Japan 4EE Input to 2nd Stakeholder Consultation – Attachment 3 as draft Appendix on substitute

Regarding an 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. We would like to propose that the result of Small WG should be attached to the methodology as an Appendix.

***

Guidance on substitute under RoHS

June 2015

Q 1 – What is a substitute?

A substitute can be an alternative substance for which there is evidence showing that it is suitable to replace the substance being considered for restriction in the specific EEE application. EU RoHS 2 also acknowledges the use of alternative technologies as a way to eliminate the use of a substance, i.e. elimination by design. The current guidance focuses on substitute substances, but certain elements, especially regarding reliability, availability and socio-economic impact, can be adapted to apply to the evaluation of alternative technologies.

Possible sources of information for identifying substitutes include:

- Documentation from REACH processes;
- Published scientific literature;
- Advertising and technical datasheets from manufacturers of substitutes and material suppliers;
- Stakeholder consultation.

Substances have multiple uses in EEE and it is common that one substance will require different alternative substances or technologies for substitution in different applications. When evaluating substitutes, it is therefore important to review these per application the substance is used in.

When identifying possible substitutes, the following cases are possible and should be clearly highlighted by the evaluator:

- Substitutes exist and are proven suitable and are therefore already used in a wide range of EEE applications;
- Substitutes exist and are proven suitable in some EEE applications, but suitability for further EEE applications remains uncertain;
- Substitutes exist and are proven suitable in applications different from EEE applications, but it remains uncertain if they can become suitable substitutes also in EEE applications;
- No substitutes exist; an estimate for the foreseeable future is given in this case.

To ensure coherence with REACH and other legislation, alternative substances that are being considered for restriction or are already restricted for relevant EEE application by REACH or other legislation should not be considered a substitute for RoHS purposes. Alternative substances that are category 1A and 1B

CMRs, PBTs, vPvBs, endocrine disruptors or radioactive could be considered as a suitable substitute for RoHS purposes only when they cause less negative impacts on the environment and health over the product´s entire life cycle.

Q 2 – Which are the process steps for evaluating substitutes in the context of a RoHS substance restriction review?
When evaluating substitute substances, the following process steps are addressed:

1. Identify possible substitute substances per EEE application, at least for the main EEE applications in which the substance under evaluation for restriction is used;
2. Evaluate the reliability of each substitute per EEE application;
3. Evaluate the impact of the proposed substitute to the environment and human safety across the entire life-cycle relevant to each EEE application;
4. Compare the impact of the proposed substitutes to the impact of the original substance under evaluation for restriction;
5. Evaluate the availability of the proposed substitutes – quantities available today and in the future;
6. Evaluate the socio-economic impact of the proposed substitute in each application.

A checklist of the above process steps with indications on where the needed information can be found is contained in Annex I hereto.

Q 3 – How is reliability of substitutes determined?
RoHS Article 3 (26) defines 'reliability' as "*the probability that an EEE using a substitute will perform a required function without failure under stated conditions for a stated period of time.*"

Information on reliability for a given application/use should ideally be collected from one or more investigations that have established sufficient short and long-term reliability of the proposed substitute within the EEE applications concerned. For some products where regulatory certification is mandatory, such certification can be an indication of the reliability and safety of the substitute substance in the given application/use. Examples of regulatory certification include the Medical Devices Directive, the Toy Safety Directive etc.

In general the findings of the reliability assessment will likely result in one of the following conclusions:

- Substitutes tested and proven reliable and therefore already used in a wide range of EEE applications;
- Substitutes tested and proven reliable in some EEE applications, but reliability in further EEE applications remains to be tested;
- Substitute tested and proven reliable in applications different from EEE applications, but testing is needed to determine if they are reliable in EEE applications;
- No substitutes have been proven to be sufficiently reliable (i.e. lifetime is shorter than with the original substance, some unexpected failures occur soon after placing on the market or reliability testing has not yet been carried out so reliability is not known).

The types and timescales of the tests that need to be carried out depend on the type of EEE application. This tends to be shorter for some simpler consumer products, whose failure is not likely to pose a safety risk, to many years for safety-critical equipment where injury, loss of life or environmental harm could occur if unexpected premature failure were to occur. These issues need therefore to be taken into account when determining the transition period for any new restriction.

Q 4 – How is impact on the environment and human health evaluated?
The method to determine if possible substitutes have a less negative impact is to carry out a risk assessment for each substitutes using the UBA methodology and considering the whole life cycle, as negative impacts of some substitutes will occur during mining, extraction, manufacture, use or end-of-life phase. Evaluators compare the substitute with the substance proposed for restriction as follows:

- Identify hazardous properties of the substitutes from harmonised classification or, failing that, self-classification (available for many substances in ECHA classification and labelling database);
- Evaluate exposure of the substitute in the life cycle stages where the substance considered for restriction has identified risks;
- Evaluate other potential impacts of the substitute throughout the different life cycle stages;
- Compare impact of substitute with impact of substance considered for restriction.

The UBA methodology considers the minimum quantity known to cause harm (e.g. NOAEL values) and the level of exposure to determine if a risk exists. Data on exposure levels can be gathered from industry reporting, where available. Where no data is available, the following options may be available:

- comparative assessments may be possible, for example, if a substitute has the same hazard classification and the NOAEL values are known, then if the substitute is more volatile, inhalation exposure levels from air would be expected to be higher;
- read across methods- follow guidance published by ECHA[1] but note that these techniques have limitations and it will not always be possible to estimate properties of substitutes;
- where substitutes are very different materials in terms of chemical structure and hazard characteristics, a qualitative expert judgement may be required and should be clearly documented.

Some substitutes for inorganic material for example may cause very large environmental and health impacts if their production processes require significantly more energy consumption. For example, if a small decrease in the use of a hazardous inorganic substance causes the emission of large amounts of toxic metals and GHGs due to fossil fuel combustion for energy generation, then the substitutes could have overall a more negative impact than the substance they replace. Nevertheless, these emissions are continuously reduced over time as a combined consequence of both technological and legislative evolution.

Q 5 - How is availability evaluated?
Article 3 (25) RoHS defines 'availability' as "the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II".

Possible information sources include:

- Volumes in REACH registrations
- Number of manufacturers on the EU and world market
- Number of importers
- Information from industry associations
- Reports on market analysis

[1] http://echa.europa.eu/documents/10162/13655/pg_report_readacross_en.pdf

- Sector specific magazines
- Internet market places
- Global capacity data from trade associations and market research reports
- Stakeholder consultation
- For inorganics, HHI (Herfindahl-Hirschman Index) values

In the assessment of the substitute availability, one or a combination of the following considerations may be of relevance:

- only one or very few suppliers
- the only substitute is patented
- the excess capacity relative to current usage is smaller than the requirement of a substitute: should then consider the time needed to increase availability to sufficient quantities
- substance is classified as 'critical raw material'
- limitations on substance quantities due to other regulations e.g. transport regulations, conflict minerals.

Q 6 - How is the socio-economic impact of the proposed substitute evaluated?
The socio-economic impact of substitution should outline both the potential benefits and the costs of substitution, measured in terms of:

- Impact on EU jobs
- Impact on EU industry's competitiveness, including in terms of access to advanced technology; specific impacts on EU SMEs are also assessed
- Impact on EU consumers and society also regarding access to affordable quality EEE.

The guidance on socio-economic assessments for restrictions that is published by the European Chemicals Agency (ECHA)[2] shall be used.

When measuring the economic cost for manufacturers, the material cost increase for a single substitution is a first cost. Other important costs will be linked to new production equipment, research and development into new designs/materials and assessment of their reliability, obtaining global approvals for new designs etc. This can significantly impact companies, including SMEs, because they have limited resources to adapt or the ability to control their global supply chains and remain competitive in the market.

Q 7 - How does the evaluation of substitutes feed into the review of the substance considered for restriction?

Information on substitutes is taken into account when:

- deciding whether or not to restrict a substance;
- determining the timescale for introducing the restriction in the targeted categories or uses/applications.

Deciding on the restriction of hazardous substances under RoHS is a complex process where multiple aspects are considered as explained in the directive, in the UBA methodology and detailed in this document. In general, the restriction for hazardous substances that fall under the conditions of article 6,

[2] http://echa.europa.eu/documents/10162/13641/sea_restrictions_en.pdf

is more appropriate when suitable substitutes exist or are likely to become available in a given timescale for a sufficient amount of EEE applications, such that, at the same time, the restriction achieves the RoHS aim to protect human health and the environment, while the subsequent expected amount and scope of exemptions is limited to specific cases, thus not neutralising the effects of the restriction itself.

Q 8 - How does the evaluation of substitutes feed into the decision on restriction transition periods?

The estimate of transition periods before substance restrictions enforcement take into account several factors: the time required to address considerations highlighted in the substitute assessment including the time necessary to: ensure sufficient current and future substitute availability, demonstrate safety and reliability, modify EEE production equipment and substance supply infrastructure to accommodate new physical and physio-chemical characteristics of the substitute, complete regulatory and commercial approvals for the modified EEE, assess risk to workers, consumers and the environment etc. These factors may vary depending on the EEE category concerned. Thus, restriction of a given substance could result in different transition times.

When estimating the transition period for a substance restriction in a certain category, it is important to consider that the time required to replace the substance for a given manufacturer may depend on many variables, for example:

- The importance of safety and reliability: extensive testing that can take several years is needed for safety critical and high reliability products such as most medical devices and accurate test equipment.
- Long lifetime products require much more extensive reliability testing than consumer products that are expected to last <5 years.
- If no substitute exists but promising research indicates that one could be developed, the timescale before it is available in sufficient quantity can be many years: to complete R&D, set up pilot scale trials, evaluation of substitute in EEE, scale up of production.
- Some sectors are required to apply for and gain approvals or certification before making changes to products. These are usually ‘niche’ products where only one version is made for the global market. Obtaining approval or certification globally can take as long as 4 years in some cases and 2 years is not uncommon, although certification for the EU is usually quicker than in some non-EU countries.
- If after extensive research and testing, no suitable substitute is found, then the manufacturer needs to be given the necessary time to apply for and have granted an exemption before the entry into force of the restriction. Past experience has shown that obtaining new exemptions can take two years or more. The higher the number of exemption requests the longer the process of obtaining an exemption is likely to become.

List of acronyms: [to be completed]

Annex I

Template for substitute evaluation

	Application [Note: Applications are not necessarily differentiated by use in different EEE, but rather by the technical function for which the substance was selected, which can typically be described as certain necessary technical performance characteristics.]						
	# 1	**# 2**	**# 3**	**…**	**…**	**…**	**# N**
Checklist Item A Provide an analysis of the human and environmental risks resulting from the use of the substance being evaluated for restriction in each application, including the analysis required by RoHS Article 6 points a, b and c. (The basis for this analysis is the UBA Methodology, Steps 1 – 4.)							
Checklist Item B Identify proposed substitutes that could achieve the desired end result (i.e. the required function) in each application. Where possible, provide results of one or more investigations demonstrating this. Possible sources to consider: ○ Advertising and technical datasheets from manufacturers of substitutes and material suppliers ○ Documentation from REACH process ○ Published scientific literature ○ Stakeholder consultation							
Checklist Item C To ensure coherence with other legislation, provide an analysis of the legislation currently relevant to the use of the proposed substitute in each application, considering market access restrictions (e.g., REACH, CLP, etc.). ○ If a substitute is considered or already restricted for relevant EEE applications by REACH or other legislation, then it should not be considered a substitute for RoHS purposes as this would not be coherent with REACH/other legislation. ○ Substances and their by-products from end of life processes that are category 1A and 1B CMRs, PBTs, vPvBs, or endocrine disruptors could be considered as being substitutes only when they cause less negative impacts on the environment and health over the product´s entire life cycle.							
Checklist Item D If available, provide results from one or more investigations that have established sufficient short and long-term reliability of the proposed substitute within the applications (e.g. for EEE end products). Possible elements to consider:							

○ industry consultation ○ available literature ○ existing regulatory certifications for products where these are required							
Checklist Item E Provide an analysis of the impact of the proposed substitute to the environment and human safety across the entire life-cycle relevant to each application. The analysis should include risks related to aquatic life, the biosphere, physio-chemical hazards, etc. Possible elements to consider: ○ Hazard properties from harmonised classification or self-classification ○ Any study performed under REACH ○ Risk assessment for each substitute: ▪ NOAEL values for substitute; ▪ Exposure levels of substitutes in life cycle stages where the proposed substance has identified risks; ▪ Read across methods, but evaluator needs to acknowledge and document limitations; ▪ energy consumption and impact (i.e. GHG emissions) of changed EEE production/transportation infrastructure to use substitute; ▪ other potential impacts of substitutes from a life cycle perspective.							
Checklist Item F Compare the impact to the environment and human health of the substance under evaluation for restriction to that of each proposed substitute. The comparison should highlight the net detriment or benefit of the proposed substitute over the substance under evaluation in protecting human health and the environment.							
Checklist Item G Determine what amounts are available now and expected in the future for the proposed substitute. Provide an analysis to determine whether these amounts are sufficient and in which time horizon. Possible elements to consider: ○ Volumes in REACH registrations ○ Number of manufacturers on the EU and world market ○ Number of importers to the EU ○ Information from industry associations ○ Reports on market analysis ○ Sector-specific magazines ○ Internet market places ○ Global capacity data from trade associations and market research reports							

○ For inorganics, HHI values							
Checklist Item H Provide an analysis of the socio-economic impacts of the proposed substitution in the main applications. Socio-economic impacts include direct and indirect impacts on EU citizens and competitiveness. Possible elements to consider: ○ Cost of substitute; ○ Cost of end product for consumers; ○ Costs of substitution to industry, including: ▪ Research and development; ▪ Design, testing and validation of product with substitute; ▪ New production materials and processes; ○ Impact on EU jobs; ○ Impact on EU's industry competitiveness; ○ Impact on EU SMEs; ○ Impact on innovation; ○ Access of EU industry to advanced technology (if substance restriction prevents advanced technology from being used in the EU, this could place EU at a significant disadvantage compared with non-EU states); ○ Guidance on socio-economic assessments for restrictions as published by the European Chemicals Agency (ECHA)[3].							
For any of the checklist items, document any assumptions made.							

[3] http://echa.europa.eu/documents/10162/13641/sea_restrictions_en.pdf