

**ECHA/2015/226**

**Service Contract**

**A coordinated approach to assessment and  
evaluation of Biocidal disinfectants for the second  
priority list**

**Open procurement procedure**

**Contract notice: OJ 2015/S 135-248773**

**Tender Specifications and  
Model Service Contract**

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## SUMMARY

<b>Contracting authority</b>	The European Chemicals Agency (ECHA) in Helsinki.
<b>Procedure</b>	Call for Tenders with publication of a Contract Notice in the Official Journal of the EU. Open procedure.
<b>Purpose</b>	Selection of a service provider for the provision of the services mentioned below. The purpose of the Contract is to ensure that Competent Authorities evaluating biocidal disinfectant will be able to meet the legal deadlines for such evaluations, and to contribute towards harmonised approaches taken in the evaluation
<b>Scope of services</b>	The contract consists of 4 work-packages.
<b>Duration of contract</b>	The duration of the contract shall be 12 months.
<b>Submission of offers</b>	Each tenderer can only submit one offer.
<b>Volume (indicative)</b>	The maximum total value of the contract is estimated at 100,000 €. Tenders presenting an offer superior to the maximum amount will be excluded from the rest of the assessment procedure.
<b>Contract</b>	The European Chemicals Agency will sign a contract with the successful Tenderer offering best value for money.
<b>Places of delivery</b>	The main place of performance of the services shall be the Contractor's premises, except for the meetings that will take place in Helsinki and Brussels as mentioned in the specifications
<b>Variants</b>	Not permitted.
<b>Joint offers</b>	Permitted as described in the current document.
<b>Subcontracting</b>	Permitted as described in the current document.

# **1 THE SERVICES (TECHNICAL SPECIFICATIONS)**

## **1.1 BACKGROUND**

### **1.1.1 The European Chemicals Agency and the Biocidal Products Regulation**

Established on 1 June 2007, the European Chemicals Agency (hereinafter referred to as ECHA or the Agency) carries out or co-ordinates the necessary activities under the REACH Regulation (REACH), the Regulation on the Classification, Labelling and Packaging of substances and mixtures (CLP), the Biocidal Products Regulation (BPR), and the legislation on Prior Informed Consent (PIC).

In 2013 ECHA took over a number of responsibilities for the BPR (Regulation (EU) 528/2012) from the European Commission. The regulation concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. This regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment. The text was adopted on 22 May 2012 and will be applicable from 1 September 2013, with a transitional period for certain provisions. It repeals the Biocidal Products Directive (Directive 98/8/EC).

All biocidal products require an authorisation before they can be placed on the market, and the active substances contained in that biocidal product must be previously approved. A large and central part of ECHA's work on biocides concern approval of active substances. More information about the Agency, its structure and activities can be found on the Agency's website<sup>1</sup>.

The purpose of this Contract is to develop and implement a harmonised and coordinated approach for risk assessment of biocidal active substances used as disinfectants. This work is now urgent as the legal deadlines for evaluating biocidal active substances already on the market are 31 March 2017 and 31 March 2019, respectively, depending on the specific use of the substances.

### **1.1.2 Approval process for biocidal active substances**

Active substances need to be approved before an authorisation for a biocidal product containing them can be granted.

The active substances are first assessed by an evaluating Member State competent authority and the results of these evaluations are forwarded to ECHA's Biocidal Products Committee (BPCs), which prepares an opinion within 270 days.

The opinion serves as the basis for the decision on approval which is adopted by the European Commission. The approval of an active substance is granted for a defined number of years, not exceeding 10 years and is renewable.

The BPR introduces formal exclusion and substitution criteria which apply to the evaluation of active substances.

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<sup>1</sup> [http://www.echa.europa.eu/home\\_en.asp](http://www.echa.europa.eu/home_en.asp)

In principle, active substances meeting the exclusion criteria will not be approved.

Active substances potentially meeting the substitution criteria will undergo a public consultation and may be designated as candidates for substitution during the approval procedure. The criteria are based on the intrinsic hazardous properties in combination with the use and potential exposure. In this case, approval of an active substance is granted for a maximum of seven years (for active substances where the assessment report was submitted before 1 September 2013, the approval period can be a maximum of 10 years, as per the transitional provisions).

Most of the active substances currently under evaluation in the Biocidal Product Committee are existing active substances evaluated in the framework of the Review Programme. This is the work programme for the examination of existing biocidal active substances contained in biocidal products. The programme was set up by the European Commission under the Biocidal Products Directive (BPD) and continues under the Biocidal Products Regulation (BPR).

Existing active substances are those substances which were on the market on 14 May 2000 as an active substance of a biocidal product (for purposes other than scientific or product and process-orientated research and development). The existing active substances which were accepted to be examined in the Review Programme were those which were identified as such and for which a notification was accepted, as set out in Annex II to Commission Regulation (EC) No 1451/2007.

The detailed rules for the Review Programme have been adapted to the provisions of the BPR in the new Review Programme Regulation (EU) No 1062/2014, which repeals and replaces Commission Regulation (EC) No 1451/2007. The regulation also contains the deadlines for evaluation of active substances belonging to the different Product Types (PT). For disinfectants in PT 1-5 that are in focus for this project the first legal deadline for submitting the Member State evaluation to ECHA is 31 December 2016 for PT 3, 4 and 5.

### **1.1.3 Evaluation of biocidal disinfectants**

Disinfectants constitute the first main group of biocidal active substances. They are used in five product types (PT) as follows:

- Product-type 1: Human hygiene
- Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals
- Product-type 3: Veterinary hygiene
- Product-type 4: Food and feed area
- Product-type 5: Drinking water

A recent overview of the evaluation of active substances used as biocidal disinfectants shows that 71 active substance PT combinations remain to be evaluated by the Member States for the Second Priority List (PT 3, 4 and 5). In addition, 41 so called 'back-log' assessment reports need to be processed in the Working Groups and BPC. These assessment reports have been discussed in technical meetings or were only commented on by other Member States but no opinions have been adopted.

Given the legal deadlines for the submission of the Member State evaluations to ECHA of 31 December 2016 for PT 3, 4 and 5 and of 31 December 2018 for PT 1 and 2 time is very short and it is questionable if all Member States will be able to deliver their evaluations on time. Alternatively, assessment reports of insufficient quality can be expected, which will then lead to substantial discussions and extra work in the peer review process.

Even if the legal deadline for PT 1 and 2 is later than for PT 2,3 and 4 it is in principle very difficult and inefficient to deal with PT 1 and 2 at a later stage, as most disinfectant dossiers cover all PTs or PTs subject to both deadlines. To avoid dealing with the dossiers twice it is in practice necessary to finalise most of the evaluation for the 2016 deadline.

To support the evaluations of the Member States and as a valuable addition to the resources in ECHA the following project proposal consisting of four work packages has been outlined. The Contractor shall prepare instructions for risk assessment of disinfectants with a particular focus on human and environmental exposure, and implement these instructions via three workshops. Furthermore the Contractor shall provide individual support to evaluating Competent Authorities, and draft guidance for efficacy testing of disinfectants.

The project requires knowledge and experience from evaluating biocidal active substances, in particular risk assessment and efficacy testing of disinfectants.

The volume of the contract over its entire duration shall be a maximum of 100,000 EUR including all expenses.

## **1.2 DESCRIPTION OF RESOURCES**

The project requires experts with university degrees in relevant scientific subjects, for example chemistry, toxicology, or microbiology.

The experts should have previous experiences with and good understanding of regulatory processes related to the Biocidal Product Regulation, including knowledge of all aspects of evaluation of biocidal active substances. In addition, understanding of issues related to disinfectants, in particular efficacy testing of drinking water disinfectants, is required.

## **1.3 DESCRIPTION OF TASKS**

### **1.3.1 Generic nature of the tasks**

The purpose of this Contract is to ensure that Competent Authorities evaluating biocidal disinfectant will be able to meet the legal deadlines for such evaluations, and to contribute towards harmonised approaches taken in the evaluation. The overall objective is to have assessment reports of sufficient quality submitted to ECHA for further processing in the BPC Working Groups and in the BPC. To this end a project consisting of four work packages has been outlined. In brief, the Contractor shall prepare instructions for risk assessment of disinfectants with a particular focus on human and environmental exposure, and implement these instructions via a series of virtual workshops. Furthermore the Contractor shall provide individual support to evaluating Competent Authorities, and draft guidance for efficacy testing of disinfectants.

The Contractor is expected to prepare a work plan that details the tasks and associated timelines that are needed to fulfil the objective of the assignment.

*Please note that to ensure that any potential conflicting interests that the Contractor may have regarding the dossiers handled in the project are adequately recorded and made accessible to ECHA the Contractor shall set up a mechanism for handling declarations of interest. This mechanism should be described in the Work Plan.*

The following work packages should be covered by the work plan.

1. WP1 - Preparation of instructions for evaluation of disinfectants (estimated 20% of the total work volume)

The Contractor should prepare detailed instructions to the evaluating Competent Authorities for evaluation of active substances used in disinfectants (biocidal products covered by Product Types 1 to 5). The aim of the instructions is to streamline and simplify the evaluations of active substances and increase work efficiency both during the evaluation phase and during the Committee phase (peer review).

The instructions should be prepared as a practical manual and it should include concrete, practical advice related to the most common problems encountered in the assessment of disinfectants. The content should be based on discussions and conclusions of the previous Technical Meetings under the BPD and in the Biocidal Product Committee and its Working Groups. To ensure all relevant areas are covered in an appropriate manner close contact with the ECHA Secretariat, and in particular the Chairs of the BPC and its WGs are necessary. The Contractor should also perform a limited telephone questionnaire survey among the Member State Competent Authorities.

The instructions should focus on risk assessment for humans and the environment. Relevant areas to address include for example what exposure scenarios should be addressed for the various PTs. To facilitate exposure assessments harmonised Excel calculation sheets for the environmental emission estimation based on the scenarios provided in the Emission Scenario Document for PT 1 to PT 5 should be developed. The contractor should further transfer the environmental emission scenarios provided in the Emission Scenario Document (ESD) for all disinfectants, i.e. the ESDs for product types 1 to 5 in Excel files per product type (whereas one Excel sheet should cover one scenario). The Excel files are intended to be published on the ECHA webpage in order to provide a harmonised basis for the emission estimation in the frame of the environmental exposure assessment.

Other important areas that should be covered by the instruction include data needs and timelines for PBT assessment and CLH proposals.

*For WP 1 one 2-day meeting in Helsinki between the Contractor and the ECHA Secretariat is foreseen for this Work Package. Travelling costs for the Contractor should be included in the bid.*

2. WP2 - Preparation of assessment and evaluation guidelines for efficacy of drinking water disinfectants (PT 5) (estimated 30% of the total work volume)

ECHA guidance has been published or is currently under preparation for most aspects related to evaluation of disinfectants. However, evaluation of efficacy for PT 5 still needs to be prepared. PT 5 covers biocidal products used to disinfect drinking water for humans and animals. They are used in large urban water networks supplying potable water, in small private systems or by individuals treating a small amount of water for their own consumption. The guidance is aimed at supporting the harmonisation of efficacy testing at the European level in order to facilitate mutual recognition of biocidal product authorisations.

Based on a currently available early draft of the PT5 guidance the Contractor should finalise a detailed draft guidance addressing among other things data requirements and acceptance criteria for biocidal products in PT 5, taking into account disinfection by municipalities and drinking water companies, disinfection of drinking water reservoirs, disinfection of water for animals.

To finalise the drafting of the first version of this guidance document constitutes therefore WP 2 of the project. Two commenting rounds (addressing members of the Efficacy WG and other experts, a total of 10 people foreseen), one virtual/webex meeting and one physical meeting/workshop with invited experts (10 people foreseen) is considered necessary to finalise the work. The workshop should be held at ECHA's premises in Helsinki back-to-back with a meeting of the BPC working group for Efficacy. No costs for the participants' travelling or meeting room should be covered by the bid, and ECHA will handle the travel arrangements for the participants. The Contractor is responsible for all other administrative issues related to the meeting (setting the agenda, invitations, chairing the meeting, taking minutes). ECHA can host the virtual meeting by using its Webex tool.

*For WP 2 one one-day meeting in Helsinki between the Contractor and the expert group for drafting of the guidance should be included in the bid.*

3. WP3 - Coordination of evaluating Competent Authorities: One physical and two virtual Workshops (estimated 20% of the total work volume)

In order to harmonise and coordinate the evaluation process between the different evaluating Competent Authorities and to better understand their support needs the Contractor shall organise four virtual workshops for evaluating Competent Authorities representatives. Each workshop should last approximately 6 hours. During these workshops participants should have the possibility to better explain and explore their needs in relation to different aspects of active substances evaluation of disinfectants.

The intention with the workshops is to present, explain and discuss the instructions prepared in WP1 and address any additional issue that may have arisen in the evaluating Competent Authorities' work. The precise content of the meetings should be decided in cooperation between the contractor and ECHA based on the evaluating Competent Authorities' need for support.

Active participation of a small number of experts per evaluating Competent Authority is foreseen. The Contractor is responsible for all administrative issues related to the meeting (circulating the agendas, invitations, chairing the meeting, taking minutes). ECHA can host the virtual meeting by using its webex tool.

4. WP4 - Providing support to individual Member States corresponding to 30 man-days (estimated 30% of the total work volume)

In order to support the evaluation of disinfectants by the individual evaluating Competent Authorities the Contractor should provide scientific and technical support to individual evaluating Competent Authorities or to ECHA upon request. Experts available to the Contractor should be able to perform all tasks commonly related to dossier evaluation, e.g. modelling work for exposure assessments, assistance in selecting reference values in the hazard assessment, or issues related to the specifications of the reference source. The support shall take place by virtual communication tools and no physical meetings are foreseen.

The Tenderer should elaborate as part of the Work Plan a method for prioritising and dividing the available time and resources for individual support between the



evaluating Competent Authorities, including criteria for selection of the most relevant issues. In case demands are larger than resources ECHA should be consulted on priorities. Support given shall be recorded in time sheets detailing the scientific/technical issue, the evaluating Competent Authority concerned and the time period under which support was given, and resources allocated.

In case the support need from the evaluating Competent Authorities does not request the above mentioned 30 man-days allocated to this Work Package by the Contractor, the Contractor will be asked to assist ECHA in tasks related to the peer review of the Competent Authority assessment reports (CARs) for disinfectants.

### **1.3.2 Evaluation of active substances by Competent Authorities**

A detailed methodology for the risk assessment of active substances is given in ECHA's Guidance on the BPR: Volume III B for human health<sup>2</sup>, and in Volume IV B for the environment<sup>3</sup>, respectively. The risk assessments (for hazard, exposure and risk characterisation) should follow this guidance. In addition, exposure scenarios for human health<sup>4</sup> and the environment<sup>5</sup> are published at ECHA's webpage.

The assessments of Review Programme dossiers shall be carried out by the responsible authority (Competent Authority) of the Member State that has received the application from industry. The assessment shall include a proposal for approval, or otherwise, of the active substance in the Union list, associated conditions for this entry or whatever specific risk reduction measures should be considered necessary for the risk management of the active substance.

The ECHA guidance identifies criteria for unacceptable/acceptable effects and associated conditions for inclusion of active substances in the Union list. They are intended primarily for the competent authorities of the Member States who shall assess the active substances, but also as guidance for the applicant.

The chapter addressing risk characterisation discusses the relevant endpoints for human health in terms of the population exposed (professional, non-professional and those exposed via the environment), followed by clarification of the roles of quantitative and qualitative risk characterisation. The environmental effects are discussed in terms of direct or indirect exposure to the different environmental compartments.

The Contractor will in the kick-off meeting receive all necessary information for his contacts with the evaluating Competent Authorities and to perform other aspects of the project, such as contact details to evaluating Competent Authorities, lists of evaluating Competent Authorities responsible for the various substances, access to applications under evaluation, and access to already submitted assessment reports (CARs).

### **1.3.3 Efficacy testing of drinking water (PT 5)**

ECHA has published guidance or is preparing guidance for approval of biocidal active substances and for authorisation of biocidal products. For efficacy testing

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<sup>2</sup> [http://echa.europa.eu/documents/10162/15623299/biocides\\_guidance\\_human\\_health\\_ra\\_iii\\_partb\\_en.pdf](http://echa.europa.eu/documents/10162/15623299/biocides_guidance_human_health_ra_iii_partb_en.pdf)

<sup>3</sup> [http://echa.europa.eu/documents/10162/15623299/bpr\\_guidance\\_ra\\_vol\\_iv\\_part\\_b\\_en.pdf](http://echa.europa.eu/documents/10162/15623299/bpr_guidance_ra_vol_iv_part_b_en.pdf)

<sup>4</sup> <http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure>

<sup>5</sup> <http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/environment-exposure>

of biocidal product in PT 5 the guidance needs to be finalised. This work will be covered by WP 2 of the present project.

Guidance for the data requirements and evaluation of the efficacy of drinking water disinfectants was discussed under the BPD. A workshop in February 2011 in Germany discussed a test protocol prepared by Germany ("Quantitative determination of the efficacy of drinking water disinfectants"). This protocol was also discussed in the TM (2012) and was endorsed during TMIII 2013.

Since this is only a test protocol and not a guidance document, a draft guidance for PT 5 was prepared by the Netherlands and send to the TMIII 2013.

Comments to the Draft PT 5 guidance were given by Germany and one Stakeholder Organisation (Cefic) only (TMIV 2013). The Netherlands revised the Draft PT 5 guidance, taking into account these comments and the guidance was added to the Draft Efficacy Guidance for PT1-5. Although some comments were given on the PT 5 chapter in this guidance this was not fully discussed in the workshop, since the working group did not included PT 5 experts.

To finalise the chapter on PT 5 in the efficacy guidance PT 5 experts should comment on this chapter (e-mail commenting round, followed up by a workshop) after which a revision of the chapter should be done. The revision of the chapter is further outlined under WP 2 above.

The Contractor will, in the kick-off meeting, receive all necessary information such as the current draft of the Guidance and contact details to experts previously involved in the work.

#### **1.3.4 Organisation of the tasks**

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

A Project Team will be put in place, comprising staff from the Agency. The ECHA Project Team will encompass scientific and technical expertise with members having experience with evaluation of biocidal active substances. This team will be responsible for providing the Contractor with all relevant information needed for the project.

The project will be formally managed by an Agency Project Manager nominated by the Biocides Assessment unit in ECHA. The Agency project manager will represent the Agency in contacts with the Contractor and external stakeholders on matters related to the work to be achieved and ensure that the contractor meets his obligations within the limits and the terms of the contract.

##### **Meetings and deliverables presentations**

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

The Contractor shall attend and/or organise meetings with the ECHA Project Team and other relevant parties. Organising physical and virtual workshops with experts from the Member States constitutes a central part of the project. The Contractor shall be prepared to participate in two face-to-face meetings in ECHA's premises in Helsinki (Finland).

Within two weeks after entry into force of the Contract, the Agency Project Manager will organise a one day kick-off meeting at the Agency with the Contractor to officially discuss in detail the planning and other organisational

aspects of the project and to have a thorough discussions about the instructions that constitute the deliverable of WP 1. This meeting will officially start the work. Members of the ECHA Project Team will attend. During this meeting the Agency will provide the Contractor with all necessary information to start the work on WP 1 and WP 2. During this meeting, the Agency and the Contractor will also fine-tune the work plan prepared by the Contractor as part of the bid. All dates for report deliverables and meeting arrangements refer to the kick-off meeting as time zero.

Table 1 outlines all meetings foreseen in the project. Meetings involving external parties are further described in section 1.3.1. above under the respective Work Packages.

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

A final tele- or video-conference will take place at month 12 of the Contract to discuss the end results.

The frequency of tele- or video-conferences can be adapted as necessary in agreement with both parties. The Contractor will produce meeting minutes for all meetings, documenting discussion points and clearly stating the results of the meeting and all decisions taken. A first draft version must be circulated within 5 working days after the meeting. Within 5 days the ECHA Project Team shall provide its comments and the Contractor shall submit the finalised minutes to the ECHA Project manager.

Table 1 Meetings during the Contract period

<b>Meeting</b>	<b>Time after kick-off meeting</b>	<b>Purpose</b>	<b>Venue</b>	<b>Attendees from the Contractor</b>
1. Kick-off meeting (face to face)	Month 0 (about 2 weeks after Contract signature)	Introduction and discussion of the project with focus on the instructions to be prepared for WP1. Discussion of organisational aspects and expected deliverables.	Agency, Helsinki (1-day meeting)	Contractor's project team representatives and key subcontractors or partners (if applicable)
2. Tele- or video-conference	Month 2	Review status, activities for subsequent months, technical issues, and discuss any outstanding issues on the Work Plan.	-	Contractor's project team
3. Virtual WS with evaluating Competent Authorities	Month 4	Present, explain and discuss the instructions prepared in WP1 with CAs evaluating disinfectants.	-	Contractor's project team
4. Virtual WS with evaluating Competent Authorities	Month 5	Present, explain and discuss the instructions prepared in WP1 with CAs evaluating disinfectants.	-	Contractor's project team
5. Tele- or video-conference	Month 6	Review status, activities for subsequent months, technical issues.	-	Contractor's project team

6. Virtual WS with evaluating Competent Authorities	Month 9	Discuss relevant issues related to evaluation of disinfectants.	-	Contractor's project team
7. Physical meeting with Expert Group for Efficacy of PT 5 products	Month 9		Agency, Helsinki (1-day meeting)	Contractor's project team
8. Tele- or video-conference	Month 9	Review progress towards final deliverables	-	Contractor's project team
9. Virtual meeting with Expert Group for Efficacy of PT 5 products	Month 11		-	Contractor's project team
10. Virtual meeting with evaluating Competent Authorities	Month 11	Discuss relevant issues related to evaluation of disinfectants.	-	Contractor's project team
11. Final tele- or video-conference	Month 12	Presentation of end-results.	-	Contractor's project team

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

## 1.4 DESCRIPTION OF DELIVERABLES

The contractor shall prepare and submit to ECHA the following deliverables during the service:

Deliverable 0: Work Plan at month 1 from kick-off meeting. The Work Plan should describe in detail the activities planned by month and by resource for the duration of the Contract. ECHA Project Team will provide feedback on the Work Plan within 2 weeks of its delivery. Outstanding issues will be discussed in the tele- or video-conference within the first 2 months of the Contract.

Deliverable 1: WP1: A document/manual containing detailed instructions for evaluation of biocidal active substances used as disinfectants in PT 1 – 5. The instruction should be ready after month 3;

Deliverable 2: WP2: A first draft of the Draft Guidance for Efficacy testing for PT 5. This draft should be ready by month 7 and will be discussed in the Efficacy WG in month 9;

Deliverable 3: WP 2: A final draft Draft Guidance for Efficacy testing for PT 5 agreed by the BPC Efficacy WG and ready for ECHAs consultation procedure for guidance (PEG). The Draft Guidance should be ready by month 11;

Deliverable 4: WP 3-1: Written reports from the first two virtual workshop including all discussion points, any issues arising in relation to the role of ECHA, summary of discussions and conclusions delivered within one week after the meeting in Month 5;

Deliverable 5: WP3-2: Written reports from the last two virtual workshop including all discussion points, any issues arising in relation to the role of ECHA, summary of discussions and conclusions delivered within one week after the respective meeting in Month 9 and 11, respectively;

Deliverable 6: WP4: Written report summarising all issues where the Contractor has provided support to individual evaluating Competent Authorities. This report should be submitted to ECHA as part of the final report from the project.

Deliverable 7: Presentation of end results. The draft final report at month 12 from the kick-off meeting

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

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

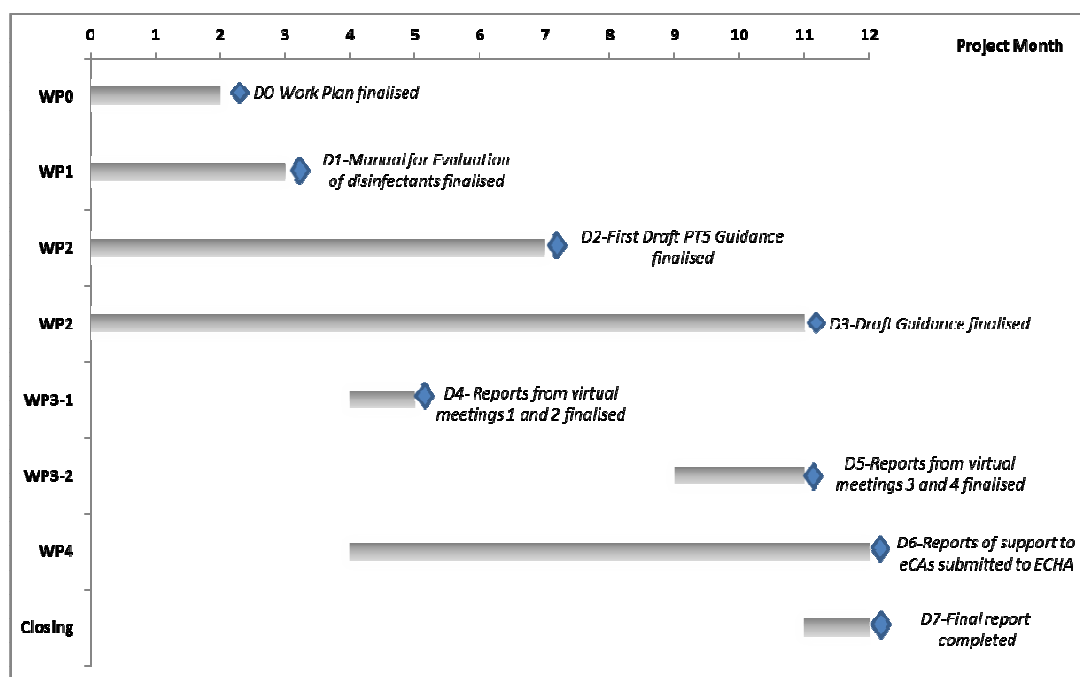


Figure 1 Milestones and indicative Gantt chart. Time zero refers to the kick-off meeting.

## **2 THE CONTRACT**

### **2.1 THE NATURE OF THE CONTRACT**

Service Contract for a coordinated approach to the assessment and evaluation of Biocidal disinfectants for the second priority list.

### **2.2 STARTING DATE OF THE CONTRACT AND DURATION OF THE TASKS**

The contract shall enter into force on the date on which it is signed by the last contracting party.

It is expected to be signed in October-November 2015.

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

The execution of the tasks may not start before the contract has entered into force. The period of execution of the tasks may be extended only with the written agreement of the contracting parties, before the end of the period originally stated in the contract.

### **2.3 PLACE OF PERFORMANCE**

The place of performance of the tasks shall be the Contractor's premises or any other place indicated in the tender specifications with regard to the meetings.

### **2.4 TERMS OF PAYMENT**

Payments shall be made in accordance with Articles I.3, I.4, II.15, II.16 and II.17 of the draft service contract (Section 4.2).

The payment scheme will consist of two interim payments:

- The first interim payment (of the amount corresponding to the price of WP 1 in the Financial offer) will be paid upon completion of Work Package 1 – Deliverable 1 (see Figure 1).
- The second interim payment (of the amount corresponding to 50 % of the price of WP 2 in the Financial offer and 50% of the price of WP 3 in the Financial offer) will be paid upon delivery of the first draft of the Efficacy Guidance for PT 5 as specified in Work Package 2 - Deliverable 2 (see Figure 1) and of the written reports from the physical workshop in Work Package 3 - Deliverable 4 (see Figure 1).

The balance will be paid upon acceptance of the project deliverables at the end of the project.

The schedule and the procedure for the approval of payments and the documents to be submitted are described in Articles I.4.

### **2.5 GUARANTEES**

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

## **2.6 LIABILITY**

### **2.6.1 Joint Offers**

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

Statements saying, for instance:

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

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

### **2.6.2 Subcontracting**

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

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

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

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

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

## **2.7 DATA PROTECTION**

Any response to the invitation to tender will require the recording and further processing of personal data (name, address, CV, for example). This data will be processed in accordance with the requirements of Regulation (EC) 45/2001 on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data. Except if mentioned otherwise, replies to questions and personal data are necessary for the purpose of assessing a tender according to the specifications of the invitation to tender and will only be processed by the Agency's Data Controller for this purpose. A tenderer may, upon request, obtain the communication of personal data and rectify any inaccurate or incomplete personal data. Any queries concerning the processing of personal data should be addressed to by the Agency's Data Controller. As regards to the processing of personal data, a tenderer has the right to recourse at any time to the European Data Protection Supervisor.

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

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

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

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



## **3 THE PROCUREMENT PROCEDURE**

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

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

##### **3.1.1.1 General**

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

Tender documents can be submitted in any of the official languages of the European Union.

Tenders must include the following information:

- all the information and documents requested by the Agency in order to assess the tender,
- the price in euro, filled in the form of the Financial offer (section 4.3.4);
- one specimen signature of an authorised agent (preferably in blue ink) on the legal entity form<sup>6</sup>, and a statement from the same agent confirming the validity of the tender, and
- the name and contact details of a contact person in relation to the submission of the bid.

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

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

##### **3.1.1.2 Content of the tender**

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

###### **Eligibility documentation**

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

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

To identify himself the tenderer must fill in a Legal Entity Form and a Financial Identification Form (see section 4.3):

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<sup>6</sup> See section 4.3

All tenderers must provide their legal entity form as well as the evidence indicated at the bottom of that form. The **Legal Entity Form**<sup>7</sup> is to be signed by a representative of the tenderer authorised to sign contracts with third parties.

The **Financial identification**<sup>8</sup> form shall be duly filled in and signed by an authorised representative of the tenderer and his or her banker.

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

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

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

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

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

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

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

In case of tenderers submitting a joint offer, the tenderers are asked to fill in and duly sign one of the attached **powers of attorney**<sup>9</sup>, depending on the set up that has been chosen by the tenderers.

If the tenderer envisages subcontracting, the tender must include:

- a **document**<sup>10</sup> clearly stating the roles, activities and responsibilities of the proposed subcontractor(s), and the reasons why subcontracting is envisaged, and
- a **letter of intent**<sup>11</sup> by each proposed subcontractor stating its intention to collaborate with the tender if the tenderer wins the contract and their

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<sup>7</sup> This form is available at:

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

<sup>8</sup> The form is available at:

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

<sup>9</sup> See section 4.3

<sup>10</sup> To be provided in free format

willingness to accept the tasks and the terms and conditions set out above, in particular article II.18 of the draft Service Contract.

### **Exclusion criteria documentation**

Tenderers or their representatives shall provide a **declaration on their honour**<sup>12</sup>, duly signed and dated in which they:

- state whether or not they are in one or more of the situations referred to in Articles 106 and 107 of the Financial Regulation and detailed in the form, and
- undertake to submit to the Agency any additional document relating to the exclusion criteria, that the Agency considers necessary to perform its checks, within seven calendar days following the receipt of the Agency's request.

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

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

Administrative or financial penalties may be imposed by the Agency on tenderers who are in one of the cases of exclusion provided for in Articles 106 and 107 of the Financial Regulation after they have been given the opportunity to present their observations.

These penalties are detailed in Article 109 of the Financial Regulation and Articles 142 and 145 of the Regulation laying down the rules for the implementation of the Financial Regulation.

### **Selection criteria documentation**

#### General

This part of the tender concerns the criteria and evidence relating to the technical and professional capacity and economic and financial capacity of the service provider(s) involved in the bid, It should also contain any other document that the tenderer(s) wish(es) to include by way of clarification. The evidence for the selection criteria shall be assessed in the second stage of the evaluation of the tenders<sup>13</sup>.

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

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,

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<sup>11</sup> See section 4.3

<sup>12</sup> See Section 4.3.2

<sup>13</sup> See Section 3.4

membership of a specific organisation, express authorisation, or entry in the VAT register.

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

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

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

The tenderer shall submit the completed Financial and Economic Capacity Overview Form<sup>14</sup>, as well as a full copy of the tenderer's annual accounts (balance sheet, profit and loss account, notes on the accounts and auditors' remarks when applicable) of the last three years, as approved by the general assembly of the company and, where applicable, audited and/or published. These documents must be certified by the tenderer.

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

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

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

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

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

a) Evidence for selection criterion 2.1:

A minimum of four CVs duly completed and presented in the appropriate format<sup>15</sup>.

b) Evidence for selection criterion 2.2:

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

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

### **3.1.1.2.2. Section Two: Technical proposal**

#### **Qualitative award criteria documentation**

This section is of great importance in the assessment of the bids, the award of the contract and the future execution of any resulting contract. Some guidelines are given below, but attention is also drawn to the award criteria, which define those parts of the technical proposal to which the tenderers should pay particular

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<sup>14</sup> See Section 4.3.3

<sup>15</sup> <http://europass.cedefop.europa.eu/europass/home/vernav/Europass+Documents/Europass+CV/navigate.action>

attention. The technical proposal should address all matters laid down in the technical specifications as described<sup>16</sup> and should include models, examples and technical solutions to problems raised in these specifications giving an answer to each of the points mentioned with regard to the methodology, deadlines and organisation. The level of practical details provided in the tender will be extremely important for the evaluation of the tender. The technical proposal must respond to these technical specifications and provide, as a minimum, all the information needed for the purpose of awarding the contract.

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

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

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

#### Assessment basis for award criterion AW1:

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

The proposal for the methodology as applied to the provision of the services must address the requirements of the technical specifications.

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

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

- the approach to be followed to identify the main issues that are to be addressed by the instruction that will be prepared as a starting point for the project,
- the approach the tenderer is proposing to follow to ensure a commonly agreed document for efficacy of drinking water disinfectants is available within the timeframes set,
- an outline for the agendas for the physical and two virtual workshops and proposed methodology for ensuring relevant issues are adequately covered,
- how the tenderer plans to support the evaluating member states with issues that arise in their evaluations, keeping consistency in the evaluations in mind, and how equal opportunities for support to the evaluating Competent Authorities will be ensured.

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<sup>16</sup> See Section 1

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

Assessment basis for award criterion AW2:

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

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

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

**3.1.1.2.3. Section Three: Financial proposal**

**Financial award criteria documentation**

Tenderers must use the financial form<sup>17</sup> 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 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,

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<sup>17</sup> See section **Error! Reference source not found.**

- prices shall not be conditional and be directly applicable by following the technical specifications, and
- prices shall be fixed and all inclusive and not subject to revision.

The reference price for the award of the contract shall consist of the sum of the price offered for the 4 work packages.

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

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

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

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

Such requests for further information may be made only in writing with the subject indication, « ECHA/2015/226 » 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 provided by the Agency will be published on the website at:

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

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

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

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

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

### 3.3 OPENING OF THE TENDERS

Tenders will be opened on Wednesday 09/09/2015 at 14:00 at the following location:

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

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

### 3.4 EVALUATION OF THE TENDERS

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

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

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

The aim of each of these stages is to:

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

#### Stage 1 – application of exclusion criteria

In accordance with Articles 106 and 107 of the Financial Regulation, tenderers shall be excluded from the selection and award procedures if they do not satisfy criteria a) to f) specified in the exclusion criteria form<sup>18</sup>.

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

#### Stage 2 - application of selection criteria

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<sup>18</sup> See section 4.3.2



These criteria will be assessed on the basis of the documents indicated<sup>19</sup>.

<b><u>SELECTION CRITERIA</u></b>
<b>1. FINANCIAL AND ECONOMIC CAPACITY</b>
1.1 Sufficient financial and economic capacity for the implementation of the contract  A minimum average annual turnover of 250,000 EUR over the past 3 financial years.
<b>2. TECHNICAL AND PROFESSIONAL CAPACITY</b>
2.1 Sufficient technical capacity to provide the human resources required for the implementation of the contract.  A minimum of four key personnel who will participate in the project and collectively possess the knowledge and skills as described in Section 1.2. All shall have a proficiency level of B1 in English, and at least two of them a minimum of five years of experience in biocides or another area of regulatory risk assessment.
2.2 Sufficient professional capacity to provide the services  A minimum of one scientific project similar in scope <sup>20</sup> executed in the past five calendar years for a minimum total value of 50.000 EUR.

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

### Stage 3 - application of award criteria

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

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<sup>19</sup> See section 3.1.1

<sup>20</sup> See section 1

No	Qualitative award criteria	Weighting (maximum points)
1.	<i>Understanding of the objectives of the project and quality of the methodological proposal for the provision of the services under the contract</i>	50
2.	<i>Quality of the composition of the project team and distribution of tasks</i>	50
<b>Total quality points</b>		100

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

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

**Tenders presenting a total price superior to the maximum amount of 100.000 € will be excluded from the rest of the assessment procedure.**

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

<b>Final Evaluation</b>	
	1000 * (Total Quality Points / Price)

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

### **3.5 AWARD OF THE CONTRACT**

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

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

However, certain information may be withheld where its release would impede law enforcement or otherwise be contrary to the public interest, or would

prejudice the legitimate commercial interests of economic operators, public or private, or might prejudice fair competition between them.

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

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

The Agency will request the tenderer proposed for award to provide the evidence on exclusion criteria defined in Articles 106 and 107 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 106(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 106(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 106 of the Financial Regulation, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance,
4. depending on the national legislation of the country in which the tenderer is established, the documents referred to in paragraphs 1, 2, and 3 shall relate to legal persons and/or natural persons including, where necessary, company directors or any person with power of representation, decision-making or control in relation to the tenderer or tenderer. This would be the case when the national legislation concerned gives juridical responsibility of the acts committed by a legal entity (moral persons) to their legal representatives. The tenderer shall provide information on the ownership or on the management, control and power of representation of the legal entity whenever necessary for the proper understanding of the evidence submitted or whenever the Agency requests it,
5. where they have doubts as to whether tenderers are in one of the situations of exclusion, the Agency may itself apply to the competent authorities referred to in paragraph 3 to obtain any information they consider necessary about that situation, and
6. the Agency may waive the obligation of a tenderer to submit the documentary evidence referred to in paragraphs 1 and 2 if such evidence

has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case, the tenderer shall declare on his honour that the documentary evidence has already been provided to the Agency in a previous procurement procedure and confirm that no changes in his situation have occurred. He shall indicate in its tender all the references necessary to allow the Agency services to check this evidence.

## **4 ANNEXES**

### **4.1 TECHNICAL DOCUMENTATION**

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

1. Information related to the Agency, [http://www.echa.europa.eu/home\\_en.asp](http://www.echa.europa.eu/home_en.asp)
2. Biocide Product Regulation, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0528-20140425&from=EN>
3. Review Programme Regulation, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2014:294:FULL&from=EN>
4. ECHA guidance under the BPR, <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>
5. Information related to approval of active substances, [http://echa.europa.eu/documents/10162/21742587/pg\\_on\\_bpr\\_1\\_approval\\_active\\_substances\\_en.pdf](http://echa.europa.eu/documents/10162/21742587/pg_on_bpr_1_approval_active_substances_en.pdf)
6. Information about the Biocidal Product Committee and its Working Groups, <http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee>

### **4.2 CONTRACTUAL DOCUMENTATION**

#### **4.2.1 Draft Service Contract**

### **4.3 PROCUREMENT DOCUMENTATION**

#### **4.3.1 Eligibility documentation**

- a) **Identification of the Tenderer (LEF)**
- b) **Model financial identification form (BAF)**
- c) **Subcontractor / Letter of Intent**
- d) **Power of Attorney**

#### **4.3.2 Exclusion criteria documentation**

#### **4.3.3 Selection criteria documentation**

- a) **Financial and Economic Capacity Overview Form**
- b) **Project reference form**
- c) **European curriculum vitae format**

#### **4.3.4 Award criteria documentation**