STUDY REQUEST

Under framework contract **N° ENV.A.2/FRA/2015/0008**

Title of the Framework contract: "Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation", with reopening of competition.

Pursuant to the above-mentioned framework contract, concluded between the Commission and your company, we request an offer for the study specified below:

1. Designation of service requested	Study to assess three (3) exemption requests relating to Annex IV to Directive 2011/65/EU: request for amendment of existing exemption 31a; request for a new exemption for Bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids; and request for a new exemption for DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils
2. Requester (name and function)	Director, Kęstutis Sadauskas
3. Specific terms of reference	See annex
4. Estimated duration of the work (calendar days)	8 months
5. Maximum budget available for the services	[redacted]
6. Expected result	Final report with scientific and technical assessment of the requests as per specific terms of reference
7. Requester's address (to which the offer is to be sent)	European Commission DG Environment, Directorate B, Unit B3 F.a.o. Karolina Zázvorková BU 9 5/106 B – 1049 Brussels
8. Requester's signature (K. Sadauskas)	[redacted]
9. Date of signing request	25/10/18

Thank you in advance for responding rapidly to this request by submitting an offer in accordance with the provisions of the framework contract within 10 working days. Please also advise the Commission services with 5 working days if you do not intend to submit an offer.

Annex: Specific terms of reference

Annex: Specific study request – 'Specific terms of reference'
(under Framework contract ENV.A.2/FRA/2015/0008)

Study to assess three (3) exemption requests relating to Annex IV to Directive 2011/65/EU: request for amendment of existing exemption 31a; request for a new exemption for Bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids; and request for a new exemption for DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils

1. Context/General Information

The Commission is launching this contract for evaluation of the following exemption requests relating to Annex IV of Directive 2011/65/EU[1]:

- amendment of the exemption 31a listed in Annex IV;
- application for a new exemption in Annex IV for the use of DEHP in ion selective electrodes for point of care analysis of ionic substances in human body fluids;
- application for a new exemption in Annex IV for the use of DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils.

The RoHS 2 directive (adopted in June 2011 and to be transposed by the Member States by 2 January 2013 at the latest) restricts the use of certain hazardous substances in electrical and electronic equipment.

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

Annex III is for all RoHS electrical and electronic equipment (EEE), while Annex IV is exclusively for medical devices and monitoring and control instruments.

Any adaptation of the above mentioned Annexes allowing the limited use of hazardous substances needs 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 applications which are temporarily exempted from the requirements of Article 4(1).

[1] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), OJ L 174, 1.7.2011, p. 88.

- Adaptation of the Annexes 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 Annexes of materials and components of EEE shall be adopted by the Commission by means of individual delegated acts.

- Article 5(1)(a) provides that the Commission can adopt measures to adapt the Annexes III and IV to exempt materials and components from the RoHS substance restrictions only if this does not weaken the environmental and health protection of Regulation (EC) No 1907/2006 and if 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 RoHS 2 Annexes III and IV on exemptions and on 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 following an application for renewal. Regarding the treatment of applications for renewal the same criteria apply as 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 shall adopt a measure (delegated directive) amending the respective Annex to the RoHS 2 Directive.

- 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.

- In July 2018, the Commission received a request for the amendment of Annex IV exemption 31a: **Bis (ethylhexyl) phthalate, Dibutyl phthalate, Di-isobutyl phthalate and Benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.**

- In July 2018, the Commission received a request for a new exemption to be added to Annex IV: **Bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids.**

- In September 2018, the Commission received a request for a new exemption to be added to Annex IV: **Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils,** expiring in January 2024.

2. Subject of the study

(1) The Commission needs clear technical and scientific evidence and an assessment of any request for granting, renewing or revoking an exemption in light of the criteria listed in RoHS 2, notably the provisions cited above, taking into consideration the differing validity periods and expiry dates for the various product categories. The number of reviewed applications under this study is **3 (-three-) exemptions in total.**

(2) Stakeholder/public consultations are to be organised in order to fulfil the first objective (as described in detail below).

3. Tasks to be performed

This evaluation may need to be divided up 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 communicated by the Commission.

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

The consultant shall provide technical and scientific evidence and an assessment including comparative information on the costs and benefits of the exemption concerned under RoHS 2 Annexes, as indicated by the Commission.

The assessment shall 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 provide a clear assessment and evaluation of whether the respective exemption is justified in line with the requirements of RoHS 2, clearly specifying which criterion that allows granting the exemption is verified;

- Clearly identify the specific application for which the exemption is requested and, where applicable following the assessment, propose a precise wording for a possible exemption;

- Assess why the restricted substance is currently required or used, and the quantity of the restricted substance present/needed for that function in the specific application;

- Assess if the elimination or substitution of the restricted substance via design changes or different materials and components is currently technically or scientifically possible;

- Assess if the elimination or substitution of the restricted substance via design changes or different materials and components is currently technically or scientifically practicable;

- Assess whether the reliability of substitutes is ensured;

- Assess the availability of substitutes;

- Assess 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; life-cycle assessment on the overall impacts of the exemption shall apply, where relevant.

- If suitable substitutes exist, assess, the case given, why they are not used;

- Assess whether a possible exemption would be in line with Regulation (EC) 1907/2006 (REACH), and indicate possible problems;

- Identify any possible adverse impacts on innovation, in particular in relation to the length of a possible exemption;

- Assess any similar applications in which the substances (or their substitutes) are used and why they are not suitable for the application in question;

- Assess, if possible, what efforts have been made by the applicant for an exemption to investigate if alternatives are available/what efforts are being made by the applicant to develop alternatives;

- Assess if alternative techniques or materials will be available by a proposed expiry date of an exemption / any other date;

- Identify and assess (see below) the socio-economic impacts of substitution;

- Work in close liaison with the Commission and, in consultation with the Commission, with the applicant or other stakeholders concerned, relevant trade associations and non-governmental organisations; any other inputs received in the context of the public consultation will be equally assessed;

- 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 be given the opportunity for a timely and appropriate contribution and participation. The same information will be published online. This exercise shall be conducted following the minimum standards for consultation set in the Commission Communication COM(2002) 704 final of 11.12.2002;

- 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.

In order to assess and provide complete information also on the socio-economic impact, the contractor shall consider (separately for each request) the two following scenarios, in a time horizon corresponding to the recommended exemption duration:

1. Business as usual, where the substance substitution in the EEE is governed by market forces (by granting the exemption requested);

2. Rejection of the exemption request and consequent prohibition of the placing on the EU market for the EEE concerned;

The consultant shall assess for each scenario by also building both on own research and on documentation provided by the Commission:

1. Volume of EEE concerned placed on the EU market annually;

2. Impact on employment in the EEE concerned industry and related upstream and downstream supply chain in the EU (job losses/gains), taking into account the manufacturer's geographical distribution; list of main EU manufacturers should also be provided;

3. Additional costs (money expenditure) through substance substitution in the EEE divided into sectors (private, industry, public);

4. Generation of additional waste;

5. Reduction in amount of restricted substances placed on the EU market.

The different impacts of substitution triggered by the exemption request rejection should be expressed not only in absolute terms, but also in differential terms in comparison to the scenario where the substitution is left to the market (exemptions request accepted).

Task 2: Stakeholder Consultation

The consultant shall organise and perform a stakeholder consultation as outlined here:

The stakeholder consultation shall be conducted following the minimum standards for consultation of interested parties. The consultation has to include the mandatory elements, i.e. use of standard template, data protection, announcement 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 for publishing on the Europa website.

Stakeholder consultation shall 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 CIRCABC website by the contractor.

The contractor shall organise at least **one round of stakeholder consultations**. The list of stakeholders to consult shall be established in close cooperation with the Commission services. The consultation shall be performed also by taking advantage of the CIRCABC platform.

The contractor shall:

(1) Prepare the consultation documents, as well as any other technical documents necessary;
(2) Follow-up the consultation. In particular, manage and maintain regular contact with stakeholders and be ready to respond to all technical questions;
(3) Provide to the Commission a summary of the stakeholder contributions through the report.

Information about the launch of the evaluation of the exemption should be clearly presented to all relevant stakeholders.

Additionally, the outcomes shall be presented by the contractor to a meeting of the Member States' expert group for delegated acts, organised by the Commission in Brussels. The contractor shall: a) prepare the draft agenda for the meeting; b) prepare the presentation of the results of his analysis, a background paper if necessary; c) respond to all technical questions.

4. Guide and details of how the tasks are to be carried out

The duration of the tasks is **8** months from the date of signature of the contract.

The execution of the tasks may not start before the contract has been signed. The contractor shall start working immediately after the signature of the contract.

Frequent contacts with the Commission can take place during the elaboration of the study in order to provide for a smooth and effective exchange as necessary. The contractor shall be available for clarification requests from the Commission (by email or phone) following the publication of the study until the Commission adopts the decision on the requests concerned.

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.

5. Estimated expertise requirement

Expert workload corresponding to maximum [redacted] (including all contractor activities mentioned in this document, and possible travel and subsistence costs).

6. 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.

  - Final Report: A draft shall be submitted to the Commission by the end of the 7th month of duration of this specific contract. The study report shall then be finalised by the end of this specific contract, by taking into account the Commission comments and shall include a concise and ready-to-print executive summary (in English and French) describing the objectives of the study and its main findings. The final report shall contain all deliverables under this contract.

  All reports shall be written in clear, good quality English language and provided in electronic form, both in MS Word and in pdf format. The contractor shall use the version of MS-Office available at the Commission at the time of delivery (presently, the Commission is using MS-Office 2010). Reports shall be concise, focusing on main messages and avoiding long sentences, redundant text, and repetition. Reports shall use effective lay-out and style to enable the easy absorption of information.

- **Duration: 8 months**

- **Budget:** [redacted]