Japan 4EE Input to 2nd **Stakeholder Consultation – Questionnaire on the revised manual (draft) methodology to identify and assess substances for possible restriction under the RoHS Directive**

December 21, 2018

Name of the associations which make this input:

The Japanese electric and electronic (E&E) industrial associations:
- Japan Electronics and Information Technology Industries Association (JEITA);
- Japan Electrical Manufacturers´ Association (JEMA);
- Japan Business Machine and Information System Industries Association (JBMIA); and
- Communications and Information network Association of Japan (CIAJ)

With cooperation of the following Medical and Monitoring & Control Equipment Industrial Associations:
- JAIMA (The Japan Analytical Instruments Manufacturers' Association);
- JEMIMA (Japan Electric Measuring Instruments Manufacturers' Association) ;
- JFMDA (The Japan Federation of Medical Devices Associations) ;
- SEAJ (Semiconductor Equipment Association of Japan); and
- NECA (NIPPON ELECTRIC CONTROL EQUIPMENT INDUSTRIES ASSOCIATION)

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We would like to submit our input to 2nd Stakeholder Consultation:
http://rohs.exemptions.oeko.info/index.php?id=302

With this document, we would like submit 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. We also prepare three attachments as draft Appendices and a separated excel document for detailed comments.

We would very appreciate it if you would carefully consider our comments.

General comments

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

Maintenance of RoHS 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 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 above items 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 stablished 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 to EU attitude to aim better regulation. All our input below and in attached Excel format 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 hazard of substances, the way of treating endocrine disruptors and "nanomaterials", definition of grouping of substances and assessment procedures.

Furthermore, it should never shift the items such as illegal exportation of wastes or correction of non-compliance to WEEE requirements in waste management facilities, which basically WEEE Directive or other waste legislation should cover as a matter of course, to RoHS Directive.

The details are listed as below and detailed comments in attached Excel format (Japan_4EE_Input_to_2nd_SC–2_detailed_comments_21-12-2018).

3. **Evaluation of substances under RoHS must be properly carried out aligning with environmental provisions under EU Treaty.**

Proposed draft methodology lists only information source of risk assessment and socio-economic impact analysis and is lack of those procedure. We consider that new and original procedure of these assessments only for RoHS Directive would not be needed and should not be made. However, existing assessment guidelines created by ECHA should be used as the guidance on procedure, not only as "information source".

Justification:
Article 191, on making environment policy under the Treaty on the Functioning of the European Union, 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 would be NO EU environmental legislations without conducting them properly. As ECHA has already established the assessment guidelines based on TFTU, assessment procedures for RoHS should also refer to them. Mere information gathering is not considered as risk assessment nor 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 chemical-related legislations 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 effective risk management can be attained even though assessment might take time more or less, because legislator would be able to choose the necessary level of the measures more precisely if based on the duly-conducted risk and socio-economic assessment. As the result, not only environmental benefit but also socio-economic benefit may increase, and it would be effective in the long run. In addition, it can avoid the contradiction among the levels of management based on 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 using existing tools.

We submitted following comment to FITNESS CHECK for chemical and chemical-related legislation at EU-level conducted in 2016. Unfortunately, concerns described below have not be swept yet.

We have serious concern about recent situation where enhancement of restrictions based on only hazard may be imposed in the name of risk management. Excessive requirements compared its risk (such as superabundant requirements for risk management on a substance with less risk because of the usage, non-manageable thresholds and/or sub-division of exempted applications) may hamper the innovation of EU industry. Especially, risk management measures on substances contained in articles tend to be set excessive restrictions because of lack or scarcity of information, and such requirements are often very far apart from the actual risk.

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

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

- Prioritizing 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 prioritization

Manufacturing chemicals and intermediates should be removed as they don't fit with RoHS framework. Concretely, following would be suggested.

Option 1: To revert proposed methodology to existing AUBA's methodology which has higher priority on the risk at WEEE treatment. i.e. removing "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 will be selected, manufacturing chemicals and intermediates should be removed from the evaluation scope.

Regarding another important point in 6(1), *"(d) could be replaced by substitutes or alternative technologies which have less negative impacts"*, the RoHS officer in the Commission at that time tried to make a "Guidance on substitute under RoHS" in "Small WG" in 2015 (Please see attached *"Japan_4EE_Input_to_2nd_SC–3_substitutes_21-12-2018"*). We would like to propose that the result of Small WG should be attached to the methodology as an Appendix.

Justification:
It is not forbidden considering the influence of the use stage under RoHS, but we consider it would be the secondary factor for consideration. 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". It is beyond the guidelines to treat other items as "shall" requirements.

Furthermore, the effects relating to use stage are also covered under REACH, RoHS should give priority to consider of effects relating to waste stage because REACH does not cover them, in considering more effective supplement between RoHS and REACH. Such differentiated prioritisation may reduce possible double regulations and save unnecessary burden both on competent authorities and the 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 hazardousness of substance present in EEE and its possible effects listed in Article 6 (1) at first, as current AUBA Methodology, and then, information on use stage should be treated as complementary. This would be important for RoHS Directive to show its own rules other than REACH sufficiently.

As a more basic fact, EEE is comprised of "article" in most cases and designed not to release its contents to outside of EEE, because EEE could not keep its life time with a certain performance if substances are easily released. Therefore, chemical substances used at the time of production of EEE (including production of raw-materials for EEE) would seldom or not have a certain direct influence from EEE. Besides it is not EEE manufacturers to manage

chemical substances in raw materials and the intermediates at the stage of producing materials. Moreover, many facilities producing materials of EEE are not located in the EU area. While substances in EEE imported into EU can be restricted. Intermediates, which do not remain in finished products and may occur ephemerally outside of EU, cannot be investigated by EEE manufacturers and therefore restricted in EU. In the first place, the benefits for EU by restricting intermediates at EEE production are unclear. Considering that the intermediates are exempted from the scope for registration under REACH, it would not be feasible and realistic for them to be covered under RoHS Directive on substances present in EEE.

We believe that treatment of production chemicals and intermediates should be fully 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 the term “use” should be replaced to “used and present in EEE”.

On the other hand, there are fewer mentions of 6.1(d) than those of 6.1(a), (b) and (c), and description on 6.1(d) lacks in concreteness of its procedures, as reading through the draft Methodology. We consider that concrete Methodology Guideline should be provided by adding the results of Small WG on substitutes as an Appendix.

5. 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 or REACH. New and original “hazardous substances inventory” should not be “created” under RoHS. Therefore, we consider that steps in current AUBA methodology would be more reasonable. Newly-proposed Step PI-1, “create/up-date inventory of hazardous substances”, should be deleted as before.

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 would be very important.

About substances suspected as hazardous, the risk cannot be precisely assumed, and then, proper socio-economic impact analysis cannot be conducted. Such uncertainness may hamper assessment more and more at later stage of the study. Especially, necessity of restriction and/or thresholds should be decided after assessing both possible risk to human health and environment and risk to be reduced by the legislative proposal. The real effective risk reduction could not be expected if a substance in product groups which are not main source of the risk of the substance is restricted under tight thresholds. Such management may only cost in vain.

Items for which criteria for evaluation have not been established at EU level, such as PB (persistent, bio-accumulative) or endocrine disruptors, should be assessed and judged by case-by-case basis. This task has already been conducted under REACH, and substances regarded as “having very high concern” would be 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.

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

Definition of substance grouping should not be defined under RoHS. Not only about 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 redundant mentions 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 (Please see attached *"Japan_4EE_Input_to_2nd_SC–4_group_of_substances_21-12-2018")*.

Justification:
Implementation harmonised with existing international and EU laws is very important also for sector-specific legislation as RoHS from the point-of-view 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 accurately 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 gap**

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 data gap and could be reassessed in the future when sufficient data is available. Treatment of data gap 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. (Please see attached *"Japan_4EE_Input_to_2nd_SC–5_data_gap_21-12-2018")*.

Justification is same as that for General comment 5.

9. Simple and understandable wording of recommendation

RoHS has now become de-facto standard in the world and supply chain of EEE industry is very broad. Therefore, RoHS wording should be more simplified taking into account Better Regulation principle. For example, substances to be restricted should be identifiable by using identifier such as CAS Number, and recommendation should aim to be simpler and easily-understandable. Recommendation of restricting unidentifiable substance(s) may cause confusion in the broad supply chain, unnecessary workload due to the confusion and eventually increase cost. That will result to hit the consumer of the EEE in EU.

Comments on draft EEE Substance Inventory

We consider that substances to be studied under RoHS should be screened based on Article 6(1) of RoHS Directive 2011/65/EU. Could you please review the draft inventory in referring to our comment for the draft Methodology?
In addition, longer period for stakeholders to collect information should be given appropriately at the review. It is unrealistic especially for EEE manufacturers to give comments on such enormous list of substances in less than two months, as most of them would not directly treat nor add chemical substances unlike REACH for the chemical industry though RoHS is applied directly to them.

Response to seven consultation questions

Q1. Please specify additional lists of relevance for specifying substances identified or suspected of having hazardous properties. (Section 1.1., p. 24)

A1. It is unnecessary to create any 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. See our general comment No.5 above. The items of 1.1 of the draft methodology (pages 23-25) shall be updated as listed below:

a) Delete 'category 2' of CMR substances

Justification:

The article 57(a), (b) and (c)[1] of the latest REACH Regulation does not say that substances "meeting the criteria of category 2 of CMR may be substances to be included in Annex XIV" (so-called "SVHC"). 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 under CMR category 2 may be included in Annex XIV. Such substances may be included in the "Substances of very high concern (SVHCs) under REACH", and they result to be included in the RoHS list Table 1-1.

Procedures for studying substances under RoHS should be as simple as possible in order to keep transparency. In this direction, the task of evaluation of a substance itself should be consistently conducted by ECHA. It would be very difficult for the external consultants to conduct such evaluation of substance because of limited timeline, resource and expertise.

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

Justification:
Article 57 of the latest REACH Regulation does not mention 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. According to the article 57(f) of the REACH, specific substances classified as PB may be substances to be included in Annex XIV. However, these substances may be included in the "Substances of very high concern (SVHCs) under REACH, and they result to be included in the RoHS list Table 1-1.

c) 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"). The European Commission has not set out criteria on the impact category for endocrine disrupting properties yet and labelling of the property has not been required under GHS as well..

According to the article 57(f) of the REACH, specific substances of endocrine disrupting properties might be substances to be included in Annex XIV. 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.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20180509&from=en
Article 57
The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:
(a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;
(b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;
(c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation(EC) No 1272/2008;

Procedures for studying substances under RoHS should be as simple as possible in order to keep transparency. In this direction, the task of evaluation of a substance itself should be consistently conducted by ECHA. It would be very difficult for the external consultants to conduct such evaluation of substance because of limited timeline, resource and expertise.

Examination under the Commission Communication on the EU Framework on endocrine disruptors (EDs)[2] is going to be launched. It would be better to wait for the establishing 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.

d) Delete SIN List from the list of databases on substance information

Justification:

SIN List is hard to be regarded as the substance list evaluated with appropriate procedures by public authorities while ECHA has already examined it[3]. 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.

Q2. Please specify additional lists of relevance for specifying substances used or suspected of being used in EEE. (Section 1.2., p. 27)

A2. There is no additional list to be 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 our general comment No. 4 about criteria of prioritizing substances.

In addition, following items proposed for specifying substances used or suspected of being used in EEE should be deleted or modified as follows:

a) Delete use descriptors newly-added to *"Information on substance uses as available from the registration process under REACH: substances with the use descriptors*", as current AUBA Methodology (Step P-I-a in 1.2 (pages 25-26)):
   - SU 2a (Mining, (without offshore industries)),
   - SU 9 (Manufacture of fine chemicals),
   - SU 11 (Manufacture of rubber products),
   - SU 12 (Manufacture of plastics products, including compounding and conversion), and

[2] COM(2018) 734 final : COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS (Brussels, 7.11.2018)
Towards a comprehensive European Union framework on endocrine disruptors
http://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF

[3] ECHA Press Release : *How are SIN List substances being addressed?*
Select " All issues" and then, "November 2017 Issue 4" in following URL:
https://newsletter.echa.europa.eu/home/
"Analysis of the SIN LIST" (24 Oct. 2017)
https://echa.europa.eu/documents/10162/19126370/sin-list_analysis.en.pdf/6248cac0-ffa8-5a14-ae55-93ace7ee9017

- SU 15 (Manufacture of fabricated metal products, except machinery and equipment)

Justification:
Substances used under such use descriptors listed above are not necessarily contained in EEE. In addition, even if such substances have concern, the best solution to reduce its risk would not necessarily be a restriction of the substance in EEE, as these use descriptors are not especially intended to manufacture EEE. Such substance used in manufacturing process of materials for many kinds of articles should be investigated under REACH whose scope is larger and horizontal. "Whether it will exist in the finished product" should be prioritised in RoHS studies according to Article 6(2) of RoHS Directive. Please see our general comment No.4.

b) Delete description on nanomaterial, or current status should be described precisely. (e.g. foot note in Step P I-b (P.27)) Please see our general comment No.7.

c) Delete description on substance having clear evidence that it is not present in EEE from here (first paragraph and the subsequent of Step P I-C (P27)). Such substances shall be examined and considered under the REACH Regulation but not under RoHS.

d) Delete or revise the description on substance which may be potential regrettable substitutes for others" from here (second sentence in the subsequent of Step P I-C (P.27)). Llisting substances "which may be potential regrettable substitutes for others" would not be feasible. Candidate substitute could be identified in later stage where the substance of concern is specified.

e) Delete the description on Intermediates/process (the last dot of Step P I-1c).

Justification:
Even the REACH Regulation, which targets chemical substances themselves, excludes intermediates from the scope of registration. It is not realistic that substances occurred as intermediates are taken into consideration under the RoHS Directive which restricts "substance in EEE". Such chemical issues should be discussed first under the REACH framework.

Q3. 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)

A3. 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 is an article. 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.

Q4. Please indicate criteria for specifying when a potential for release is to be considered significant. (Section 2.2., pg. 35)

A4. 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.

Q5. 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)

A5. In case the rise of the end-point related to limit value in the environment around certain waste management facilities was found, the following points should be evaluated at first.

- To weight each information (Please also refer to the comments regarding data gap.)
- To evaluate whether the rise of end-point related limit value was caused from EEE/WEEE. Lack of this evaluation could result inappropriate measures.
- In the case the rise was caused from EEE/WEEE, to evaluate whether those were due to non-compliance of existing legislations (e.g. WEEE Directive and Waste Framework Directive). If so, the issue of non-compliance should be appropriately treated through assured operation of such legislations.

It should be also mentioned that Nanomaterials and endocrine disrupter do not have endpoint of DMELs, PNECs etc. therefore, they cannot be covered with this method.

Q6. 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)

A6. 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 3.

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

However, if you like to clarify the procedures of assessment in the Methodology, following description should be inserted at the beginning of 3.13 *"Socio-economic impact analysis*", for example.

Socio economic analysis is the final step of detailed assessment of prioritized/selected substances, and should draw clear and rational conclusions for followings;

1. Is the risk posed by the substance intolerable to society?
   - PNEC/PEC ≥ 1?
   - Hazard Quotient (HQ) ≥ 1?
   - Margin of Exposure (MOE) ≤ Uncertainty Factors (UFs)?
   - For genotoxic carcinogen, estimated cancer risk > 1E-5 ?
   - Contribution ratio of EEE to human/environmental exposure ≥ 10%?

2. Is risk trade-off consideration justifies substitution?
   - Is BAT for engineering control applied to EEE management site satisfactory control the risk of the substance in EEE?
   - Is the substitute/alternate technique available and applicable?
   - Is the substitute/alternate technique functions equivalent or superior to the substance to be substituted?
   - Is the cost for the substitution/alteration is well below of the benefit of the substitution/alteration?

3. What is the priority of the substance substitution?
   - Is the risk of the substance imminent?
   - Will the regulation under RoHS be well superior to other chemical management scheme such as REACH?

When these all conclusions are justified, then the substance will be a candidate for restriction under RoHS.

We consider that the good results below are attained by considering the points mentioned above in Socio-economic impact analysis:
- to ensure transparency by showing clearly that the proposal is appropriate and can be validated in light of current science; and
- to ensure social fairness by preventing the outbreak of the new risk, such as incretion of the fire dead by substitution of flame-retardants, which put a new social burden by a substitution on somebody.

Q7. Further comments

A7. Please see our separate Excel document with detailed comments and word files for Appendices.

About Japanese electric and electronic (E&E) industrial associations:

About JEITA
The objective of the Japan Electronics and Information Technology Industries Association (JEITA) is to promote the healthy manufacturing, international trade and consumption of electronics products and components in order to contribute to the overall development of the electronics and information technology (IT) industries, and thereby further Japan's economic development and cultural prosperity.

About CIAJ
Mission of Communications and Information network Association of Japan (CIAJ). With the cooperation of member companies, CIAJ is committed to the healthy development of info-communication network industries through the promotion of info-communication technologies (ICT), and contributes to the realization of more enriched lives in Japan as well as the global community by supporting widespread and advanced uses of information in socio-economic and cultural activities.

About JBMIA
Japan Business Machine and Information System Industries Association (JBMIA) is the industry organization which aims to contribute the development of the Japanese economy and the improvement of the office environment through the comprehensive development of the Japanese business machine and information system industries and rationalization thereof.

About JEMA
The Japan Electrical Manufacturers' Association (JEMA) consists of major Japanese companies in the electrical industry including: power & industrial systems, home appliances and related industries. The products handled by JEMA cover a wide spectrum; from boilers and turbines for power generation to home electrical appliances. Membership of 291 companies, http://www.jemanet.or.jp/English/

About Medical and Monitoring & Control Equipment industrial associations:

About JAIMA
The Japan Analytical Instruments Manufacturers' Association (JAIMA) is a sole industry association of Analytical Instruments in Japan, which established under the Japanese law. Member of JAIMA are more than 200 leading companies in Japan. JAIMA is to contribute to the development of the Japanese economy and the cultural lives of citizens in Japan through efforts to improve and advance technologies related to analytical instruments and the analytical instruments industry for the purpose of the advancement of science & technology.

About JEMIMA
Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA) has been an active forum for measuring instruments manufacturers since its establishment in 1948. It has 85 companies as regular members and 29 companies & 7 organizations as supporting members. JEMIMA members contribute to a wide variety of industries by supplying products as "Mother Tools of the industry" for R&D design, and manufacturing. JEMIMA activities are becoming more and more global, since most of the issues our industry is facing are also global. By actively working on these issues, we help our members to meet the challenge and promote the development of the industry worldwide. To achieve these goals, JEMIMA take "Globalization & promotion of International activities" to be one of the focal activities.

About JFMDA

The Japan Federation of Medical Devices Associations (JFMDA) was founded in February 1984 by medical device associations consisting of manufacturers and suppliers of medical and health-care devices, equipment, instruments and materials. Since then, JFMDA has been addressing various national and international issues related to all its member associations. By taking appropriate actions on these issues, and through the support of innovation and sustainable supply of medical devices and technologies to the world, JFMDA has contributed to the growth of the industries it represents and to the improvement of welfare and health care in Japan. JFMDA became a legal entity as of January 6th, 2014.

About SEAJ

Semiconductor Equipment Association of Japan (SEAJ), founded in March 1985, promoted by the major semiconductor equipment manufacturers, is a nationwide organization of semiconductor manufacturing equipment, flat panel display (FPD) manufacturing equipment and equipment manufacturers that applied their technology and related equipment manufacturers.
SEAJ had existed as an incorporated association from July in 1995. From April 1st in 2012, SEAJ has been authorized by Cabinet Office as a General Incorporated Association that related to the reform of the public-interest corporations system.
The Japanese semiconductor manufacturing equipment, FPD manufacturing equipment and equipment industries that applied their technology is playing great role in supporting the world's semiconductor industry due to the manufacture of semiconductors, FPDs that lay the foundation of the advanced information oriented industries by supplying manufacturing equipment and the indispensable producer goods to the semiconductor industry to Japan and abroad.
In order to promote the development of the semiconductor manufacturing equipment industry and other related industries and to contribute to the further development such as investigative research on production and distribution, proposing and indicating the direction of semiconductor equipment technologies, investigating and studying the area of Emerging Technology, the activities of popularization and enlightenment by conducting of various seminars and lectures, planning of project and promotion of standardization.

About NECA

NIPPON ELECTRIC CONTROL EQUIPMENT INDUSTRIES ASSOCIATION (NECA) was established in 1964 and promoting the growth of the electric control equipment fields such as Relays, Switches, Sensors, PLC/FA System Equipment and others, Safety Control Equipment.
NECA has 35 companies as regular members and 43 companies as support members, and shipping amount of relevant products were 738.6billion Yen in FY2017. Our website provides further information on our recent news and activities:
https://www.neca.or.jp/en