the Agency.

For Specific Contracts with a value below 500 000 EUR, the Contractor may be required to provide a guarantee. The guarantee may also be constituted by deductions from payments as and when they are made.

ARTICLE I.6 - BANK ACCOUNT

Payments shall be made to the Contractor's bank account denominated in euro, identified³³ as follows:

Name of bank: [complete] Address of branch in full: [complete] Exact designation of account holder: [complete] Full account number including codes: [complete] [IBAN³⁴ code: [complete]]

ARTICLE I.7 – GENERAL ADMINISTRATIVE PROVISIONS

Any communication relating to the Contract or to its implementation shall be made in writing and shall bear the Contract and specific contract numbers. Ordinary mail shall be deemed to have been received by the Agency on the date on which it is registered by the department responsible indicated below. Communications shall be sent to the following addresses³⁵:

Agency:

European Chemicals Agency Annankatu 18 00-100 Helsinki Finland

Contractor:

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

ARTICLE I.8 – APPLICABLE LAW AND SETTLEMENT OF DISPUTES

³³ By a document issued or certified by the bank.

³⁴ BIC or SWIFT code for countries with no IBAN code.

³⁵ 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).

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

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

ARTICLE I.9 – DATA PROTECTION

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

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

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

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

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

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

ARTICLE I.10 – TERMINATION BY EITHER CONTRACTING PARTY

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

ARTICLE I.10a – CONTRACT CONCLUDED DURING STANDSTILL PERIOD

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

II - GENERAL CONDITIONS

ARTICLE II. 1 – PERFORMANCE OF THE CONTRACT

- II.1.1 The Contractor shall perform the Contract to the highest professional standards. The Contractor shall have sole responsibility for complying with any legal obligations incumbent on him, notably those resulting from employment, tax and social legislation.
- II.1.2 The Contractor shall have sole responsibility for taking the necessary steps to obtain any permit or licence required for performance of the Contract under the laws and regulations in force at the place where the tasks assigned to him are to be executed.
- II.1.3 Without prejudice to Article II.3 any reference made to the Contractor's staff in the Contract shall relate exclusively to individuals involved in the performance of the Contract.
- II.1.4 The Contractor must ensure that any staff performing the Contract have the professional qualifications and experience, as well as the knowledge and skills, required for the execution of the tasks assigned to him.
- II.1.5 The Contractor shall neither represent the Agency nor behave in any way that would give such an impression. The Contractor shall inform third parties that he does not belong to the European public service.
- II.1.6 The Contractor shall have sole responsibility for the staff who execute the tasks assigned to him.

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

- staff executing the tasks assigned to the Contractor may not be given orders direct by the Agency;
- the Agency may not under any circumstances be considered to be the staff's employer and the said staff shall undertake not to invoke in respect of the Agency any right arising from the contractual relationship between the Agency and the Contractor.
- II.1.7 In the event of disruption resulting from the action of a member of the Contractor's staff working on Agency premises or in the event of the expertise of a member of the Contractor's staff failing to correspond to the profile required by the Contract, the Contractor shall replace him without delay. The

Agency shall have the right to request the replacement of any such member of staff, stating its reasons for so doing. Replacement staff must have the necessary qualifications and be capable of performing the Contract under the same contractual conditions. The Contractor shall be responsible for any delay in the execution of the tasks assigned to him resulting from the replacement of staff in accordance with this Article.

- II.1.8 Should any unforeseen event, action or omission directly or indirectly hamper execution of the tasks, either partially or totally, the Contractor shall immediately and on his own initiative record it and report it to the Agency. The report shall include a description of the problem and an indication of the date on which it started and of the remedial action taken by the Contractor to ensure full compliance with his obligations under the Contract. In such event the Contractor shall give priority to solving the problem rather than determining liability.
- II.1.9 Should the Contractor fail to perform his obligations under the Contract in accordance with the provisions laid down therein, the Agency may without prejudice to its right to terminate the Contract reduce or recover payments in proportion to the scale of the failure. In addition, the Agency may impose penalties or liquidated damages provided for in Article II.16.
- II.1.10 The Agency reserves the right, prior to the signature of a specific contract, to proceed to security screenings of any individual proposed and to refuse those individuals on security grounds, without giving any further explanation. The Agency reserves the right, after the signature of a specific contract, to require any person working on its premises to attend security briefings, follow security-related trainings and/or sign a security statement.
- II.1.11 During the performance of the contract, members of the Contractor's staff working on Agency premises must respect the Agency's security policies, as notified by the Agency.

ARTICLE II. 2 – LIABILITY

- II.2.1 The Agency shall not be liable for damage sustained by the Contractor in performance of the Contract except in the event of wilful misconduct or gross negligence on the part of the Agency.
- II.2.2 The Contractor shall be liable for any loss or damage caused by himself in performance of the Contract, including in the event of subcontracting under Article II.13. The Agency shall not be liable for any act or default on the part of the Contractor in performance of the Contract.
- II.2.3 The Contractor shall provide compensation in the event of any action, claim or proceeding brought against the Agency by a third party as a result of damage caused by the Contractor in performance of the Contract.

- II.2.4 In the event of any action brought by a third party against the Agency in connection with performance of the Contract, the Contractor shall assist the Agency. Expenditure incurred by the Contractor to this end may be borne by the Agency.
- II.2.5 The Contractor shall take out insurance against risks and damage relating to performance of the Contract if required by the relevant applicable legislation. He shall take out supplementary insurance as reasonably required by standard practice in the industry. A copy of all the relevant insurance contracts shall be sent to the Agency should it so request.

ARTICLE II. 3 - CONFLICT OF INTERESTS

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

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

- II.3.2 The Contractor shall abstain from any contact likely to compromise his independence.
- II.3.3 The Contractor declares:
 - that he has not made and will not make any offer of any type whatsoever from which an unjustified advantage can be derived under the Contract,
 - that he has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept, any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to performance of the Contract.

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

ARTICLE II. 4 – INVOICING AND PAYMENTS

II.4.1 Pre-financing:

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

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

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

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

II.4.2 Interim payment:

At the end of each of the periods indicated in the Special Conditions 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 and of the order or specific contract to which they refer;
- statements of reimbursable expenses in accordance with Article II.7.

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

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

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

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

II.4.3 Payment of the balance:

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

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

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

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

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

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

ARTICLE II. 5 – GENERAL PROVISIONS CONCERNING PAYMENTS

- II.5.1 Payments shall be deemed to have been made on the date on which the Agency's account is debited.
- II.5.2 The payment periods referred to in Article I.5 may be suspended by the Agency at any time if it informs the Contractor that his payment request is not admissible, either because the amount is not due or because the necessary supporting documents have not been properly produced. In case of doubt on the eligibility of the expenditure indicated in the payment request, the Agency may suspend the time limit for payment for the purpose of further verification, including an on-the-spot check, in order to ascertain, prior to payment, that the expenditure is eligible.

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

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

ARTICLE II. 6 – RECOVERY

- II.6.1 If total payments made exceed the amount actually due or if recovery is justified in accordance with the terms of the Contract, the Contractor shall reimburse the appropriate amount in euro on receipt of the debit note, in the manner and within the time limits set by the Agency.
- II.6.2 In the event of failure to pay by the deadline specified in the request for reimbursement, the sum due shall bear interest at the rate indicated in Article II.5.3. Interest shall be payable from the calendar day following the due date up to the calendar day on which the debt is repaid in full.

ARTICLE II. 7 - REIMBURSEMENTS

- II.7.1 Where provided by the Special Conditions or by Annex I, the Agency shall reimburse the expenses that are directly connected with execution of the tasks on production of original supporting documents, including receipts and used tickets.
- II.7.2 Travel and subsistence expenses shall be reimbursed, where appropriate, on the basis of the shortest itinerary.
- II.7.3 Travel expenses shall be reimbursed as follows:
- a) travel by air shall be reimbursed up to the maximum cost of an economy class ticket at the time of the reservation;
- b) travel by boat or rail shall be reimbursed up to the maximum cost of a first class ticket;
- c) travel by car shall be reimbursed at the rate of one first class rail ticket for the same journey and on the same day;
- d) travel outside Union territory shall be reimbursed under the general conditions stated above provided the Agency has given its prior written agreement.
- II.7.4 Subsistence expenses shall be reimbursed on the basis of a daily allowance as follows:
- a) for journeys of less than 200 km (return trip) no subsistence allowance shall be payable;
- b) daily subsistence allowance shall be payable only on receipt of a supporting document proving that the person concerned was present at the place of destination;
- c) daily subsistence allowance shall take the form of a flat rate payment to cover all subsistence expenses, including accommodation, meals, local transport, insurance and sundries;
- d) daily subsistence allowance, where applicable, shall be reimbursed at the rate specified in Article I.3.
- II.7.5 The cost of shipment of equipment or unaccompanied luggage shall be reimbursed provided the Agency has given prior written authorisation.

<u>ARTICLE II. 8 – OWNERSHIP OF THE RESULTS - INTELLECTUAL AND</u> INDUSTRIAL PROPERTY

Any results or rights thereon, including copyright and other intellectual or industrial property rights, obtained in performance of the Contract, shall be owned solely by

the Agency, which may use, publish, assign or transfer them as it sees fit, without geographical or other limitation, except where industrial or intellectual property rights exist prior to the Contract being entered into.

ARTICLE II. 9 – CONFIDENTIALITY

- II.9.1. The Contractor undertakes to treat in the strictest confidence and not make use of or divulge to third parties any information or documents which are linked to performance of the Contract. The Contractor shall continue to be bound by this undertaking after completion of the tasks.
- II.9.2. The Contractor shall obtain from each member of his staff, board and directors an undertaking that they will respect the confidentiality of any information which is linked, directly or indirectly, to execution of the tasks and that they will not divulge to third parties or use for their own benefit or that of any third party any document or information not available publicly, even after completion of the tasks.
- II.9.3. The Contractor shall ensure that each member of his staff working on Agency premises complies with ECHA Security instructions and policies concerning the access to the building and the information.

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

- II.10.1 The Contractor shall authorise the Agency to process, use, distribute and publish, for whatever purpose, by whatever means and on whatever medium, any data contained in or relating to the Contract, in particular the identity of the Contractor, the subject matter, the duration, the amount paid and the reports. Where personal data is concerned, Article I.9 shall apply.
- II.10.2 Unless otherwise provided by the Special Conditions, the Agency shall not be required to distribute or publish documents or information supplied in performance of the Contract. If it decides not to publish the documents or information supplied, the Contractor may not have them distributed or published elsewhere without prior written authorisation from the Agency.
- II.10.3 Any distribution or publication of information relating to the Contract by the Contractor shall require prior written authorisation from the Agency and shall mention the amount paid by the Union. It shall state that the opinions expressed are those of the Contractor only and do not represent the Agency's official position.

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

ARTICLE II. 11 – TAXATION

- II.11.1 The Contractor shall have sole responsibility for compliance with the tax laws which apply to him. Failure to comply shall make the relevant invoices invalid.
- II.11.2 The Contractor recognises that the Agency is, as a rule, exempt from all taxes and duties, including value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union.
- II.11.3 The Contractor shall accordingly complete the necessary formalities with the relevant authorities to ensure that the goods and services required for performance of the Contract are exempt from taxes and duties, including VAT.
- II.11.4 Invoices presented by the Contractor shall indicate his place of taxation for VAT purposes and shall specify separately the amounts not including VAT and the amounts including VAT.

ARTICLE II. 12 – FORCE MAJEURE

- II.12.1 Force majeure shall mean any unforeseeable and exceptional situation or event beyond the control of the contracting parties which prevents either of them from performing any of their obligations under the Contract, was not due to error or negligence on their part or on the part of a subcontractor, and could not have been avoided by the exercise of due diligence. Defects in equipment or material or delays in making it available, labour disputes, strikes or financial problems cannot be invoked as force majeure unless they stem directly from a relevant case of force majeure.
- II.12.2 Without prejudice to the provisions of Article II.1.8, if either contracting party is faced with force majeure, it shall notify the other party without delay by registered letter with acknowledgment of receipt or equivalent, stating the nature, likely duration and foreseeable effects.
- II.12.3 Neither contracting party shall be held in breach of its contractual obligations if it has been prevented from performing them by force majeure. Where the Contractor is unable to perform his contractual obligations owing to force majeure, he shall have the right to remuneration only for tasks actually executed.

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

ARTICLE II. 13 – SUBCONTRACTING

- II.13.1 The Contractor shall not subcontract without prior written authorisation from the Agency nor cause the Contract to be performed in fact by third parties.
- II.13.2 Even where the Agency authorises the Contractor to subcontract to third parties, he shall none the less remain bound by his obligations to the Agency under the Contract and shall bear exclusive liability for proper performance of the Contract.
- II.13.3 The Contractor shall make sure that the subcontract does not affect rights and guarantees to which the Agency is entitled by virtue of the Contract, notably Article II.17.

ARTICLE II. 14 – ASSIGNMENT

- II.14.1 The Contractor shall not assign the rights and obligations arising from the Contract, in whole or in part, without prior written authorisation from the Agency.
- II.14.2 In the absence of the authorisation referred to in 1 above, or in the event of failure to observe the terms thereof, assignment by the Contractor shall not be enforceable against and shall have no effect on the Agency.

ARTICLE II. 15 – TERMINATION BY THE AGENCY

- II.15.1 The Agency may terminate the Contract, a pending order or a specific contract in the following circumstances:
- a) where the Contractor is being wound up, is having his affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- b) where the Contractor has not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which he is established or with those of the

country applicable to the Contract or those of the country where the Contract is to be performed;

- c) where the Agency has evidence or seriously suspects the Contractor or any related entity or person, of professional misconduct;
- d) where the Agency has evidence or seriously suspects the Contractor or any related entity or person, of fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Union's financial interests;
- e) where the Agency has evidence or seriously suspects the Contractor or any related entity or person, of substantial errors, irregularities or fraud in the award procedure or the performance of the Contract;
- f) where the Contractor is in breach of his obligations under Article II.3;
- g) where the Contractor was guilty of misrepresentation in supplying the information required by the Agency as a condition of participation in the Contract procedure or failed to supply this information;
- where a change in the Contractor's legal, financial, technical or organisational situation could, in the Agency's opinion, have a significant effect on the performance of the Contract;
- i) where execution of the tasks under a pending order or a specific contract has not actually commenced within fifteen days of the date foreseen, and the new date proposed, if any, is considered unacceptable by the Agency;
- j) where the Contractor is unable, through his own fault, to obtain any permit or licence required for performance of the Contract;
- where the Contractor, after receiving formal notice in writing to comply, specifying the nature of the alleged failure, and after being given the opportunity to remedy the failure within a reasonable period following receipt of the formal notice, remains in serious breach of his contractual obligations;
- I) when due to the termination of the contract with one or more of the contractors there is no minimum required competition within the multiple framework contract with reopening of competition.
- II.15.2 In case of force majeure, notified in accordance with Article II.12, either contracting party may terminate the Contract, where performance thereof cannot be ensured for a period corresponding to at least to one fifth of the period laid down in Article I.2.3.

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

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

II.15.4 Consequences of termination:

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

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

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

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

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 of fraud.

ARTICLE II. 16 – LIQUIDATED DAMAGES

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

0.2% of the amount of the relevant purchase per calendar day of delay. The Contractor may submit arguments against this decision within thirty days of notification by registered letter with acknowledgement of receipt or equivalent. In the absence of reaction on his part or of written withdrawal by the Agency within thirty days of the receipt of such arguments, the decision imposing the liquidated damages shall become enforceable. These liquidated damages shall not be imposed where there is provision for interest for late completion. The Agency and the Contractor expressly acknowledge and agree that any sums payable under this Article are in the nature of liquidated damages and not penalties, and represent a reasonable estimate of fair compensation for the losses that may be reasonably anticipated from such failure to perform obligations.

ARTICLE II. 17 – CHECKS AND AUDITS

- II.17.1 Pursuant to Article 142 of the Financial Regulation applicable to the general budget of the European Communities, the Court of Auditors shall be empowered to audit the documents held by the natural or legal persons receiving payments from the budget of the Union from signature of the Contract up to five years after payment of the balance of the last implementation.
- II.17.2 The Agency or an outside body of its choice shall have the same rights as the Court of Auditors for the purpose of checks and audits limited to compliance with contractual obligations from signature of the Contract up to five years after payment of the balance of the last implementation.
- II.17.3 In addition, the European Anti-Fraud Office may carry out on-the-spot checks and inspections in accordance with Council Regulation (Euratom, EC) No 2185/96 and Parliament and Council Regulation (EC) No 1073/1999 from signature of the Contract up to five years after payment of the balance of the last implementation.

ARTICLE II. 18 – AMENDMENTS

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

ARTICLE II. 19 – SUSPENSION OF THE CONTRACT

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

SIGNATURES

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

In duplicate in English.

ANNEX I TENDER SPECIFICATIONS

ANNEX II CONTRACTOR'S OFFER

ANNEX III MODEL SPECIFIC CONTRACTS

FIXED PRICE

SPECIFIC CONTRACT No [complete]³⁶

implementing Framework Contract No ECHA/2011/01

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

of the one part,

and

[official name in full] [official legal form] [statutory registration number] [official address in full] [VAT registration number]

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

of the other part,

HAVE AGREED

ARTICLE 1: SUBJECT

- 1.1 This Specific Contract implements Framework Contract No ECHA/2011/01 signed by the Agency and the Contractor on [complete date] [*and renewed on* complete date].
- 1.2 The subject of this Specific Contract is [short description of subject].

³⁶ Options [in italics] to be deleted where not applicable. Options [in roman] to be completed.

1.3 The Contractor undertakes, on the terms set out in the Framework Contract and in this Specific Contract and the annex[es] thereto, which form an integral part thereof, to perform the tasks as specified in Annex A of the Specific Contract.

ARTICLE 2: DURATION

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

ARTICLE 3: PRICE

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

ARTICLE 4: PAYMENTS

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

4.1 Pre-financing:

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

A pre-financing of 30 %³⁷ equal to the amount of the Specific Contract shall be made.

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

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

Within 30 days of the latest of the following dates:

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

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

4.2 Interim payment:

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

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

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

provided the above report and/or deliverable has been approved by the Agency.

If not specified otherwise in Annex A to the Specific Contract, the approval of the report and/or Deliverable by the Agency will be given according to the acceptance procedure as laid out in Annex I to the Framework Contract. [Depending on the

³⁷ A pre-financing may not exceed 30% of the total amount as specified in Article 3.1.

complexity of the project, the Agency may foresee a longer period for approval or rejection of reports and/or deliverables. However, this will be specified in the Service Request].

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

4.3 Payment of the balance:

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

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

provided the above report and/or Deliverable has been approved by the Agency.

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

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

ARTICLE 5: GENERAL ADMINISTRATIVE PROVISIONS

- 5.1 Any communication under this Specific Contract shall be made in accordance with Article I.7 of the Framework Contract.
- 5.2 The persons responsible for the implementation of this Specific Contract are:

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

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

ARTICLE 6: PLACE OF PERFORMANCE

The tasks shall be executed at the premises of [the Contractor] and/or [the Agency].

ARTICLE 7: ANNEXES

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

Annex A: Technical annex Annex B: Contractor's offer dated and accepted by the Agency

SIGNATURES

For the Agency
Mr
Director
signature[s]:
Done at Helsinki, [date]

In duplicate in [English].

Specific Contract N°XXXX

Annex A

Technical Annex

1 Services

Description of tasks/activities

- 2 Deliverables
- 2.1 The specific deliverables, which are all the subject of acceptance unless specified otherwise, are:

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

2.2 Delivery schedule

The delivery schedule is as follows:

- T0 being the date of signature of this agreement;
- [list of all requested deliverables with timetable]
- 2.3 Quality requirements
- 2.4 Security requirements
- 3 Resources

Requirements for the profiles

Annex B

Contractor's Offer

ANNEX III MODEL SPECIFIC CONTRACTS

TIME & MEANS

SPECIFIC CONTRACT No [complete]³⁸

implementing Framework Contract No ECHA/2011/01

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

of the one part,

and

[official name in full] [official legal form] [statutory registration number] [official address in full] [VAT registration number]

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

of the other part,

HAVE AGREED

ARTICLE 1: SUBJECT

1.1 This Specific Contract implements Framework Contract No ECHA/2011/01 signed by the Agency and the Contractor on [complete date] [and renewed on complete date].

³⁸ Options [in italics] to be deleted where not applicable. Options [in roman] to be completed.

- 1.2 The subject of this Specific Contract is [short description of subject].
- 1.3 The expert(s) shall be (name of the expert)
- 1.4 The Contractor undertakes, on the terms set out in the Framework Contract and in this Specific Contract and the annex[es] thereto, which form an integral part thereof, to perform the tasks as specified in Annex A of the Specific Contract.

ARTICLE 2: DURATION

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

ARTICLE 3: PRICE

3.1. The Agency undertakes to pay the Contractor, in consideration for the services rendered under this Specific Contract.

 an amount of EUR XXX per day of actual services rendered, for XX days for (name of service provider), i.e. a total of EUR XXXXX

Profile of service provider:

(specify the profile of the service provider in accordance with the profiles listed in the "PRICES" Annex to the Framework Contract)

 an amount of EUR XXX per day of actual services rendered, for XX days for (name of service provider), i.e. a total of EUR XXXXX

Profile of service provider:

(specify the profile of the service provider in accordance with the profiles listed in the "PRICES" Annex to the Framework Contract)

The total amount to be paid by the Agency under this Specific Contract shall be EUR XXX [amount in figures] covering all tasks executed.

- [3.2. This amount shall cover all expenditure incurred by the Contractor in performing this Specific Contract.]
- [3.2. In addition to the amount specified in Article 3.1, travel and subsistence expenses up to a maximum amount of EUR [amount in figures and in words] shall be reimbursed according to the provisions of the Framework Contract. The daily subsistence allowance as mentioned in Annex IV of the FWC

ARTICLE 4: PAYMENTS

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

4.1 Pre-financing:

Pre-financing shall not be applicable.

4.2 Interim payment:

Payments shall be carried out monthly.

The request for payment, shall be valid if accompanied by:

 the technical report(s) and/or Deliverable(s) in another format in accordance with Annex A of the Specific Contract;

provided the above report and/or deliverable has been approved by the Agency.

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

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

- time sheets signed by the service provider

Provided the above time sheet has been countersigned by the Agency for approval, following verification against its flexitime system at the end of each calendar month.

- statements of reimbursable expenses in accordance with Article II.7 of the Framework Contract, where applicable;
- the relevant invoices, indicating the reference number of the Framework Contract and the Specific Contract to which they refer
- 4.3 Payment of the balance:

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

 the technical report(s) and/or Deliverable(s) in another format in accordance with Annex A of the Specific Contract;

provided the above report and/or deliverable has been approved by the Agency.

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

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

- time sheets signed by the service provider

Provided the above time sheet has been countersigned by the Agency for approval, following verification against its flexitime system at the end of the last calendar month, during which services have been provided.

- statements of reimbursable expenses in accordance with Article II.7 of the Framework Contract, where applicable;
- the relevant invoices, indicating the reference number of the Framework Contract and the Specific Contract to which they refer

ARTICLE 5: GENERAL ADMINISTRATIVE PROVISIONS

- 5.1 Any communication under this Specific Contract shall be made in accordance with Article I.7 of the Framework Contract.
- 5.2 The persons responsible for the implementation of this Specific Contract are:

For the Agency:

Administrative matters:	European Chemicals Agency
	P.O. Box 400,
	00121 HELSINKI, Finland
	Fax: +358 9 68618210
	[Name & Office address]
	Email: [to be completed]

Technical questions: European Chemicals Agency P.O. Box 400, 00121 HELSINKI, Finland Fax: +358 9 68618210 [Name & Office address] Email: [to be completed]

For the Contractor: Mr/Mrs

[Function] [Company name] [Official address in full]

ARTICLE 6: PLACE OF PERFORMANCE

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

ARTICLE 7: ANNEXES

The following annexes form an integral part of this Specific Contract: Annex A: Technical annex Annex B: Contractor's offer dated and accepted by the Agency Annex C: Time sheet

For the Contractor,	For the Agency
[Company	Mr
name/forename/surname/function]	Director
signature[s]:	signature[s]:
Done at [place], [date]	Done at Helsinki, [date]

In duplicate in [English].

Specific Contract N°XXXX

Annex A

Technical Annex

1 Services

Description of tasks/activities

- 2 Deliverables
- 2.1 The specific deliverables, which are all the subject of acceptance unless specified otherwise, are:

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

2.2 Delivery schedule

The delivery schedule is as follows:

- T0 being the date of signature of this agreement;
- [list of all requested deliverables with timetable]
- 2.3 Quality requirements
- 2.4 Security requirements
- 3 Resources

Estimated maximum total number of person-days for the profile(s)

Requirements for the profiles

Annex B

Contractor's Offer

Annex C

Model Time sheet

		Annex C to Time	and Means Conti	act (model Time Sheet)						
		YEAR:		MONTH:						
Na	me of serv	ice provider	Number and date of contract	ECHA Unit						
			contractor							
Adminis provide		dress of service		Telephone						
Day	Date	Description of the	ne activities		Working hours					
Mon										
Tue										
Wed										
Thu										
Fri										
Sat										
Sun										
Mon										
Tue										
Wed										
Thu										
Fri										
Sat										
Sun										
Mon										
Tue										
Wed										
Thu										
Fri										
Sat										
Sun										
			AL HOURS		0.0					
		TOTAL DAYS	6 (1 day = 7.5 hou	rs)	0.0					
Signature of service provider Signature of ECHA Contract Manager										
Date			Date							
Name			Name							
Signatur	e		Signature	9						

ANNEX IV REIMBURSEMENT OF DAILY SUBSISTENCE EXPENSES

Subsistence expenses incurred in connection with meetings which the Contractor is required to attend by the Agency or in connection with events organised by the Contractor, as provided for in a specific contract, shall be reimbursed in euro at the euro accounting rates in force during the month of travel.

The daily subsistence allowance is deemed to cover all expenses incurred during one day of travel, such as hotel, meals and local transport expenses (e.g. taxis and transport from place of departure to the airport/station and from the airport/station to the hotel) and are reimbursed on the basis of the following table:

Travel location	Daily allowance	Travel location	Daily allowance
Austria	225	Latvia	211
Belgium	232	Lithuania	183
Bulgaria	227	Luxembourg	237
Czech Republic	230	Malta	205
Cyprus	238	Netherlands	263
Denmark	270	Poland	217
Estonia	181	Portugal	204
Finland	244	Romania	222
France	245	Slovak Republic	205
Germany	208	Slovenia	180
Greece	222	Spain	212
Hungary	222	Sweden	257
Ireland	254	United Kingdom	276
Italy	230		

For travels outside the European territory, the Agency will inform the contractor, upon his request, of the applicable rates.

CALCULATION

Daily subsistence allowances are calculated according to the length of the trip:

- six hours or less: reimbursement of actual expenses (on production of supporting documents)
- more than six hours but not more than twelve hours: half the daily allowance;
- more than twelve hours, but not more than twenty-four hours: full daily allowance;
- each successive 12-hour period: half the daily allowance.

4.2.2. Model Service Request



Helsinki, D(201X)XXXX

Sent by e-mail to: [...]

Subject: ECHA/2011/01- Service Request (SR [...])

We request an offer for a Specific Contract under our above-mentioned Framework Contract.

For the purpose of the preparation of your offer, information specific to this reopening of competition is provided in the the technical specifications and the draft specific contract, here enclosed, in addition to the general information contained in the specifications of our above-mentioned Framework Contract.

Your offer must contain a technical and a financial offer. The technical offer must [...]. The Financial offer must [...].

For the submission of your offer, the deadline is xxx indicated. Your offer must be submitted as follows:

Option 1/ Paper submission

a) <u>either by post or by courier</u> not later than [...], in which case the evidence of the date of dispatch shall be constituted by the postmark or the date of the deposit slip, to the following address:

European Chemicals Agency Finance Unit P.O. Box 400 (in case it is sent by post) or Annankatu 18 (in case it is sent by courier) 00121 Helsinki Finland b) <u>or delivered by hand</u> to the above mentioned address of the European Chemicals Agency not later than [...] 16:00 Helsinki time. In this case, a receipt must be obtained as proof of submission, signed and dated by the official in the Agency's central mail department who took delivery. The department is open from 08.00 to 17.00 Monday to Thursday, and from 8.00 to 16.00 on Fridays. It is closed on Saturdays, Sundays and Agency holidays.

The offer must be placed inside two sealed envelopes. The outer envelope should bear the address as mentioned above as well as the reference to this invitation to tender as indicated in the subject of this letter. The inner envelope should be addressed to the Finance unit R1 and also bear the reference to this invitation to tender as indicated in the subject of this letter as well as the mention: "Not to be opened by the internal mail department". If self-adhesive envelopes are used, they must be sealed with adhesive tape and the sender must sign across this tape.

The inner envelope must be sealed and contain two offers: one should be bound and one unbound. In addition, the inner envelope must contain a CD ROM containing the offer in a format that can be accessed by Microsoft Office software.

Option 2/ Electronic submission:

The deadline for submission of your offer is [date], by ...am/pm Helsinki time at the latest.

Your offer should be submitted as follows:

- In electronic form to the following e-mail: procurement@echa.europa.eu
- Deadline for submission: ECHA should receive your offer in the abovementioned
- Functional Mailbox by a.m. Helsinki time on
- Indicate clearly the reference number ECHA/2011/01/SR....

OR

The deadline for submission of your offer is [date], by ...am/pm Helsinki time at the latest.

Your offer should be submitted as follows:

- (i) be submitted on line, and
- (ii) be received by the submission deadline.

FOR SUBMISSION: Go to the procurement section of ECHA's website at the following URL: http://echa.eu/opportunities/...

Tenders submitted in other forms or after the deadline will not be considered.

The period of the validity of the tender, during which tenderers may not modify the terms of their tender in any respect, is ... months from the above-mentioned deadline for submission.

Contacts between the contracting authority and tenderers are prohibited throughout the procedure save in exceptional circumstances and under the following conditions only:

- a) Before the final date for submission of tenders:
 - At the request of the tenderer, the contracting authority may provide additional information solely for the purpose of clarifying the nature of the contract. Any requests for additional information must be made in writing only to the following e-mail address: procurement@echa.europa.eu. Please mention as subject the reference of this call for tender indicated in the subject of this letter.
 - Requests for additional information received less than five working days before the closing date for submission of tenders will not be processed.
 - ECHA may, on its own initiative, inform interested parties of any error, inaccuracy, omission or any other clerical error in the text of the service request and annexes.
 - Any additional information including that referred to above will be sent simultaneously to all addressees of this letter by e-mail.
- b) After the opening of tenders:
 - If clarification is required or if obvious clerical errors in the tender need to be corrected, ECHA may contact the tenderer provided the terms of the tender are not modified as a result.

Your offer will be evaluated against the award criteria for specific contracts laid down in the specifications annexed to our above-mentioned Framework Contract.

This request for services is in no way binding on the ECHA. ECHA's contractual obligation commences only upon signature of the contract with the successful tenderer. Up to the point of signature, ECHA may decide either to abandon the procurement or to cancel the award procedure, without the tenderers being entitled to claim any compensation. Such a decision must be substantiated and all tenderers notified.

The contracting authority explicitly reminds the contractor of its obligations to take all necessary measures to guarantee the impartial and objective performance of the contract in accordance with Article II.3 -Conflict of interests- of the Framework Contract.

Yours sincerely

[...] Director for [...]

Enclosures:

Technical specifications for Fixed price or Time and Means specific contracts Draft specific contract (including Technical Annex)



PRE-FINANCING GUARANTEE

<To be completed on paper bearing the letterhead of the financial institution >

For the attention of

European Chemicals Agency (ECHA)

Financial Unit

referred to below as the "Contracting Authority"

Subject: Guarantee No...

Financing Guarantee for the repayment of pre-financing payable under Specific Contract ECHA/2011/01 (please quote number and title in all correspondence)

We, the undersigned, <name, and address of financial institution>, hereby irrevocably declare that we guarantee as primary obligor, and not merely as surety on behalf of <Contractor's name and address>, hereinafter referred to as "the Contractor", the payment to the Contracting Authority of EUR [...] ([...]), corresponding to the pre-financing as mentioned in Article 4.1 of the Specific Contract ECHA/2010/93/LOT [...]/SC[...] concluded between the Contractor and the Contracting Authority, hereinafter referred to as "the Contract".

Payment shall be made without objection or legal proceedings of any kind, upon receipt of your first written claim (sent by registered letter with confirmation or receipt) stating that the Contractor has not repaid the pre-financing on request or that the Contract has been terminated. We shall not delay the payment, nor shall we oppose it for any reason whatsoever. We shall inform you in writing as soon as payment has been made.

We accept notably that no amendment to the terms of the Contract can release us from our obligation under this guarantee. We waive the right to be informed of any change, addition or amendment of the Contract.

We note that the guarantee will be released in accordance with Article II.4.1 of the General Conditions of the Framework Contract [and in any case at the latest on (at the expiry of 18 months after the implementation period of the Contract)]³⁹.

The law applicable to this guarantee shall be that of the Contract. Any dispute arising out of or in connection with this guarantee shall be referred to the courts of Finland.

The guarantee will enter into force and take effect on receipt of the pre-financing payment in the account designated by the Contractor to receive payments.

Name: Position: Signature:⁴⁰ Date: <Date>

³⁹ This mention can be inserted only where the law applicable to the guarantee imposes a precise expiry date

⁴⁰ The name(s) and position(s) of the persons signing on behalf of the guarantor must be shown in printed characters.

4.2.4. Model Performance Guarantee



PERFORMANCE GUARANTEE

<To be completed on paper bearing the letterhead of the financial institution >

[Place/Date]

European Chemicals Agency Annankatu 18 00-120 Helsinki Finland

Contract performance guarantee No ECHA/2011/01

We hereby confirm that we give the European Chemicals Agency an unconditional and irrevocable joint and several guarantee for an unlimited period to the value of EUR [...]

(in words: ... euro) for performance of the Contract concluded between the European Chemicals Agency

and

[Firm/Name/Address – as given in the Contract (No/exact title – hereinafter "the Contract")] (hereinafter "the Contractor").

If the European Chemicals Agency gives notice that the Contractor has for any reason failed to fulfil his obligations under the Contract by the due date, the Bank, acting on behalf of the Contractor, undertakes to pay up to the above amount into a bank account designated by the European Chemicals Agency immediately on receipt of a first written request from the European Chemicals Agency (sent by registered post, with acknowledgement of receipt).

The Bank waives the right to require exhaustion of remedies against the principal, any right to withhold performance, any right of retention, any right of avoidance, any right to offset, and the right to assert any other claims which the Contractor may have against the European Chemicals Agency under the Contract or in connection with it or on any other grounds. The Bank may be released from this guarantee only with the European Chemicals Agency's written consent and does not have the right of deposit without its consent.

The Bank's obligations under this guarantee are not affected by any arrangements or agreements made by the European Chemicals Agency with the Contractor which may concern his obligations under the Contract.

This guarantee shall take immediate effect. It shall expire on return of this document, which must occur within 12 months after the final payment under the Contract has been made.

This guarantee is governed by the law applicable to the Contract.

The courts having jurisdiction for matters relating to the Contract shall have sole jurisdiction in respect of matters relating to this guarantee.

[Place/Date]

[Signature/Function]

[Signature/Function]

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						
NGO	YES	NO	(Non Gouvernemental Organisation)			
NAME(S)						
		<u></u>				
ABBREVIATION						
ADDRESS OF THE HEAD						
OFFICE						
POSTAL CODE			Р.О. ВОХ			
СІТҮ						
-						
COUNTRY						
VAT						
PLACE OF R	EGISTRATION					
DATE OF I	REGISTRATION	D D				
REGISTRATION	NR					
PHONE						
E-MAIL						
CONTACT PERS						
THIS "LEGAL ENTITY" FORM SHOULD BE FILLED IN AND RETURNED TOGETHER WITH:						
			ENT (E.G. OFFICIAL GAZETTE, REGISTER OF			
			NTRACTOR'S NAME AND ADDRESS AND THE TO IT BY THE NATIONAL AUTHORITIES;			
* A COPY	OF THE VAT REG	GISTRATION	DOCUMENT IF APPLICABLE AND IF THE VAT			
NUMBER	DOES NOT APPE	AR 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					
NAME		\Box			
FIRST NAME		\Box			
(NAME 2)		\Box			
(NAME 3)		\Box			
OFFICIAL ADDRESS					
	(OFFICIAL Address = Your PERMANENT address; generally the one which is registered on your identity card)				
POSTAL CC	DDE P.O. BOX				
TOWN/ CITY		\Box			
COUNTRY		\Box			
VAT NR		\Box			
IDENTITY	CARD NUMBER O				
PASSPOF	RT NUMBER O				
DATE OF BIRTH					
COUNTRY OF E	BIRTH				
PHONE		\Box			
E-MAIL		\Box			
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								
NGO	YES NO (Non Gouvernemental Organisation)							
NAME(S)								
ABBREVIATION								
OFFICIAL								
ADDRESS								
POSTAL CODE	P.O. BOX							
CITY								
COUNTRY								
VAT								
PLACE OF R								
DATE OF REGISTRATION $\square \square \square$								
PHONE								
E-MAIL								
CONTACT PERS	SON							

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.

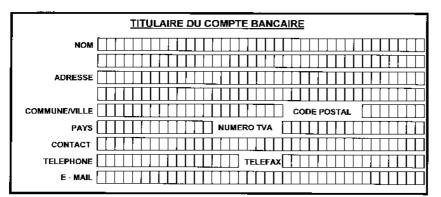
DATE :	STAMP
NAME AND FUNCTION OF THE AUTHORISED REPRESENTATIVE	
SIGNATURE	

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



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	BANQUE																							
NOM DE LA BANQUE			Π													I			T	Ϊ				\Box
			Π																		[Ι	<u> </u>	\Box
ADRESSE (DE L'AGENCE)																								\Box
				Τ							Τ	Τ.				Ι				Ι	Γ			\Box
COMMUNE/VILLE			Π	Τ	Π		Ι	Π			Ι	Γ		co	DE	PO	ST	AL			Ι			Π
PAYS			Π					[[Ţ	Γ	ļ									_		
NUMERO DE COMPTE			Π		Π							Ι				Ι					L		Ι	D
IBAN (optionnel)			\square																			Ĩ		\Box

REMARQUES:

CACHET de la BANQUE + SIGNATURE du REPRESENTANT DE LA BANQUE (Los deux obligatoires)	DATE + SIGNATURE DU TITULAIRE DU COMP <u>TE :</u> (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 tender 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 operator⁴¹)
 - or
- representing (if the economic operator is a legal person)

official name in full (only for legal person):

official legal form (only for legal person):

official address in full:

VAT registration number:

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

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

⁴¹ 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).

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.
- I) 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 above⁴².

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

⁴² Mandatory for contracts of value above $\leq 133\ 000\ only$ (see art. 134(2) of the Implementing Rules). The contracting authority can nevertheless request such evidence for contracts with a lower value.

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

4.3.3. Selection criteria documentation

Financial and Economic Capacit	y Overview				
Currency : EURO	Figures (00				
	N* (* most recent figures available)	N-1	N-2		
Total Balance Sheet					
TRADE DEBTORS					
Amounts due by commercial customers					
CAPITAL and RESERVES					
(Equity) Amounts owned by the company					
TRADE CREDITORS					
Amounts due to commercial suppliers					
SHORT TERM DEBT					
LONG TERM DEBT					
LIQUIDITY					
Bank accounts, cash at hand					
About PROFIT & LOSS					
TURNOVER					
ORDINARY RESULT					
EXTRAORDINARY RESULT					
INCOME TAX					
NET RESULT					

Financial and Economic Capacity Overview Form

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

<u>Comments</u>: 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.

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:

- o Front page
- o Description page

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

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

Project Reference Form (page 1 of 2)

Project reference n°_____

Project reference front page

Project name:			
Start date (mm/yy):	End date (mm/yy):		
Client name:	Contact person:	Phone:	

Project type

Area of expertise mentioned under Section covered (check the appropriate):

□ Chemistry (organic, inorganic, analytical, etc), chemical and process engineering, substance identification including the application of the guidance for identifying and naming of substances under REACH, the chemical nomenclature (i.e. IUPAC rules), IUCLID and various chemical databases	□ Toxicology and ecotoxicology; including experimental testing, alternative testing methods, computational and other predictive methods	 Environmental and industrial economics, socio-economic assessment relevant for the regulatory management of chemicals
 Hazard assessment, exposure assessment, risk assessment and risk management related to industrial chemicals and biocides 	□ Tools supporting chemical safety assessment (CSA) and its implementation such as, IUCLID, and Chesar, and tools supporting exposure estimation such as ECETOC TRA, Stoffenmanager, ART, Consexpo	□ ChemoInformatics including: generation and use of different notations for chemical structure, quantitative structure-activity relationships (QSAR), (eco)toxicological information and fate modelling and reviewing highly specialised literature and extracting meaningful information on the subject

Tasks covered : With reference to the list of tasks in Section 1.3, please, indicate which of these tasks were covered by the project. Please, give further explanation on the Project description page.

1 🗆									
11 🗆		13 🗆	14 🗆	15 🗆	16 🗆	17 🗆	18 🗆	19 🗆	20 🗆
21 🗆	22 🗆	other							

Value of the project (in EUR) :

Total value of the project:

For joint projects – value of tenderer's contribution to the project:

Principal contractor for this project (check the appropriate):			
Tenderer			
Other			
Principal location for this project:			
Tenderer premises			
Client's premises			
Other			
Number of tenderer's own experts involved and their profile			
1.			
2.			
3.			
4.			
5.			
Total:			
Methodologies involved:			

Project Reference Form (page 2 of 2)

Project reference n°_____

Project description page

EUROPEAN CURRICULUN	I VITAE FORMAT
EUROPEAN CURRICULUM VITAE FORMAT	
PERSONAL INFORMATION	
Name Address Telephone Fax E-mail	[SURNAME, other name(s)] [House number, street name, postcode, city, country]
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 	[Add separate entries for each relevant course you have completed, starting with the most recent.]
	110

- subjects/occupational skills covered
- Title of qualification awarded
 - Level in national classification (if appropriate)

PERSONAL SKILLS AND COMPETENCES

Acquired in the course of life and career but not necessarily covered by formal certificates and diplomas.

MOTHER TONGUE	[Specify mother tongue]
OTHER LANGUAGES	
 Reading skills Writing skills Verbal skills 	[Specify language] [Indicate level: excellent, good, basic.] [Indicate level: excellent, good, basic.] [Indicate level: excellent, good, basic.]
SOCIAL SKILLS AND COMPETENCES Living and working with other people, in multicultural environments, in positions where communication is important and situations where teamwork is essential (for example culture and sports), etc.	[Describe these competences and indicate where they were acquired.]
ORGANISATIONAL SKILLS AND COMPETENCES Coordination and administration of people, projects and budgets; at work, in voluntary work (for example culture and sports) and at home, etc.	[Describe these competences and indicate where they were acquired.]
TECHNICAL SKILLS AND COMPETENCES With computers, specific kinds of equipment, machinery, etc.	[Describe these competences and indicate where they were acquired.]

ARTISTIC SKILLS AND COMPETENCES Music, writing, design, etc. [Describe these competences and indicate where they were acquired.]

OTHER SKILLS AND COMPETENCES Competences not mentioned above. DRIVING LICENCE(S)	[Describe these competences and indicate where they were acquired.]
DRIVING LICENCE(S)	
ADDITIONAL INFORMATION	[Include here any other information that may be relevant, for example contact persons, references, etc.]
Annexes	[List any attached annexes.]

EUROPEAN LEVELS – SELF ASSESSMENT GRID

		A1	A2	B1	B2	C1	C2
UNDERSTAN		I can understand familiar words and very basic phrases concerning myself, my family and immediate concrete surroundings when people speak slowly and clearly.	I can understand phrases and the highest frequency vocabulary related to areas of most immediate personal relevance (e.g. very basic personal and family information, shopping, local area, employment). I can catch the main point in short, clear, simple messages and announcements.	I can understand the main points of clear standard speech on familiar matters regularly encountered in work, school, leisure, etc. I can understand the main point of many radio or TV programmes on current affairs or topics of personal or professional interest when the delivery is relatively slow and clear.	and lectures and follow even complex lines of argument provided the topic is reasonably familiar. I can understand most TV	I can understand extended speech even when it is not clearly structured and when relationships are only implied and not signalled explicitly. I can understand television programmes and films without too much effort.	I have no difficulty in unders any kind of spoken languag whether live or broadcast, e when delivered at fast native speed, provided. I have som to get familiar with the accer
D I N G	Reading	I can understand familiar names, words and very simple sentences, for example on notices and posters or in catalogues.	I can read very short, simple texts. I can find specific, predictable information in simple everyday material such as advertisements, prospectuses, menus and timetables and I can understand short simple personal letters.	I can understand texts that consist mainly of high frequency everyday or job-related language. I can understand the description of events, feelings and wishes in personal letters.	I can read articles and reports concerned with contemporary problems in which the writers adopt particular attitudes or viewpoints. I can understand contemporary literary prose.	I can understand long and complex factual and literary texts, appreciating distinctions of style. I can understand specialised articles and longer technical instructions, even when they do not relate to my field.	forms of the written languag including abstract, structura linguistically complex texts s manuals, specialised article
SPEAK		simple questions in areas of	I can communicate in simple and routine tasks requiring a simple and direct exchange of information on familiar topics and activities. I can handle very short social exchanges, even though I can't usually understand enough to keep the conversation going myself.	I can deal with most situations likely to arise whilst travelling in an area where the language is spoken. I can enter unprepared into conversation on topics that are familiar, of personal interest or pertinent to everyday life (e.g. family, hobbies, work, travel and current events).	I can interact with a degree of fluency and spontaneity that makes regular interaction with native speakers quite possible. I can take an active part in discussion in familiar contexts, accounting for and sustaining my views.	I can express myself fluently and spontaneously without much obvious searching for expressions. I can use language flexibly and effectively for social and professional purposes. I can formulate ideas and opinions with precision and relate my contribution skilfully to those of other speakers.	I can take part effortlessly in conversation or discussion a have a good familiarity with idiomatic expressions and colloquialisms. I can expres myself fluently and convey f shades of meaning precisel do have a problem I can ba and restructure around the so smoothly that other peop hardly aware of it.
I N G	Spoken Production	I can use simple phrases and sentences to describe where I live and people I know.	I can use a series of phrases and sentences to describe in simple terms my family and other people, living conditions, my educational background and my present or most recent job.	I can connect phrases in a simple way in order to describe experiences and events, my dreams, hopes and ambitions. I can briefly give reasons and explanations for opinions and plans. I can narrate a story or relate the plot of a book or film and describe my reactions.	I can present clear, detailed descriptions on a wide range of subjects related to my field of interest. I can explain a viewpoint on a topical issue giving the advantages and disadvantages of various options.	I can present clear, detailed descriptions of complex subjects integrating sub-themes, developing particular points and rounding off with an appropriate conclusion.	I can present a clear, smoot flowing description or argum a style appropriate to the co and with an effective logical structure which helps the re to notice and remember sign points.
W R I T I N G		I can write a short, simple postcard, for example sending holiday greetings. I can fill in forms with personal details, for example entering my name, nationality and address on a hotel registration form.	I can write short, simple notes and messages. I can write a very simple personal letter, for example thanking someone for something.	I can write simple connected text on topics which are familiar or of personal interest. I can write personal letters describing experiences and impressions.	I can write clear, detailed text on a wide range of subjects related to my interests. I can write an essay or report, passing on information or giving reasons in support of or against a particular point of view. I can write letters highlighting the personal significance of events and experiences.	I can express myself in clear, well- structured text, expressing points of view at some length. I can write about complex subjects in a letter, an essay or a report, underlining what I consider to be the salient issues. I can select a style appropriate to the reader in mind.	I can write clear, smoothly-f text in an appropriate style. write complex letters, report articles which present a cas an effective logical structure helps the recipient to notice remember significant points write summaries and review professional or literary work

4.3.4. Award criteria documentation

4.3.4.1. Qualitative Award criteria documentation

4.3.4.1.1 Questionnaire

All below questions shall be answered and attached to your offer. The maximum number of pages is indicated for each relevant section. The questionnaire shall be completed using a 12pt Times New Roman font.

This questionnaire forms the assessment basis for Award criterion 1 as follows:

Understanding of the tasks and quality of the proposed services

This criterion serves to assess the tenderer's understanding of the tasks (Section 1.3) and the degree to which the tender shows how carrying out the tasks of the contract would help in the implementation of the REACH Regulation, CLP Regulation, the Biocides Regulation or the PIC Regulation.

This criterion also assesses how the tenderer intends to deliver the multidisciplinary services covering the different tasks (in depth⁴³ and breadth⁴⁴)

1.1. Taking into account the tasks outlined in Section 1.3., give a description of how your organisation would deliver each task. Explain how successful delivery of such tasks would aid in the implementation of the legal obligation that ECHA has under the REACH Regulation, CLP Regulation, Biocides Regulation and PIC Regulation. If your organisation/consortium does not have competence related to a particular task then this shall be indicated.

(total maximum of 22 pages, maximum 3 pages per task).

Answer: _____

1.2. Organisational structure allowing the delivery of the required services - maximum 15 pages total (for questions 1.2.1. - 1.2.5):

1.2.1. Describe how your organisational structure would facilitate the delivery of the required services detailing the departmental expertise and allocated number of staff in the division(s) responsible. If relevant, include the relationships between the tenderer and other organisations within the same group/consortium, including all those that could participate (e.g. as subcontractor) in the delivery of the requested services.

Answer: ____

⁴³ In terms of specific expertise related to a given task

⁴⁴ In terms of coverage of different tasks

1.2.2. In case you have a scientifically/technically relevant knowledge base, describe how your staff would access it in order to deliver the service. Otherwise indicate how you guarantee the availability of information relevant to the scientific/technical knowledge for the services required.

Answer: _____

1.2.3. How do you guarantee staff competence to support the quality of the services required (e.g. in terms of training programmes)?

Answer: _____

1.2.4. Give a risk analysis linked with the delivery of the services. How will you treat problems that you may encounter? Give practical examples.

Answer: _____

1.2.5. Describe your procedures for ascertaining the requisite quality of services you deliver to clients regarding conformity of outputs to task requests within the agreed deadlines.

Answer: _____

4.3.4.1.2. Case studies

Introduction to case studies

The two case studies form the assessment basis for the Award Criterion 2 – Efficiency and project management as follows:

Efficiency and project management

This criterion relates to the quality of methods and approaches, project planning, team organisation, communication/interaction methods, project management and quality assurance methods with a view to execute multidisciplinary projects well.

The studies referred to are examples of two types of tasks that may be required to be developed by the chosen tenderers but do not necessarily reflect an actual task that the tenderers will be asked to perform.

The foreseen deliverables from these case studies do not require that the tenderers have any specific experience/knowledge in performing the tasks outlined in the studies. As such, the tenderers' offers will be evaluated based on their capacity to prepare suitable offers and not on any specific content knowledge. For information purposes only, the annexed documents contain templates which outline how the output reports from the respective case studies might look. The tenderers shall <u>not</u> include a completed output report (real or fictional) for these case studies but shall focus their offers on the methods and approach to be employed in providing an output report such as that outlined in the template.

The tenderers need to develop both case studies in order to score as many points as possible in terms of Award Criterion 2.

Content of the offers

The tenderer should develop an offer for each of the case studies that would demonstrate how well the tenderer would be able to organise the overall management of the services to develop the final reports as efficiently as possible and to the highest level of quality.

The offer, in particular, must include:

- a description of the proposed approach and methods as well as the expertise needed to undertake the task,
- a description of the proposed organisation in terms of the team structure and how the various expertises required are arranged within the team; in the case of a tender being submitted by a consortium, a description of the input from each consortium member, the distribution of tasks, collaborative interaction and individual member responsibilities should be included,

- a description of the project management and quality assurance methodology,
- a project plan including timetable, meetings, milestones and reporting,
- a description of the coordination and communication plans and tools for communication with ECHA,
- a description of any potential constraints and how these would be resolved.

Offers should not exceed 10 pages per case study (12pt Times New Roman font).

CASE STUDY I

1. Subject

The European Chemical Agency is involved in collecting and analysing information to identify the possible options for further regulatory risk management needed to address concerns related to a substance.

The duration of the project is three months.

2. Objectives

The objective of the service is to develop a risk management option analysis for a substance. There are normally several options for addressing concerns related to a substance. The aim of a systematic analysis of the risk management options (RMOs) is to facilitate the identification and choice of the most appropriate instrument (or combination of instruments) for the case at hand.

3. Deliverable of the project (for information purpose only - not to be prepared for this case study)

An RMO analysis drafted in English specifying all conclusions.

4. Annex

RMO template (Annex)

ANALYSIS OF THE MOST APPROPRIATE RISK MANAGEMENT OPTION FOR [SUBSTANCE][GROUP OF SUBSTANCES]

Substance name: EC number: CAS number:

Submitted by: Date:

1. Background

- Information on any previous RMO analyses;
- Is the substance already addressed under restriction or authorisation procedures?
- Description on already existing legal requirements under other EU legislation;
- Is the substance discussed under UN/ECE POP Protocol or Stockholm Convention? What is the status / phase?
- Any other information which facilitates the understanding of the case, e.g. information on hazard or risk assessments carried out at the EU, OECD or other fora.

2. Objectives for (further) risk management

- Description of the concern(s) which triggers the consideration of further risk management;
- Objectives for further risk management, which could include e.g.:
 - o Immediate, intermediate and/or long term objectives;
 - Use-specific or protection target -specific objectives.

3. Available information

- Short description of key information available for the substance(s). This can be e.g. information on:
 - Substance Identity;
 - Hazard, emission, exposure and/or risk(s);
 - o Uses, including number and type of users;
 - o Alternatives, including R&D;
- Where relevant, identification of main missing information which potentially could affect the conclusion on the most appropriate RMO.

4. Identification of risk management options

- List of potential (combination of) RMOs:
 - N.B. The identified RMOs may cover only authorisation or a restriction under REACH or assess benefits and drawbacks related to the use of only one RMO (e.g., inclusion of the substance in the Candidate list). It may also eventually consider other non-REACH RMO;
- Checking whether the concern(s) regarding the substance/exposures/uses is (are) within the scope of the identified RMOs;
- Short explanation for not assessing one or more of the potential RMOs.

5. Assessment of the identified risk management options

- Comparative assessment of the potential (combination of) RMOs considering:
 - Ability to achieve the risk reduction objectives described under section 2 in a reasonable timeframe;
 - Balance of the costs compared to the benefits of the reduced risks, cost-effectiveness of the options;
 - o Clarity of the obligations imposed on operators;
 - Regulatory consistency.

6. Conclusions on the most appropriate (combination of) risk management option(s)

- Conclusion made on the basis of the assessment;
- Main sources of uncertainties related to the conclusions;
- Suggestion on the way forward, including foreseen timeline for taking action and by when comments and contributions on the RMO analysis are expected.

References

- A list of main information sources.

CASE STUDY II

1. Subject

The European Chemical Agency needs assistance in the identification of groups and development of clusters of UVCB substances to facilitate substance priority setting within REACH processes.

The duration of the project is 5 months.

2. Objectives

The objective of the study is to identify groups and develop clusters of UVCB substances by analysis of the substance identity, hazard profile, identified risks and other property information from different sources.

The aim of the identification of groups and development of clusters of substances is to assist in substance identification and prioritisation within REACH processes and to facilitate evaluation of the need to obtain further information on such substances.

Relevant information regarding the substance may be obtained:

- from the registration dossier(s) (it is assumed that the contractor has access to the relevant data submitted)
- from regulatory sources or international regulatory reviews
- from consultation with industrial manufacturers and/or their representatives
- from scientific literature and databases
- from the tenderer's internal documentation and/or databases

3. Deliverable of the project (for information only - not to be prepared for this case study)

An output report drafted in English specifying the conclusions of the clustering analysis and compiling and summarising all the relevant information. A critical scientific opinion on the validity and robustness of the methodologies used for the cluster(s) development should also be included. The report should contain sufficient information to allow a decision to be taken on the validity of the developed cluster grouping(s) for REACH process purposes.

4. Annex

Clustering analysis template (Annex)

Annex to Case study II

ANALYSIS FOR CLUSTERING OF UVCB SUBSTANCES

Substance name: EC number: CAS number:

Substance name: EC number: CAS number:

Substance name: EC number: CAS number:

etc

Background

- Information about the identity of the substance;
- Information about the manufacture technologies and use of feedstock(s), process unit operations, operating conditions and any other characteristics which may have influence on the substance identity;
- Is it a phase in or a non phase in substance?
- Is the substance classified? Is the substance meeting the criteria referred to in Article 57 of the REACH Regulation?
- Is there enough experimentally derived information about the hazardous properties of the substance?
- Are there data gaps? How can data gaps can be filled with non- testing infomation?
- Are there other alternative data sources to be used?
- How could the adequacy of the data be judged for the purposes of classification/labeling and/ or risk assessment?
- Description on already existing legal requirements under other EU legislation;
- Any other information which facilitates the understanding of the substance case, e.g. information on the substance identity, manufacture technologies, hazard or risk assessments carried out at the EU, OECD or other fora.

Available information

- Description of key information available for each of the substances. This can be e.g. information on:
 - Substance identity: substance name, composition of the substance including its mineralogical phases, if applicable; spectral data and

other appropriate analytical methods; information on constituents including molecular and structural formula; optical activity, if applicable; molecular weight or molecular weight range, Physical and chemical properties that the identification of the substance type may require as well as any relevant additional identifiers including the manufacturing processe(s);

- Hazards: physico-chemical properties, environmental toxicity and fate, and adverse health effects;
- Use(s), emission(s), exposure(s) and/or risk(s),
- Where relevant, identification of the main data gaps and proposals for solutions to fill them using relatively simple and more complex cheminformatics techniques;
- Where relevant, identification of the main missing information, which potentially could affect the conclusion on the clustering.

Assessment of hazard(s) and identified risk(s)

- Assessment of the substance identity of members of the cluster(s), physical, environmental and/or health hazard(s) as a function of the substance main constituent(s), of the manufacturing process(es) and compositions; selection of appropriate data sets; proposed classification and labelling.
- Assessment of the identified hazards taking into account different types of data, including non-test and alternative data.
- Assessment of the identified risk(s) taking into account uses, emissions and exposures;

Conclusions on the clustering

- Conclusions: justifications for cluster grouping and validity of the developed cluster(s) on the basis of the available information including substance identity, hazard and risk assessment;
- Main sources of uncertainties related to the conclusions.

References

- A list of main information sources.

4.3.4.2. Financial Offer

Price component 1 regarding Fixed price contracts (off-site) (in EUR, without VAT)					
Category of expert Maximum price per man-day		Price weighting regarding category of expert (%) ⁴⁵	Weighted price regarding category of expert		
1. Senior expert	. Senior expert		[1]		
2. Expert		35%	[2]		
3. Junior expert 15% [3]					
100% Sum [1]+[2]+[3]					

Price component 2 regarding Time and Means contracts (on-site) (in EUR, without VAT)				
Category of expert	Maximum price per man-day	Price weighting regarding category of expert (%) ⁴⁵	Weighted price regarding category of expert	
1. Senior expert		50%	[1]	
2. Expert		35% [2]		
3. Junior expert		15%	[3]	
		100%	Sum [1]+[2]+[3]	

⁴⁵ The actual division of workload per category of expert in the service requests launched under the Framework contract may differ from the hypothetical model above

Financial offer for the Framework contract

Price component 1 + 2				
	Sum of weighted price for all categories of experts	Weighting regarding contract type (%)	Total weighted price	
Price component 1		90%	[1]	
Price component 2		10%	[2]	
Total Price		100%	[Sum (1+2)]	

4.3.5.Checklist of documents to be submitted

The purpose of the table below is to facilitate the preparation of the tender by providing an overview of the documents that must be included (marked by \blacksquare) depending on the role of each economic operator in the tender (coordinator/group leader in joint bid, partner in joint bid, single contractor, main contractor, subcontractor).Some of the documents are only relevant in cases of joint bids or when subcontractors are involved. Additional documents might be necessary depending on the specific characteristics of each tender.

Description	Coordin ator or group leader in joint bid	All partner s in joint bid	Single or Main contra ctor	Sub- contrac tor
Power of attorney of partners in joint bid indicating the group leader (see Section 4.3.1)				
Letter of intent of subcontractor (see Section 4.3.1)				
Legal Entity Form (see Section 4.3.1)				
Download the form from : <u>http://ec.europa.eu/budget/info_contract/legal_entities_en</u> <u>.htm?submenuheader=0</u>				
Supporting documents for the Legal Entity File Form				
Financial Identification form (see Section 4.3.1)				
Download the form from:				
http://ec.europa.eu/budget/info_contract/ftiers_en.htm				
Exclusion Criteria form (See Section 3.1.1.2.1 and Section 4.3.2)				
Evidence of Economic and financial capacity (see Section 3.1.1.2.1 and Section 4.3.3)				
Evidence of Technical and professional capacity (see Section 1.2, Section 3.1.1.2.1 and Section 4.3.3)				
Go to the following page to fill in the CV: <u>http://europass.cedefop.europa.eu/europass/pr</u> <u>eview.action?locale_id=1</u>		-		-
Evidence of Technical and professional capacity: Project reference form (see Section 3.1.1.2.1 and Section 4.3.3)				

The following Sections must be provided in the bid, their absence would mean rejection of the bid for incompleteness:

Description	Coordinator or single tenderer
Technical offer (see Section 4.3.4.1)	
Financial offer (see Section 4.3.4.2)	