2nd Stakeholder Consultation – Questionnaire on the revised manual (draft) methodology to identify and assess substances for possible restriction under the RoHS Directive

JBCE would like to thank the European Commission for the opportunity to provide input 2nd Stakeholder Consultation – general comments for the revised manual (draft) methodology to identify and assess substances for possible restriction under the RoHS Directive and our response to Questionnaire on the revised manual (draft) methodology.

- ✓ Pack_15_Substance_Review_Manual_Methodology_first_Draft_20181022 http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/2nd_Consultation/Pack_15_Substance_Review_Manual_Methodology_first_Draft_20181022.pdf
- ✓ Substance_Methodology_Consultation_Questionnaire http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/2nd_Consultation/Substance_Methodology_Consultation_Questionnaire.pdf

as follows:

General comments

1. Respect for "Better Regulation" principle and documented methodology

Substance restriction under EU RoHS (2011/65/EU) must be carried out in line with Better Regulation Principle. Concretely, items below should be well considered:

- to ensure that decision-making is open and transparent
- to strengthen preparation
- to strengthen subsidiarity and proportionality,
- to make sure that RoHS is fit for its purpose,
- to increase cooperation between EU institutions
- to keep international regulatory cooperation (UN, OECD, etc.)

As a result, the following objectives should be achieved.

- Risk assessment and socio-economic impact analysis should be appropriately carried out during legislation development process.
- Avoidance of double-regulation and reduced administrative burden to the authorities and industries caused by it.
- Simple and easily-understandable legal text and requirements as much as possible in order to achieve "Doing Less More Efficiently"

- Coherence in interpretation and their operation among existing EU legislations.
- Coherence in internationally-recognised definitions and their operation.

To meet the objectives of the Better Regulation initiative, clearly-documented procedures on substance restriction is indispensable. This methodology guidance should be used by the Commission, consultants and other stakeholders as guidance of procedures to study substances under RoHS Directive.

Justification:
These issues are covered under recent EU Better Regulation initiatives:
"Better regulation: why and how"
https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en
All of aims mention above are listed in or derived from this site.

For improvement of EU legislation, European Commission President Jean-Claude Juncker officially published *"Communication – The Principles of subsidiarity and proportionality: Strengthening their role in EU policymaking"* and established the "Task Force on Subsidiarity, Proportionality" and "Doing Less More Efficiently" to make recommendations on how to better apply the principles of subsidiarity and proportionality, in 2017.
https://ec.europa.eu/info/publications/communication-principles-subsidiarity-and-proportionality-strengthening-their-role-eu-policymaking_en

Also the Commission published *"Communication – The Principles of subsidiarity and proportionality: Strengthening their role in EU policymaking*" in 3 October 2018.
https://ec.europa.eu/commission/priorities/democratic-change/better-regulation/task-force-subsidiarity-proportionality-and-doing-less-more-efficiently_en

We sincerely respect the EU's intention to aim for better regulation. All our input below respect the Better Regulation initiative above, and we believe that they would be able to contribute to achievement of the initiative . We would very appreciate it if you would well consider them with care.

2. **Alignment and coordination with other existing EU legislation, especially REACH, CLP and WEEE**

   REACH and CLP Regulations are fundamental EU chemical legislation, and ECHA, as an agency having enough expertise, evaluates substances. In order to keep coherency and predictability as EU legislation, RoHS should align and coordinate with current progress in these legislations, especially on hazards of substances, including endocrine disruptors and "nanomaterials", definition of grouping of substances and assessment procedures.

   Furthermore, illegal exportation of wastes or other non-compliance to WEEE requirements in waste management facilities should be covered by WEEE Directive or other waste legislations.

   The details are listed as below.

3. **Scope of considering prioritisation should be substances present in EEE and effects of the end-of-life stage should be prioritised.**

In the event of prioritisation, following balance should be kept as well as current methodology proposed by AUBA in 2013.

- Prioritising based on hazardous properties of substances used in EEE and possible impact during WEEE management listed in EU RoHS2 Article 6(1).
- Take into account the information during use phase as complementary information for prioritisation

Manufacturing chemicals and intermediates should be removed as they do not fit with RoHS framework. Concretely, we suggest the following.

Option 1: To revert the proposed methodology to existing AUBA's methodology, which placed higher priority on risk at WEEE treatment, *i.e.* removing the term "use", or

Option 2: All scopes under the framework of EU RoHS Directive to be replaced to "used and present in EEE".

In addition, whichever option is selected, intermediates and other chemicals used in manufacture and which are not present in EEE should be removed from the evaluation scope.

Justification:
EEE are comprised of "articles" and generally designed not to emit or release substances outside EEE, because EEE could not maintain its certain performance and lifetime if substances were released easily. Therefore, chemical substances used at manufacture of EEE (including production of raw-materials for EEE) would rarely or never have a particular direct influence.

As described in its recital 16, the RoHS Directive is coherent with and complementary to REACH. Because REACH covers the manufacture and use of substances, but not their presence in EEE waste and resulting exposure of workers in waste handling or release into the environment, Article 6 of RoHS Directive, "Review and amendment of list of restricted substances in Annex II", describes in 6(a) describes three environmental aspects to which "the Commission shall take special account in order to review and amend Annex II".

Furthermore, the hazards relating to the use of substances in the manufacturing stage are properly covered under REACH, which applies to all manufacturing uses, not just EEE. RoHS should give priority to effects relating to waste stage because REACH does not cover them. By focussing on substances in EEE, RoHS would complement REACH in an effective way, avoiding double regulation and preventing unnecessary burden both on competent authorities and industry. Regarding the relationship between REACH and RoHS, please also see *"Common understanding of REACH vs RoHS in CARACAL, CA/36/2014"* published in July 2014,
http://ec.europa.eu/DocsRoom/documents/5804/attachments/1/translations/en/renditions/native

Accordingly, prioritisation should be performed according to the hazards of a substance present in EEE and its possible effects listed in Article 6 (1) at first, as in the current AUBA Methodology, and only treat information about hazards in the manufacturing stage as complementary. This focus on potential risks not covered by REACH would be important for RoHS Directive to achieve its goals without trying to become a "second REACH".

We believe that treatment of production chemicals and intermediates should be sufficiently discussed within the scheme of REACH at first.

In addition, the draft Methodology describes that the recommendation on the threshold value would be provided as % by weight contained in the homogeneous material. Therefore, if the Methodology would like to refer to "use" in order to consider the effects in use stage, all instances of the term "use" or "used" should be replaced with "used and present in EEE".

4. Only "hazardous substances" whose evaluation is established by existing chemical legislations such should be covered by the study for prioritisations under RoHS.

"Hazardous substances" to be evaluated should be substances whose classification are determined or identified as substances of very high concerns based on CLP classification or REACH. A "hazardous substances inventory" should not be newly "created" under RoHS. Therefore, we consider that steps in the current AUBA methodology would be more reasonable. The newly-proposed Step PI-1, "create/up-date inventory of hazardous substances", is not necessary and should be deleted.

Justification:

Please also see the justification for our general Comment 2 above. In order to keep coherency and to ensure predictability as EU law, the consistency between chemical and chemical-related legislations at EU-level is very important.

When substances are merely suspected to be hazardous, their risk cannot be precisely assessed and proper socio-economic impact analysis cannot be conducted. Such uncertainty would hamper assessment more and more at later stages of the assessment. In particular, the necessity of restriction and/or thresholds should be decided after assessing both the possible risk to human health and environment and if it would be reduced in a meaningful way by the legislative proposal. If the exposure to the substance were mainly from other uses, merely restricting its presence in EEE would be counterproductive.

In cases for which evaluation criteria have not been established at EU level, such as PB (persistent, bio-accumulative but not toxic) or endocrine disruptors, assessment and judgement should be done case-by-case. This task is already being conducted under REACH, and substances regarded as having "very high concern" are listed in "Substance of very high concern (SVHC) under REACH, as the results of the assessment. Therefore, such substances should be considered only after the results of assessment by ECHA are published.

5. Evaluation of substances under RoHS must be properly carried out aligning with environmental provisions under TFEU.

The proposed draft methodology lists only information sources of risk assessment and socio-economic impact analysis and does not contain a procedure. We consider that new and unique procedure of these assessments only for RoHS Directive would not be needed and should not be made. The existing assessment guidelines created by ECHA should be used as the guidance on procedure, not merely as an "information source".

Justification:

Article 191, on making environment policy under the Treaty on the Functioning of the European Union (TFEU), describes risk assessment and socio-economic impact analysis as follows:

TITLE XX ENVIRONMENT
Article 191
3. In preparing its policy on the environment, the Union shall take account of:

- available scientific and technical data,
- environmental conditions in the various regions of the Union,
- the potential benefits and costs of action or lack of action,
- the economic and social development of the Union as a whole and the balanced development of its regions.

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT

In other words, there should be NO EU environmental legislation without conducting them properly. As ECHA has already established the assessment guidelines based on TFEU, assessment procedures for RoHS should also refer to them. Mere information gathering is not considered to be a risk assessment or socio-economic impact analysis.

Studies and decision-making on all the chemical legislations should properly conduct risk assessment of substances under consideration and consider the results, in a reasonable and consistent manner common to EU chemical legislation. Furthermore, also for the EU legislations related to chemicals other than REACH, risk should be adequately assessed, based on chemical expertise and according to ECHA assessment guidance.

For risk assessment:
Guidance for the preparation of an Annex XV dossier for restrictions
https://www.echa.europa.eu/documents/10162/23036412/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6

For Socio-economic assessment:
Guidance on Socio-Economic Analysis – Authorisation
https://www.echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e
Guidance on Socio-Economic Analysis – Restrictions
https://www.echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d

More robust risk management is achievable through assessment based on the proper risk and socio-economic impact assessment, because it allows the legislator to choose the necessary level of the measures more precisely. As the result, not only environmental benefit but also socio-economic benefit may increase, and it would be more effective in the long run. In addition, this would avoid contradictory levels of management in different chemical legislations.

We would like to call your attention to the fact that ordinal risk assessment such as under REACH covers “intended and foreseeable conditions of use (including reasonably foreseeable misuse)” as exposure scenario first. Improper use or accident scenarios are not typical exposure scenario and cannot be adequately defined. Tools to describe exposure scenario are already available, and we consider that the basic risk assessment should be appropriately conducted by utilizing existing tools.

6. **Definitions and judgement of substance grouping should be harmonised with those which are internationally recognized or established in EU.**

Definitions of substance grouping should not be defined under RoHS. Not only this issue, but definition and judgement relating to chemical substances should be harmonised with those which are internationally recognized or established in EU. More concretely, substance grouping should be judged in accordance to the procedure indicated in OECD guidance or ECHA guideline based on the OECD guidance.

- This definition and judgement of substance grouping should be clearly described at earlier section of the methodology, and all other sentences on group of substance should be deleted from each sections of current draft revised methodology.
- Appendix 6 should be replaced to the summary of the ECHA guideline.

Justification:
Implementation harmonised with existing international and EU laws is very important for sector-specific legislation such as RoHS from the viewpoint of Better Regulation. Under RoHS, a group of substances subject to assessment for potential restriction of use in EEE should be investigated in accordance with OECD GUIDANCE ON GROUPING OF CHEMICALS, SECOND EDITION (ENV/JM/MONO(2014)4). This OECD Guidance has been incorporated also in "Guidance on information requirements and chemical safety assessment" of ECHA and used in REACH. Thus, it would only lead to lack of transparency if arbitrary standards are used only for RoHS Directive though available and established standards have already existed and are used.

7. **Description on Nanomaterials should be removed or otherwise the current situation should be precisely described.**

Justification
The methodology should refer to the current definition of nanomaterials (COMMISSION RECOMMENDATION of 18 October 2011 on the definition of the nanomaterials (2011/696/EU)) until such time as this has been revised, and not try to develop a special new definition only for EEE. The current definition,

> *"a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm […]"*

refers to particles in an unbound state. Under this current definition, materials that contain particles in this size range embedded in a solid matrix or sintered together, as well as materials with nanostructured surfaces, are not nanomaterials. They also do not expose humans or the environment to nanomaterials during the use of EEE. If and when this definition is revised, the new definition should be used.

In any event, even if a material is considered as "nanomaterial", there is no reason to regard it as necessarily presenting risk and requiring to special treatment without any the risk assessment. We do not consider that nanomaterials or materials that contain them automatically present unacceptable risks. Nanomaterials should be treated depending on the properties, hazards and the risks of each substance, like other chemical substances, and therefore, information gathering under REACH framework should be carefully monitored at present and we should wait until final decision under the framework of chemical legislation such as REACH will be made.

8. **Treatment of data gaps**

This draft methodology suggests applying precautionary approach or assumption for decision making when there is lack of knowledge or uncertainty in data. However, such substances should be placed as low priority if there is a data gap and could be reassessed in the future when sufficient data is available. Treatment of data gaps was discussed at informal Small WG organised by former RoHS Policy Officer in 2015 and it is proposed to attach the result as an Appendix.

Justification is same as that for General comment 4.

9. Substances to be restricted should be identifiable.

Substances to be restricted should be clearly identifiable by using identifiers such as CAS Number. RoHS has now become de-facto standard in the world and the supply chain of EEE industry is very long. Substance restriction using unclear terms will inevitably cause confusion in the long supply chain, unnecessary workload due to the confusion and eventually increase cost, which EU consumers would have to pay.

Response to 7 consultation questions

1. Please specify additional lists of relevance for specifying substances identified or suspected of having hazardous properties. (Section 1.1., p. 24)

It is unnecessary to create a new inventory of hazardous substances only for addition of restricted substances of the RoHS Directive. Hazardous substance lists which are /will be published by international and EU specialised authorities should be referred to. See our general comment No.4 above. The items of 1.1 of the draft methodology (page 23-25) shall be updated as listed below:

- **Delete CMR category 2**

Justification:
Article 57 of the latest REACH Regulation does not include category 2 CMR substances as possible additions to Annex XIV" (so-called "SVHC"). Taking into account the scope of the RoHS Directive, which is EEE (article), expanding beyond REACH should not be required under RoHS framework.
According to the article 57(f) of the REACH, specific substances of category 2 could be substances to be included in Annex XIV under equivalent level of concern. These substances may be included in the "Substances of very high concern (SVHCs) under REACH, and they result to be included in the list Table 1-1.
ECHA can conduct risk assessment of the substances. Procedures on substance restriction should be as simple as possible in order to maintain transparency.

- **Delete PB (persistent, bio-accumulative)／High PB-score**

Justification:
Article 57 of the latest REACH Regulation does not mention this combination as the condition of inclusion to "substances to be included Annex XIV" (so-called "SVHCs"). While this list is created by Member States authorities, it has not been examined in EU (ECHA) level. Taking into account the scope of the RoHS Directive, which is EEE (article), strict standard beyond REACH should not be required under RoHS framework. According to the article 57(f) of the REACH, specific substances classified as PB could be substances to be

included in Annex XIV under equivalent level of concern. However, these substances may be included in the "Substances of very high concern (SVHCs) under REACH, and they result to be included in the list Table 1-1.

- **Delete the sentence "Considered to have endocrine disrupting properties". Otherwise, the sentence should be replaced to '"Endocrine disruptors" may be considered as the scope of the prioritization only if they are listed in the "Substance of very high concern (SVHC) under REACH"'.**

Justification:

Article 57 of the REACH Regulation does not mention endocrine disrupting property for the condition of inclusion to "substances to be included Annex XIV" (so-called "SVHCs"). There are now criteria for endocrine disruptors in plant protection products and biocides, but general EU criteria for endocrine disrupting properties have not yet been defined.

According to the article 57(f) of the REACH, specific substances of endocrine disrupting properties could be substances to be included in Annex XIV. However, these substances may be included in the "Substances of very high concern (SVHCs) under REACH under equivalent level of concern, and they result to be included in the list Table 1-1.
ECHA can conduct risk assessment of the substances. Procedures on substance restriction should be kept as simple as possible in order for transparency.

Examination under the Commission Communication on the EU Framework on endocrine disruptors (EDs)[1] will be launched. It would be better to wait for the establishment of the necessary measures in chemical substance level at this moment. As current REACH covers ED having concern, it would be reasonable to refer the SVHC list at present.

- **delete SIN List from the list of databases on substance information**

Justification:

SIN List cannot be regarded as a substance list evaluated with appropriate, transparent procedures by public authorities. ECHA has already examined it. Over 900 substances listed in SIN list were examined by ECHA in 2017 and only 7 substances were found to require assessment whether risk assessment is needed. If any hazard and risk would be found, the result will be reflected to REACH/CLP Regulations. Therefore, if these regulations are referred properly under this methodology, it is not necessary to take into account the SIN list during the substance assessment under RoHS Directive. It would be sufficiently reasonable to follow the assessment by ECHA in terms of further substance addition in the future.

2. Please specify additional lists of relevance for specifying substances used or suspected of being used in EEE. (Section 1.2., p. 27)

There is no additional list that is relevant. Candidate substances to be restricted under the RoHS Directive should not be "substances used or suspected of being used in EEE", but should be "substances used and present in EEE". See the general comment No. 3 about criteria of prioritizing substances.

[1] http://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF

3. **Please submit reference to legislation and/or to standards where thresholds are defined for the criteria mentioned, e.g. under what circumstances and measurement conditions would the volatility of a substance potentially lead to emissions from an article in which it is contained (including non-intended use such as in case of breakage)? (Section 2.2., pg. 35)**

We do not have such information. In case there is a risk of emissions as a result of an intentional use, it should be appropriate to be covered by REACH, such as a restriction for nickel.

Justification:

In most cases, EEE are articles. We consider it unnecessary to consider the case stated in this question except for intentional release from an article. As EEE is a product with a certain lifetime which is used with certain stable functions, it is designed so that the contained substances cannot be easily released.

Basically, what is to be treated as an exposure scenario under risk assessment is not in an unintentional use or an accident, but “rational and foreseeable use (including misuse). As a tool on exposure scenario is already available, firstly basic risk assessment should be thoroughly carried out using the existing tool.

In addition, since examples stated as releases caused from improper uses and accidents are the same risk as the risk at the treatment of WEEE, it is not necessary to review these accidents separately.

4. **Please indicate criteria for specifying when a potential for release is to be considered significant. (Section 2.2., pg. 35)**

It is unnecessary to consider potential release except for intentional release from an article. Please refer to No.3 of Response to consultation questions above.

5. **Evidence of elevated levels measured in the environment shall be considered significant when end-point related limit values are exceeded (i.e. DMELs, PNEC, etc.). Do you support this specification - please explain your views and provide supporting data to explain them if relevant. (Section 2.2., pg. 35)**

If an end-point were to rise near a limit value in the environment around certain waste management facilities, the following points should be evaluated first.

- Weigh each information (please also refer to the comments regarding data gap.)

- Evaluate whether the rise of end-point related limit value was caused by EEE/WEEE. Lack of this evaluation could result inappropriate measures.

- In the case the rise was caused from EEE/WEEE, evaluate whether those were due to noncompliance with existing legislations, (e.g. WEEE Directive and Waste Framework Directive). If so, the issue of noncompliance should be appropriately treated through assured operation of such legislations.

6. For the purpose of specifying an exhaustive list of socio-economic impacts to be considered, please specify categories that should be taken into consideration. (Section 3., pg. 43)

Socio-economic impact analysis is not only information gathering but should be considered as procedures for assessing and evaluating the potential benefits and costs of taking legislative action or no action. "An exhaustive list" cannot be created because all the potential items including economic (monetary) factors which can influence the issue could be the scope of consideration. This procedure is essential for transparent and rational regulation, and should be fully justified for all cases. Please also see our General Comment 5.

Guidance on Socio-Economic Analysis – Authorisation
https://www.echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e
Guidance on Socio-Economic Analysis – Restrictions
https://www.echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d

7. Further comments

Please see our General Comments above.

ABOUT JBCE

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Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, railway, textiles and glass products.

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