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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Hiroyuki Ishii
Organisation/company	Japan Electronics and Information Technology Industries Association (JEITA)
Country	Japan
Email Address	
Q2: If you have a Transparency Register ID number, please provide it below. If your organisation is not registered, you have the opportunity to register now by following this link. If your entity responds without being registered, the Commission will consider its input as that of an individual/private person and, as such, will publish it separately.	*Respondent skipped this question*
Q3: Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution. Please note that regardless of the option chosen, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.	My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication
Q4: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted
Q5: Please indicate whether you are replying to this questionnaire as:	An industry association

Q6: If a business or industry association, please indicate your field(s) of interest or activity(ies) - the letters in between brackets correspond to NACE codes [multiple choice]:	Manufacture of computer, electronic and optical products (C26) , Manufacture of electrical equipment (C27), Manufacture of machinery and equipment (C28), Manufacture of motor vehicles, trailers and semi-trailers (C29) , Manufacture of other transport equipment (C30), Manufacture of games and toys (C32.4), Manufacture of medical and dental instruments and supplies (C32.5)
Q7: For businesses, please indicate the size of your business:The definition of small and medium-sized enterprises depends on the staff headcount and either the annual turnover or the balance sheet of the company. Please consult the following website: http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm	*Respondent skipped this question*
Q8: Please indicate the level at which your organisation is active:	Global

PAGE 3: Part II – General Questions

Q9: How important is it in your view that there is chemical and chemical-related legislation* at EU-level in order to achieve the following objectives? (1 = not important; 5= very important)*This comprises the chemical-related provisions in all legislation within the scope of this fitness check. It encompasses legislation governing hazard identification and classification, as well as risk management measures, including chemical-related aspects of legislation on worker safety, transport, environmental protection, chemicals controls and supporting legislation, excluding REACH. The full list of legislation can be found here.The internal market of the European Union (EU) is a single market in which the goods, services, capital and persons can move freely across borders. One of the key objectives of chemical and chemical-related legislation is to have a single market for chemical substances and mixtures, as well as products containing chemicals.**

Protecting human health	5
Protecting the environment	5
Ensuring a well-functioning internal market**	4
Stimulating competitiveness and innovation	4

Q10: Do you think the EU chemical and chemical-related legislation has been effective in achieving the following objectives? (1= not effective, 5= very effective). Please only consider chemical-related provisions in the legislation.

Protecting human health	3
Protecting the environment	3
Ensuring a well-functioning internal market	2
Stimulating competitiveness and innovation	1

Q11: If you think the EU chemical and chemical-related legislation is not effective (1) or only somewhat (2,3) effective, please indicate what you believe are the main reasons for this limited effectiveness in the following table:

Protecting human health	No opinion or not applicable
Protecting the environment	No opinion or not applicable
Ensuring a well-functioning internal market	No opinion or not applicable
Stimulating competitiveness and innovation	No opinion or not applicable

Q12: To what extent do you consider that EU chemical and chemical-related legislation has had an added value above what could have been achieved through action at a national level? (1= no value, 5= a very high added value)

EU-level legislation adds value to national level action	1

PAGE 4: Part III - Specific Questions

Q13: For businesses and industry associations - Please select the legislation that regulates or otherwise affects your sector's or your company's activities.For other stakeholders - Please select the legislation you are familiar with.

Classification, labelling and packaging (Regulation No (EC) 1272/2008)
,

Biocidal products (Regulation (EU) No 528/2012),

REACH, Annex XIII (Regulation (EC) No 1907/2006)
,

Waste framework (Directive 2008/98/EC) and List of Waste
,

Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
,

End of life vehicles (Directive 2000/53/EC),

Batteries (Directive 2006/66/EC),

Packaging and Packaging Waste (Directive 94/62/EC)
,

Persistent organic pollutants (Regulation (EC) 850/2004)
,

Safety of toys (Directive 2009/48/EC),

Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, under revision)
,

Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)
,

General Product Safety (Directive 2001/95/EC),

Other (please specify)
Waste electrical and electronic equipment (Directive 2012/19/EU)

PAGE 5: Effectiveness

Q14: In the EU legislative framework for chemicals, risk management measures are, in some cases, determined directly based on the identified hazard using generic risk considerations (e.g. widespread exposure or exposure of vulnerable groups), which justify the automatic adoption of such measures. In other cases, the risk management measures are determined by a specific risk assessment that assesses the probability of adverse health and environmental effects resulting from the specific exposure scenarios associated with the proposed use(s) of the chemical. In your view, do you think EU chemical and chemical-related legislation should, in general:

a. Be more oriented towards specific risk assessments (i.e. differentiate more between chemicals depending on their use despite the possibility of prolonged discussions and implementation delays)
,

If you answered a or b, please explain
We checked on “a”, but our intention is to choose most appropriate risk management of each substance. Depending on the characteristics and uses of a substance to be studies, option b may be more appropriate in some cases. 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 in any consideration on the substance under any EU chemical legislations other than REACH. *1 http://www.echa.europa.eu/documents/10162/13641/restriction_en.pdf *2 https://echa.europa.eu/documents/10162/13641/sea_restrictions_en.pdf 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.

Q15: In your view, apart from the hazard and/or risk of a chemical substance or mixture, are all relevant considerations taken into account in regulatory decision making on risk management (e.g. whether there will be combined effects of chemicals, whether there are certain vulnerable groups, whether there will be impacts on jobs or on the competitiveness of EU industry, etc.)? Please explain your answer.

No,

If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to.
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) *1 requires socio-economic impact analysis as “Step A 6)” (page 52) of the 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. *2. We appreciate such harmonized procedures in the EU chemical legislation, provided that socio-economic impact analysis would be duly conducted according to the guidance. *1
http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex1_Manual.pdf
*2
https://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf

Q16: In your view, to what extent are the following elements of the overall EU legislative framework for chemicals satisfactory? (1= not satisfactory, 5= very satisfactory)

Transparency of procedures	1
Speed with which hazards/risks are identified	I don't know
Speed with which identified risks are addressed	I don't know
Time to allow duty holders to adapt	4
Predictability of the outcomes	2
Stability of the legal framework	3
Clarity of the legal texts	2
Guidance documents and implementation support	3
Effective implementation and enforcement across Member States	I don't know
Consistent implementation and enforcement across Member States	1

Public awareness and outreach	I don't know
International collaboration and harmonisation	2
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	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. 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.

Q17: In your view, to what extent are the following elements of risk management satisfactory? (1= not satisfactory, 5= very satisfactory)

Hazard identification criteria	4
Risk assessment and characterisation	1
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	4
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	I don't know
Risk management measures restricting or banning the use of chemicals	I don't know
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	I don't know

If you answered 1, 2 or 3 above and would like to provide further information (in particular on specific pieces of legislation), please explain your answers.	We send our comments concerning "risk assessment and characterisation" having, in particular, RoHS in mind. 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: 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? 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.)

Q18: Safety data for chemicals is subject to quality requirements, notably Good Laboratory Practice (GLP), aimed at ensuring the reliability and reproducibility of the data. Do you consider these requirements to be appropriate?	Yes

PAGE 6: Efficiency

Q19: In your view, what are the most significant benefits generated for EU society by the EU chemical and chemical related legislation? (one or more answers possible)	Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc. , Reducing the damage to the environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollinisation, etc.
Q20: In your view, what are the most significant costs incurred by EU society due to EU chemical and chemical related legislation? (one or more answers possible)	Costs for authorities at EU level , Costs for large enterprises

Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	Risk management measures under the different legislation , Understanding and keeping up-to-date with changes in legal requirements , Training staff to ensure compliance with legal requirements , Inspections and administrative requirements , Other (please specify) 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
Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?	Yes, If you answered yes, please indicate what these are. Our comments below are mainly on practices of RoHS Directive. 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.

PAGE 7: Relevance

Q23: To what extent has the EU legislative framework for chemicals contributed to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives? (1= no contribution, 5= a large contribution)

Framework has led to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives	3

Q24: To what extent does the existing EU legislative framework sufficiently address emerging areas of concern, e.g. arising from advances in science and technology? (1= emerging areas of concern are not sufficiently addressed, 5 = emerging areas of concern are sufficiently addressed)

Novel areas of concern sufficiently addressed by framework	3

PAGE 8: Coherence

Q25: Please indicate the extent to which you agree with the following statements relating to the EU chemicals legislation framework overall

The EU chemicals legislation framework contains gaps and missing links	Disagree
The EU chemicals legislation framework has overlaps	Strongly Agree
The EU chemicals legislation framework is internally inconsistent	Strongly Agree

Q26: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between the different pieces of legislation which are under the scope of this fitness check. Please only consider aspects related to hazard identification, risk assessment and risk management of chemicals. The legislation covered by this fitness check can be found here.

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.
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.

Q27: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between legislation which are covered by this fitness check and any other legislation you consider relevant as regards the regulation and risk management of chemicals.

We feel serious concern about possible double-regulation by REACH and RoHS recently. For example, the resent restriction report on 4 phthalates
http://echa.europa.eu/documents/10162/e06ddac2-5ff7-4863-83d5-2fb071a1ec13
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.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.137.01.0010.01.ENG
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?

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” published in July 2014,
http://ec.europa.eu/DocsRoom/documents/5804/attachments/1/translations/en/renditions/native
“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.

PAGE 9: Part IV: Specific questions on the CLP Regulation

Q28: CLP communicates hazards to workers and consumers through various label elements, including danger words, pictograms, hazard statements and precautionary statements. (1= not effective; 5= very effective)

To what extent are CLP labels effective in communicating hazards to workers?	I don't know
To what extent are CLP labels effective in communicating hazards to consumers?	I don't know

Q29: Do the hazard classes in the CLP Regulation cover all relevant hazards?

Environmental	I don't know
Physical	I don't know
Human health	I don't know

Q30: How effective is the support to companies through formal guidance documents and national helpdesks? (1= not effective; 5= very effective)	
Guidance documents	No experience
Helpdesks	No experience
Industry association guidance and materials	No experience
Other (training, conferences, etc.)	No experience
Q31: To what extent is CLP enforced in a harmonised manner across Member States?	I don't know
Q32: To what extent are the current elements relating to the CLP classification criteria satisfactory? (1= not satisfactory; 5= very satisfactory)	
Ease of implementation for duty holders	I don't know
Appropriateness of classification criteria and methods for substances	I don't know
Appropriateness of classification criteria and methods for mixtures	I don't know
International harmonisation through the Globally Harmonised System (GHS)	I don't know
Q33: CLP is revised on a regular basis through adaptations to technical progress. Do transitional periods allow sufficient time to implement new or revised classification criteria?	I don't know or have no opinion
Q34: To what extent are the current elements of the procedures for harmonised classification & labelling (CLH) satisfactory? (1= not satisfactory; 5= very satisfactory)	
Transparency of the procedures	I don't know
Involvement of stakeholders	I don't know
Quality of scientific data and related information	I don't know
Speed of the procedure	I don't know

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	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.