

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

Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2

1. Context/General Information

The Commission is launching this contract to support the review of the list of restricted substances in Annex II of the RoHS Directive 2011/65/EU (RoHS 2)¹ pursuant to RoHS 2 Article 6(1) (first part of the study) and to assess a new exemption request under RoHS 2 pursuant to RoHS Article 5(1) (second part of the study).

First part of the study - substance restriction

The key provisions of RoHS 2 can be found in Article 4(1): Member States shall ensure that EEE (electrical and electronic equipment) placed on the market, including cables and spare parts, does not contain the substances listed in Annex II (restricted substances) in excess of the maximum tolerated value in homogeneous materials. The restricted substances and the tolerated maximum concentration values are listed in RoHS 2 Annex II. RoHS 2 requires periodical reviews of the list of restricted substances and stipulates rules for amending the substance list.

Article 6(1) (Review and amendment of list of restricted substances in Annex II) states:

With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and amendment of the list of restricted substances in Annex II shall be considered by the Commission before 22 July 2014, and periodically thereafter on its own initiative or following the submission of a proposal by a Member State containing the information referred to in paragraph 2.

The review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006, and shall take into account, inter alia, Annexes XIV and XVII to that Regulation. The review shall use publicly available knowledge obtained from the application of such legislation.

In order to review and amend Annex II, the Commission shall take special account of whether a substance, including substances of very small size or with a very small internal or surface structure, or a group of similar substances:

- (a) could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;*
- (b) could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or*

¹ OJ L 174, 1.7.2011

transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;
(c) could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;
(d) could be replaced by substitutes or alternative technologies which have less negative impacts.

During that review, the Commission shall consult interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations.

The rationale for these provisions is explained in RoHS recital 10:

The measures provided for in this Directive should take into account existing international guidelines and recommendations and should be based on an assessment of available scientific and technical information. The measures are necessary to achieve the chosen level of protection of human health and the environment, with due respect for the precautionary principle, and having regard to the risks which the absence of measures would be likely to create in the Union. The measures should be kept under review and, if necessary, adjusted to take account of available technical and scientific information.

The annexes to this Directive should be reviewed periodically to take into account, inter alia, of Annexes XIV and XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency². In particular, the risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered as a priority. With a view to further restrictions of substances, the Commission should re-investigate the substances that were subject to previous assessments, in accordance with the new criteria set out in this Directive as part of the first review.

Article 6(2) lists the requirements for any future proposals to review and amend the substance list:

The proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II shall contain at least the following information:

- (a) precise and clear wording of the proposed restriction;*
- (b) references and scientific evidence for the restriction;*
- (c) information on the use of the substance or the group of similar substances in EEE;*
- (d) information on detrimental effects and exposure in particular during waste EEE management operations;*
- (e) information on possible substitutes and other alternatives, their availability and reliability;*

² OJ L 396, 30.12.2006, p.1.

- (f) justification for considering a Union-wide restriction as the most appropriate measure;*
- (g) socioeconomic assessment.*

Pursuant to Article 6(3), any Annex II amendment shall be adopted by means of a delegated act. The first (and to date only) delegated act adopted on this basis is Commission Delegated Directive (EU) 2015/863 of 31 March 2015, meanwhile entered into force³, thus following the 2011 RoHS recast by around four years. The preliminary studies supporting the Commission for delegated act were launched in 2013.

In line with the four-year timeframe adopted for the first additional restriction, the Commission intends now to undertake again the exercise to verify whether additional substances should be restricted. No proposals for substance restriction pursuant to Article 6 were submitted by Member States to the Commission until November 2017.

Second part of the study - exemptions

The Commission is launching this contract also for:

- the evaluation of an application for a new exemption in Annex III/IV to Directive 2011/65/EU (RoHS 2).

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).
- 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:

³ OJ L 137, 4.6.2015, p.10.

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 September 2017 the Commission received a request for a new exemption to be added to Annex III: **Cadmium in luminescent material for on-chip application on LED semiconductor chips.**

2. Subject of the study

The subject of this study is as follows:

1. First part:

- Update of the existing methodology⁴ to identify and assess substances based on the criteria in Recital 10 and Article 6(1) and 6(2). The methodology should also explain the link with methodological guidelines on exemptions, developed under the second part below.
- Detailed assessment in line with the updated methodology of the substances listed in the section 0.o, assessment of the impacts in case of their possible restriction and the related substance dossiers.
- Determination of the quantitative usage data for other substances used in EEE, or where this is not possible, of a magnitude ranking, with a view to a refined prioritisation for future restriction review cycles.

2. Second part:

⁴ http://ec.europa.eu/environment/waste/rohs_eee/review/results_en.htm

- Update of the existing methodology for the decision on exemption applications pursuant to criteria in Article 5(1), by also tacking stocks of methods applied in previous cases under RoHS 2; this guidance shall also provide elements through an LCA approach for the comparison of quantified impacts in the application of the third bullet of Article 5(1)(a), in particular for the cases where the positive environmental impacts stem from energy efficiency gains or recycled materials use.
- Assessing an exemption request for the use of cadmium in luminescent material for on-chip application on LED semiconductor chips.

Stakeholder consultations shall be organised in order to fulfil the above listed objectives.

Frequent contacts with the Commission will take place during the performance of the contract, with the possibility of updating detail of tasks in the light of interim findings and consultations.

The contractor does not have the authority to publish the deliverables without prior authorisation from the Commission. All matters related to this study shall be treated with confidentiality, including this terms of reference.

3. Tasks to be performed

Task 1: Update the existing methodology to identify and assess substances for possible restriction

The contractor shall, in close cooperation with the Commission and with stakeholders, update the methodology that details the technical and procedural provisions set out in Article 6 and the rationales of Recital 10. The methodology shall cover all necessary steps and decisions from the first identification of a potentially relevant substance to the proposal of a respective legal measure. The existing methodology was previously used when preparing the restriction of four phthalates to Annex II⁵. Following this first methodology application, a Commission expert group was created to accompany future restrictions⁶ under the RoHS directive. The group shall be used to gather expert opinion.

The updated methodology shall include transparent decision criteria for each step. These steps include:

- Coordination with interested parties;
- Identification of relevant substances for future restrictions;
- Evaluation of review proposals;
- Evaluation of additional input;
- Weighing of assessment criteria;
- Criteria for grouping of chemicals with similar properties (e.g. toxicity, physical or chemical similarities or technical use);
- Assessment of available scientific and technical information on the substances concerned;

⁵ Commission Delegated Directive (EU) 2016/585 of 12 February 2016, OJ L 137, 4.6.2015, p.10.

⁶ Commission expert group accompanying future substance reviews under Directive 2011/65/EU, <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3063>.

- Description of data quality, data gaps and uncertainties, also in relation to the application of the precautionary principle;
- Information on substitutes;
- Drafting of recommendations for legal measures.

This is only an indicative list. The contractor shall update the methodology in writing and compile a manual for future reviews. The updated methodology shall not include or imply provisions other than those listed in Article 6.

The contractor shall take into account the documents provided by the Commission and other inputs received from stakeholders to update the methodology. Two rounds of comments from the specific group and from the Commission shall be collected before delivering the updated methodology. This task can be combined with the task 4.

Task 2: Assess substances with a view to their possible future restriction

The contractor shall apply the updated methodology for the assessment of the substances/group of substances given in the table below. The listed substances were selected as potential candidates in former RoHS 2 studies⁷ and recommended for further RoHS action in other studies⁸ launched by the European Commission. In line with RoHS Article 6, the REACH status and information for the substances, including the EU Risk Assessment Report, shall be duly taken into account. In addition to this, a particular focus shall be on the waste phase of EEE cycle, as provided for in RoHS Article 6.

	Substance	Information on status in REACH and other legislation
1.	Diantimony trioxide (flame retardant)	Substance included in the Community Rolling Action Plan (CoRAP⁹), indicating as initial grounds for concern for the substance: • Carcinogenic • Exposure of workers • High (aggregated) tonnage • High risk characterisation ratio (RCR) for dermal and inhalation exposure • Other exposure/risk based concern • Wide dispersive use In CLP: Carcinogenic 2 - H351 (Suspected of causing cancer via

⁷ Former RoHS 2 studies are available at http://ec.europa.eu/environment/waste/rohs_eee/substances_en.htm and http://ec.europa.eu/environment/waste/rohs_eee/studies_rohs3_en.htm

⁸ <http://ec.europa.eu/environment/chemicals/non-toxic/pdf/NTE%20main%20report%20final.pdf>, p. 72.

⁹ https://www.echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=1&p_p_col_count=2&disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

		inhalation)
2.	Tetrabromobisphenol A (TBBP-A, flame retardant) (2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol)	Not in REACH, but substance included in the Community Rolling Action Plan (CoRAP), indicating as initial grounds for concern for the substance: • Suspected Reprotoxic • Potential endocrine disruptor • Suspected PBT/vPvB • Consumer use • Exposure of environment • Exposure of workers • High (aggregated) tonnage • Wide dispersive use In CLP: Aquatic Acute 1 - H400, Aquatic Chronic 1 - H410
3.	Indium phosphide	Carcinogen 1B - entry 28 of annex XVII
4.	Medium chain chlorinated paraffins (MCCPs) - Alkanes, C14-17, chloro	Not in REACH, but substance in the Community Rolling Action Plan, indicating as initial grounds for concern for the substance: • Suspected PBT/vPvB • High (aggregated) tonnage • Wide dispersive use
5.	Beryllium and its compounds	In REACH as carcinogen 1B - entry 28 of annex XVII See also EEA publications ¹⁰
6.	Nickel sulphate and nickel sulfamate	In REACH as Carcinogen 1A - entry 28 of annex XVII
7.	Cobalt dichloride and cobalt sulphate	In REACH as Carcinogen 1B - entry 28 of annex XVII

The grouping of substances (e.g. for cobalt or nickel compounds or for MCCPs) shall be possible by following the approach determined in the updated methodology, once agreed.

Key data to be collected and analysed refer to substance classifications, usage, emissions, exposure, impacts and costs. This list is not exhaustive. Further input could be provided by the Commission during the assessment, including if substance restriction dossiers would have been submitted in the meantime by Member States in line with RoHS Article 6.

The study shall also look into possible timelines and scenarios for a restriction, i.e. try to identify sectors and products where this substance is most relevant, and suggest a realistic compliance date.

The assessment shall be based on the available scientific and technical information with due respect for the precautionary principle in line with the RoHS criteria. Clear explanations on the application of the precautionary principle shall be given.

¹⁰ EEA report n. 1/ 2013, Late lessons from early warnings: science, precaution, innovation, p. 131-144
EEA Report n. 6/2017, Circular by design, p. 16

The result of the overall assessment shall be a clear recommendation for each substance for or against a future restriction measure that is necessary to achieve the chosen level of protection of human health and the environment.

The recommendation for a future substance restriction measure shall be accompanied by a dossier similar to the available dossiers for previous cases¹¹ and complemented with the additional information required by the updated methodology.

In case of a future restriction recommendation, this shall include also a wording proposal (scope, category applicability, potential sector exclusions) to be included in RoHS Annex II and an implementation timetable, if appropriate.

Task 3: Determination of the quantitative usage data for substances used in EEE

An updated substance inventory and a substance priority list shall be provided on the basis of the updated methodology. The consultants shall quantify the usage of further substances of potential concern used in EEE, or where this is not possible, produce a magnitude ranking, with a view to a refined prioritisation for future review cycles. On the basis of the updated methodology and of updated substance inventory, the consultant shall identify the substances to consider for future restriction with different level of priority.

Evidence to recommend that further substances should be subject to an assessment (e.g. if high amount of substance is used and the RoHS criteria are verified for the substance) shall not hamper the completion of this mandate, but could rather suggest a follow up activity by the Commission (outside the scope of this study).

Task 4: Exemption methodology

Methodology derived from the criteria and updating applied methods in existing cases under RoHS 2.

The contractor shall, in close cooperation with the Commission and with stakeholders, update the methodology that details the technical and procedural provisions set out in Article 5. The methodology shall cover all necessary steps and decisions from the verification of an exemption request to the proposal of a respective legal measure. The existing methodology was previously used¹² when preparing several additional measures¹³ to add to Annexes III or IV.

In particular, the guidance shall produce evidence of the method to use for the 3rd criterion in Article 5(1)(a), also in relation to the application of a Life Cycle Assessment, which should be used at least for the cases where the requested exemption is supposed to have positive impacts in terms of energy efficiency or recycled material use. In this respect, the latter policy output¹⁴ from the Commission should be considered.

¹¹ See note 7

¹² Studies for the assessment of submitted exemptions requests are available at:
http://ec.europa.eu/environment/waste/rohs_eee/studies_rohs1_en.htm

¹³ Additional measures have been adopted through delegated acts available at:
http://ec.europa.eu/environment/waste/rohs_eee/legis_en.htm

¹⁴ For example horizontal policy documents stemming from:

Task 5: Exemption assessment

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, on the basis of the agreed updated methodology.

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;
- As regards the length of a possible exemption, also take into account possible adverse impacts on innovation;
- Assess any similar applications in which the substances (or their substitutes) are used and why they are not suitable for the application in question;

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- Analysis of the interface between chemicals, products and waste legislation and identification of policy options http://ec.europa.eu/smart-regulation/roadmaps/docs/plan_2016_116_cpw_en.pdf
 - Documents in relation to energy efficiency in products

- 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;
- 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, if any;
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 6 (horizontal task): accompanying stakeholder consultation

The contractor shall complete tasks 1, 2 and 3 in close cooperation and consultation with stakeholders, which is an essential step of the methodology. 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 CIRCA website.

The contractor shall organise at least **three rounds 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.

The contractor shall publish the non-confidential contributions on the RoHS-specific Circabc pages.

In addition, the contractor shall organise **three 1-day stakeholder meetings** to inform the stakeholders and the Commission of the results, and in order to gather comments of the stakeholders on these results. The meetings shall take place in Brussels. The meeting room will be booked by the Commission. 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. Participation costs shall be covered by the participants.

Additionally both the methodological updates and the restriction and exemption outcomes shall be presented by the contractor to a meeting of the group for delegated acts; the related feedback shall be used to further shape and apply the methodology.

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; d) prepare the minutes and a short report with the conclusions from the meeting. The results of the meeting shall be reflected in the final report.

4. Deliverables

In addition to the stakeholder/expert meetings and a kick-off meeting, the contractor offer shall include the participation to three meetings with the Commission services in Brussels. Next to this, contact will be kept via e-mail and telephone.

The contractor shall take up immediately after the signature of the 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.

Details of the work plan, as presented in the offer, shall be finalised in agreement with the Commission within one month from the date of signature of the contract. This can be done in a kick-off meeting, via e-mail or via telephone (to be decided in collaboration with the Commission).

The contractor shall be ready to undertake work in parts, starting with task 1 immediately after the signature of the contract. The following deliverables are expected:

First interim report: Three months after signature of the contract. This report shall include the setup of the project and preliminary analysis indicating the project way forward.

Second interim report: Eight months after signature of the contract. This report shall include the draft updated methodology manual (task 1).

Third interim report (containing draft Task 2): Twelve months after signature of the contract.

Draft final report (containing draft Task 2 and 3): Sixteen months after signature of the contract. The Commission services will send observations in two weeks and the contractor shall then respond/integrate them in the report.

The **final report** shall take fully into account the comments and suggestions made by the Commission, 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.

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. Timetable

➤ **Kick-off meeting:**

Within 1 month 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 and meetings** (periods following the signature of the contract):

- First interim report: Three months;
- Second interim report: Eight months;
- Stakeholder meeting on methodological updates: during the ninth month;
- Third interim report: Twelve months;
- Draft final report: Sixteen months;
- Stakeholder meeting on the outcome on substances: during the seventeenth month;
- The final report shall be finalised by the end of the contract.

➤ **Duration: 18 months**

➤ **Budget:** [REDACTED]