

STUDY REQUEST – ANNEX “Specific Terms of Reference”

1. Context/General information

The Commission is launching this contract for the evaluation of two applications for granting an exemption to be included in either Annex III or Annex IV of the RoHS Directive 2011/65/EU (RoHS 2)¹.

Directive 2002/95/EC² on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 1) restricts the use of certain hazardous substances in electrical and electronic equipment. The Commission launched the recast of RoHS 1 in 2008. RoHS 2 was adopted in June 2011 and had to be transposed by the Member States by 2 January 2013 at the latest.

RoHS 2 is regularly updated according to scientific and technical progress. The adaptation to scientific and technical progress is reflected in the lists of very specific exemptions from the substance restrictions in Annexes III and IV to RoHS 2.

The basic system of exemptions from the RoHS 1 substance restrictions remains unchanged under RoHS 2; however the rules for applications and for granting exemptions are more refined and more clear-cut. Annex III (stemming from the RoHS 1 Annex) is not reserved for specific categories, while Annex IV is exclusively for the categories "medical devices" and "monitoring and control instruments".

The use of hazardous substances and any adaptation of the above mentioned Annexes need to follow specific requirements. In particular:

- Articles 4(1) and 4(2) provide that Member States shall ensure that EEE (as referred to in Articles 2(1) and 3(1)) placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II. The maximum concentration value by weight in homogeneous materials as specified in Annex II shall be tolerated.
- Annexes III and IV to the Directive currently list a limited number of specific applications of lead, mercury, cadmium and hexavalent chromium, which are exempted from the requirements of Article 4(1).
- Adaptation to scientific and technical progress is provided for under Article 5 of the Directive. Pursuant to Article 5(1), the inclusion in or deletion from above mentioned

¹ OJ L 174, 1.7.2011.

² OJ L 37, 13.2.2003.

Annexes of materials and components of EEE shall be a measure adopted by the Commission by means of individual delegated acts (cf. Articles 20-22).

- Article 5(1)(a) provides that materials and components shall be exempted from the RoHS substance restrictions if this does not weaken the environmental and health protection of Regulation (EC) No 1907/2006 and where any of the following conditions is fulfilled:
 1. their elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to in Article 4(1) is scientifically or technically impracticable;
 2. the reliability of substitutes is not ensured;
 3. the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof;
- The decision on inclusion of materials and components of EEE in Annexes III and IV on exemptions and the duration of possible exemptions shall take into account the availability of substitutes and the socio-economic impact of substitution. Decisions on the duration of possible exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant.
- Pursuant to Article 5(2), all exemptions have expiry dates and can only be renewed after an application for renewal. For applications for renewal the same criteria apply as for those for new exemptions.
- On the basis of these provisions, the Commission is receiving requests for (granting, renewing, but possibly also for revoking) exemptions that need to be evaluated in order to assess whether these requests fulfil the requirements of Article 5(1). Where the requirements of Article 5(1) are fulfilled, the Commission can propose a measure amending the Annexes to the RoHS Directive.
- For new exemption requests, certain rules apply. An application for granting, renewing or revoking an exemption shall be made to the Commission in accordance with Annex V. This annex specifies the mandatory content of an application.
- On 2 July 2015 the Commission received a request for an exemption for **“lead in solders used to construct and connect to Peltier thermal cyclers used for in-vitro diagnostic analysers that use polymerase chain reaction”** (for in-vitro diagnostic medical devices, Annex IV).
- On 29 July 2015 the Commission received a request for an exemption for **“lead in bearings and bushes of professional-use non-road equipment engines”** (Annex III).

2. Subject of the request

- (1) The Commission needs clear technical and scientific evidence and an assessment of any new request for granting, renewing or revoking an exemption in light of the criteria listed in RoHS 2, taking into consideration the differing validity periods and expiry dates for the

various product categories. The number of reviewed applications under this study is **2 (-two-) exemptions in total.**

- (2) Public stakeholders' consultation should be organised in order to fulfil the first objective as described in detail in the next section.

3. Tasks to be performed, guide and details of how the tasks are to be carried out, meetings to be held

If the contractor is performing several studies to assess applications for exemptions at the same time, the evaluation of exemptions may need to be divided into parts, covering different groups of exemptions according to the directive or different expiry dates. The contractor should be prepared to structure the process of evaluation according to the priorities indicated by the Commission and deliver some of the final results before the others. The Commission and the contractor shall keep record of incoming applications throughout the contracting period.

Task 1: Assessment and evaluation of the exemption requests under RoHS 2

The consultant shall provide technical and scientific evidence and an assessment with comparative information on the costs and benefits of **above mentioned two exemptions** under RoHS 2 Annex III or IV, as indicated by the Commission.

The assessment should comply with the requirements of RoHS 2 and be in line with the Commission's mandate for an Annex review. The consultant shall discuss and agree the detailed boundaries of the assessment with the Commission services at the beginning of the project.

Building on the criteria set out in Article 5(1)(a), the consultant shall:

1. Provide a clear assessment and evaluation of whether the respective exemption is justified in line with the requirements of RoHS 2;
2. Indicate the specific application for which the exemption is requested and propose a precise and clear wording for a possible exemption;
3. Indicate why the restricted substance is currently required or used, and the quantity of the restricted substance present in the specific application;
4. Indicate if the elimination or substitution of the restricted substance via design changes or different materials and components is currently technically or scientifically possible;
5. Indicate if the elimination or substitution of the restricted substance via design changes or different materials and components is currently technically or scientifically practicable;
6. Indicate whether the reliability of substitutes is ensured;

7. Indicate if the (total) negative environmental, health and/or consumer safety impacts caused by substitution are likely to outweigh the (total) environmental, health and/or consumer safety benefits;
8. Indicate whether a possible exemption would be in line with Regulation (EC) 1907/2006 (REACH), and indicate possible problems;
9. If suitable substitutes exist, indicate why they are not used;
10. Take into account the Commission Communication on a resource-efficient Europe (COM(2011) 21);
11. Take into account the availability of substitutes;
12. Take into account the socio-economic impact of substitution;
13. As regards the duration of a possible exemption, also take into account possible adverse impacts on innovation;
14. Indicate any similar applications in which the substances (or their substitutes) are used and why they are not suitable for the application in question;
15. Indicate, if possible, what efforts have been made by the applicant for an exemption to find out if alternatives are available/what efforts are being made by the applicant to develop alternatives;
16. Indicate if alternative techniques or materials will be available by an expiry date of an exemption / any other date;
17. Work in close liaison with the Commission and with the parties which submitted the request for the exemption or other relevant evidence, relevant industrial and trade associations and non-governmental organisations;
18. Having regard to confidentiality issues, ensure, inter alia through setting up a dedicated website, that all relevant stakeholders will receive all the necessary information about launching and progress of the project and the opportunity for a timely and appropriate contribution and participation. This exercise shall be conducted following the minimum standards for consultation of interested parties set in the Commission Communication COM(2002) 704 final of 11.12.2002;
19. Consider previous assessments of the exemption requests published at http://ec.europa.eu/environment/waste/rohs_eee/studies_rohs1_en.htm.

The above list is not exhaustive.

Task 2: Stakeholder Consultation

This exercise shall be conducted following the minimum standards for consultation of interested parties set in the Commission general principles and minimum standards established and defined in Communication COM (2002) 704 final of 11.12.2002, COM(2012) 746, COM(2012) 746, SWD(2012) 422, COM(2014) 368, and SWD(2015) 111. The consultation has to include the

mandatory elements, i.e. use of standard template, data protection, announcement on Your Voice in Europe (YVIE) for public consultations linking to the consultation on the DG ENV consultation page, publication of answers/results/report on the web. Before the end of the contract, the contractor shall deliver the results of the consultation in pdf format for publishing on the Europa website.

Stakeholders' consultation should be an iterative process. At the beginning of the project, the contractor shall set up a website and keep it updated with regular reports indicating the progress of work. The contractor shall host the website. The non-confidential contributions of the stakeholders shall be posted on the CIRCA website.

Information about the launch of the evaluation of the exemption should be clearly presented to all relevant stakeholders. The list is to be assembled by the contractor, with the approval and possible modifications of the Commission; the list should also be updated with stakeholders sending spontaneous request.

A half day workshop, or if required and in consultation with the Commission, several smaller stakeholder meetings should be organised towards the end of the evaluation to inform the stakeholders and the Commission of the results, and in order to gather comments of the stakeholders on these results. The workshop shall take place in Brussels. The meeting room will be booked by the Commission. The Commission will send out the invitation to the stakeholders. The number of stakeholders to be invited will be limited to about 50 participants to be selected by the Commission in collaboration with the consultant.

The contractor shall: a) prepare the draft agenda for the workshop; b) prepare the presentation of the results of his analysis and be ready to respond to all technical questions; c) prepare the minutes and a short report with the conclusions from the workshop. The results of the workshop should be reflected in the final report.

Frequent contact with the Commission will take place during the elaboration of the study in order to provide for a smooth and effective exchange as necessary.

The contractor shall present the final report to a meeting of the specific Commission expert group for RoHS delegated acts, unless the Commission indicates differently (e.g. in case of written consultations).

The contractor does not have the authority to publish the deliverables without prior authorisation from the Commission. All matters related to this study should be treated with confidentiality.

4. Estimated expertise requirement

Expert workload corresponding to maximum [REDACTED] (including possible travel and subsistence costs).

5. Estimated timetable

➤ **Kick-off meeting:**

Within 2 weeks of the specific contract signature, the contractor shall participate in a kick-off meeting with the Commission to discuss the details of the study, in particular the criteria and requirements that need to be assessed. This meeting will be held in the Commission's offices in Brussels unless both parties agree to a telephone conference.

➤ **Reports:**

- Interim report: Shall be submitted to the Commission before the end of the third month following the signature of the specific contract. It will include preliminary considerations related to point 14 of the above-described task 1.
- Final Report: Shall be submitted to the Commission by the end of the duration of this specific contract.

➤ **Duration: 9 months (Budget: [REDACTED])**