European Commission (Directorate-General for Environment, Directorate B; and Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate C)

Att: Mr Kestutis SADAUSKAS, and Ms Fulvia Raffaelli

Cc: Mrs Sarah Nelen, Mrs Bettina Lorz, Mrs Karolina Zazvorkova, Mr Michal Kubicki, Mr Anestis Filopoulos, and Mr Davide Polverini

Oeko-Institut

Att: Mr Carl-Otto Gensch, Ms Yifaat Baron, Mr Otmar Deubzer, Ms Katja Moch, and Mr Christian Clemm

21 December 2018

Subject: Stakeholder consultations on i) the draft manual methodology for identification and assessment of substances for inclusion in the list of restricted substances (Annex II) under the RoHS 2 Directive and ii) the Guidance on the updating of the RoHS inventory.

Dear authorities and experts involved in the above-mentioned consultations,

We write you on behalf of several industry associations representing companies involved in different stages of the electronic and electrical equipment (EEE) supply chain, including producers and importers of substances, spare parts, EEE, etc. and recycling.

The aforementioned associations and their members are committed to the protection of the environment through the implementation and enforcement of the RoHS Directive, and willing to submit their highest priority concerns on the first draft manual methodology and RoHS substance inventory published for consultation until 21 December 2018.

It is our view that the current draft methodology still requires quite some elaboration and refinement to deliver the structured stepwise approach needed to identify and assess substances to be restricted under RoHS. Furthermore, the inventory should be compiled as a result of an approved methodology, and not in parallel to its development.

We are particularly worried that the draft methodology as it stands, fails to meet the better regulation objective that EU laws, policies and funding program deliver the expected results at minimum cost. "*For the Commission this means delivering [its] ambitious policies in the simplest, least costly way, and avoiding unnecessary red tape.*[1]" Unless it undergoes a significant update, the current methodology will result in a disproportionate and inefficient use of Commission, Member State, and Industry resources, with no measurable added-value for the environment or human health. Furthermore, these adverse consequences could multiply beyond EU borders, where the EU RoHS Directive is often used as an example for local legislation.

[1] EU Commission. 2017. Better regulation: why and how. Available on: https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en.

For more clarity, we have provided our comments in two parts: (i) on the methodology, and (ii) on the inventory. Under (i), a set of comments have been divided into aspects related to: 1) objectives of the study, 2) level of detail provided in the draft methodology, and 3) omissions in the current methodology. These will be found in the Annex to this letter.

In light of the number and importance of the concerns shared in this letter, we believe that a second draft methodology should be produced, duly reflecting all comments raised above. We look forward to provide comments on such a refined and more mature methodology, via the relevant stakeholder consultation.

We remain available for any questions or comments you may have.

Sincerely,

- *Roger Coelho*, Policy Director, American Chamber of Commerce to the EU (AmCham EU)
- *Paolo Falcioni*, Director General, Home Appliance Europe (APPLiA)
- *Kevin Bradley*, Secretary General, International Bromine Council (BSEF)
- *Maggie Saykali*, Director Plastics Additives & Resins, European Chemical Industry Council (Cefic)
- *Brigitte Amoruso*, Advocacy and Public Relations Manager, Cobalt Institute
- *Nicole Denjoy*, Secretary General, European Coordination Committee of the Radiological, Electromedical and Healthcare Industry (COCIR)
- *Xavier Ibled*, President, European Domestic Glass (EDG)
- *Norbert Zonneveld*, Secretary-General, European Electronics Recyclers Association (EERA)
- *Cornelius Eich*, Secretary-General, European Power Tool Association (EPTA)
- *Thomas Hunlich*, President, European Special Glass Association (ESGA)
- *Geoffroy Tillieux*, Director of the Technical Department, European Plastics Converters (EuPC)
- *Violaine Verougstraete*, EHS Director, Non-Ferrous Metals Association (Eurometaux)
- *Caroline Braibant*, Secretary general, International Antimony Association (i2a)
- *Ourania Georgoutsakou*, Secretary-General, LightingEurope
- *Mark Mistry*, Senior Manager Public Policy, Nickel Institute
- *Leonor Garcia*, Director Public Affairs, PlasticsEurope
- *Emir Demircan*, Senior Manager Advocacy and Public Policy, global industry association representing the electronics manufacturing supply chain (SEMI)
- *Meglena Mihova*, Test & Measurement Coalition
- *Malte Becker*, RoHS Technical Expert

Annex – Comments on the RoHS draft manual methodology and inventory

i) On the draft manual methodology for identification and assessment of substances for inclusion in the list of restricted substances (Annex II) under the RoHS 2 Directive

First, the draft methodology fails to implement all requirements and recommendations laid down in the '**Specific terms of reference**' of the study, and the minutes of the 27 March 2018 Meeting of the Commission Expert Group:

1. **The RoHS restriction methodology should provide an adequate level of detail.** In line with the CARACAL document '**REACH and Directive 2011/65/EU (RoHS) – A Common Understanding**', there is a good general reference to REACH and ECHA Guidance documents and databases. However, no equivalent level of detail is provided in the draft RoHS methodology compared to what is provided e.g. in an ECHA Guidance on restrictions, particularly section 5. Preparation of an Annex XV Restrictions Dossier, when there are multiple elements of great similarity between the two processes.

    - We request that the next draft methodology under RoHS provides the same level of systematic and rigorous description of the steps and evidence required for a robust assessment that can be found in Section 5 of the ECHA for the preparation of an Annex XV dossier for restrictions (cf. https://echa.europa.eu/documents/10162/23036412/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6).

2. **The RoHS restriction methodology should reflect the content of documents produced by Commission Expert Group.** As instructed in the '**Specific terms of reference**' for the study, "*The contractor shall take into account the documents provided by the Commission and other inputs received from stakeholders to update the methodology.*" At the 27 March Meeting of the Commission Expert Group, "*some experts from the side of the industry organisations asked that the documents drawn up by the expert group in 2015 be taken into account for the further work of the group.*" However, the draft methodology clearly fails to consider these documents, except for the document on grouping, which has been added as an Annex to the draft methodology. The methodology should actually refrain from including any specific examples, interpretations or translations on grouping. Grouping remains to be applied in a very case-by-case basis, and follow the considerations outlined in the Expert Group document when it is applied. As pointed out by German Competent Authorities in their letter to the Commission[2], grouping under RoHS will not necessarily be more efficient, and it should not become the default approach for determining RoHS restrictions.

    - We request that the next draft methodology takes into account all documents drawn up by the expert group, in accordance with their purpose and content.

    - We request that the references made to grouping of substances in the next draft methodology are removed, and that a reference is made to the Annex instead.

[2] Letter by BMU to DG ENV dated 24 November 2014, titled "Working Group on RoHS2 substance restrictions – Grouping of substances".

3. **A RoHS restriction assessment should use quality data.** Related to the point 2 above, available data must be checked for relevance and reliability before it is used in the assessment. Various sources mentioned in the draft methodology contain irrelevant and non-reliable information on substances. When a substance is claimed to be hazardous, it is important to ensure that the underlying evidence used in the assessment meets the minimum relevance and reliability (e.g. can be assigned a Klimish rank 1 or 2).
   If substances are restricted on the basis of available data, without due consideration of the quantity, quality and adequacy of this data, decision-making will be made only on the basis of approximate estimations and worst-case assumptions. This can only result in an important rise of exemption requests and repeated renewals, known to trigger significant workload and cost increases for both Industry and the EU Commission.
   - We request that the next draft methodology better reflects the content of the Commission Expert Group document on data quality and data gaps so that only data which meets specified quality criteria is used in RoHS restriction assessments.

4. **The RoHS restriction methodology should use data generated under other legislation.** As stated in recital 14 of the RoHS Directive "*This Directive should apply without prejudice to Union legislation on safety and health requirements […]*". Recital 16 further notes "*the review and amendment of the list of restricted substances in Annex II should be coherent, maximise synergies with, and reflect the complementary nature of the work carried out under other Union legislation […]*". Article 6(1) further completes with "*The review shall use publicly available knowledge obtained from the application of such legislation.*" Nothing in the current methodology refers to accessing specific workplace exposure or environmental emission release databases, although these are compiled with data collected from Industry as part of their compliance with existing workplace (e.g. Carcinogens and Mutagens and Chemical Agents Directives and their Occupational Exposure Limit values (OELs)) and environmental legislation (e.g. Industrial Emissions Directive and its Best Available Techniques Associated Emission Limit values (BAT-AELs)).

   - We request that the next draft methodology includes a reference to the existing Union and National databases for occupational and environmental emission data that should be considered in any assessment; and the identification of data gaps as well as the relevant targeted consultations or studies that would be required to generate the missing information, for the assessment to take place on the basis of sufficient evidence, both in terms of quantity and quality.

5. **The RoHS restriction methodology should foresee a specific periodicity for Annex II revisions.** Article 6(1) of RoHS indeed foresees that Annex II is reviewed periodically. At the 27 March Meeting of the Commission Expert Group, "*[some experts from the side of the industry organisations] highlighted the need for planning certainty with regard to the frequency of substance review.*" However, the methodology does not at all address this aspect of periodicity or frequency (cf. item 12 below for more details).

   - We request that the next draft methodology includes a specific reference and description of the periodicity or frequency of substance reviews.

Second, the draft methodology fails to provide the level of clarity, completeness and robustness required for the methodology to be relevant, reliable, repeatable and reproducible:

6. **The draft methodology starts from a list of all classified substances and an imprecise definition of what 'hazardous substance' means.** Would the current approach applied, virtually all substances registered in ECHA's database (more than 20,000 substances) would need to be scrutinized for possible restriction under RoHS. Manually scrutinizing such a large list of substances without a proper definition for 'hazardous substance' is practically impossible. The proposed methodology furthermore suggests expanding the scope by adding additional hazard criteria, which have not been used before in EU regulatory contexts, such as "PB" (persistent and bioaccumulative – as opposed to the accepted vPvB criterion). It also suggests adding "suspected" substances to the inventory list, which essentially means that any substance can be added without clear transparent criteria. Only after 'hazardous substance' is precisely defined (for example, on the basis of Article 3 of the CLP Regulation), can a first list of substances be extracted. Subsequently, this list of 'hazardous substances' should be refined on the basis of their actual use/presence in EEE, in order to be considered for further possible RoHS assessment.

    - We request that the next draft methodology provides a precise and workable definition of 'hazardous substance', on which to base all its subsequent steps.

7. **The draft methodology makes incorrect references to hazard, exposure/emissions and risk.** Once 'hazardous substance' has been defined more precisely, and their actual use/presence in EEE confirmed, there is a need to understand the exposure likelihood for each substance. Hazard alone does not imply risk. There is no risk without exposure/emissions. Relevant wording can be found in the ECHA Guidance on information requirements and chemical safety assessment (PART A), for example.

    - We request that the next draft methodology correctly refers to the terms hazard, exposure/emissions, and risk which apply in any risk assessment, as explained in the ECHA Guidance on information requirements and chemical safety assessment. We especially stress section A.1.2.2 on compiling and assessing available information, to section A.1.2.5 on decision making on refining the assessment (Iteration) (cf. https://echa.europa.eu/documents/10162/13643/information_requirements_part_a_en.pdf/4d25d209-00a8-4a1b-97e5-5adae231b205).

8. **The draft methodology does not provide a precise definition for 'used in EEE'.** According to Article 4(1) of RoHS, "*Member States shall ensure that EEE placed on the market […]* ***does not contain*** *the substances listed in Annex II.*" Annex III of RoHS, furthermore refers to the amount of restricted substance *contained in* a given (part of) EEE; for example: exemption 6(b) "*Lead as an alloying element in aluminium* ***containing*** *up to 0,4 % lead by weight*", or exemption 6(c) "*Copper alloy* ***containing*** *up to 4 % lead by weight*". The same applies to exemptions in Annex IV of RoHS, for example: 2. "*Lead bearings in X-ray tubes*", or 20. "*Cadmium in X-ray measurement filters*". The way in which the draft methodology applies the concept 'used in EEE' results in the inclusion of substances used in the manufacturing of EEE, which may not be present in the EEE. This is not in accordance with definition of 'placing on the market' available in the 'Blue Guide' on the implementation of EU products rules 2016 (one of the main reference documents explaining how to implement the legislation). A substance which is not present in the EEE cannot be considered as placed on the market.

- We request that the next draft methodology refers to hazardous substances correctly, in line with the legal text, contained in (i.e. present in) EEE.

9. **The draft methodology foresees an assessment of the need to restrict hazardous substances used in EEE by considering exposure and the risk occurring during improper, illegal or unpredictable use or practices.** Improper use of EEE, accidents related to EEE, or as a result of either illegal waste shipment outside of the EU or illegal WEEE management practices are outside the scope of a RoHS restriction, as indicated by Mr Janez Potocnik, European Commissioner for the Environment, in his response to a letter from the EEB in 2013. Considering these scenarios assumes that existing EU legislation is not functioning well and contradicts the legal requirement that RoHS should be coherent with other EU legislation (e.g. WEEE Directive and Waste Shipment Regulation). The insufficient or lacking enforcement of existing legislation should not and will not be remediated with a RoHS restriction. Retaining these out-of-scope scenarios in the methodology will furthermore cause virtually all hazardous substances used in EEE to be restricted, as it is impossible to address improper, illegal or unpredictable use or practices with legislation, only by enforcement.

    - We request that the next draft methodology refers to normal and foreseeable conditions of use of EEE in determining the likelihood of exposure/emissions, and the resulting risk, which includes taking into account also the realistic situation where EEE products are collected and treated separately at their end-of-life stage, and managed by specialized recyclers equipped to mitigate exposure, emissions and risks.

Third, there are parts of the restriction process which have been omitted in the draft methodology:

10. **The draft methodology is neither objective or neutral.** On various points in the text, it refers to specific chemicals to illustrate a given step of the methodology. This may infer that substances such as those used as examples, or substances similar to these, are considered to meet a given criteria, or to clear a given step in the methodology by default. Such an approach is misleading and improperly casts doubts on a number of substances.

    - We request that the next draft methodology removes all specific examples and that it eventually includes instead, in an Annex, a developed example of the application of the methodology on a substance which is already included in Annex II of RoHS.

11. **The draft methodology misses to include the active retrieval and generation of data.** The draft methodology makes several references to 'potential', 'assumed', 'presumed', 'estimated' or 'suspected' scenarios, and does not foresee the possibility of retrieving existing data or generating data when there is uncertainty which prevents a proper assessment.

    - We request that the methodology includes the requirement to proceed to active retrieval of existing data (e.g. workplace exposure data or environmental emission data collected by the relevant Industry and Member State authorities) and generation of missing/insufficient data (through targeted consultations or studies) where necessary.

12. **The draft methodology does not include a recommended time interval for the various steps embedded in the methodology.** Without such a specified time intervals, proposals for restriction may be submitted at any point in time, and assessed over variable periods of time, thereby preventing an effective preparation by the Commission, Member States, Industry and other stakeholders, who are unable to generate, gather, and duly submit all the information relevant for a correct RoHS assessment to be conducted.

- We request that the next draft methodology includes a specified timeframe for the submission of proposals for RoHS restrictions, ideally the 2-year/4-year frequency agreed upon by the expert group in 2015, and a more detailed timeline for each step of the methodology, compatible with the inherent complexity of each step.

13. **The draft methodology does not describe how proposals for restriction submitted by Member States will be checked for accordance or conformity with the final methodology.** There is no objective reason for Member State proposals to by-pass the earlier steps of the methodology and to enter directly the detailed assessment phase. As a minimum, Member State proposals should be checked for accordance and conformity with all the steps of the methodology.

    - We request that the next draft methodology describes how proposals for restriction submitted by Member States will be checked for accordance or conformity with the final methodology

14. **The draft methodology does not describe who will perform the RoHS assessment, and in particular what skillsets are required to perform a robust and efficient RoHS assessment.** For example, assessing socio-economic impact evidence requires a different scientific profile than that necessary to assess the technical feasibility of substitution possibilities, or to characterize or assess a given risk. These are rarely available in a single place, and may require a consortium of experts rather than only one expert.

    - We request that the next draft methodology indicates which skillsets are required to assess each type of evidence considered in a RoHS assessment.

15. The draft methodology does not explicitly consider the need to assess the impact of a restriction on the end-of-life treatment and recycling of products containing the restricted substance. A RoHS restriction will either modify the requirements around the management of an end-of-life, and/or create a change in composition in the end-of-life materials, after substitution has taken place. This triggers considerable changes for recyclers, who need to adapt their processes and require time and investments to manage new obligations and new materials. The new composition, including the substitute for the restricted substance, may be 'incompatible' with the recycling processes and constitute an obstacle for recycling and circularity.

    - We request that the next draft methodology explicitly includes a step to address the impacts of a possible restriction on end-of-life processing.

16. **The draft methodology does not describe how the multiple types of evidence gathered and assessed will be considered to conclude on whether or not a restriction under RoHS is appropriate**. In spite of the need for a case-by-case approach, there should be a specific order and hierarchy through which evidence is assessed, and either confirms or rejects the need for a RoHS restriction. Evidence should have a relative weight in decision-making, which should be announced upfront. Contrary to the interpretation proposed by the consultants in the draft methodology, all four criteria of Article 6(1) ((a) to (d)) should be met to justify a restriction proposal.

    - We request that next draft methodology describes how any and all evidence gathered for a given substance should be considered to demonstrate whether or not a RoHS restriction is justified.

ii) On the proposed RoHS substance inventory

1. **It is unclear how the proposed RoHS substance inventory was compiled before defining 'hazardous substance' or 'used in EEE'.** It is also not clear whether the proposed RoHS substance inventory has been published to gather comments on its purpose, format and content, or whether it has been published as a call to fill it in in its current form. It is our view that the proposed inventory should be compiled following the approach described in the methodology for the identification of substances for inclusion in Annex II of RoHS, and only after, put forward for comment and/or completion.

    - We request that the next draft methodology for the identification of substances for inclusion in Annex II of RoHS covers: i) the purpose and format/template of the RoHS substance inventory, ii) how each set of information and data included in the inventory will be assessed and considered during the assessment, and iii) how the RoHS substance inventory will be refined and kept to date as new information becomes available.

2. In addition to the need for a definition of 'hazardous substance' and 'used in EEE', **the nature and purpose of the 'volume' data covered in the inventory are not clear either**. The current template requests EU production or import volumes. These do not necessarily match volumes present in EEE on the EU market, or volumes present in WEEE managed in the EU.

    - We request that only volume data which is pertinent for the RoHS assessment is collected.

3. **The main source of information on substances undergoing a RoHS restriction assessment should be REACH**, which is the primary vehicle to gather information about substances.

    - We request that the approach used to compile a RoHS inventory starts from the existing REACH lists such available in Annexes XIV and XVII.

4. **Only upon availability of a final methodology for the identification of substances for inclusion in Annex II of RoHS and the production of a first draft RoHS inventory, can there be a call for information or data on such substances and uses.**

    - We request that the call for information on the substances included in the RoHS substance inventory is issued once the purpose, format and actual use of the information or data has been described in a final methodology for the identification of substances for inclusion in Annex II of RoHS.