Japan 4EE Written Comments of on "FITNESS CHECK" of chemical legislation other than REACH Regulation

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JBMIA (Japan Business Machine and Information System Industries Association)
JEMA (Japan Electrical Manufacturers' Association)

We, Japanese electric and electronic (E&E) industrial associations (JEITA, CIAJ、JBMIA and JEMA), have been vigorously committed to protecting human health and the environment and to complying with chemical substance regulations set by many countries including EU. We would like to express our gratitude to the European Commission for conducting a fitness check of the most relevant chemicals legislation (excluding REACH) from the viewpoints of "better regulation", and for giving opportunity to give comments on this important issue. http://rpaltd.co.uk/chemicals_fitness_check

We sent our comments via Survey Monkey under the name of JEITA, the secretariat of 4EE European chemical regulations WG, however, we also send our written comments in case text submitted via the web-site might be hard to read.

We made our comments having, in particular, RoHS in mind. Once legislation is finalized, most of Japanese manufacturers would sincerely try to meet it with their best effort even if it is impractical or nearly unfeasible. That is why we hope proportionate and practical chemical legislation based on risk assessment.

1. About "sufficient risk assessment before proposing legislation" (relating to Question 14)

We have serious concern about recent situation where enhancement of restrictions based on only hazard may be imposed in the name of risk management. We believe that the methods of consideration of results of the risk assessment on a candidate substance for possible risk reduction measures should be rationally harmonized among all the chemical legislation based on regulatory science.
More concretely, risk of a substance should be duly assessed based on chemical expertise beforehand, according to "Guidance for the preparation of an Annex XV

dossier for restrictions"[1] and "Guidance on Socio-Economic Analysis – Restrictions"*2[2] in any consideration on the substance under any EU chemical legislations other than REACH.

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.

On the contrary, 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.

2. Relevant considerations taken into account in regulatory decision making on risk management (relating to Question 15)

To alleviate the negative socio-economic impact (such as "impacts on jobs or on the competitiveness of EU industry"), cost-benefit assessment between "actual risk to be reduced by the regulation" and "cost posed on the society including the industry by the regulation" should be duly implemented.

Socio-economic impact analysis is indispensable especially when the possible restriction of a substance may affect on complicated products manufactured in multi-tiered global supply chain. Currently, section 5.12 of "Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive" (Jan., 2014)[3] requires socio-economic impact analysis as "Step A 6)" (page 52) of the

[1] http://www.echa.europa.eu/documents/10162/13641/restriction_en.pdf

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

[3] http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex1_Manual.pdf

procedure to evaluate a candidate substance for RoHS restriction. The description of socio-economic impact analysis in the "Manual Methodology" is based on "ECHA – European Chemicals Agency (2011): Guidance on the preparation of socio-economic analysis as part of an application for authorization" ECHA-11-G-02-EN[4]. We appreciate such harmonized procedures in the EU chemical legislation, provided that socio-economic impact analysis would be duly conducted according to the guidance.

3. About elements of the overall EU legislative framework (relating to Question 16)

Our comments below are mainly on practices of RoHS Directive.

About "transparency of procedures", practices on criteria to choose a candidate substance seem to be unclear because sometimes substances have been chosen as candidates for restriction even though they are hardly used and therefore the actual risk would not be high. Especially, proposals from Member States seem to have this tendency more.

About "speed with which identified risks are addressed", we consider that the real issue is not speed but the matter about whether appropriate risk management measures would be chosen or not. If risk assessment is not well done before a proposal for restriction, the question on speed would not be worth-while. 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.

About "predictability of the outcomes", we consider it would be unpredictable if a proposal on extending an exempted application would be rejected by the European Parliament at the final stage of legislation. (For example, Exemption 39)

About "stability of the legal framework", we have serious concern about the possible double-regulation and/or inconsistency and contradiction between the levels of regulation under other chemical legislation.

[4] https://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf

About "clarity of the legal texts", possible legal text considered in recent consultation on RoHS exempted applications are very difficult even for the manufacturers to interpret, and we feel concern about possible confusion in supply-chain. Especially in consideration not by an official EU agency but by external consultants, the timeline of the contract is the first issue for the consultants, and we feel doubt that the matter about whether such complicated text may contribute to actual reduction of the risk compared with simple and clear text or not has not been properly judged. The criteria of judgement seem to lack.

We consider that "guidance documents and implementation support" are relatively well provided in the EU. However, there is no guidance on legislative procedures after choosing a candidate substance for restriction under RoHS and on procedures for application of the new exemptions for newly-restricted substances. In addition, current RoHS Directive seems to lack consideration on newly-covered scope, category 11 (whether current exemptions in Annex III would be applicable also to category 11 or not).

About "consistent implementation and enforcement across Member States", it would be problematic that some Member States sometime try to introduce stricter regulations than EU laws. It may cause confusion in the internal market and it would not be desirable.

4. About Risk assessment and characterization (relating to Question 17)

In the case of RoHS, the various evaluations concerning regulation tightening are done not by expert agencies such as ECHA; judgments are done rather only by representatives of the Commission agencies and consultants having, in many cases, poor technical chemical knowledge.

The consequence is that "risk characterisation and assessment" is not implemented up to a necessary and sufficient degree. That means, in addition, that the various comments provided in the public consultations held during the evaluation of regulations are not sufficiently reflected from an expert knowledge aspect.

- We provide two examples of the above:
  a. The first example has to do with the evaluation of exemption renewal concerning lead.
     In this case, in order to eliminate a few hundred grams of lead per year in EEE

as a whole, a large amount of money was spent for the evaluation on whether the exemption should be renewed or not. And in case the extension of the exemption is not approved, industry will need to incur into considerable costs in order to implement necessary measures, with rise in product prices becoming unavoidable. So, is there a meaning in conducting such evaluation on regulation tightening which is negative from both the risk and the socio-economic aspects?

b. The second example concerns new addition of regulated substances; it should be asserted that there is absolutely no meaning in implementing regulation on substances for which there is no information in particular on their use in EEE.

Currently, as RoHS has influence not only within the EU dominion but also in the whole world, decisions on the various evaluations for regulation tightening should be made based on fair risk assessment acceptable to stakeholders all over the world.
Herein, we have particular concern on the current situation where the European Commission entrusts risk assessment to external consultants.

The reason is that, adding to the fact that the expertise of entrusted consultants are oftentimes thought to be insufficient, the procedure itself has the risk of looking ambiguous as the consultants, even though unwilling, might be direct beneficiaries of the regulatory implementation, and even if the risk assessment criteria are appropriate, in many cases evaluations might be apparently conducted in a contradictory manner where it might seem that a conclusion outline was somewhat set from the beginning (a consultant could get further business in the future by proposing regulation.)

5. Significant cost for the industry (relating to Question 21)

The scheme of RoHS Directive itself which restricts substances at "homogeneous material" leads to high cost for substitution, application for exemptions and management in the global supply-chain. Even if a certain substance is seldom used in EEE, restriction (elimination) of it in the whole stream of supply-chain of EEE will needs huge costs.

In "Economic Impact of the European Union RoHS Directive on the Electronics Industry January 21, 2008", conducted by TECHNOLOGY FORECASTERS INC., stats that Estimated Total Industry Costs are:

Cost to electronics industry to achieve EU RoHS compliance: US$32.7 billion (B)
Cost for annual maintenance: US$3.7B

Reference: TECHNOLOGY FORECASTERS INC. (2008), Economic Impact of the European Union RoHS Directive on the Electronics Industry, January 21, 2008

Though this report is currently not available on the web, a summary can be seen at: http://www.smfederation.org.sg/Portals/0/Events/Ppt%20Slides/Report%20FINAL%20TFI-CES%202008-01-23%20JS.pdf

6. Significant cost for the authprity (relating to Question 22)

Irregular (at any time) restrictions may lead to significant cost for EU authorities. Addition of newly-restricted substances under RoHS, etc. should be considered regularly by defining the interval. If considered regularly, legislators can study a number of candidate substances at a time, and securing resources and budget would be easier, and as the result, high-level consideration may be implemented with lower cost.

Double regulation also leads to significant cost for authorities, and it should be avoided to increase cost for study and management.

7. Overlaps and inconsistencies (relating to Question 26)

< Overlaps >

ELV Directive and RoHS Directive covers different final product categories, but many of their covered applications (parts) and supply chain are common. Therefore, from the point of view of supply-chain, different directives regulate same parts and same restricted substances with overlapping. Especially, revising same exempted applications at different timeline may impose huge burden on the industry for assessing risk, etc.

Furthermore, if harmonization between overlapped regulations is lost, negative impact on supply-chain would be huge, and it makes the industry difficult to cope with it. We consider that such situation would not be desirable for not only the industry but also EU authorities. Sufficient consideration should be given on the implementation of such overlapped directives.

< Inconsistencies >

The wording for the applications exempted from ELV Directive whose scope and

supply chain are often overlapped with those of RoHS has been harmonized so far, however, we feel that the harmonization would not be fully considered in the recent review of the RoHS exemptions. Though an identical part would be at the same risk level, we have serious concern that chaos may be caused in the global supply chain if such identical part is covered at the same time both by an exemption under one Directive and by several exemptions under another Directive, only depending on its final use.

8. Incoherence between legislation which are covered by this fitness check and any other legislation (relating to Question 27)

We would like to give comments on relationship between RoHS and REACH here.

We feel serious concern about possible double-regulation by REACH and RoHS recently. For example, the resent restriction report on 4 phthalates[5] There is no exemption for EEE under RoHS, though RoHS will restrict 4 phthalate from 2019, under Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU[6]. Both requirements are slightly different, however, we believe that the restriction of EEE under RoHS would be reasonable from the point of view on the risk,.

The reasons why RoHS is not exempted from proposed restriction are, in short, as follows:

1) restriction by combination of 4 phthalates are not covered by RoHS (therefore, requirement under REACH would be tighter than RoHS) ; and
2) by restricting these substances under REACH, future possible exemptions under RoHS make impossible (!!!)

Those who made this dossier would like to restrict wire or cable without any exemption (including, those as spare parts of existing products) in spite of existing RoHS execlusion.

We have serious concern on its logic in itself. If the future proposals on substances restricted under RoHS are in line with this logic, any exclusions and exemptions might be made invalid by REACH restriction proposed later. If such non-sense is allowed, what is the raison d' être for RoHS?

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[5] http://echa.europa.eu/documents/10162/e06ddac2-5ff7-4863-83d5-2fb071a1ec13

[6] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.137.01.0010.01.ENG

According to "Common understanding of REACH vs RoHS in CARACAL, CA/36/2014" and as described in A.1 of "REACH AND DIRECTIVE 2011/65/EU (RoHS) A COMMON UNDERSTANDING"[7] published in July 2014,

> *"The simplest way to avoid duplications and/or inconsistencies for a given substance already included in RoHS is, to exclude EEE within the scope of RoHS from the scope of a proposed REACH restriction also covering EEE. This approach was adopted for Diphenylether, octabromo derivative (entry 45 of Annex XVII to REACH). It avoids the problem described in the REACH review, relating to the use of cadmium in electrical contacts (entry 23.7.) where both instruments cover the same substance and applications but slightly differently."*

We think the EU law-makers should follow this position to avoid redundant regulation and to save useless burden both on competent authorities and the industry.

9. Other comments (relating to Question 35)

Last year, EU published circular economy policy. We consider this may affect also on chemical regulations in future. Legislations both for chemical and for circular economy should be carefully considered on balancing with the other existing schemes of laws and regulations. Especially, an individual law scheme should not be planned but legislators should think about the balance of many other fields of various existing laws. For example, if the reuse of recycled parts is mandatory required under current situation where there is almost no special consideration on spare parts or recycled materials in chemical regulations, the industry would not be able to find the way of balancing both requirements, and it may hamper circulation economy.

We appreciate it if you take our comments into consideration carefully.

[7] http://ec.europa.eu/DocsRoom/documents/5804/attachments/1/translations/en/renditions/native