Japan 4EE Input to 2nd Stakeholder Consultation – Attachment 5 as draft Appendix on 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. We would like to propose that the result of Small WG should be attached to the methodology as an Appendix.

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Data quality and dealing with data gaps

When do the recommended data quality requirements apply?

The methodology described in the manual[1] consists of three stages. The first two stages are aimed at the prioritisation of substances which will be assessed in the last stage. The issue of data quality and data gaps is mainly relevant for the implementation of stage three. Only the assessment in stage three is dealt with in this FAQ section.

What kind of data is requested in the legal text?

The legal minimum requirements of data in an Annex II restriction dossier are listed in article 6.2 in the directive.

(a) Precise and clear wording of the proposed restriction;
(b) References and scientific evidence for the restriction;
(c) Information on the use of the substance or group of similar substances in EEE;
(d) Information on detrimental effects and exposure in particular during waste EEE management operations;
(e) Information on possible substitutes and other alternatives, their availability, reliability and hazard profile;
(f) Justification for considering a Union-wide restriction as the most appropriate measure;
(g) Socio-economic assessment.

Is there any additional guidance available?

Additional guidance is available in Recital 10 of the RoHS directive, i.e. that measures should be based on an assessment of available scientific and technical information.

[1] Manual on the Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive (see References)

Further details, albeit not legally binding, are provided in the manual. A detailed assessment for a possible inclusion in Annex II is described to contain the following items:

1. A description of the use of the substance in EEE and its legal status in the EU
2. An assessment of risks to human health and/or the environment during WEEE management
3. A consideration of other negative impacts on WEEE management
4. A description of substitutes and alternative technologies and their hazard(s)
5. A description of socio-economic impacts of a restriction of the substance of concern
6. A rationale for or against a recommendation of the substance of concern

Some of these detailed parameters are already mentioned in the manual and the first dossiers. A list of recommended parameters is described in **Table 1**. A similar set of data should be collected for the substance and/or the substance group being assessed for a restriction and for each of its identified alternatives. All parameters may not be relevant in the assessment of every substance, due to e.g. different hazard or physical properties.

What is the main purpose of defining data quality?

The most important reason is to avoid that poor quality data are used to show that a restriction is justified. The assessment should collect and review all available data and (1) only use results that are non-controversial within the research community and (2) assess thoroughly research that gives unusual and inconsistent data compared to the non-controversial data. These inconsistent data may be correct and usable, but they may also be wrong due to incorrect/unrealistic testing conditions.

How can "data quality" be defined?

Data quality for a certain parameter can be described by a set of meta-data (data about data) that can for instance be related to the data source (literature reference, date, place/region, experimental procedure, test method, standards, reproducibility, uncertainties, owner, author, etc.).

One fundamental requirement for data is the need for a clear and traceable source. Data should be used and documented in a transparent and reproducible way.
Documented use of meta-data includes an assessment as to whether the data are:

- adequate (useful, certain and accurate);
- relevant (fit for purpose);
- reliable (related to standardised methodology, experimental procedure or test method);
- subject to controversy within the scientific community.

Concrete examples on data quality that can be of help (from OECD Manual and ECHA Guide):
1. OECD Manual for the Assessment of Chemicals
http://www.oecd.org/chemicalsafety/risk-assessment/manualfortheassessmentofchemicals.htm
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282014%294&doclanguage=en
Chapter 3: techniques or methods for data gap filling

Chapter 4: analogue approach
Chapter 5: category approach
Chapter 6: guidance on specific types of categories
2. ECHA Practical Guide 6: How to report read-across and categories http://echa.europa.eu/documents/10162/13655/pg_report_readacross_en.pdf)

What data can be used to fulfil the quality requirements?

Where available, data from the REACH (Registration dossier, CORAP evaluation, Annex XV dossiers, authorisation dossiers, etc. …) for each substance are recommended as a first choice. All relevant Risk Analysis Committee (RAC) opinions, Socio-Economic Analysis Committee (SEAC) opinions and the regulatory decision of the European Commission should be taken into account.

Other potential sources for relevant information can for instance be OECD reports, WHO reports, reports of EU environmental agencies, data from reliable regulatory frameworks outside of the EU, studies from the waste management streams statistics, economic reports, market analysis from manufacturers and authorities, etc. …

Should data still be missing after the stakeholder consultation stage, it is recommended to widen the search for information, possibly expanding the search beyond existing publications[2] or requesting input from stakeholders.

How should gaps be dealt with when collecting data?

Bearing in mind all uncertainties and difficulties with the data gathering and the fact that 100% sound data will never be available for the generation of all individual substance dossiers, the possibility of data gaps in the final dossiers has to be envisaged.

The lack of appropriate data may be due to the absence of actual data, or data not compiled in a format that fits the intended purpose or that it is not made public by the data owners. Data owners might not be aware that their specific data input is requested and it is therefore necessary during the working process to raise the awareness and motivation to make the information available. Sometimes data may be known, but still not possible to use in a dossier as it is regarded as confidential business information (CBI). In such cases at least the fact that more data are available could be documented for the sake of transparency.

In order to identify data gaps as early as possible in the substance dossier preparation, a 2-step approach is recommended. A first check should be carried out before a substance dossier is submitted for a stakeholder consultation. This will allow very specific information requests to be sent out to all stakeholders with the aim of filling identified data gaps during the consultation. A final sanity check

[2] It should be noted that special attention should be given to references to existing publications, due to the risk of using inappropriate information based on specific and inappropriate study conditions or misleading cross-referencing

would be carried out at the completion of the dossier in order to ensure that a potential proposal for an additional restriction in Annex II is fully substantiated by the best available relevant data.

Stakeholders who already use alternatives and have experience with substitution should be encouraged to make their voice heard during the public consultation phase. All data and meta-data collected through the process should be properly verified and documented.

The omission from concerned parties to share relevant and important information should not be a reason to not proceed with the assessment of a restriction proposal.

How should data gaps be documented?

In some cases where existing and important data gaps still exist, assumptions could be needed to complete the assessment. As a rule, the introduction of assumptions should be kept to an absolute minimum. In particular multiple assumptions could render results of an assessment meaningless. Each assumption needs to be logical, based on facts as well as transparently stated, documented and substantiated.

The dossier must be fully transparent and describe all results including uncertainties and shortcomings. Such open communication allows final decisions being taken in the full awareness of all uncertainties and bearing full responsibility for all consequences.

Furthermore, if the final assessment were inconclusive due to lack of data, it could be acceptable to reassess again a few years later and to encourage research to fill the data gaps. Timing for the reassessment is appropriately determined by the Commission.

Concretely, it is recommended that the final documentation of evaluation results is presented in a reproducible and transparent manner. More specifically, the following aspects related to the question as to whether additional substance restrictions are ultimately justified under the RoHS2 Directive should be clearly presented:

1. all information that could be gathered,
2. all relevant information that had ultimately not been available,
3. all assumptions used, and for each assumption its rationale,
4. all conclusions that have been drawn **including the indication of uncertainties**.

References:

RoHS2 Directive (2011/65/EU) on the restriction of the use of certain hazardous substances in electrical and electronic equipment)

Manual; Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive; Umweltbundesamt GmbH; January 2014

Table 1. Summary of data quality parameters and requirements in a dossier to assess substance for potential restriction under RoHS2 directive

Reference in previous lists	*Requirement description*	*Type (to check quality against)*	*Ideal quality level*	*Other options for quality level* [3]	*Acceptable quality level*	*What if quality level is not fulfilled?*
General Provisions						
a	precise and clear wording of the proposed restriction					
b	references and scientific evidence for the restriction	Text/Descriptive				
1	status in other legislation	Descriptive list				Not relevant; Status = Time of Dossier
f; 6	justification for considering a EU-wide restriction as the most appropriate measure	Descriptive				Not relevant; Output from the assessment
Substance or group						
a; 1	Name	Text or YES/NO	IUPAC name		Synonym(s)	
1	CAS and EC number	YES / NO	CAS no EC no		Not mandatory	If relevant use other identifiers, e.g. structural formula, chemical formula, molecular weight
Uses						
c	information on the use of the substance or the group of similar substances in EEE					

[3] Other options could be either above or below a recommended acceptable quality level.

Reference in previous lists	*Requirement description*	*Type (to check quality against)*	*Ideal quality level*	*Other options for quality level* [3]	*Acceptable quality level*	*What if quality level is not fulfilled?*
c; 1	Likeliness presence in EEE	Descriptive	ECHA risk assessment reports	Information from E&E manufacturers or associations thereof		1. Determination based on updated info 2. Clear and transparent documentation of uncertainty
c; 1	Main function in EEE	Descriptive		Information from E&E manufacturers or associations thereof		1. Determination based on updated info 2. Clear and transparent documentation of uncertainty
Hazard						
1	Hazardous properties health and environment (CLP classification)		Harmonised CLP classification (prepared by official bodies)	Self-classification	Prepared by Consortium	
1	SVHC proposal or (if available, in order to avoid legal uncertainty) MSC decisions on SVHC proposals	YES / NO				Not relevant
Exposure						

Reference in previous lists	*Requirement description*	*Type (to check quality against)*	*Ideal quality level*	*Other options for quality level* [3]	*Acceptable quality level*	*What if quality level is not fulfilled?*
d	information on detrimental effects and exposure in particular during waste EEE management operations	Relevant information available in authorisation dossiers submitted by recyclers	From peer-reviewed publications	From Not-yet-published reports		1. Determination based on updated info 2. Clear and transparent documentation of uncertainty
2	Exposure estimates for workers in recycling	Value	Monitoring data	BAT-Reference Document for the Waste Treatment Industries ECETOC TRA or EUSES modelling data	"best possible estimates"	1. Determination based on updated info 2. Clear and transparent documentation of uncertainty
3	Environmental exposure from handling of EEE waste and recycling	Value	Monitoring data	EUSES modelling data	"best possible estimates"	1. Determination based on updated info 2. Clear and transparent documentation of uncertainty
Risks						
	Information on health risks	Authorisation dossiers RAC/SEAC opinions on authorisation dossiers and restriction proposals	DNEL / DMEL from ECHA (RAC) or EFSA	OELs to confirm a risk, but not for rejecting a proposed risk management measure.	Source: other official internationa l bodies	Clear and transparent documentation of uncertainty

Reference in previous lists	*Requirement description*	*Type (to check quality against)*	*Ideal quality level*	*Other options for quality level [3]*	*Acceptable quality level*	*What if quality level is not fulfilled?*
	Information on environmental risks	Authorisation dossiers RAC/SEAC opinions on authorisation dossiers and restriction proposals	PNEC from ECHA (RAC)	Environmental Quality standards under Water Framework Directive?		Clear and transparent documentation of uncertainty
Impact						
3	Technical impacts from the recycling	Descriptive				Clear and transparent documentation of uncertainty
2; 3; 5	Used volumes	Value	Aggregates of quantified volumes from use in specific manufacturing sites and content in imported articles	Use in EU manufacturing from public data in Reach registration dossiers Estimates of total market flow from EU manufacturing and import of articles		1. Determination based on updated info 2. Clear and transparent documentation of uncertainty
	Recycling rate	Value	Official data from recyclers and waste stream actors	Estimate from industry associations Consultants' reports		1. Determination based on updated info 2. Clear and transparent documentation of uncertainty

Reference in previous lists	***Requirement description***	***Type (to check quality against)***	***Ideal quality level***	***Other options for quality level*** [3]	***Acceptable quality level***	***What if quality level is not fulfilled?***
	Collection rate	Value	Official data from recyclers and waste stream actors	Estimate from industry associations Consultants' reports		1. Determination based on updated info 2. Clear and transparent documentation of uncertainty
g; 5	Socioeconomic assessment	Descriptive, values				Clear and transparent documentation of uncertainty
	Market trends	Descriptive, values, SEAC opinions on authorisation dossiers and restriction proposals				
	Life time of the articles		Published market studies	Life Cycle Assessments (LCAs)		
Alternative						
e; 4	Information on possible substitutes and other alternatives, their availability and reliability					1. Determination based on updated info 2. Clear and transparent documentation of uncertainty
	Investment costs for alternatives			Industry information		1. Determination based on updated info 2. Clear and transparent documentation of uncertainty

Reference in previous lists	***Requirement description***	***Type (to check quality against)***	***Ideal quality level***	***Other options for quality level*** [3]	***Acceptable quality level***	***What if quality level is not fulfilled?***
	Transition time for implementation of new processes / material/substances			Industry information		1. Determination based on updated info 2. Clear and transparent documentation of uncertainty
	Burden-shifting between various hazard topics of alternatives					