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Revised Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive

Prepared in the framework of the Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS
(RoHS Pack 15)

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Head Office Freiburg
P.O. Box 17 71
79017 Freiburg
Street address
Merzhauser Strasse 173
79100 Freiburg
Tel. +49 761 45295-0

Office Berlin
Schicklerstrasse 5-7
10179 Berlin
Tel. +49 30 405085-0

Office Darmstadt
Rheinstrasse 95
64295 Darmstadt
Tel. +49 6151 8191-0

info@oeko.de
www.oeko.de

Partner

Fraunhofer IZM

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Disclaimer

Fraunhofer-Gesellschaft e.V. – Institute for Reliability and Microintegration (IZM)

Hansastraße 27c, 80686 München, Germany

Dr.-Ing. Otmar Deubzer

Tel. +49 30 / 46403-157, Otmar.Deubzer@izm.fraunhofer.de

Fraunhofer IZM

Table of Contents

List of Figures

List of Tables

Abbreviations and definitions

AEL	Acceptable exposure level
BCF	Bioconcentration factor
BAT	Best available technology
BREF	Best available technology references document
CLP	Classification and Labelling Regulation
CMR	Carcinogenic category 1 or 2; mutagenic category 1 or 2, toxic for reproduction category 1 or 2
CSR	Chemical safety report
DMEL	Derived minimum exposure level
DNEL	Derived no effect level
ECHA	European Chemicals Agency
EEE	Electrical and electronic equipment
IT	Information technology
Log K_{ow}	Logarithm of the octanol/water partition coefficient
MBT	Mechanical-biological treatment
NOAEC	No observable adverse effect concentration
NOAEL	No observable adverse effect level
OEL	Occupational exposure level
PBT	Persistent, bioaccumulative and toxic
PNEC	Predicted no effect concentration
POPRC	Persistent Organic Pollutants Review Committee
RAC	Risk assessment committee
RAR	Risk assessment report
REACH	Registration, Evaluation and Authorisation of Chemicals
RoHS	Restriction of Hazardous Substances
RCR	Risk characterisation ratio
SCCS	Scientific Committee on Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
SCOEL	Scientific Committee on Occupational Exposure Limits
SEAC	Socio-economic Committee
STOT SE	Specific target organ toxicity: single exposure
STOT RE	Specific target organ toxicity: repeated exposure
SVHC	Substance of very high concern
vPvB	Very persistent and very biooaccumulative
WEEE	Waste electrical and electronic equipment

I Summary

The following report constitutes a draft version of the Draft Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS Directive. This draft is based on a revision of the previous manual prepared in 2013 by the Austrian Umweltbundesamt (AUBA 2013). In parallel to its preparation, collection of information for preparing the inventory of substances relevant for future assessment and for assessing seven substances, specified by the terms of reference of this study, has begun based on the methodology detailed herein.

In relation to the AUBA methodology, the following aspects have been subject to a more thorough revision:

- The interpretation of Article 6 has been revised. In particular a revision has been undertaken of the criteria specified therein, fulfilment of which is to be established to justify the listing of additional substances in Annex II of the Directive (the list of restricted substances). In cases where the use of a substance could give rise to uncontrolled or diffuse releases into the environment (Article 6(1)(b)), a restriction may now also be justified. To this end, the methodology has been revised to take into consideration the occurrence of such impacts.
- The link to other legislations and policies of relevance has been detailed in relation to the Waste Framework Directive and in relation to the Communication on the interface between chemical, product and waste legislation.
- Detail as to the relation between the REACH Regulation and the RoHS Directive has been revised, following the publication of the Common Understanding Paper (COM 2014) as to the relation between these two legislations.
- The various sources specified for collection of information for the update of the substance inventory and for the assessment of substances have also been updated - revising links to such sources in some case and adding further sources where relevant.

A first draft of this methodology was subject to a stakeholder consultation held between 26 October 2018 and 21 December 2018. A list of stakeholders who have made a (non-confidential) contribution has been added in Appendix A.7. A summary of the main issues addressed through contributions is available on the consultation website[1]. Among others, the following issues raised through contributions have furthermore been integrated into the current draft methodology:

- Reference to Directive 2018/851/EU (Waste Framework Directive) and to Communication on the interface between chemical, product and waste legislation has been revised.
- Additional detail has been added on how the precautionary principle is to be applied.
- Additional detail has been added on when RoHS restrictions can be considered justified based on the 6(1) criteria in connection with the Article 6(2) information requirements, in particular when the benefits expected to incur through a restriction are considered proportionate to the costs of its implementation.
- Information on endocrine disruptive properties of substances has been updated on the basis of the Communication Towards a comprehensive European Union framework on endocrine disruptors.

[1] See: https://rohs.exemptions.oeko.info/index.php?id=341

- Some clarifications have been added regarding Member State proposals.
- Criteria have been added to the methodology for substance assessment to demonstrate when the Article 6(1) criteria are considered to be fulfilled.
- Reference to sources on data emissions and monitoring data results have been added in the assessment methodology step on exposure estimation.
- An appendix has been added with guidance on Data quality and dealing with data gaps, based on a revision of the document prepared by the RoHS Substance Working Group.
- The methodology for identifying and prioritising substances has been revised: At the onset of the study, the inventory established by the Austrian Umweltbundesamt was updated and subjected to a stakeholder consultation to collect further data. The list posted for consultation included over 800 substances and information was asked among others as to the actual use and/or presence of substances in EEE and relevant volumes of use. This exercise returned additional information for only a small sub-set of substances and it was concluded, that such exercises required more focus to allow stakeholders to allocate their resources more efficiently in relation to a smaller number of substances. It was thus decided in coordination with the EU Commission to revise the methodology in this respect. Following the initial updating of the list of substances in the inventory in relation to data on hazard properties and data on possible use and/or presence in EEE, the inventory is now submitted to a pre-prioritisation prior to a stakeholder consultation. This allows specifying the focus of the consultation on the substances in the higher priority groups of the inventory, whereas stakeholders may still submit information as to other substances on the list as well as identifying new substances of relevance. A further change is the shift of the stage for evaluating the potential for fulfilment of the Article 6(1) criteria of specific substances from the inventory (P I) to the prioritisation (P II). This shift has been performed for pragmatic reasons and should allow a further fine-tuning of the internal ranking of the prioritised substances, i.e. the RoHS shortlist.

A second draft of this methodology was submitted to the EC on 14 August 2019 for final approval. The methodology described in this manual was applied in the assessment of 7 substances (two cobalt compounds, two nickel compounds, indium phosphide, antimony trioxide, TBBPA and beryllium and its compounds) and in the preparation of the RoHS inventory of substances. During the first application of the revised methodology a few shortcomings were identified and thus the following aspects have been fine-tuned:

- In the methodology for compiling the inventory, substances under assessment should not be erased, but rather kept in the inventory and specified as such.
- The methodology for the pre-prioritisation of the substances in the inventory has been revised in light of the limited data available on the volumes of substances used in EEE. The pre-prioritisation now gives higher priority to substances with hazard classifications in the top two priority categories also in cases where no data on use is available. For further details, see Section 1.3.1 P I Step 2a) Pre-prioritisation of substances, Part 3) “How to determine the overall priority of substances /substance groups”.

II Introduction

Electrical and electronic equipment (EEE) contains an increasing variety of organic and inorganic chemical substances. Some of these substances have properties which are hazardous and which can lead to adverse impacts on human health and/or the environment when they are present in EEE applications.

According to Directive 2002/95/EC (RoHS 1), the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE)[2] in EEE has been banned / restricted since 2006. Maximum concentration values by weight in homogeneous materials were specified[3]. Furthermore, for particular applications of lead, mercury, cadmium and hexavalent chromium, exemptions from these restrictions were laid down, partly indicating acceptable maximum concentration values or total contents.

In 2008, a proposal for a **recast of the RoHS Directive** was made[4]. The recast (RoHS 2) came into force in July 2011 (Directive 2011/65/EU - hereafter RoHS). It aims at developing a better regulatory environment and at specifying the conditions for adapting the RoHS Directive to the technical and scientific progress. This includes adaptation of the list of substances being restricted in EEE and the exemptions from these restrictions. Furthermore, it aims at a better prevention of risks to human health and the environment, with a particular focus on workers involved in the management of waste electrical and electronic equipment (WEEE).

Another objective of the recast of the RoHS Directive was to ensure coherence of RoHS with other pieces of EU legislation such as chemicals legislation, in particular the system of Registration, Evaluation, Authorisation and Restriction of Chemicals introduced by Regulation (EC) No 1907/2006 (REACH) and provisions related to waste management; in particular the Directive 2012/19/EU (WEEE).

Annex II of RoHS specifies the list of restricted substances. Article 6 of the Directive stipulates that the list is to be reviewed periodically[5] and amended periodically, also specifying various aspects to be considered as well as the criteria to be taken into account in the review of substances for possible future restrictions. Against this background, a methodology for the identification, prioritisation and assessment of substances present in EEE and for the review and amendment of the list of restricted substances provided in Annex II of RoHS was prepared in 2012-2013 by the Austrian Umweltbundesamt (AUBA 2013). This document has been revised in relation to various developments in policy and is now being published for consultation with stakeholders.

[2] For lead, mercury, cadmium, hexavalent chromium the restriction is on the use of these elements and their compounds. For PBB and PBDE the restriction applies to all members of these substance groups.

[3] Decision 2005/618/EC

[4] Proposal for a Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (COM(2008) 809)

[5] Article 6(1) further specifies that the periodic reviews should take place on the Commissions own initiative or following the submission of a Member State restriction proposal.

Please note

The following divergent formatting style is used for emphasis throughout this document:

INTERPRETATION

Where the Directive legal text or statements from other documents published by the European Union are interpreted, the text appears as an **INTERPRETATION** and is formatted as grey text.

II.I Background

During the preparation of RoHS, an expansion of the list of restricted substances was discussed. Preparatory studies, in particular the review of restricted substances under RoHS 1 (Groß et al. 2008), revealed that certain hazardous substances associated with negative impacts on the environment and/or on health are widely used in EEE in considerable quantities, which are not regulated under the Directive yet. For several substances negative health and environmental impacts were documented, which could justify a restriction of further use in EEE. Namely the flame retardants tetrabromobisphenol A (EU RAR 2006, 2007a[6]) and hexabromocyclododecane (EU RAR 2007b[7]) and the phthalates bis (2-ehtylhexyl) phthalate, butyl benzyl phthalate and dibutyl phthalate (EU RAR DEHP 2008, EU RAR BBP 2007 and EU RAR DBP 2003[8]) were identified as high priority substances. Due to insufficient data on environmental, economic and social impacts, in particular on possible substitutes at that point, it was decided to postpone the review of the list of restricted substances to after the approval of RoHS. For his purpose the recast required a first review to be carried out by 22 July 2014 under Article 6(1), which inter alia specifies when a review of the list of restricted substances by the European Commission (the Commission) is to be carried out. For the first review, priorities as to the substances to be reviewed were assigned in Recital 10 to the following substances:

- Hexabromocyclododecane (HBCDD);
- Bis (2- ethylhexyl) phthalate (DEHP);
- Butyl benzyl phthalate (BBP);
- Dibutyl phthalate (DBP).

The first review of the substances specified in Recital 10 was carried out in 2012-2013 by the Austrian Umweltbundesamt (AUBA 2013), followed by a further review of diisobutyl phthalate (DiBP) carried out on behalf of the Commission by the Oeko-Institut in 2014 (Baron et al. 2014). As a result of this process, the four phthalates were included in Annex II of the RoHS Directive following an amendment published in March 2015 (COM 2015).

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6 Specified in Groß et al. (2008) among others on the basis of: EU Risk Assessment Report 2,2',6,6'-Tetrabromo-4,4'-Isopropylidene Diphenol (Tetra-bromobisphenol-A), Final Environmental Draft (2007); EU Risk Assessment Report 2,2',6,6'-Tetrabromo-4,4'-Isopropylidenediphenol (Tetra-bromobisphenol-A or TBBP-A), Part II – Human Health, Final Report (2006); and Johnson-Restrepo, B. et al. (2008): Tetrabromobisphenol A (TBBPA) and hexabromocyclododecanes (HBCDs) in tissues of humans, dolphins, and sharks from the United States; Chemosphere 70 (2008) 1935–1944.

7 Specified in Groß et al. (2008) among others on the basis of: Risk Assessment Hexabromocyclododecane. Final Draft October (2007)

8 Specified in Groß et al. (2008) among others on the basis of: EU Risk Assessment Report bis(2-ethylhexyl)phthalate (DEHP), Final Report (2008); EU Risk Assessment Report Benzyl butyl phthalate (BBP), Final Report (2007); and EU Risk Assessment Dibutylphthalate (DBP), Final Report (2003).

In the course of the AUBA review, an inventory of substances of relevance for EEE was also generated[9] with the aim to provide support to the Commission in identifying substances for assessment in future reviews.

II.I.I Requirements related to substance review and restriction under RoHS

Article 6(1) of RoHS stipulates various **requirements related to substance review and restriction under RoHS**. It requires that the review and amendment of the list of restricted substances in Annex II shall be based on a "thorough assessment", "*taking account of the precautionary principle".* Recital 10 of RoHS also refers to the **precautionary principle.**

Within the methodology described in this manual, the precautionary principle shall be applied according to the Commission guidelines (COM 2000 1 final)[10], following basic principles of proportionality, consistency, responsibility, taking into account impacts on society and on the environment. Decisions taken might be subject to review in case where additional data becomes available, as laid down in the Commission's communication.

Though a methodology for the evaluation of chemical substances to be listed in Annex II is not detailed in the RoHS Directive, elements to be assessed during the review and amendment of Annex II are specified in Article 6(1 and 2) .

According to Article 6(1) of RoHS, "*the review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006, and shall take into account, inter alia, Annexes XIV and XVII to that Regulation. The review shall use publicly available knowledge obtained from the application of such legislation*".

Special account shall be given to "*whether a substance, including substances of very small size or with a very small internal or surface structure, or a group of similar substances:*

(a) could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;

(b) could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;

(c) could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;

(d) could be replaced by substitutes or alternative technologies which have less negative impacts."

The criteria focus on possible environmental and health impacts that could arise during use and/or during waste management. However, for the implementation of the RoHS Directive, product de-

[9] See AUBA (2013) inventory under: http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex3_EEE-substance-inventory.xls

[10] The European Commission outlines its approach towards applying the precautionary principle in a communication published in 2000. This document provides guidelines and builds a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully. The aim of this guidance is to avoid unwarranted recourse to the precautionary principle, as a disguised form of protectionism. Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, but that scientific evaluation does not allow the risk to be determined with sufficient certainty. (COM 2000 1 final)

sign and manufacturing necessarily need to be taken into account and may also be affected from the Directive provisions. In this respect, though RoHS "*does not specifically regulate the manufacturing process itself, the methodology behind the listing of substances in Annex II to RoHS could address risks arising at this stage*" (COM 2014).

Furthermore, RoHS specifies that interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations shall be consulted during the review of the list of restricted substances.

INTERPRETATION:

Though the title of the RoHS Directive refers to the restriction of **hazardous substances**, it does not include a definition for this term, referring only to the "List of restricted substances", for example in Article 6 and Annex II. According to Article 3(1) of REACH (or Article 3(8) of CLP) "***substance****: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition*". The term **hazard** is not defined, however, Recital 10 of CLP explains its objective to "*be to determine which properties of substances and mixtures should lead to a classification as hazardous, in order for the hazards of substances and mixtures to be properly identified and communicated. Such properties should include physical hazards as well as hazards to human health and to the environment, including hazards to the ozone layer*".

Coherence with other legislation is required in Article 6.

In this respect, Directive 2008/98/EC on waste (Waste Framework Directive - WFD (EP 2008)) should be noted. The WFD "*defines key concepts such as waste, recovery and disposal and puts in place the essential requirements for the management of waste*" (Recital 1). It also provides clarification on "*the distinction between waste and non-waste, and for the development of measures regarding waste prevention and management*" (Recital 2). The first objective of the WFD is to minimise negative effects of waste generation and management on human health and the environment (Recital 6). In this sense, Article 13 of the WFD requires Member States to take the necessary measures to ensure that waste management does not endanger human health and/or the environment. This is understood to be an overarching objective of all Waste legislation, and thus also relevant for RoHS, which calls for the substitution of hazardous substances used in EEE as a means to prevent such impacts. Annex III of the WFD furthermore specifies properties of waste which render it as hazardous. Properties mentioned are parallel to many of the hazards requiring classification under the CLP Regulation, including also hazards of relevance for use and for waste management such as irritant, toxic, carcinogenic, etc.

In the recent amendment of the WFD (Directive 2018/851/EU), waste management has been defined as "the collection, transport, recovery (including sorting), and disposal of waste, including the supervision of such operations and the after-care of disposal sites, and including actions taken as a dealer or broker". This definition clarifies what is in the scope of waste management and which actions are included therein. This is to be considered in assessing whether a substance fulfils the RoHS Article. 6(1)(a) criterion. Of further interest is the amendment of Article. 9 of the WFD, which concerns the prevention of waste, and requires Member States to take measures to prevent waste generation:

> *"(i) promote the reduction of the content of hazardous substances in materials and products, without prejudice to harmonised legal requirements concerning those materials and products laid down at Union level, and ensure that any supplier of an article as defined in point 33 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (*5) provides the information pursuant to Article 33(1) of that Regulation to the European Chemicals Agency as from 5 January 2021*;"

Information provided to ECHA pursuant to this Article in connection with Article 33(1) of REACH regarding the presence of hazardous substances in EEE could provide an important source of information on substances present in EEE and should be used in the future to support the identification, prioritisation and assessment of substances in the context of RoHS.

> *"(j) reduce the generation of waste, in particular waste that is not suitable for preparing for re-use or recycling;*"

This reference suggests that waste, containing hazardous substances, that is not suitable for preparation for re-use or recycling could be of particular interest in assessing the fulfilment of the Article 6(1) criteria.

Furthermore, the Communication on the interface between chemical, product and waste legislation published by the European Commission in 2018 (COM 2018 32 final) is to be mentioned. The Communication indicates possible future developments of legislation and should thus be noted and followed for possible future linkage. The Communication explains that recycling and re-use can be hampered by the presence of certain chemicals. In parallel, a growing number of chemicals hazardous to humans or the environment are being subjected to legal restrictions. In both cases, removal of such substances from the waste stream is understood to contribute to recycling of waste and to the reuse of secondary materials. The Communication thus identifies the four most critical issues "*in the way the legislation on chemicals, products and waste work together and how these are hampering a circular economy development"*:

- Lacking information on the presence of substances of concern in materials and components that are part of the waste stream;
- Substances already subject to restrictions may still be contained in material and components to be subject to waste management;
- The rules defining "end of waste" (when waste ceases to be seen as such) are not harmonised in EU legislation;
- Rules as to when wastes and chemicals are to be considered hazardous are not aligned between chemical and waste legislation, affecting possible uptake of secondary materials.

Further details as to these issues are given in the document.

RoHS restricts the presence of hazardous substances in EEE, in this sense contributing to the presence of substances of concern in the waste stream and subsequently to the ability to recycle materials and use secondary materials in new production has various links to the issues raised in the Communication on the interface between chemical, product and waste legislation. Measures to be initiated as a result of the Communication could affect how substance restriction is to be practiced in the future and should be taken into consideration as they develop.

Article 6 particularly requires coherence with chemical legislation and REACH. Moreover, the Directive in its Article 2(3) sets the obligation to observe Union legislation on safety and health as well as waste management. There is however, neither a legal mandate nor an obligation to copy

the procedure of substance restriction developed under REACH nor to involve ECHA and its scientific committees (RAC, SEAC) in the assessment process of substances under RoHS. Coherence is interpreted to mean that amendments of Annex II shall not result in contradictions, duplication and uncertainties between RoHS and other chemical legislation and in particular between RoHS and REACH. The relation between these two legislations has been established and published in the document "REACH and Directive 2011/65/EU (RoHS) - A Common Understanding" (COM 2014). This document provides guidance for various scenarios in which substances are regulated under these legislations in various ways. A summary of the considerations and action courses to be taken during an assessment of a substance for restriction under RoHS, in cases where regulation already exists under REACH is provided in Table I.

Table I: The relation between REACH and RoHS in respect of the restriction or authorisation of substances

REACH Restrictions and RoHS

Case	REACH Annex XVII Restriction	RoHS Annex II Restriction	Rational	Action under REACH	Conclusion / Action
I	Under Consideration	In force	RoHS Restriction affords the same or a higher level of protection to that proposed in the REACH Restriction.	REACH: Exclude EEE in scope of RoHS from restriction; indicate the use of substance in EEE to be restricted by RoHS. RoHS: No action	Irrelevant
			Proposed REACH restriction affords higher level of protection	Not detailed in common understanding paper. Consultants' interpretation: REACH measure to be preferred to achieve a higher level of protection, for example where RoHS is not effective in this respect.	
II	In force	Under Consideration	If REACH restricts the use of a substance inter alia in EEE, RoHS restriction may be redundant.	REACH: No action RoHS: No need to restrict as substance already restricted through REACH.	No need to restrict under RoHS where REACH restriction affords higher level of protection.
			If the same or more stringent measures (restriction) are proposed under RoHS:	REACH: Exclude EEE in scope of RoHS from restriction; indicate the use of substance in EEE to be restricted by RoHS. RoHS: Restrict substance	Restrict under RoHS where it can achieve the same or a higher level of environmental and health protection.
III	Under Consideration	No measure	A REACH restriction could be imposed. Should RoHS restrict in the future, EEE could be excluded from REACH measure subsequently.	Restriction under REACH. RoHS: No action.	Should a RoHS restriction be considered in the future, case II is to be followed.

REACH Restrictions and RoHS

Case	REACH Annex XVII Restriction	RoHS Annex II Restriction	Rational	Action under REACH	Conclusion / Action
			Alternatively: REACH restriction procedure could be used to prepare a RoHS Annex II amendment outside the periodic review period.	REACH and RoHS amendments to be synchronised: REACH: REACH restriction not to address EEE. RoHS: Amendment of RoHS Annex II to restrict substance	If necessity to restrict under RoHS identified at early stages of REACH substance assessment, this could trigger a substance review under RoHS.

REACH Authorisation and RoHS

Case	REACH Annex XIV Authorisation	RoHS Annex II Restriction	Rational	Conclusion / Action
I	Under Consideration	In force	No exemptions under RoHS: Use in EEE placed on EU market prohibited in all applications. Listing in Annex XIV of REACH shall prohibit use of substance in EU manufacture of EEE, i.e., for export.	Measure consistent with existing regulation.
			Exemptions exist: Measure shall apply to EEE manufactured in EU*.	Alternative 1: EEE covered by RoHS restriction (and by exemptions) could be excluded from REACH Annex XIV listing pursuant to Article 58(2).
				Alternative 2: if the RoHS restriction does not constitute proper control according to Article 58(2) of REACH, the REACH authorisation requirement could apply to EEE, though only affecting EU manufacturers.
II	In force	Under Consideration	Listing in Annex XIV of REACH already prohibits use of substance in EU manufacture.	Alternative 1: RoHS restricts without exemptions - if REACH Authorisations have been granted, they shall become redundant unless parallel exemption granted under RoHS.
				Alternative 2: RoHS restricts with exemptions. It may be considered if there is added value in continuing the REACH authorisation requirement for RoHS exempted applications.
III	Under Consideration	No measure	Introduce REACH authorisation requirement.	Should a RoHS restriction be considered in the future, Case II to be followed.
			Delay REACH measure until substance can be included in RoHS Annex II (restriction).	REACH substance assessment can be used to trigger RoHS substance evaluation to avoid Case II situation.

*Authorisations could be applied for RoHS exempted EEE and granted to allow use for a limited duration, assuming they are justified.

Source: Own compilation on the basis of COM (2014)

Furthermore, the RoHS Directive interpretation of the precautionary principle may differ from that of the REACH Regulation. From REACH (Article 7(5)(b)) it can be understood that release of a substance classified as hazardous, for example from an article, is a precondition for the assessment of the risk[11].The REACH Restriction process is further based on the criteria that a risk to human health or the environment exists, which is not adequately controlled and which needs to be addressed (Article 69). However, looking at the RoHS Article 6(1) criteria suggests that it suffices for a substance to have a potential for risk ("could have...") during use and/or during waste management in order to justify its restriction under RoHS. In this sense, if a substance is classified with a hazard potentially resulting in risk in these phases, a restriction would be justified regardless of actual occurrence and risk management options. It is thus interpreted that a stricter approach can be taken by RoHS, provided that scientific and technical information show that there is a probability that at least one of the Article 6(1) criteria is fulfilled. It is nonetheless noted that the need for costs of a restriction to be proportionate to expected benefits suggests that a restriction would only be possible where negative impacts on health and/or on the environment are expected in connection to the fulfilment of Article 6(1) (see following detail). Furthermore costs of implementing a restriction in such a case are to be proportionate to the benefit a restriction would generate through the prevention of such impacts:

- negative impacts occurring during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE (Article 6(1)(a));
- negative impacts as a result of uncontrolled or diffuse release of a substance used in EEE into the environment during use (Article 6(1)(b)(first part));
- negative impacts as a result of hazardous residues, or transformation or degradation products of a substance released in the waste phase that occur through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions (Article 6(1)(b)(second part);
- unacceptable impacts on the health of workers involved in the waste EEE collection or treatment processes (Article 6(1)(c));
- in relation to the above criteria, negative impacts of the use of a substance are higher than those of a possible substitute or alternative technology (Article 6(1)(d)).

Article 6(1) specifies that the review shall be based on a thorough assessment, taking account of the precautionary principle and that it shall also:

- *Be coherent with other legislation related to chemicals, and particularly REACH.*
  Though it is understood that discrepancies should be avoided, coherence is not interpreted to mean that RoHS could not be stricter in certain cases. This could occur where action taken through REACH provides a lower level of environmental and health protection as the level that could be achieved through RoHS. For example, in the case of a REACH Authorisation that prohibits the use of a substance in EU manufacture and thus also its presence in EEE, the Authorisation obligation only prevents impacts related to use of the substance in EU manufacture. Where the substance is used in manufacture outside the EU, a RoHS restriction could addition-

[11] Under REACH, it can be understood that the Agency (ECHA) may require a substance to be registered when it has grounds to suspect that the substance is released from articles and where the release may present a risk to human health or the environment.(Article 7(5)(b)). It is thus understood that though hazards may be associated with a substance, this does not necessarily mean that a risk is present.

ally prevent impacts related to the presence of the substance in imported EEE during use and/or during the waste phase. See further detail below.

- *take account inter alia of Annexes XIV (Authorisations) and XVII (Restrictions) of the REACH Regulation* – Seeing as restrictions and authorisations for using certain substances may affect the need to restrict a chemical under RoHS (or the scope of such a restriction), changes of the Annexes should be taken into consideration. See further details below.
- *use publicly available knowledge obtained from the application of other legislation related to chemicals.* The knowledge base generated in relation to other legislation should be used where available in the review process of substances under RoHS. In this respect, information generated by REACH and other chemical related legislation is to be used for the restriction process under RoHS. The most recent information should be taken into consideration where multiple versions exist. This does not necessarily give priority to such information and data, assuming other sources shall be available with a similar level of certainty, but specifies a first basis of available knowledge, seeing as the reviews are to be carried out on the basis of available information.
- Consideration should be given as to the level of certainty of information and data used in the assessment of substances. It can be assumed that knowledge (documents, data) generated through the application of other legislation has been submitted to scrutiny and can be assumed to have a relatively high level of certainty. For the purpose of this study, the weight of evidence approach may be applied to consider the certainty of different sources and the weight which is attributed to data and information provided therein (see “Part III DETAILED ASSESSMENT OF SUBSTANCES”, Section II, for details).

Furthermore, Article 6(1) specifies four criteria which also have to be taken into account while reviewing and amending Annex II. Fulfilment of each of these criteria is interpreted as a possible justification for a future restriction; however a differentiation might be necessary in relation to the range (time, geography) and magnitude (volume) of impacts specified in these criteria. There are two reasons for this differentiation: It is to serve as a basis for deciding on the proportionality of a restriction, as well as allowing a prioritisation between substances.

The criteria are interpreted as follows:

- Criterion 6(1)(a) refers to substances whose presence in EEE may lead to negative impacts at the end-of-life of that article when it is subjected to waste management. This includes impacts arising through operations related to the treatment and handling of waste, including but not limited to: sorting, shredding, preparing for the reuse of waste EEE or preparing for the recycling of materials from waste EEE;
- Criterion 6(1)(b) refers to substances whose presence could give rise to impacts during the use of the article and/or at its end-of-life, when it is subjected to waste management. This includes:
  - uncontrolled or diffuse release of the substance into the environment during its use; or
  - generation and release of hazardous residues of the substance through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions.
  - generation and release of transformation or degradation products of the substance through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions
- Criterion 6(1)(c) refers to substances whose presence in EEE may lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;

- Criterion 6(1)(d) refers to substances present in EEE which lead to various negative impacts on the environment and/or on health throughout the lifecycle of the product and which could be replaced by substitutes or alternative technologies which have less negative impacts and which would thus lead to a decrease in total negative impacts on environment and health.

As regards substance groups[12] mentioned in Article 6(1), the grouping of similar substances[13] describes the approach for considering more than one single substance at the same time in the various steps of the methodology. Assessing a group of substances could in some cases provide an alternative to the individual assessment and restriction of individual substances, mainly in order to maximise efficiency both, in the review and amendment of the list of restricted substances as well as during implementation, e.g. to ensure market surveillance. This could be relevant for example when individual group members of a certain group exhibit the same hazard properties, and where similar exposures could arise within the waste management processes. This could be the case, for example, if group members are transformed into particular hazardous transformation or degradation products. Basically, categories of chemicals are selected due to the hypothesis that the properties of chemicals with identical structural features may show similar trends in their physico-chemical properties, and even more importantly, in their toxicological profile, which includes human health and ecotoxicology and environmental fate properties.

Article 6(2) of RoHS requires that "*proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II"* contain certain types of information and these requirements are to be taken into consideration in the assessment of a substance under RoHS and in the preparation of a proposal for restriction (RoHS dossier). See "Introduction", Section II, for further detail.

According to Article 6(3) of RoHS the measures related to the review and amendment of the list of restricted substances shall be adopted by the Commission by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22 of the Directive.

II.II Objective of the manual

This manual describes how to identify substances used in EEE which may have a negative impact on human health and or the environment during use and/or during WEEE management[14] and how to assess them in order to conclude if their future restriction under RoHS is justified.

II.III Scope of the manual

Primarily, the methodology described in this manual is addressed to the Commission and provides guidance for future reviews of Annex II (list of restricted substances) to RoHS.

Two triggers are possible for future reviews:

- A review on the Commission's initiative (periodic or triggered through the assessment of substances under REACH – see Table I, p. 16);
- A review following submission of a restriction proposal by a Member State.

[12] For example the restriction of cadmium applies to cadmium metal and to its compounds.

[13] Appendix A.6 0provides guidance on groups of similar substance.

[14] Impacts during the production and use of EEE are not a part of the criteria specified under Article 6(1) for justifying a restriction of substances under RoHS.

In addition, the manual could be used as guidance by Member States when they intend to prepare a restriction proposal, though this is not obligatory (see further detail in P III).

II.IV Overview of the methodology

The methodology described in this manual consists of three parts:

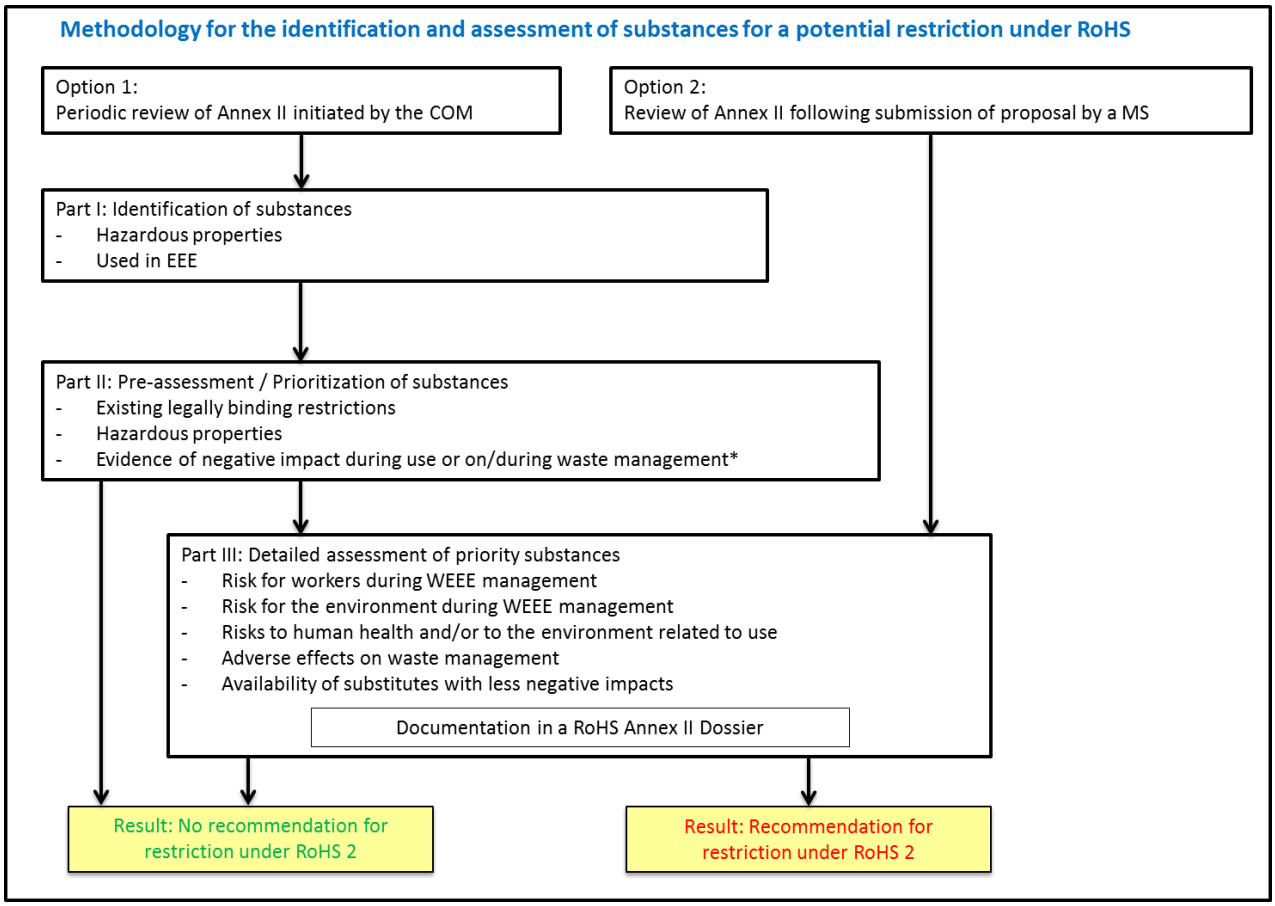
- PART I: Identification of substances[15] used and/or present in EEE, which may have negative impacts on human health, the environment or resource efficiency during use and/or during WEEE management according to RoHS Article 6(1). In this stage a first inventory of substances used in EEE is created (updated). Existing databases and computer based tools are then used to establish a comprehensive database with information on the substances concerned (hazard properties, use aspects). Finally, chemicals are selected by applying defined criteria (hazardous properties, evidence that the substance is used in EEE). The information collected is used for further substance assessment and considerations;
- PART II: Prioritisation of substances used in EEE, which may most likely have negative impacts on human health, the environment or resource efficiency during use and/or during WEEE management according to RoHS Article 6(1). This part is applied to a sub-selection of the substances identified in P II, understood to have the highest priority for assessment in P III. Information is collected and reviewed on actual volumes of use and on typical applications in EEE. Based on this information and the hazard properties of the substance a first estimation is made as to whether the use and/or presence of the substance in EEE could result in the fulfilment of the Article 6(1 criteria). On this basis the prioritisation for assessment is further refined.
- PART III: Detailed assessment of high priority substances with a view to concluding on the necessity for restriction under RoHS. In addition to the substance's impacts on health, environment and resource efficiency, the availability and hazardous properties of potential substitutes/alternatives and socio-economic aspects of a potential future restriction are investigated.

According to RoHS Article 6(1), the focus of assessment lies on the impacts on human health and environment during use and/or during waste treatment.

[15] Means substances and substance groups, for reasons of readability "substances" is used throughout this manual.

Figure I provides an overview of the overall methodology described in detail in this manual.

Figure I: Overview of the methodology (*as specified by Article 6(1) of RoHS2)



Source: Adapted with revisions from AUBA (2013)

1. Part I IDENTIFICATION OF SUBSTANCES

The **aim** of Part I is to identify all substances in EEE, which may cause risks for the environment during use[16] or risks for the environment and workers during WEEE management or have any other negative impacts during waste management, as specified by RoHS 2, Article 6.

Article 6(1) requires taking special account of whether a substance, including substances of very small size, or with a very small internal or surface structure, or a group of similar substances:

a) "*could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE*;

b) *could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions*;

c) *could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;*

d) *could be replaced by substitutes or alternative technologies which have less negative impacts*."

Approach: The standardised methodology as described below shall allow for a stepwise procedure for assessing substances for possible future restriction under RoHS in order to fulfil the overall goal of protecting human health and the environment from negative impacts related to use or to WEEE management.

The identification of potentially RoHS-relevant substances used in EEE involves three major tasks:

- Creation of an inventory of substances (P I Step 1):
  - Updating information on substances classified or suspected as hazardous (P I Step 1a);
  - Updating information on substances used and/or present[17] in EEE (P I Step 1b);
- Pre-assessment of priority of substances listed in the inventory (P I Step 2):
  - First run of the pre-assessment to establish classification of substances to priority groups (P I Step 2a);
  - Stakeholder consultation for collecting information on substances in the inventory with focus on the substances in the highest priorities (P I Step 2b);
- Update information in the inventory and re-run pre-assessment to conclude on substances in highest priorities[18] to be subject refined prioritisation in P II (P I Step 3).

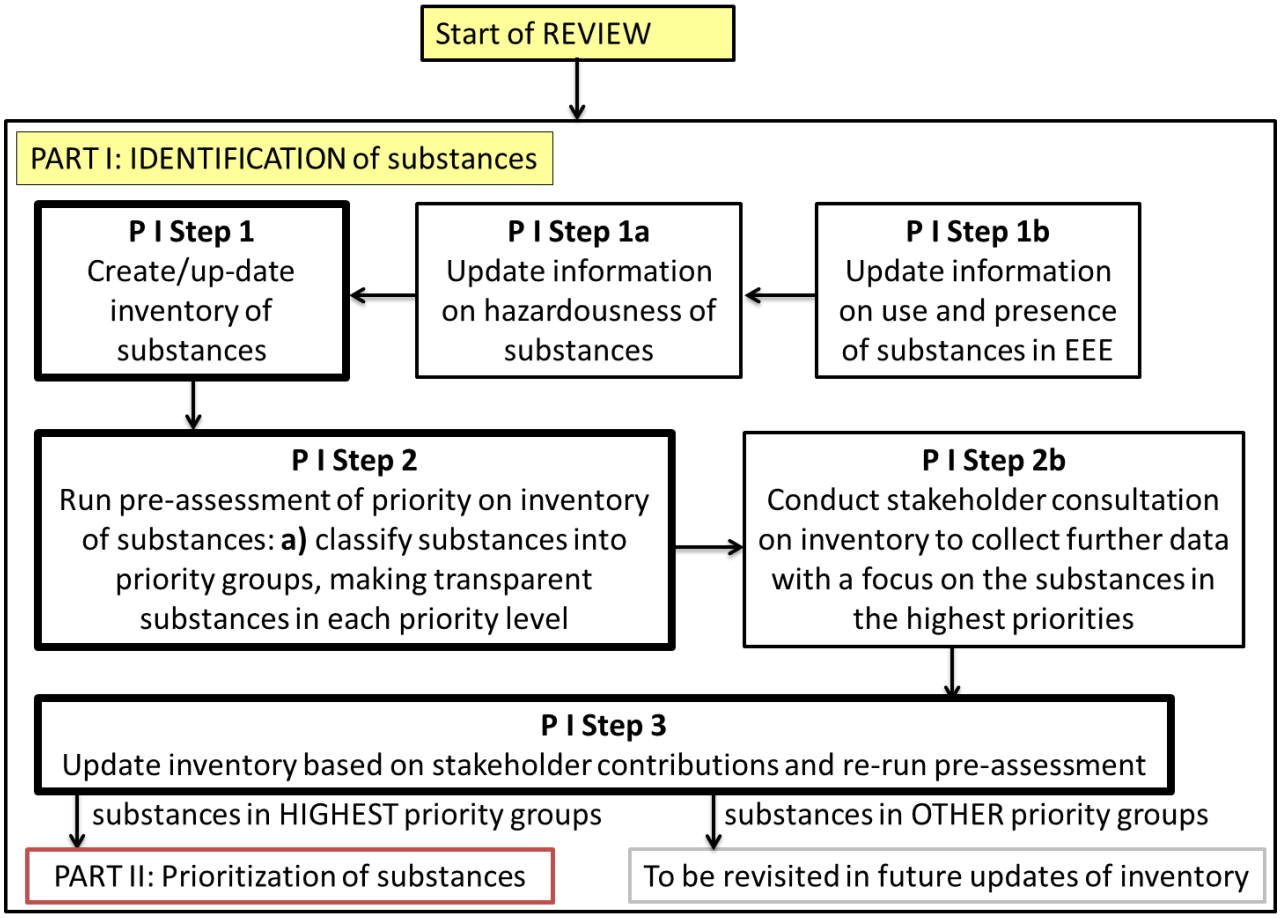
[16] Article 6(1)(b) provides inter alia the basis for restricting a substance, should its uses give rise to uncontrolled or diffuse release into the environment of the substance. This is understood to refer to possible releases related to the intended use of a substance but also to non-intended use, for example in the case of breakage.

[17] Substances used in manufacture of EEE may or may not be present in the final product. Similarly, substances present in EEE may or may not have been applied in this form in the manufacture. The inventory shall update information on substances used in manufacture and on substances present in EEE, specifying presence where this data is found to allow a differentiation at later stages.

[18] The number of substance (priority classes) to be subjected to the prioritisation of P II shall be discussed and approved with the EC, also depending on the study framework.

Figure 1-1 below provides an overview of how to identify these substances and illustrates the flow of decisions.

Figure 1-1: Workflow of identifying substances used in EEE with a potential negative impact during use, and/or on or during waste management



Source: Adapted with revisions from AUBA (2013)

An inventory of substances used in EEE was established during the first review of Annex II of RoHS in 2013-2014. The inventory established in 2013 AUBA provides a first basis to be updated in the following periodic reviews. Each further revision should use the initial inventory of the last revision as a first basis to be updated, adding and updating existing data before applying the various selection and prioritisation stages. For establishing the 2013 inventory, two main sources of information were used:

- Existing databases on substances where information is gathered and presented on the use of substances in products:
  - IEC 62474 database on material declaration
  - ZVEI-Umbrella specifications
  - ECHA-registered substances with the use descriptor “SU 16: Manufacture of computer, electronic and optical products, electrical equipment”

  - SPIN (Substances in Preparations in Nordic Countries) listed substances with NACE codes C26 “Manufacture of computer, electronic and optical products” and C27 “Manufacture of computer, electronic and optical products”
- Several studies conducted in past years dealing with the identification and evaluation of specific harms occurring from the use of hazardous substances in EEE.

A compilation of the databases and studies which were used for the 2013 inventory is provided in the Appendix, Section A.1.

On the basis of the information used, it is concluded that for substances in the 2013 AUBA inventory, evidence exists or existed at the time that the substance is present in EEE or suspected of such. In this sense, it is assumed that all substances in the 2013 AUBA inventory are in use in the manufacture of and/or present in EEE, though the range of volumes used is not known for most substances[19].

1.1. P I Step 1: Compile inventory of substances

Approach/Criteria: The final inventory (list of substances in excel form) from the last revision is to be used as a first basis and to be updated where relevant in relation to additional substances present in EEE or used in the manufacturing of EEE (e.g. new substances). Information for substances on the list should be updated where relevant in relation to hazard properties of the substances and their use or presence is EEE where such information is available.

Additional substances to be added to the inventory may be derived from sources that are specific for EEE in products or for manufacturing of EEE (e.g. IEC 62474, ZVEI umbrella specifications, and relevant studies/reports). The review of such sources is performed in P I Step 1b which runs in parallel to P I Step 1a and not included as a separate step.

1.1.1. P I Step 1a): Update information on substances which are hazardous

Approach/Criteria: To establish the initial inventory, data on hazardous properties of substances shall be updated in the list as relevant (i.e., where there have been changes). This shall include actual classifications and information for substances suspected of having hazardous properties, specifying the hazard properties of relevance.

On the one side, substances which have a harmonised classification of their hazardous properties (substances listed in Annex VI of the CLP regulation), and/or which have been identified as having PBT, vPvB and/or PB[20] properties and/or as having endocrine disruption properties shall be included in the inventory. Additionally substances that are suspected of having such properties shall also be included, based on the process described below.

[19] In its final report AUBA wrote that the list compiled on the basis of the above mentioned sources was manually screened for those substances, whose presence in EEE is not plausible, e.g. solvents. Some of those were subsequently removed from the EEE inventory and listed in a separate list titled “substance removed.

[20] In some cases a substance could be classified as persistent and bioaccumulative (PB), but not as toxic (T) seeing as existing classifications do not comply with the REACH Annex XIII, 1.1.3 criteria for fulfilling the PBT toxicity criterion. In other cases, a substance may be persistent and bioaccumulative (PB) but not toxic and still have negative impacts on the environment, such as for example in the case of micro plastics. For such cases it is of relevance to check possible fulfilment of the Article 6(1) criteria of the substance, depending on the priority assigned to the substance in the pre-prioritisation.

It is noted that though the term substance is not defined under RoHS, its definition under REACH and CLP are considered to clarify how this term is to be understood (see “Background”, Section II.I):

> *“substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition”*

In this respect it is also noted that both regulations define the term polymer to mean “*a substance consisting of molecules characterised by the sequence of one or more types of monomer units [...]*” (REACH Article 3(5); CLP Article 3(11)). As polymers are considered to be substances it stands to reason that they could be considered for restriction under RoHS, i.e. included in the inventory list.

Table 1-1 gives an overview of the selection criteria.

Table 1-1: Criteria for the identification of candidates in the inventory master list as hazardous

The substance is/shows
Listed in Annex VI CLP (or fulfils the criteria that would justify a listing in Annex VI CLP)
Carcinogenic OR mutagenic OR reprotoxic [Categories 1A and 1B and 2]
PBT (persistent, bio-accumulative, toxic)
vPvB (very persistent, very bio-accumulative)
PB (persistent, bio-accumulative)
Substance of very high concern (SVHC) under REACH
Considered to have endocrine disrupting and/or other properties identified in accordance with Article 57(f) of REACH]
Suspected as any of the above (based on CoRAP; SIN List)

Source: Adapted with revisions from AUBA (2013)

Database on substance information: In order to update hazard information for substances in the list information on the identified or suspected priorities is to be compiled. A differentiation between identified properties (e.g., classification category) and between suspected properties shall be applied to allow prioritising substances identified as having hazardous properties at later stages. Exploration of the data is to be enabled by the filtering and sorting functionality supplied by standard spreadsheet software. Finally a “flat table”, using separate columns for the various hazard categories shall be generated.

Databases on hazardous substances on one side, as well as governmental lists on European, national and international level and lists from non-governmental organisations shall be screened or compiled and used for the identification of hazardous substances in the EEE inventory. The lists associated with a substance, hazard classifications and additional data can be gathered easily in the process and will facilitate selection and pre-assessment of specific substances later on.

The following references are to be used for the purpose of the update at hand:

- Classification and Labelling

Occurrence of a substance in Annex VI to the CLP Regulation (EC) No 1272/2008 is documented in the ECHA Table of harmonised entries in Annex VI to CLP[21]. Annex VI to the CLP Regulation lists the harmonised classifications and labelling for certain substances or groups of substances which are legally binding within the European Union.

- SVHC substances

Substances of very high concern which are candidates for future mandatory authorisation of use are found in the so-called "candidate list"[22]. The list currently contains 197 substances[23], and the respective reasons for concern are documented in Annex XV dossiers of the Member States (accessible under 'Details' in the Candidate List).

- Substances subject to Authorisation

SVHCs on the Candidate List can be prioritised for inclusion in Annex XIV (Authorisation List)[24]. There are currently 43 substances on the Authorisation List[25], which means that these substances cannot be placed on the Union market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. Information on substances recommended to be added to the Annex XIV list should also be compiled in the inventory master list in order to include information on substances where the process is still pending[26].

- Substances subject to restriction

When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a community-wide basis, a restriction may be added to Annex XVII of REACH for the substance or group of substances. The specified substance (or substances) on its own, in a mixture or in an article, for which restrictions are specified in Annex XVII shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction[27]. There are currently 69 substances listed on the list of restrictions[28].

- PBT properties

Data and results of the PBT working group of ECHA shall be considered for future reviews[29]. Furthermore, results of PBT/vPvB assessments performed under the previous EU chemicals legislation can be found on the ECHA website[30]. 127 substances are included in this data base[31], though not all have been found to comply with PBT or vPvB criteria.

21 https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp
22 http://echa.europa.eu/candidate-list-table
23 Last viewed on 11.04.2019
24 https://echa.europa.eu/authorisation-list
25 Last viewed on 11.04.2019
26 https://echa.europa.eu/previous-recommendations
27 The list of restriction is available under https://echa.europa.eu/substances-restricted-under-reach
28 Last viewed on 11.04.2019
29 https://echa.europa.eu/de/pbt-expert-group
30 https://echa.europa.eu/information-on-chemicals/pbt-vpvb-assessments-under-the-previous-eu-chemicals-legislation
31 Last viewed on 11.04.2019

- High PB-score (RIVM-list)

RIVM, the National institute of Public Health and the Environment of the Netherlands, has developed a methodology to screen long-term fate and bioaccumulation potential in the environment. RIVM published a list of the 250 highest scoring PB substances[32].

- Endocrine disruptors

On 7 November 2018, the Commission published a communication "*Towards a comprehensive European Union framework on endocrine disruptors*" (COM 2018 734 final). This communication specifies that among others the Commission has taken action over the years "*against endocrine disruptors in line with the different requirements laid down in the relevant legislation*" with specific provisions for addressing endocrine disruptors having been included in the legislation on pesticides and biocides, in the REACH Regulation, and in relation to medical devices and water. "*These requirements vary depending on the specific legislation*". The Communication further specifies that "*substances with endocrine disrupting properties are subject to case-by-case regulatory action on the basis of the general requirements of the legislation*". It is thus understood that, substances with endocrine properties could be restricted under RoHS on a case-by-case basis, i.e. where justified on the basis of the Article 6(1) criteria.

The 7th Environment Action Programme (EAP), adopted in 2013 by the European Parliament and the Council, provided for the harmonisation of hazard-based criteria for the identification of endocrine disruptors. Scientific criteria have been established to identify substances with endocrine disrupting properties under the Plant Protection Products (PPP) Regulation (EC) 1107/2009 and the Biocidal Products (BP) Regulation (EU) 528/2012. [33, 34]

The REACH legislation (Article 57(f)) associates endocrine disrupting properties with a potential to generate both human and environment impacts. This approach has also been adopted here, meaning that consideration of a substance as endocrine disruptive would be taken into consideration for both environmental and health impacts and in relation to fulfilment of the Article 6(1) criteria on a case-by-case basis.

For the purpose of determining whether substances in the inventory have endocrine disrupting properties, the following sources shall be taken into account:

- Endocrine Active Substances Information System (EASIS): https://easis.jrc.ec.europa.eu/

  EASIS is a web-based application that allows searching and collecting results from different scientific studies on chemicals related to endocrine activity.

- ECHA's endocrine disruptor (ED) assessment list: https://echa.europa.eu/de/ed-assessment

  This list includes the substances undergoing an ED assessment under REACH or the Biocidal Products Regulation that have been brought for discussion to ECHA's ED Expert Group

[32] http://www.rivm.nl/bibliotheek/rapporten/601356001.pdf

[33] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties; https://eur-lex.europa.eu/eli/reg/2018/605/oj

[34] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council; https://eur-lex.europa.eu/eli/reg_del/2017/2100/oj

Data and results of the Endocrine Disruptor working group of ECHA shall also be considered for future reviews.[35]

- The Community Rolling Action Plan (CoRAP)

CoRAP indicates substances that are to be evaluated by the Member States over the next three years. It is updated each year in March. ECHA prepares and adopts the CoRAP list in cooperation with the Member States on an annual basis, taking into account the criteria for selection of substances.

The initial concerns are related to potential hazardous properties: persistency, bioaccumulation and toxicity (PBT), endocrine disruption, or carcinogenicity, mutagenicity and toxicity to reproduction (CMR); in combination with wide dispersive use or consumer uses. The evaluation aims to clarify the initial concern, i.e. whether the manufacture and/or use of these substances could pose a risk to human health or the environment. Substances added to the inventory from the CoRAP list are to be specified as "suspected" of having respective properties, unless the properties are also identified in international and/or EU legislation. The current CoRAP list[36], published in March 2019, contains 375 substances.

- The ECHA public activities coordination tool (PACT)

The ECHA website includes a public activities organisation tool (PACT) [37] which gives an overview of the activities that authorities are performing under REACH and the CLP Regulation in relation to specific substances, as well as providing access to information generated through such activities. The data base is updated every 48 hours and specifies activities planned, ongoing or completed by the various authorities (ECHA, MS) in line with ECHA's Integrated Regulatory Strategy in the following areas:

  - Data generation and assessment related to the evaluation of substance dossiers, substance evaluation, information generated through informal hazard assessment (PBT/vPvB/ED), etc.
  - Activities related to the Regulatory management option analysis (RMOA).
  - Activities related to regulatory risk management, such as in the process of harmonised classification and labelling (CLH) and of SVHC identification and restriction.

- The International Chemical Secretariat (ChemSec) SIN List

The International Chemical Secretariat (ChemSec) has specified and updates the SIN List, which identifies potential substances of concern based on the criteria defined within REACH. The list is explained to be a measure for putting pressure on legislators to assess and where relevant address substances identified therein in the future in respect of relevant chemical legislation. It is also understood to give indication to manufacturers as to substances the use of which should be avoided, as listed substances are suspected as hazardous and could be regulated in the future. Based on the EU REACH criteria for identifying substances as SVHC, Chemsec applies a number of categories for adding substances to the SIN List, including substances that can cause cancer, alter DNA or damage reproductive systems (CMR properties); substances that do not easily break down and that accumulate in the food chain (PBT/vPvB substances); and substances of equivalent concern that give rise to an equivalent level of concern in terms of potential damage to health and environment (such as substances with endocrine disrupting properties). The rational for in-

[35] https://echa.europa.eu/endocrine-disruptor-expert-group

[36] https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

[37] https://echa.europa.eu/de/pact

cluding substances in the SIN List is based on a scientific review and the reasons for the addition of substances to the list are specified.[38] Substances added to the inventory from the SIN list are to be specified as "suspected" of having respective properties, unless the properties are also identified in international and/or EU legislation.

- Nano Materials

According to the RoHS Directive, special account shall be given to nanomaterials[39]. This is taken into account through adding information on the possible use and/or presence of substances in nanomaterial form in EEE. Following the precautionary principle, it is relevant to gather information as to the possible use of a substance in nanomaterial form alongside information on the hazardous properties of a substance. This should support the assessment of actual impacts in use and or WEEE management at a later stage on a case-by-case basis. In this sense, the fact that a substance may be applied in nanomaterial form does not on its own comprise a hazard. However, for some substances, the size of the particle applied, in combination with its hazards, may affect the severity of impacts to occur[40] or under which conditions they occur. In this sense, adding such information to the inventory at this stage is to indicate for the prioritisation and assessment stages that it should be reviewed whether the substance is applied in EEE among others also in nanomaterial form and whether such applications actually lead to impacts of relevance for the Article 6(1) criteria.

General information on nanomaterials can be found on the European Commission website on nanotechnologies[41]. In 2012, the Commission published a "Communication on the Second Regulatory Review on Nanomaterials" that assesses the adequacy and implementation of EU legislation for nanomaterials and indicates follow-up actions in order to improve EU law and its application to ensure their safe use.[42] This document is accompanied by a Commission Staff Working Paper on nanomaterials, which provides an overview of available information on nanomaterials on the market, their types and uses, as well as on safety aspects[43]. Additional information on data sources on the use of nanomaterials is provided in Annex A.1.1.

In future reviews of the inventory, following the initial update of the list established in the past review in P I Step 1, information on hazardous properties shall be updated in Step 1a concerning:

- additional substances that have been added to the inventory in light of evidence on use and/or presence in EEE;
- changes in identification of the hazard properties of the substances already appearing in the list.

[38] http://chemsec.org/business-tool/sin-list/about-the-sin-list/, last viewed 24.07.2018

[39] Various uses of nanomaterials in electronics are reported. Nanomaterials are used in energy generation (e.g. photovoltaics) and storage (e.g. fuel cells and batteries), information and communication technologies, electronics and photonics (e.g. semiconductor chips, new storage devices and displays); security (e.g. sensors). Whereas exposure to humans and the environment at the use stage is considered to be low because it is bound in a matrix in most uses, there are ongoing discussions whether release at the waste stage could lead to exposure to significant amounts of nanoparticles. Impacts on recycling are also under investigation.

[40] For example, impacts occurring in the case of substances used in nano-form and identified with hazard properties related to respiration and inhalation (e.g. H330 - fatal if inhaled, etc.) may be more severe than when the substance is used in bulk form. In such cases, exposure to the nano-form of a substance, may allow the substance to penetrate deeper in the respiratory system. Additional information can be found in the various studies referenced here and in Appendix A.1.1.

[41] See: http://ec.europa.eu/research/industrial_technologies/nanoscience-and-technologies_en.html

[42] For further information see: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52012DC0572

[43] For further information see: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012SC0288

1.1.2. P I Step 1b): Update information on use and presence of substances in EEE

Approach/Criteria:

EEE contain a wide variety of substances and materials, including toxic or otherwise hazardous ones. Possible impacts of relevance to Article 6(1) can only be expected to be relevant for substances actually present in EEE. It is thus of importance to identify whether substances in the inventory are used or could be used (potential substitutes) in EEE as a step towards prioritisation. It is noted that the fact that information on use in the public realm is lacking shall not be a basis of excluding potential use, but rather feed into the later prioritisation stages. It is also noted that substances that react during use or are intermediates nonetheless are to be kept in the inventory and prioritised (see 1.1.2.1 for further detail).

The list updated through Step 1a is to be updated in parallel in relation to available information as to the use and/or presence of the substance in EEE. Where such data includes information as to volumes of use, this information should also be specified in the inventory. This step can be performed in parallel to PI Step 1a. Where substances are identified in this stage that were not on the initial list, care should be taken to check and add information as to their hazard properties as described n P I Step 1a.

For the purpose of this up-date stage, among others, the following lists and sources should be consulted with:

- Substances listed in the IEC 62474 Database „Declarable substance groups and declarable substances“ (IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry). It is understood that substances or substance groups are added to the list of declarable substances on the basis for example of regulatory requirements or requirements of industry standards that set reporting thresholds[44]. Three categories are specified in this respect:
  - Criteria 1: Currently Regulated;
  - Criteria 2: For assessment;
  - Criteria 3: For information only.
- ZVEI-Umbrella specifications[45]: A copy of the last version of the Umbrella specifications published online, still available in 2009, was submitted to the Commission and should be used for this step as far as newer versions do not become available.
- Information on substance uses as available from the registration process under REACH: substances with the use descriptor SU 16 “Manufacture of computer, electronic and optical products, electrical equipment” (to be specified in search under Uses and exposures>Sector of use)[46].
- Information on substance uses (Nace-codes C26 “Manufacture of computer, electronic and optical products” and C27 “Manufacture of computer, electronic and optical products”[47]) as availa-

[44] For further details see: http://std.iec.ch/iec62474/iec62474.nsf/MainFrameset

[45] See: https://www.zvei.org/verband/fachverbaende/fachverband-electronic-components-and-systems/materialdatendeklaration-auf-produktebene-und-mittels-umbrella-specifications-auf-basis-von-produktgruppen-als-effizientes-beispiel/

[46] See: https://echa.europa.eu/information-on-chemicals/registered-substances

[47] Relevant uses to be selected

ble from the Nordic Product Register (SPIN – substances in preparations in Nordic countries - register)[48];

- Information from requests for new RoHS exemptions / renewal of exemptions / withdrawal of exemptions, in which potential substitutes are addressed.

1.1.2.1. P I Step 1b.1) Quality check of the inventory of substances used in EEE

Due to the different nature of the above mentioned substance lists an initial comparative screening of the obtained substances has to be performed. The purpose of this screening shall be to identify where there are discrepancies related to the use and presence of substances in the various sources consulted. Such discrepancies should be noted, however even where clear evidence exists that a substance is not present in EEE, it should not be excluded from the list, but rather the information should be noted. As clear from the following examples, lack of presence does not always indicate no risk of impacts on health and environment:

- Some substances may be potential regrettable substitutes for others[49]. Should the latter be restricted or proposed for restriction, it may become relevant to restrict a substance that is not present in EEE in order to prevent regrettable substitution.
- Some substances are used as intermediates/process chemicals, particularly as reacting agent within a process. In such cases, the substance may not be present in the final component, or may be present in non-relevant quantities. Nonetheless, assessment of such substances should not be excluded as in some cases, this is a starting point for identifying residues, transformation or degradation products of the substance[50] of hazardous nature which remain in the final component and could be eligible for restriction in the future.

Reference to the discrepancies is thus relevant to later stages, for considering how to proceed with prioritisation and how this information should be considered in an assessment of the substance or of substances for which it may be a substitute.

1.2. P I Step 2: Priority Pre-assessment of priority of inventory substances

Approach/ Criteria: Pre-assessment of the identified relevant substances **aims** at determining which substances / substance groups have the highest potential for fulfilling the Article 6(1) criteria and should be subjected to the prioritisation in P II. The process described in this section aims at establishing a sub-selection of the substances initially identified for the inventory in relation to the priority for further assessment.

Substances addressed through existing restrictions that cover EEE shall be excluded from the inventory.

In order to select the substances with the highest potential for fulfilling the Article 6(1) criteria, a pre-assessment of the priority of the substances in the inventory shall be applied. This shall result in substances being classified into priority groups based on information of their hazard properties and of their volume of use/presence in EEE. This shall make transparent which substances are in each priority level and allow stakeholders to identify which substances shall be submitted to the

[48] See: http://spin2000.net/

[49] For example, di-isobutyl phthalate (DiBP) was restricted on the basis of its potential to be used as a substitute for other restricted phthalates.

[50] An example is AsO_3, where – even if not contained in a glass matrix as AsO_3 - in cases of use, contained compounds may be released during the crushing or milling of glass.

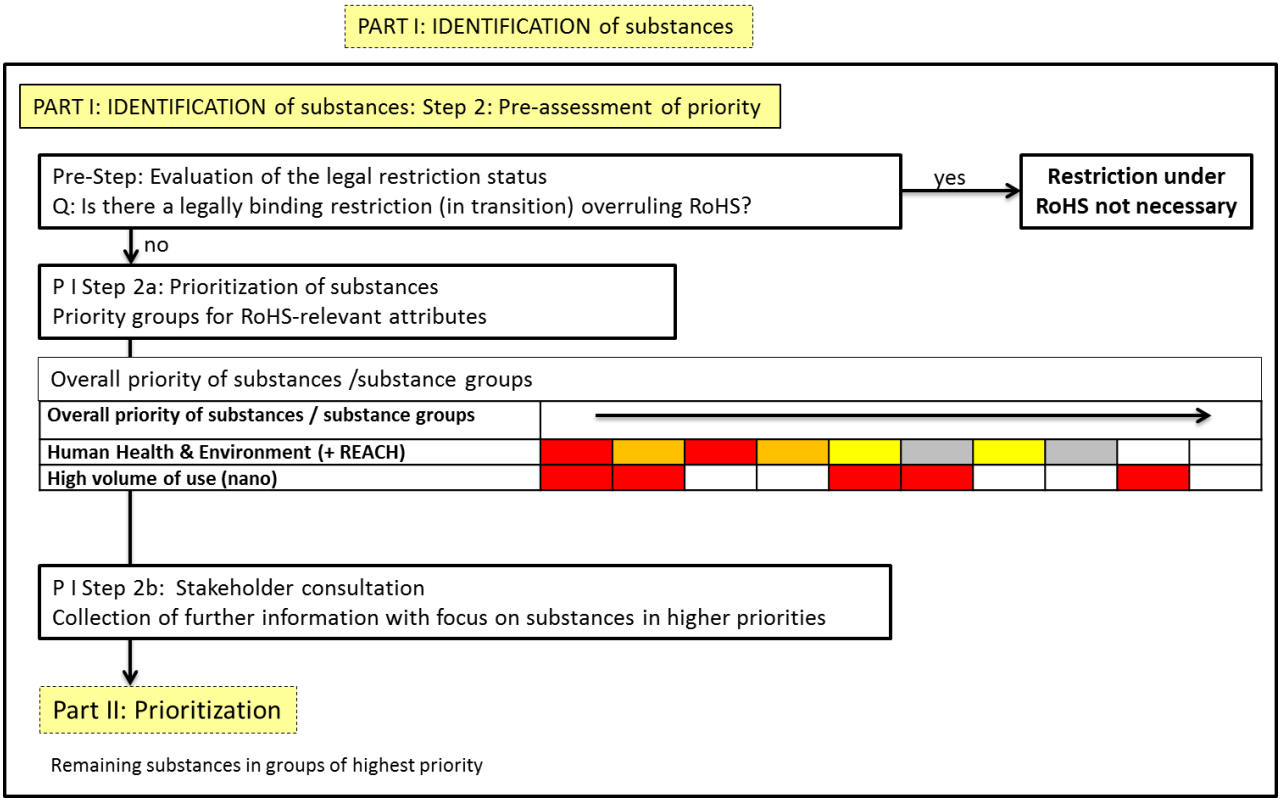
prioritisation in P II, assuming additional data is not available through stakeholder consultation prior to the final pre-assessment of priority to be carried out in P I Step 3.

The exclusion of a substance from the inventory at this stage (or allocation of a lower priority for its review) is applied during a revision of the substance inventory. However, the substance is not removed from the initial inventory to be processed in future reviews, i.e., the relevant legal status and fulfilment of Article 6(1) are to be revised during each periodic review. Substances with no data in relation to hazard properties and use/presence shall be classified in a group of the lowest priority and shall not be explicitly viewable in the inventory.

Additional information shall then be collected through a stakeholder consultation, with a focus on the substances classified with higher priority in the inventory. See 1.3.2 in this respect.

Figure 1-2 below provides an overview of the individual steps of the pre-assessment and illustrates flows of information and decisions.

Figure 1-2: Workflow of priority pre-assessment of identified substances (the arrow displays decreasing priority)



Source: Adapted with revisions from AUBA (2013)

1.3. P I Pre-Step 2 Evaluation of the legal restriction status

The **aim** of the Pre-step is to exclude substances, where a restriction under RoHS is not required, as the substance is already restricted under RoHS or at a level overruling RoHS in other legislation or where a legally binding restriction is underway, i.e., expected in the foreseeable future.

- **Criteria**: The substance is excluded if it is:

- Restricted or to be restricted (within duration of the transition period) under the RoHS Directive. Generally, substances that are under assessment for a possible RoHS restriction could be excluded from the inventory, however a future assessment may be needed in cases where information is identified as lacking or where in the future new evidence becomes available. Thus substances under assessment should be left in the inventory and specified as such. Substances assessed in the past and found not to fulfil the Article 6(1) criteria should also be noted as such and only submitted to the pre-prioritisation where new evidence has become available.
- Restricted in accordance with the REACH Regulation (Annex XVII), provided that the scope of the restriction would make a RoHS restriction redundant;
- Prohibited and/or restricted in accordance with the POPs Regulation (EC) No 850/2004 and its amendments, provided that the scope of the decision (exemptions/acceptable uses) would make a RoHS restriction redundant;
- A decision to list the substance (or substance group) in Annex A (elimination) and/or Annex B (restriction) of the Stockholm Convention has been taken by the Conference of the Parties (COP) and its implementation is pending, provided that the scope of the decision (exemptions/acceptable uses) would make a RoHS restriction redundant[51]:
  - Identification of the substance as a candidate for listing in the Convention shall not result in the exclusion of a substance. If the Persistent Organic Pollutants Review Committee (POPRC) has recommended inclusion in Annex A and/or Annex B of the Convention[52], and provided that the scope of the decision (exemptions/acceptable uses) would make a RoHS restriction redundant, the substance should be specified with a lower prioritisation.
- Covered by the Montreal Protocol, the Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, and the F-gas Regulation (EC) No 842/2006. [53]

1.3.1. P I Step 2a) Pre-prioritisation of substances

The **aim** of step 2 is to identify those substances or groups of substances which are of highest concern regarding their potential negative impact on human health and/or the environment during use and/or WEEE management.

The pre-prioritisation at this stage is performed to allow a differentiation between substances that should be assessed earlier than others. To refine this prioritisation a first estimation of fulfilment of the Article 6(1) criteria is to be performed in the prioritisation (P II), whereas an actual assessment of the actual range and severity of possible impacts shall be investigated in more detail during the assessment of a substance (P III). In this sense the pre-prioritisation should not be seen as an actual assessment of impacts but rather of the potential for various impacts to occur.

Approach: In order to prioritise substances / substance groups, a grouping system based on the assessment of the following three attributes shall be applied:

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[51] See further information under:
- Convention text and amendments: http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx
- Reports and decisions of the COP: http://chm.pops.int/TheConvention/ConferenceoftheParties/ReportsandDecisions/tabid/208/Default.aspx

[52] See POPRC “reports and decisions” and “recommendations” under following links:
- http://www.pops.int/TheConvention/POPsReviewCommittee/ReportsandDecisions/tabid/3309/Default.aspx
- http://www.pops.int/TheConvention/POPsReviewCommittee/Recommendations/tabid/243/Default.aspx

[53] See: http://ozone.unep.org/montreal-protocol-substances-deplete-ozone-layer/32506

- Hazardous properties / Human Health & Environment (including special consideration where substances appear in Annex XIV or Annex XVII of REACH);
- High volumes of use and/or presence in EEE (including special consideration for substances used among others in form of nanomaterials); and
- Possible use of a substance as a substitute for a substance restricted or to be restricted (in transition period) under RoHS.

1) Hazardous properties

The grouping system for hazardous properties developed for this methodology is based on the following considerations:

- hazard categories according to CLP;
- criteria for PBT/vPvB/endocrine disrupting properties as specified in REACH;
- PB properties (seeing as in some cases, toxic properties may not yet be classified, but evidence of impacts may exist in test results or other information and data).
- hazardous properties of waste specified in Annex III of the WFD; and
- properties according to the SVHC criteria.

In general, the CLP hazard categories (1, 1A, 1B) as well as substances identified as SVHC substances according to REACH (PBT; endocrine, equivalent level) are considered to represent the most severe effects in relation to a specific hazard property, whereas the CLP category 4 stands for the least severe hazard in relation to a specific hazard property.

Two main hazard categories, i.e. Human Health Hazards and Environmental Hazards, with three groups (Group I, Group II, Group III) each have been defined (see Table 1-2 and Table 1-3). The differentiation between the respective hazard groups is based on a combination of hazard properties (and where relevant also category) of substances on the REACH Candidate list (SVHC) with the Hazard Statement weighting factors of the Technical Rules for Hazardous Substances (TRGS) of the German BAuA [54]. Hazard properties (and where relevant also category) that fulfil the SVHC criteria are included in Group I. Such properties typically have a weighting factor (WF) of 1000 and above. In some cases (Toxic for reproduction Cat. 1 and 2; Respiratory sensitisation Cat. 1), properties with a WF of 500 are also on the REACH Candidate list (i.e. SVHC) and thus would also be included in Group I. Group II includes properties (and where relevant also category) with a weighting factor of 500, which not on the Candidate list and Group III includes properties with a weighting factor of 100 or below.

The hazardous properties prioritisation is specified below:

1a) Hazardous properties / **Human health**

Table 1-2 shows the allocation of individual substance properties to three human health hazard groups.

[54] See Technical Rule for Hazardous Substances (TRGS) 600 Substitution, established by the Committee on Hazardous Substances (AGS) and announced by the German Federal Ministry of Labour and Social Affairs, Edition: August 2008 (unofficial version; mandatory is the current German version), Annex 2 Comparative assessment of the health and safety hazards (column and effect factor model), 2: The effect factor model, pg. 21: https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/pdf/TRGS-600.pdf?__blob=publicationFile&v=2

Table 1-2: Human Health Hazard Groups

Human Health Hazard – Group I
Carcinogenic (CLP Category 1A or 1B)* (WF 1000)
Germ cell mutagenic (CLP Category 1A or 1B)* (WF 1000)
Toxic for reproduction (CLP Category 1A, 1B, or 2)* (WF 500)
Specific target organ toxicity after repeated exposure (CLP STOT RE Category 1)* (WF 500)
Specific target organ toxicity after single exposure (CLP STOT SE Category 1) (WF 1000)
Endocrine disruptive
Respiratory sensitisation (CLP Category 1) WF 500 (where included in the candidate list)
Acute toxic (CLP Category 1 and 2) WF ≥1000
Aspiration toxicity (CLP Category 1) (WF 1000)
Human Health Hazard – Group II
Skin sensitisation (CLP Category 1) (WF 500)
Respiratory sensitisation (CLP Category 1) WF 500 (other)
Respiratory sensitisation (CLP Category 2)
Human Health Hazard – Group III
Specific target organ toxicity at single exposure (CLP STOT-SE Category 2 and 3) (WF ≤100)
Acute toxic (CLP Category 3 and 4) (WF ≤100)
Carcinogenic (CLP Category 2) (WF 100)
Reprotoxic (CLP Category 2; Lact.) (WF ≤100)
Mutagenic (CLP Category 2) (WF 100)
Skin corrosion/irritation (CLP Category 1A, 1B, 1C, 2) (WF ≤100)
Serious eye damage/eye irritation (CLP Category 1, 2) (WF ≤100)

Source: Adapted and revised from AUBA (2013)

Notes: *The criteria for toxicity of a substance as specified under Annex XIII, 1.1.3 of REACH refer to STOT RE 1 and 2, however this is assumed to be in group 1 only when PBT are all identified, whereas where only T is identified, the weighting factors are considered.

1b) Hazardous properties / **Environmental hazards**

Table 1-3 below provides the allocation of individual substance properties to three environmental health hazard groups. As there is no CLP classification on PB properties (persistency and bioaccumulation potential), other data sources are used and shall be checked to gain additional information on potential P and B properties. The listed sources should only be deemed relevant if final conclusions on assessment are available.

For example:

- Results of the PBT- working group at ECHA[55];
- Evaluations of UNEP, UNECE and POP-RC[56];
- The European Commission's Joint Research Centre (JRC) Risk assessment reports/Existing substances information system/PBT assessment[57]:

[55] See: https://echa.europa.eu/pbt-expert-group

[56] See: www.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC14/Overview/tabid/7398/Default.aspx

[57] See: https://ec.europa.eu/jrc/en/publications-list/pbt

- US National Library of Medicine, Toxicology Data Network (Toxnet)[58]

Table 1-3: Environmental Hazard Groups

Environmental Hazard Group I
PBT (persistent, bioaccumulative, toxic) according SVHC criteria REACH
vPvB (very persistent and very bioaccumulative) according SVHC criteria REACH
Endocrine Disruptive
Hazardous to the aquatic environment (CLP Chronic Category 1, 2) (WF 1000)
Hazardous to the aquatic environment (CLP Acute Category 1) (WF 1000)
Hazardous to the ozone layer (CLP Category 1) (WF 1000)
Environmental Hazard Group II
PB (persistent and bio-accumulative)*,**
Environmental Hazard Group III
Hazardous to the aquatic environment (CLP Chronic category 3, 4)
Persistent (REACH criterion)* or Bioaccumulative (REACH criterion)**

Source: Adapted and revised from AUBA (2013)
Notes: * REACH Annex XIII, 1.1.1
** REACH Annex XIII, 1.1.2

The information required under Part I, Step P I-2b1a, shall be analysed systematically and shall constitute the following criterion:

- Criterion A: There is evidence that the substance/ substance group has relevant hazard properties.

Fulfilment of this criterion shall be decided considering the hazard level resulting from the classification conducted on the basis of Table 1-2 and Table 1-3. Where substances are only suspected of a certain hazard (overall hazard group IV - see Table 1-4 below), this shall be updated in the inventory (grey colour), and reviewed in the future if evidence becomes available.

Refinement of the Criteria A Prioritisation due to authorisation/restriction under REACH

In certain cases a substance may be addressed under the REACH Regulation (Authorisation, Restriction) or regulation may be under consideration. On the basis of the Common Understanding (COM 2014), and to ensure coherence with REACH, in such cases, as explained below, it shall be of a higher priority to assess whether such substances when used and/or present in EEE fulfil the RoHS Article 6(1) criteria and whether a RoHS restriction would achieve a higher level of protection than the REACH route.

If the substance is listed in Annex XVII[59] under REACH (Restriction on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles) and the restriction covers applications in EEE or if such a restriction has been proposed, the substance shall be prioritised for assessment. Substances proposed for restriction shall be specified with the highest priority, so that the assessment process under RoHS is completed so as to allow the re-

[58] See: http://toxnet.nlm.nih.gov/

[59] See list of restrictions under REACH under: https://echa.europa.eu/substances-restricted-under-reach

strictions under REACH and RoHS to be amended in proximity. The logic behind this prioritisation is related to REACH having a focus on the manufacturing and use phases in contrast to RoHS which focuses on the waste phase as well as the use phase. In this sense, it is possible that for certain substances, impacts during the waste phase would justify a stricter restriction (e.g. threshold, scope) to allow prevention of impacts during the waste phase. Where a restriction is under consideration, it would also be of importance to conclude under which legislation the restriction would be more effective so as to avoid uncertainties related to double legislation. In this sense, the parallel or proximate assessment under RoHS could in some cases be important to conclude if EEE should be excluded from a REACH restriction where RoHS could ensure a higher level of environmental protection (i.e. similar level in relation to use along with prevention of waste phase impacts not addressed through REACH).

If the substance is listed in Annex XIV of REACH[60] (List of substances subject to authorisation) and is used and/or present in EEE or if it has been proposed to add the substance to Annex XIV, it should then be prioritised for assessment under RoHS. Such substances shall be specified with the highest priority, to complete the assessment process under RoHS so as to allow the authorisations under REACH and the restriction under RoHS to be amended in proximity. Substances, for which an authorisation for manufacture and use is required under REACH, cannot be used in EEE manufacture that takes place within the EU. Nonetheless, such substances could still be placed on the EU in imported EEE articles, i.e. manufactured outside the EU. Thus, the REACH authorisation route in this case would not prevent impacts related to the use of a substance in an imported article. Therefore, the aim of the assessment is to clarify if the use and presence of the substance in (imported) EEE results in the fulfilment of the Article 6(1) criteria.

Therefore, where a substance is listed in Annex XIV and/or in Annex XVII of the REACH Regulation or if such a listing is under consideration, a RoHS assessment should be prioritised for this purpose and would result in the substance being moved to Group I in relation to its hazard group prioritisation (i.e. red colour).

2) Use relevance

For evaluating the relevance of a substance / substance group in relation to its use and/or presence in EEE, the grouping system described as follows shall be applied.

Where information indicates use and/or presence of the substance /substance group in EEE in high volumes it is assumed to indicate a higher potential for the criteria specified in Article 6(1) of RoHS to be fulfilled. Thus for the following grouping system, the information required under P I, Step 1b, shall be analysed systematically and shall constitute the following criterion:

- Criterion B: There is evidence that the substance/ substance group is used and/or present in EEE in high volumes;

For the purpose of determining this criterion, the REACH registration volume principles are to be used. High volume of a substance is to be assumed when

- the annual use is ≥ 1 tonne for substances exhibiting CMR properties; or
- the annual use is ≥ 100 tonnes for substances classified as very toxic to aquatic organisms; or
- the annual use is ≥ 1000 tonnes for all other substances.

[60] See list of authorisations under REACH under: https://echa.europa.eu/authorisation-list

Where there is information that a substance is used in such volumes, criterion B shall be considered fulfilled (red colour).

It can be understood that in some cases, impacts of a substance used in nanomaterial form may be more severe than when used in bulk form. It should thus also be considered for the interpretation of high volume use, whether the substance could be applied as a nanomaterial in EEE applications. Where this is the case, it is possible that a smaller volume of use would result in severe impacts in relation to the Article 6(1) criteria. To take consideration of this aspect in the pre-prioritisation, criterion B is to be considered fulfilled (red colour) when a substance may be used in nanomaterial form in certain EEE applications, despite its EEE use volume being below the above specified thresholds.

Fulfilment of criteria B shall be concluded on a yes/no basis depending on whether supporting information exists or not.

3) How to determine the overall priority of substances / substance groups

To determine the overall priority of a substance, all data compiled are to be reviewed and categorised.

Fulfilment of criterion A shall be based on the colour coding specified in Table 1-2 and Table 1-3 and shall result in priority groups being associated with the relevant colour coding for the (health and environmental) hazard groups. The overall relevance of a substance / substance group regarding its hazardous properties (human health & environment) is determined as described in Table 1-4 below.

Table 1-4: Hazard Groups

Hazard Group (Human Health & Environment) I
Properties of the substance/substance group are allocated either to Human Health Hazard – Group I or* to Environment Hazard – Group I
Hazard Group (Human Health & Environment) II
Properties of the substance/substance group are allocated either to Human Health Hazard – Group II or* to Environment Hazard – Group II (none to Group I)
Hazard Group (Human Health & Environment) III
Properties of the substance/substance group are allocated either to Human Health Hazard – Group III or* to Environment Hazard – Group III (none to Group I or II)
Hazard Group (Human Health & Environment) IV
Substance is only suspected of one or more of the hazard properties specified in Table 1-2 or Table 1-3.

Source: Adapted with revisions from AUBA (2013)

Notes: * properties of a substance could be allocated in some cases to both human health and environment hazards. Nonetheless, it suffices that one hazard is allocated to the groups described above to result in the specified ranking, thus the term “or” is used.

Fulfilment of criterion B shall be based on the information on use relevance (high volume of use and nanomaterials). Criterion B (high volume) shall be specified either as fulfilled (red) or not (no colour):

- where there is evidence that a substance/substance group is used/present in high volumes in EEE; or

- where there is evidence that a substance/substance group is used/present in EEE and may be applied in nanomaterial form.

The differing colour coding of the two criteria might result in evidence related to use relevance having a higher weight than the hazard class of a substance alone. This is justified with the understanding that despite the hazard class of a substance, impacts related to the Article 6(1) criteria would not be expected where the substance is not in use/present in EEE. In cases where data on volumes of use if not sufficiently available, a staggered approach is used: The final prioritisation gives preference:

- first of all to cases where there is indication of higher use volumes in the higher hazard classes (high and moderate),
- then to cases in these hazard classes with no data on use;
- and then to the other hazard classes depending on the availability of data on use.

The higher weight of data on waste is related to the possibility that there may be cases where the hazard class suggests no or low hazard, but where use results point to negative impacts during the use and/or waste phase nonetheless (particularly in cases of "new" substances where evidence supporting classification has not yet been established or processed)[61]. For example, if the substance could give rise to uncontrolled or diffuse release into the environment or could give rise to hazardous residues. Nonetheless, the objective of the RoHS Directive is understood to be "*contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE*" (Article 1). Against this background, it is assumed that where Article 6(1)(a-c) criteria are fulfilled, the substance/substance group would likely be associated with human health or environmental hazards.

The awarded colour coding is to be compiled and the overall priority determined based on Table 1-5 below. The overall priority of a substance or substance group is defined by the frequency of particular priority groups (colours) for criterion A (human health hazards & environmental hazards) and for criterion B (high use volume/use+nano).

Table 1-5: Overview of possible colour combinations for the highest overall priority categories

Criteria	Colour coded priority									
Human Health & Environment (REACH Annexes)										
High volume of use (nano)										
Resulting overall priority of substances / substance groups	I	II	III	IV	V	VI	VII	VIII	IX	X

Source: Adapted with revisions from AUBA (2013)

[61] It is noted that that in such cases, there would need to be evidence of negative impacts related to the Article 6(1) criteria. The mere use and/or presence of a substance in high volumes in EEE would not on its own justify a restriction.

Substances where the human health & environmental hazards are of high priority (red) and where criteria B is fulfilled are classified with the highest priority.

Substances where the human health & environmental hazards are of moderate (orange) priority and where criteria B is fulfilled are classified with the second highest priority.

Substances where the human health & environmental hazards are of high priority (red) or moderate priority and where criteria B is not fulfilled are classified with the third and fourth highest priorities, respectively.

Substances, where the human health & environmental hazards are of low priority (yellow) and criterion B is fulfilled are classified as the fifth highest priority.

Substances, where the human health & environmental hazards are only at suspicion level (grey) and criterion B is fulfilled are classified as sixth highest priority.

Substances, where the human health & environmental hazards are of low priority (yellow) or at suspicion level (grey) and criterion B is not fulfilled are classified as seventh highest priority

Further priority (colour) combinations are displayed in Table 1-5 above.

1.3.2. P I Step 2b): Stakeholder consultation of substances in inventory with focus on substances in higher priority groups

Approach: For a further differentiation of substances / substance groups of equal priority, further information on volumes used in EEE should be sought through a stakeholder consultation. This consultation should be held according to the specifications of the EU guidelines for stakeholder consultations and should give stakeholders sufficient time to provide contributions.[62]

Following the pre-assessment of priority, the substances in the lowest priority group (X) shall be kept in the database but not be explicitly listed in the inventory. Substances in the highest priorities shall be highlighted. Decision on the highest priorities to be highlighted shall be taken after consultation and approval by the Commission, depending on the number of substances to be subject to the prioritisation in P II. Questions should be prepared for stakeholders, emphasizing that the substances included in the highest priority groups shall be subjected to the prioritisation in P II provided further information collected shall not change the group classification. In this way, stakeholders shall be asked to concentrate their efforts in collecting and providing further information on substances in the higher priority groups with the aim of either:

- Providing evidence that a substance in the highest priorities should have a lower priority based on new evidence related to, e.g. a lower volume of use or no suspected use in EEE;
- Providing evidence that a substance in a priority group not subject to the prioritisation in P II should have a higher priority, based on new evidence related to, e.g. a high volume of use in EEE or evidence of impacts related to the Article 6(1) criteria;

A substance could fulfil the Article 6(1) criteria in some cases regardless of its hazardous substance properties or their severity. Thus, care should be taken that stakeholders invited to participate in the stakeholder consultation represent "*interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associa-*

[62] The online stakeholder consultation shall be conducted following the minimum standards for consultation of interested parties set out in the Commission Communication COM (2002) 704 final of 11.12.2002, COM(2012) 746, COM(2012) 746, SWD(2012) 422, COM(2014) 368, and SWD(2015) 111.

tions" (Article 6(1)) and not just manufacturers and the supply chain. For example, waste operators shall be able to contribute relevant information for cases where a substance should be prioritised as it "*could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE*".

Stakeholders should also be asked to provide information as for substances that should be considered in the prioritisation and or in the assessment as members of a substance group.

1.4. P I Step 3: Update inventory based on stakeholder contributions and re-run pre-assessment

Approach: Information on the volumes of the substance / substance groups used in EEE entering the Union market and other information gathered through the stakeholder consultation held in P I Step 2b (see Section1.3.2) should be added to the inventory. Subsequently the pre-assessment of priority run in P I Step 2a should be performed a second time to determine which substances are in the highest groups and thus which substances shall be subjected to the prioritisation in P II.

At this stage, it should also be considered that substitutes for substances that are already restricted, soon to be restricted (transition) or that shall possibly be restricted (recommended for restriction) should be attributed a higher priority if it has been determined during a substance assessment that they have a similar potential for fulfilling the Article 6(1) criteria and thus could be considered a regrettable substitution. In cases of a substance being recommended for restriction, the Commission could conclude on regrettable substitution based on the information available and could initiate a substance assessment bypassing the identification and prioritisation process.

Substances in the highest priority groups shall be put on a short list, creating a so called "RoHS-Working-List"[63]. This list shall be subjected to the prioritisation in P II.

2. Part II: PRIORITISATION OF SUBSTANCES: Targeted approach for refined prioritisation of high priority substances

Approach: For substances / substance groups of the highest priority, additional information shall be compiled to allow a refined prioritisation of substances in the "RoHS-Working-List" according to the following approach.

For all substances from the highest priority groups, information shall be collected from publicly available sources and compiled into a tabulation[64] based on the template provided in the Appendix, Section A.2. The tabulation should include the information for each substance regarding the following parameters and topics:

- Substance identity (Name, CAS and EC identifiers);
- Information on the substance classifications as collected in the inventory.

[63] The groups for which the refinement is to be performed shall be discussed and approved with the Commission. The selection can be performed automatically using the features of the established substance database (RoHS-working-list.xls)

[64] This format was developed in the course of a study prepared by Baron et al. (2014). An example can be viewed here: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/Questionaire_Background_Info_Substances_prioritisation.xlsx.

- Information on uses (i.e. typical general uses and applications, and typical EEE uses and applications);
- Quantities of use (i.e. typical use volumes and EEE use volumes for the EU and/or globally, depending on availability of information);
- First indication if the use and presence of the substance in EEE could potentially lead to impacts related to Article 6(1). This should be estimated based on a short review of the most recent available REACH documents (Annex XV Dossier, SEAC and RAC opinions, etc. and in relation to the information available on hazards and use ad presence of the substance in EEE);

The tabulation shall be supplemented with questions for stakeholders (see template provided in the Appendix, Section A.3). A stakeholder consultation should be held to collect additional information on the substances. Stakeholders should be asked to use the excel format to provide information for all substances subject to the refined prioritisation, though provision of additional data and information shall also be possible. This consultation should be held for a sufficient period of time, typically eight weeks, according to the specifications of the EU guidelines for stakeholder consultations.[65] Given that it is targeted at a limited number of substances a shorter period may suffice.

Grouping of substances may also be relevant at this stage e.g. in line with a simultaneous presence of substances and/or same behaviour of individual group members within the use phase or within waste management processes. This could be the case, for example, if group members are transformed into particular hazardous transformation or degradation products. Whether a grouping approach is reasonable or not has to be decided on a case-by-case basis. Guidance on grouping of substances is provided in Appendix A.6 Guidance on groups of similar substances.

It is important that, following the precautionary principle, the most hazardous group member will be taken into consideration for the prioritisation of members of the substance group for which data as to hazardous classification is missing (see data from P I Step 1a).

Detailed information on principles of the grouping approach is also given in the guidance provided by ECHA: http://echa.europa.eu/de/support/grouping-of-substances-and-read-across.

Following the consultation, all information shall be compiled into a substance background document format including the following sections:

- Substance classifications;
- Uses and quantities;
- Presentation and review of stakeholders contributions;
- Summary of the aspects identified as crucial for concluding the priority to perform a RoHS substance assessment of the substance in view of a possible future restriction, including first estimation as to fulfilment of Article 6(1); and
- References.

[65] The online stakeholder consultation shall be conducted following the minimum standards for consultation of interested parties set out in the Commission Communication COM (2002) 704 final of 11.12.2002, COM(2012) 746, COM(2012) 746, SWD(2012) 422, COM(2014) 368, and SWD(2015) 111.

The substance specific background documents shall be compiled into a report, which shall be followed with recommendations as to the refined priority of the substances reviewed, explaining the general approach in the refined prioritisation and general aspects of relevance and including a usage magnitude ranking and recommendations for each substance[66].

[66] This reporting format was developed in the course of a study prepared by Baron et al. (2014). An example can be viewed here: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/20140806_Substance_Review_revised_version_final_plus_Dossier.pdf

3. Part III DETAILED ASSESSMENT OF SUBSTANCES

The **aim** of the detailed assessment is to conclude whether a substance or substance group[67] should be recommended for restriction under RoHS or not.

The decision on which substances are to undergo a detailed assessment is to be taken by the Commission. Prioritisation of substances, performed according to Part II, shall feed into such decisions. Nonetheless, the Commission may decide to prioritise substances for assessment that were not specified with the highest priority or with any priority for that matter. This may be the case for example:

- when a RoHS assessment is initiated in the context of the various assessments performed under REACH, for example under the risk management option analysis (RMOA) or under the restriction procedure; or
- when a Member State submits a proposal for a RoHS restriction.

Article 6(2) of RoHS stipulates which types of information shall be included in a proposal to review and amend the list of restricted substances specified in Annex II of the Directive (see detail below). It is thus concluded that an assessment may address both, new substances as well as possible changes to substances already specified in the Annex, for example when it becomes relevant to change the scope of substances restricted or the conditions of the restriction (e.g. specified threshold) in light of scientific and technical progress.

Article 6(1)(a-d) of RoHS specifies criteria which have to be taken into account while assessing a possible amendment of the restriction list (see detail in “Background”, Section II.I.I). A substance assessment shall thus focus on information of relevance to allow assessing whether the criteria are fulfilled and whether a restriction would be justified.

Approach: The objective of the detailed assessment is to determine whether the Article 6(1) criteria in connection with information requirements set out in Article 6(2) are fulfilled, justifying a restriction. The following guidance has been prepared to allow the documentation of the assessment in the form of a RoHS dossier which fulfils the information requirements of Article 6(2) of the Directive. This includes the following (interpretations follow the cited requirements and appear in grey):

“(a) precise and clear wording of the proposed restriction;”

This element is interpreted to be the formulation of the recommended restriction and should include at least:

- The name of the substance/compound;
- A threshold above which the substance is restricted
- A date for application (category specific if relevant[68])

Additionally, in some cases, it may be relevant to specify equipment groups or sub-groups to be excluded from the scope of the restriction[69].

[67] For simplicity’s sake, within this manual, reference is always made to a substance, with substance groups being implied

[68] For example, in the case of the DEHP, BBP and DBP restriction under RoHS, longer transition periods were granted to categories 8 and 9 (medical devices and monitoring and control instruments, respectively).

"(b) references and scientific evidence for the restriction;"

If relevant, distinction should be made as to the certainty of information provided by various references – harmonised classifications for example shall be assumed to have a higher certainty than self-classifications[70] made by suppliers in safety data sheets. Various sources may also differ in their certainty and this should be taken into consideration and be communicated where relevant. For the purpose of evaluating the certainty of various sources, the so called weight of evidence approach may be applied[71]. This approach involves an assessment of the relative values/weight of different pieces of available information that have been retrieved and gathered in previous steps. The quality and consistency of the data of cited references shall be given appropriate weight. It shall be documented and justified in a clear and transparent manner. The principles of weighing of evidence shall be considered in order to decide whether certain sources should be considered to have a higher weight than others in light of their higher certainty. For further information as to data quality and dealing with data gaps, see Appendix A.7.

"(c) information on the use of the substance or the group of similar substances in EEE;"

Such information should include detail of relevant products and components in which the substance (or group of substances) is used and/or present, detail of its function in applications in which it is used and/or present and estimated volumes of use and/or presence in EEE in the EU and globally. An estimated distribution of the total volume between typical uses in EEE should be detailed.

"(d) information on detrimental effects and exposure in particular during waste EEE management operations;"

Information should relate to impacts addressed under Article 6(1)(a-d), so as to clarify the types of impacts and the range at which they are expected to occur and subsequently to what degree the criteria specified under Article 6(1)(a-d) are fulfilled.

"(e) information on possible substitutes and other alternatives, their availability and reliability;"

Information should allow understanding in which applications substitutes or alternative technologies are already applied and subsequently to what degree the substance (or substance group) has been phased-out. Where differences occur related to substitute or alternative technology implementation, such as between manufacturers of certain regions, product or component categories, etc., this should be specified. It should also be specified whether substitutes or alternative technologies can be considered to have less negative impacts (interpreted in comparison with the impacts of the substance in relation to the Article 6(1)(a-c) criteria).

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69 As performed in the case of the DEHP, BBP and DBP restriction under RoHS and its applicability to toys, for which a restriction for use in toys was already valid at the time of recommendation through entry 51 of Annex XVII to Regulation (EC) No 1907/2006 (REACH), see http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015L0863 for detail.

70 The CLP Regulation requires suppliers of substances and mixtures to decide on the classification of a substance or mixture to be placed on the market. This information needs to be taken into consideration for example in the labelling of the substance, in its safety data sheets, etc. This is called a self-classification.

71 The so-called weight of evidence approach is described more precisely in ECHA's practical guide: "How to report weight of evidence?" (published in 2010) as well as in Annex I of the CLP regulation (EC) No 1272/2008 and is also outlined in the general approach for prioritisation of SVHC substances for inclusion in the list of substances subject to authorisation . It is also well described in the 2012 memorandum of the Scientific Committees on Emerging and Newly Identified Health Risks (SCENIHR).

"(f) justification for considering a Union-wide restriction as the most appropriate measure;"

The assessment should detail the rationale for recommending a restriction under the RoHS Directive and why legislation at this level is understood to have benefits over the alternative of national legislation.

"(g) socioeconomic assessment."

Information should analyse whether the benefits related to a restriction scenario under RoHS are considered proportionate in relation to costs expected to arise through the enforcement of the restriction. Proportionality is interpreted to mean that while some costs may be acceptable and justified as improving the protection of environment and of health can be assumed to have a price, where costs are significantly higher than expected benefits this relation is to be considered for the purpose of establishing whether the benefits justify the restriction and its costs. For this purpose, the following socio-economic impacts should be considered (non-exhaustive- see further detail in Section 3.12):

- Impact on chemicals industry (EU and non-EU, substance manufactures and substitute manufacturers);
- Impact on EEE producers industry (EU and non-EU, suppliers and manufacturers of substance and substitute based technologies);
- Impact on EEE users (private users, commercial users);
- Impact on waste management (impacts related to EEE containing the substance or EEE containing substitutes or alternative technologies);
- Impact on public administration (for regulators at EU level and national level);
- Impacts on environment (during use, during waste management; impacts on different media, e.g. air, water, soil);
- Impacts on health (consumers, workers, residents in proximity of waste management facilities)
- Total socio-economic impact (relation of costs and benefits);

It is stated in the Directive (Recital 10, Article 6,) that the amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular the REACH Regulation and shall use publicly available knowledge obtained from the application of such legislation. Therefore, the methodology for assessment of substances under RoHS relies on existing data from the REACH Regulation, and will take into account, inter alia, Annexes XIV and XVII to that Regulation and documents established in relation to their entries. Further, Annex XV dossiers for Restriction and other documents prepared for regulatory purposes under REACH will be considered. Impact Assessments and Risk Assessment Reports of the European Commission (in the framework of Council Regulation (EEC) No 793/93 also known as Existing Substances Regulation (ESR), scientific opinions of any of the European scientific committees e.g. SCHER, SCENIHR, SCCP, SCCS, RAC, SEAC, SCOEL[72] shall be taken into account. International guidelines and recommendations and other relevant available scientific and technical information, shall be considered.

[72] SCHER: Scientific Committee on Health and Environmental Risks; SCENIHR: Scientific Committee on Emerging and Newly Identified Health Risks; SCCS: Scientific Committee on Consumer Safety; RAC: Committee for Risk Assessment; SEAC: Socio-Economic Analysis Committee, SCOEL: Scientific Committee on Occupational Exposure Limits

In general, the main principles of a risk assessment as implemented by ECHA shall be followed. A short overview is given in the ECHA guidance “Chemical safety assessment: guidance in a nut-shell”[73]. Further in depth guidance documents are provided on the ECHA website[74].

A proposal for the template RoHS-Annex II-Dossier will be provided as a separate Document (attached to this report). In the preparation of a dossier for a specific substance:

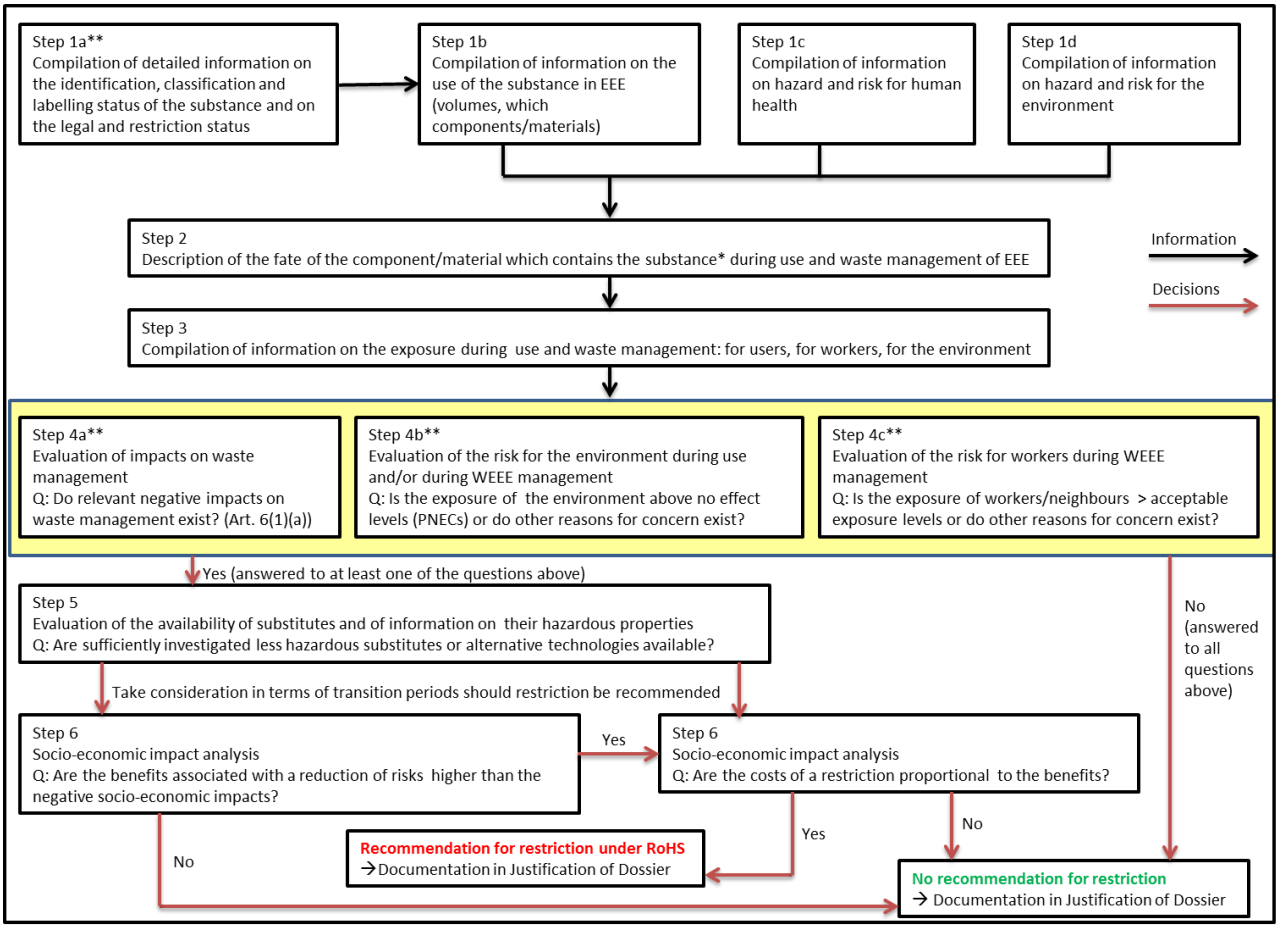
- information is to be collected and documented in the dossier in relation to:
  - the substance identification, classification and labelling and legal status (Figure 3-1, step 1a);
  - the substances use in EEE (typical function and applications, volumes of use) (Figure 3-1, step 1b);
  - the hazard risk of the substance for health (Figure 3-1, step 1c);
  - the hazard risk of the substance for the environment (Figure 3-1, step 1d);
  - the fate of components and materials containing the substance during use and during waste management (Figure 3-1, step 2); and
  - possible exposures during use and during waste management (Figure 3-1, step 3).
- The analysis undertaken and findings related to impacts related to the use of the substance in EEE is to be documented in the dossier in relation to:
  - Impacts expected during use and/or during waste management (Figure 3-1, step 4a). To estimate whether impacts are to be expected during the use phase and/or during the waste phase, the expected exposure under certain conditions needs to be estimated as part of the evaluation. For this purpose, specific exposure scenarios for assessing substances during WEEE management have been developed for this manual;
  - Risks for the environment on WEEE management (Figure 3-1, step 4b);
  - Risks for workers during WEEE management (Figure 3-1, step 4c);
  - The availability of substitutes and of information on their hazardous properties (Figure 3-1, step 5);
  - Socio-economic impacts (Figure 3-1, step 6);
- Finally a recommendation is to be included in the dossier and where relevant the rational for a restriction is to be detailed.

Figure 3-1 below provides an overview of the individual steps of the detailed assessment and illustrates flows of information and decisions.

[73] See: http://echa.europa.eu/documents/10162/13632/nutshell_guidance_csa_en. pdf

[74] See: http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation

Figure 3-1: Workflow of the detailed assessment



Source: Adapted and revised from AUBA (2013)

Notes: * The substance and/or its derivatives.

** , "Shortcuts" may be taken should the initial investigation of the substance indicate:

- In relation to step 1, that the level of protection of the environment and or of health achieved through a RoHS Restriction shall not be higher than the level achieved through other legislation under which restrictions exist (e.g. POPs Regulation, Ozone and F-gas Regulation). See 3.1P III Step 1a) Compilation of basic information on the identification, classification, labelling and legal status of the substance in this respect.
- in relation to step 4 that it is not expected to be present in EEE, seeing as impacts related to the presence of a substance in EEE would not be expected

See further detail in the following sections.

Article 6(1), last paragraph specifies that during a review of the list of substances in Annex II, the Commission shall consult interested parties, i.e. stakeholders of relevance to EEE.

- To comply with this provision, the process of substance assessment should include a stakeholder consultation on the complete draft dossiers of each substance under review, to allow stakeholders among others the possibility of contributing information where data gaps exist (no data or conflicting views). The duration of the consultation should provide stakeholders with sufficient time for preparing and submitting their responses. In cases of a proposed substance re-

striction it is recommended to hold the consultation for 8 weeks. This consultation should be held according to the specifications of the EU guidelines for stakeholder consultations.[75]

- The assessment of substances could furthermore include a stakeholder consultation at the beginning of the process, calling stakeholders to prepare and submit information of relevance as to the use of the substances under review in EEE manufacture and their impacts on the environment and on health during the use phase and the waste phase. Such contributions are understood as an important source of information for the assessment, particularly where publicly available data is less recent and thus possibly not sufficiently reflecting the current status of use and presence of a substance in EEE.
- The assessment should also include direct consultation with targeted stakeholders, for example:
  - Manufacturers or suppliers of EEE and EEE components, in which each substance under review (or its derivatives) is expected to be used in manufacture and/or present in the final product;
  - Manufacturers of the substances under review;
  - End-users of relevant of EEE and EEE components that can provide information on impacts related to use - this may include both commercial users such as users of medical equipment, but also consumer organisations;
  - Representatives of Member States which have investigated the substances under review in the past or which have access to market surveillance data of relevance to the review;
  - Representatives of the waste management value chain (collection and treatment operators, etc.) that can provide data as to possible impacts on the waste phase.

The methodology is not a legally binding instrument. Article 6(1) of the Directive refers to proposals of Member States for the review and amendment of the list of restricted substances in Annex II, stating that these shall contain the information referred to in Article 6(2), i.e., the information specified above. In this sense, proposals submitted by Member States could consider the methodology to ensure compliance with the Article 6(2) information requirements, but are not obliged to do so. A review and possible amendment of the list based on a Member States' proposal would follow the same assessment steps as review triggered by a Commission initiative.

3.1. P III Step 1a) Compilation of basic information on the identification, classification, labelling and legal status of the substance

The **aim** of this first step is to provide basic information on the substance.

Furthermore, information on regulatory measures to minimize health and environmental impacts caused by the substance of concern shall be provided.

Information required

The following information, structured as described below, is required:

- Identification of the substance

[75] The online stakeholder consultation shall be conducted following the minimum standards for consultation of interested parties set out in the Commission Communication COM (2002) 704 final of 11.12.2002, COM(2012) 746, COM(2012) 746, SWD(2012) 422, COM(2014) 368, and SWD(2015) 111.

  - Name, other identifiers and composition of the substance
  - Physico-chemical properties

- Classification:
  - Harmonised classifications at community level shall be specified from Annex VI of Regulation 1272/2008(EC) where such classifications exist.
  - Self-classification(s) notified by industry according to the CLP-regulation are also to be taken into consideration. Self-classifications shall be specified in detail where harmonised classifications are lacking. Self-classifications may differ among notifiers as well as from harmonised classifications, referring to additional end-points in terms of risks or specifying a hazard at a different level. Should a significant share of self-classifications (10% of notifiers and above) address additional end-points of concern or classify higher levels of hazard than those specified in the respective harmonised classification, these should be summarised as well. This should allow consideration whether additional impacts of relevance to the Article 6(1) criteria may incur.

- Legal status and restrictions of use
  - International agreements
  - Regulation of the substance under REACH
  - Other legislative measures
  - Non-governmental initiatives
  - Voluntary restrictions by industry

For substance groups, including elements and their compounds, a list of known members of the group should be compiled to identify possible group members. In the case of organic chemicals, this could include theoretical structural members, for example where all members are to share a certain molecular structure. In cases where a structural and / or functional definition of members included in the group can be formulated so that it is clear, which substances are in the group and which are not, this may be applied to avoid the generation of extensive lists, provided that members of the group for which data is available are specified. The information related to the parameters above should be compiled for all group members for whom data is available.

Result/Expected Outcome: A clear documentation of substance specific information including the legal status and possible conflicting legislation shall be provided.

If information collected at this stage should show that the substance is already restricted by the POPs Regulation, by the Regulation on substances that deplete the ozone layer or by the F-gas Regulation covering the use in EEE, the assessment should take consideration of whether a restriction under RoHS would achieve the same or a higher level of environmental and health protection (for example through a stricter threshold). The assessment should only continue where a RoHS restriction can be expected to achieve a higher level of protection or where this cannot yet be concluded. This approach should also be followed where a restriction under one of these regulations is expected in the near future.

If information collected at this stage should show that the substance is listed in Annex XIV (Authorisation) or Annex XVII (Restriction) of the REACH Regulation, the assessment should take consideration of whether a restriction under RoHS would achieve the same or a higher level of envi-

ronmental and health protection. In the case of an Annex XIV listing, granted authorisations should also be reviewed to understand implications for the transition period and for possible exemptions required should a RoHS restriction be recommended.

Sources of information

- Classification and Labelling Inventory (ECHA)[76]
- ECHA substance information system[77].
- European Union law and other documents considered to be public are provided on EUR-Lex homepage[78].
- Stockholm Convention website[79]
- Montreal Protocol website[80].

Further information sources:

- eChemPortal of the OECD[81].
- ChemIDplus of the U.S. National Library of Medicine[82]
- Subsport[83] (provides information on international agreements, EU regulatory, governmental and NGO, Trade Union and company lists)

This information will be documented in Chapter 1 of the Dossier.

3.2. P III Step 1b) Compilation of detailed information on the use of the substance in EEE

The **aim** of this step is to provide information on the substance use which is essential for P III Step 3 “Determination of the relevant waste streams and treatment processes and release estimation “ and P III Step 5 “Substitutes”.

Information required

- Compile information on EEE in which the substance is used: This information is needed in order to determine relevant waste streams (WEEE categories) (see P III Step 2). Information shall also be compiled in which main materials/components of EEE the substance is present.
- Compile information on the functions for which the substance is used: In order to evaluate substitutes, the information on the function of the substance (e.g. use as a plasticiser, stabiliser, flame retardant, solder, etc.) or the properties that it enables in EEE (e.g., conductivity, corrosive resistance, machinability, etc.) is also to be compiled.

[76] See: https://echa.europa.eu/information-on-chemicals/cl-inventory-database
[77] See: http://echa.europa.eu/information-on-chemicals
[78] See: https://eur-lex.europa.eu/homepage.html
[79] See: http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx
[80] See: http://ozone.unep.org/montreal-protocol-substances-deplete-ozone-layer/32506
[81] See: https://www.echemportal.org/echemportal/index.action
[82] See: https://chem.nlm.nih.gov/chemidplus/
[83] See: www.subsport.eu

- Compile information on the annual volumes of the substances used in/present in EEE placed on the global and on the EU market. If available, information should also be compiled on the distribution of these volumes in relation to the typical application sub-groups.
- Compile information, where available, on possible impacts of the substance and/or its derivatives on the environment and on health that are associated with the use phase. This should include both impacts expected during intended use (e.g. skin exposure to surface areas, inhalation of emissions of volatile substances) and during non-normal use (e.g. emissions during a fire, emissions of liquid or powder substances as a result of breakage). Where available, information should furthermore be specified regarding the likelihood of the various impacts to occur and the range of possible impacts (emissions) or to allow making assumptions as to the likelihood and range of possible impacts. Such data shall support the performance of exposure estimation in P III Step 3 (see Section 3.6).

For substance groups, including elements and their compounds, information related to the parameters above should be compiled for all group members for whom data is available. It is assumed that members shall have similar functions and uses as this is often the rational for group restriction, where one member may constitute a substitute for another. In such cases, the substitution of one member through another would constitute a regrettable substitution as impacts in the use and/or waste phase are expected to be of a similar order. Thus, where a high use or waste management relevance is identified, the most hazardous representative of the group is to be chosen for developing estimations to be included in the dossier (exposure estimations, risk assessment and socio-economic analysis).This shall allow determining the possible impacts related to hazardous properties (human health) of the substance group in the context of the assessment.

Possible sources of information

- Information from substance registration dossiers
- Studies and working papers
- Product and material databases (for details see P III Step 1a - Section 3.1, Sources of information)
- Websites of relevant companies and business associations
- Stakeholder consultation (both online consultation and direct correspondence with stakeholders)

Detailed information on uses of the substance in EEE will be compiled in Chapter 2 of the Dossier.

3.3. P III Step 1c) Compilation of information on human health hazards

The **aim** of this step is to describe the hazard of the substance and provide information on safe exposure levels.

Information required

- Compile **information** on hazards identified in relation to human health: The hazard of the substance and related effects on human health shall be described. The reliability, relevance and adequacy of information shall be assumed in case of recent assessments conducted by or on behalf of EU bodies (e.g. ECHA, JRC and the COM), but should be evaluated if any original literature is available. Specific attention shall be given to the respective endpoints of concern (the organs and/or organ systems of the human body which are assumed to be the most sensitive).

Safe exposure threshold levels and other guidance values from European and international bodies will be listed.

- Results of hazard assessments if already available by a EU body
- Comprehensive risk profile of the substance
- Endpoints of concern and No Observable Adverse Effect Levels (NOAELs)
- Guidance values (AELs, DNELs, DMELs, OELs; Reference levels, etc.)
- Derivation of DNELs according to the ECHA guidance document in case no reliable DNEL is available

For substance groups, including elements and their compounds, information should be compiled for all group members for whom data is available. Differences in associated hazards and exposures should be addressed to allow concluding at later stages if the rational for a group restriction is justified (i.e. that impacts related to the Article 6(1) criteria are expected to be similar for all group substances or for a sub-set thereof). It is assumed that members shall have similar classifications as this is often the rational for group restriction, where one member may constitute a substitute for another. In such cases, the substitution of one member through another would constitute a regrettable substitution as impacts in the use and/or waste phase are expected to be of a similar order. Thus, where a high use or waste management relevance is identified, the most hazardous representative of the group is to be chosen for developing estimations to be included in the dossier (exposure estimations, risk assessment and socio-economic analysis).This shall allow determining the possible impacts related to hazardous properties (human health) of the substance group in the context of the assessment.

Result/Expected Outcome: A hazard assessment and threshold levels for exposure below which risks for human health are considered to be controlled shall be documented as basic requirements for risk characterisation. In case no threshold can be established, respective DMELs and unit risk levels shall be discussed.

Sources of information

For substances already under consideration within the REACH process, available Annex XV dossiers, risk assessment reports (RARs) gained from the Existing Substances Regulation (EEC) No 793/93) and documents provided by ECHA, including the Chemical Safety Reports, are considered as first hand references.

- European Chemical Agency (ECHA), Annex XV dossiers: Registered Substances information, restriction proposals, risk assessment reports, guidance documents[84] (e.g. R7[85], R8[86])
- Opinions of the Scientific Committees of the European Commission (SCOEL, SCHER, SCENIHR, SCCP, SCCS, RAC, SEAC)

Examples of further relevant information sources:

Other EU sources:

- European Agency for Health and Safety at Work (OSHA)[87]

[84] See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

[85] Guidance on Information Requirements and Chemical Safety Assessment

[86] Characterisation of dose [concentration] - response for human health

- Occupational exposure limits set-out in the Carcinogens and Mutagens Directive (CMD) and/or in the Chemical Agents Directive (CAD) for protecting workers against risks to their health and safety arising, or likely to arise, from exposure to carcinogens and mutagens or to chemical agents at work[88].
- European Food Safety Authority (EFSA)[89]

International sources:

- eChem Portal of OECD[90]
- OECD QSAR toolbox[91]
- WHO Library information system (WHOLIS)[92]
- International Agency of Research on Cancer (IARC)[93]
- International Program of Chemical Safety (IPCS)[94]
- POPRC: Persistent Organic Pollutants Review Committee[95]
- UNEP United Nations Environmental Programme[96]
- UNECE United Nations EconomicCommission for Europe[97]

Member States:

- Gefahrenstoffinformationssystem (GESTIS) der deutschen gesetzlichen Unfallversicherung[98],
- ANSES (French Agency for Food, Environmental and Occupational Health & Safety[99], INERIS (French National Institute for Industrial Environment and Risks[100] and INRS (French National Institute for Research and Occupational Health and Safety[101].
- RIVM (National Institute for Public Health and the Environment, Netherlands[102]

Non EU countries and other sources:

- Agency of Toxic Substances and Disease Registry (ATSDR) of the U.S. Department of Health and Human Services[103]

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87 See: https://osha.europa.eu/en
88 See:
89 See: http://www.efsa.europa.eu/
90 See: http://www.oecd.org/
91 See: http://www.qsartoolbox.org/
92 See: http://www.who.int/library/en/
93 See: http://www.iarc.fr/
94 See: http://www.inchem.org/
95 See: http://www.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx
96 See: http://www.unep.org/
97 See: http://www.unece.org/
98 See: http://gestis.itrust.de/nxt/gateway.dll/gestis_de/000000.xml?f=templates$fn=default.htm$vid=gestisdeu:sdbdeu$3.0
99 See: https://www.anses.fr/en
100 See: https://www.ineris.fr/fr
101 See: http://en.inrs.fr/
102 See: https://www.rivm.nl/en/
103 See: https://www.atsdr.cdc.gov/

- Chemical Carcinogenesis Research Information System (CCRIS) of the US National library of medicine[104]
- Integrated Risk Information System (IRIS) of the US National library of medicine[105]
- Toxicology Data Network (ToxNet) of the US National library of medicine[106]
- National Institute of Technology and Evaluation (NITE); Japan[107]
- Scientific literature (e.g., PubMed, Web of Knowledge)[108]
- European Centre for Ecotoxicology and Toxicology of Substances (ECETOC)[109]

This information will be compiled in Chapter 3 of the Dossier.

3.4. P III Step 1d) Compilation of information on hazard(s) for the environment

The **aim** of this step is to provide basic information to be used for identification of the environmental hazard, including bioaccumulation potential or secondary poisoning and the potential for long range transport.

Information required

- Compile **information** on hazards - identification of hazard(s) for the environment: The hazard of the substance and effects on the environment shall be described. The reliability, relevance and adequacy of information shall be assumed in case of recent assessments conducted by or on behalf of EU bodies (e.g. ECHA, JRC and the COM), but should be evaluated if any original literature is available.. Specific attention shall be given to PBT properties of a substance.
- Predicted No Effect Concentration (PNEC) and guidance values from European and international bodies will be listed. The lowest PNEC for each environmental medium will be reported and be used for risk characterisation.
- PNECs and guidance values of European and international bodies
- NOAEC values for the aquatic compartment
- NOAEC values for the terrestrial compartment if available
- Half-life in air, soil, water, water-sediment
- LogK_{ow} as indicator for bioaccumulation
- Bio-concentration factor (BCF) values
- Risk of secondary poisoning and bioaccumulation

Hazard assessment and threshold levels for exposure below which risks for the environment are considered to be under control shall be documented as basic requirements for risk characterisation. PBT properties shall be documented.

[104] See: https://toxnet.nlm.nih.gov/newtoxnet/ccris.htm
[105] See: https://www.epa.gov/iris
[106] See: https://toxnet.nlm.nih.gov/
[107] See: https://www.nite.go.jp/index-e.html
[108] See: https://www.ncbi.nlm.nih.gov/pubmed/
[109] See: http://www.ecetoc.org/

For substance groups, including elements and their compounds, information should be compiled for all group members for whom data is available. Differences in associated hazards should be addressed to allow concluding at later stages if the rational for a group restriction is justified (i.e. that impacts related to the Article 6(1) criteria are expected to be similar for all group members or for a sub-set thereof).It is assumed that members shall have similar classifications as this is often the rational for group restriction, where one member may constitute a substitute for another. In such cases, the substitution of one member through another would constitute a regrettable substitution as impacts in the use and/or waste phase are expected to be of a similar order. Thus, where a high use or waste management relevance is identified, the most hazardous representative of the group is to be chosen for developing estimations to be included in the dossier (exposure estimations, risk assessment and socio-economic analysis).This shall allow determining the possible impacts related to hazardous properties (environmental) of the substance group in the context of the assessment.

Possible sources of information

See sources of information as listed in P III Step 1c (see Section 3.3).

Additional information sources:

- Syracuse Research Cooperation (SRC); Environmental fate database[110].
- ECHA guidance documents[111]:
  - Guidance on Information Requirements and Chemical Safety Assessment (R7)
  - PBT Assessment (R11)
  - Environmental exposure estimation (R16)

These facts will be documented in Chapter 4 of the Dossier.

3.5. P III Step 2 Determination of the relevant waste streams and treatment processes and release estimation

The **aim** of this step is to determine which steps of the overall WEEE management are relevant in terms of expected release of the substance and to generate information and data on the basis of which the relevant release estimations shall be evaluated. It is noted that the scope of the WEEE directive and the scope of the RoHS Directive are not completely aligned and there are differences related to the categorisation of EEE in the two Directives. For example, photo-voltaic panel systems benefit from an exclusion from scope under RoHS (Article 2(2)(i)) but are not excluded from the scope of WEEE. Detail of the EEE categories specified under the WEEE Directive and equipment considered to be covered therein is provided in the Appendix, Section A.4.

P III Step 2a) Determine which treatment processes does the equipment containing the substance undergo

Management of WEEE in many cases consists of several steps before individual material streams are re-used, recycled or disposed of. It includes collection, transport, storage and treatment of separately collected WEEE. Separation and recovery of the main materials/components is for

[110] https://www.srcinc.com/what-we-do/environmental/scientific-databases.html

[111] See https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

most types of separately collected WEEE one of the initial treatment steps – performed either by manual dismantling or by automated shredding and subsequent sorting.

Treatment processes applied include manual dismantling (where also hazardous components may be removed), mechanical disintegration and crushing of the appliances (various types of shredding, grinding processes etc.) and manual or automated sorting of materials. Furthermore, thermal processes – such as, for example, for the stripping of hazardous fractions from gas discharge lamps, flat screens or cooling and freezing equipment – are applied.

Due to differences in the material composition, the treatment options for individual WEEE categories, respectively groups of appliances, differ too. It is thus necessary as a first step, to identify the waste streams in which the typical applications, containing a substance in question, are be found in and what types of treatment such waste stream undergoes.

A significant share of WEEE is not collected by the foreseen systems so that the average share of WEEE collected in 2016 out of the EEE "placed on the market" in 2013-15 was ca. 50% [112]. Furthermore, a considerable part of WEEE arising in Europe is shipped to third countries (for 2012, Huisman et al. (2015) estimated ≈ 1.5 million tonnes) and subjected to treatment under uncontrolled conditions[113]. Therefore, also processes applied in the treatment of waste streams, where the non-appropriately collected WEEE typically end up have to be considered, i.e. treatment of other waste fractions (e.g., municipal waste), incineration and mechanical treatment and sorting and in some cases also land-filling.

Information required

- The following information is needed to determine which treatment processes the substance undergoes:
  - information on the main materials in which the substance is present (see P III Step 1b "Information on the use of the substance")
  - information on the WEEE categories in which the substance is present, i.e. EEE applications in which it is present.

Information shall be compiled as to the main materials/components in which the substance is expected to be contained (or, in case of lack of data, assumed to be contained based on the typical applications addressed in P III Step 1b). Materials shall be specified based on the main materials/components usually resulting from treatment of WEEE. Where available, data should be specified as to the quantities/concentrations in which the substance is expected to be present. The following list details materials usually resulting from the treatment of WEEE:

- Ferrous metals (except those being part of electronic components)
- Non-ferrous metals (except those being part of electronic components)
- Plastics (except those being part of electronic components)
- Electronic components (those which are known to be separated to a large extent from WEEE as a separate fraction, including printed circuit boards, engines, motherboards connectors, etc.; the

[112] Data is representative for EEE in scope of the WEEE Directive, which may differ from the scope of EEE in the scope of the RoHS Directive. Data is based on EUROSTAT data, online data code: env_waselee. See also https://ec.europa.eu/eurostat/statistics-explained/index.php/Waste_statistics_-_electrical_and_electronic_equipment#Collection_of_WEEE_by_country

[113] See: http://www.cwitproject.eu/wp-content/uploads/2015/09/CWIT-Final-Report.pdf

substance may be contained in metals, plastics, ceramics or any other material of the component)

- Cables
- Glass
- Powders
- Fluids (except those being part of electronic components)
- Others (wood, concrete and ceramics, rubber, etc.)

As the next step, typical EEE containing the substance should be associated with the WEEE categories (see below) according to Annex III of the WEEE Directive (2012/19/EU). In case of lack of data, estimation shall be attempted based on existing knowledge acquired during the first parts of the assessment, i.e. based on the applications in which the substance is present and the EEE categories in which these are expected to be found. For this purpose, an alignment is provided in the Appendix, Section A.4. In cases where the scopes of the directives do not overlap, and equipment understood to be in the scope of RoHS is not under the scope of WEEE[114], information should be sought as to what waste stream such equipment (or its components) are treated with, how this is performed and possible impacts of relevance to the Article 6(1) criteria.

1. Temperature exchange equipment
2. Screens, monitors
3. Lamps
4. Large equipment
5. Small equipment
6. Small IT and telecommunication equipment

It is necessary to have knowledge about the presence of the substance in the individual WEEE categories for the following reasons:

- The rate of separate collection varies considerably between the WEEE categories (and types of appliances).
- The amount of shipments to third countries varies between WEEE categories.
- The treatment options vary between individual WEEE categories. Certain WEEE categories or product groups, such as gas discharge lamps, screens and cooling and freezing appliances, undergo dedicated treatment processes under special conditions as a first treatment step, whereas WEEE from certain product groups is treated together with other product groups.

The following table can be used to summarize the **initial treatment** processes, applied according to the WEEE category in which EEE containing the substance is to be found. This shall later allow specifying the relevant waste streams for which it is to be assessed if emissions occur that would fulfil the RoHS Article 6(1) criteria.

Table 3-1: Initial treatment processes for WEEE

Initial treatment process	The substance is present in appliances belonging to

[114] For example, some medical devices, such as blood analyses equipment, include components exposed to bodily fluids during use. Such components are required to be treated as medical waste.

	Cat1	Cat2	Cat3	Cat4	Cat5	Cat6
For WEEE collected separately						
Collection and transport	x	x	x	x	x	x
Dedicated treatment processes for cooling & freezing appliances	x					
Dedicated treatment processes for screens		x				
Dedicated treatment processes for lamps			x			
Manual dismantling	x	x		x	x	x
Shredding (and automated sorting)	x			x	x	x
For WEEE not collected separately						
Landfilling (of residual waste)		x	x		x	x
Mechanical treatment (of residual waste)		x	x		x	x
Incineration		x	x		x	x
Uncontrolled treatment in third countries	x	x		x	x	x

Source: Adapted from AUBA (2013)

Note - the indications in the table serves as an example. Where the table is to be used as described above, an x should be indicated where there is evidence that the substance (i.e. respective applications) is present in the relevant category and waste treatment. Specifying the x in brackets is to indicate that evidence is not available and that indication is based on suspicion. This should enable differentiating in later phases between differences in the level of certainty of specific results.

Treatment of secondary waste: The following table can be used to summarise intermediate and final treatment processes applied to secondary waste streams derived from WEEE treatment, for the main material/component in which the substance is present. This shall later allow specifying the relevant waste streams for which it is to be assessed if emissions occur that would fulfil the RoHS Article 6(1) criteria.

Table 3-2: Treatment processes for wastes derived from WEEE

Treatment process for wastes derived from WEEE treatment	The substance is present in the following main component/material								
	Ferrous metals	Non-ferrous metals	Plastics	Electronic components	Cables	Glass	Powders	Fluids	Others
Under current operational conditions in the EU									
Storage of secondary wastes	x	x	x	x	x	x	x	x	x
Shredding and automated sorting of secondary wastes	x	x	x	x	x	x			
Recycling of ferrous metals	x								
Recycling of NE metals		x			x				
Recycling of plastics			x		x				
Recycling of glass						x			
Recycling as building material						x			x
Landfilling of residues	(x)	x	x	x	x	x	x		
Incineration of residues		x	x	x	x		x		x
Co-incineration of residues			x	x					x
Dedicated processes for hazardous residues				x			x	x	
Under uncontrolled conditions									
Acid leaching				x					
Grilling/desoldering				x					
Uncontrolled combustion			x	x	x		x		x
Uncontrolled dumping of residues			x	x		x	x		x

Source: adapted from AUBA (2013)

Note - the indications in the table serves as an example. Where the table is to be used as described above, an x should be indicated where there is evidence that the substance (i.e. respective applications) is present in the relevant category and waste treatment. Specifying the x in brackets is to indicate that evidence is not available and that indication is based on suspicion. This should enable differentiating in later phases between differences in the level of certainty of specific results.

P III Step 2b) Determination of processes to undergo exposure assessments

The applied treatment processes can be divided into two types:

- Processes dedicated to WEEE or waste derived thereof
- Processes where WEEE and waste thereof are processed together with other waste

The table below provides guidance on which processes are dedicated specifically to WEEE or wastes derived thereof and which are not.

Table 3-3: Overview of WEEE treatment processes

Processes dedicated to WEEE or wastes derived thereof	Co-processing with other wastes
Collection and transport of WEEE*	Landfilling of residual waste containing WEEE
Storage of secondary wastes*	Mechanical treatment of residual waste
Dedicated treatment processes for cooling & freezing appliances, screens, lamps	Incineration of residual waste
Manual dismantling of WEEE	Shredding/sorting of metals
Shredding (and automated sorting) of WEEE	Recycling of ferrous metals
Shredding/sorting of cables	Recycling of non-ferrous metals
Shredding/sorting of electronic components	Recycling of glass
Shredding/sorting of plastics	Recycling as construction material
Recycling of plastics	Landfilling of residues from WEEE treatment
Uncontrolled treatment in third countries**	(Co-)Incineration of residues
	Uncontrolled dumping of residues**
	Uncontrolled burning of residues**

Source: adapted from AUBA (2013)

Notes: * Collection, transport and storage should be assessed if the following criteria apply: the substance is used as (or in) a liquid (e.g. cooling agents, electrolytes), the substance is used as a gas, the substance is used in powders in components which can easily be damaged during the handling of WEEE, or the substance is (or is bound to) a solid or liquid under normal conditions of use but may easily evaporate at higher temperatures (e.g. in closed metal vessels exposed to sunlight).

** For uncontrolled treatment in third countries, uncontrolled dumping of residues or burning of wastes, caution is to be used as the data quality may be insufficient for quantitative release estimation.

Information required

A quantitative release estimation related to waste management operations shall be performed based on available information regarding the substance content in the typical waste processes and the amounts treated per annum. Depending on data availability and the waste management routes of typical EEE of relevance to the substance under assessment, the estimation shall take into account possible emissions from both dedicated and non-dedicated WEEE installations. Where data is not available as to the actual quantities, assumptions shall be made as to the amount of relevant WEEE treated per annum, respective volumes of the substance therein and respective shares of the substance to be emitted to the environment (air, water, soil as supported by available data). Such assumptions are to be made on the basis of existing evidence as far as possible. For example, the level of emissions may differ between various operators and data on total emissions associated with relevant EEE placed on the EU market will not always be available. In such cases, evidence on substance emissions at a certain WEEE management operator or an average where data from a few operators is available is to be used to estimate total emissions in relation to all relevant EEE placed on the market. On the basis of these assumptions, estimation shall be carried out, specifying how results have been derived and possible uncertainties.

Based on the collection rates for a particular WEEE category, the material composition of the relevant WEEE category and the distribution of such WEEE between specific application treatment operations, the overall amount of the substance treated in a particular process on EU level can be estimated.

Appendix A.5 (to be added) will provide values for separate collections of individual WEEE categories; average material composition of WEEE; the share of applied treatment processes; values for the number of installations and the operational hours of individual treatment processes; and examples of release factors for WEEE treatment processes. This data is provided to support assumptions for estimating the amount of substance treated and respective emissions.

The quantitative assessment of substance released from WEEE treatment processes should be based on:

- the amount of substance entering treatment;
- physico-chemical properties of the substance (volatility, water solubility, degradability and adsorption behaviour, etc.);
- formation of hazardous degradation/transformation products;
- conditions under which the treatment is performed.

The outcome of the qualitative assessment should include:

- a qualitative justification as to why release of the substance from a particular WEEE treatment process is to be expected (or why they are not expected where this is the case).
- a qualitative justification as to why the conditions in the specified treatment will result in release of the substance or in the generation of hazardous degradation products in the process (or why this shall not happen where this is the case).

- In cases where the assessment has established in P III Step 1b) Compilation of detailed information on the use of the substance in EEE or in this step that the substance under review does not remain in its specific form in EEE, it may be possible to conclude at early stages that impacts are not expected during use and/or in the waste phase.

  – Before such a conclusion is reached, it should also be considered if releases of possible derivatives may be expected in the waste phase. Derivatives to be considered shall include hazardous residues, transformation and/ degradation products of the substance. Should this be the case, the assessment of possible releases of the substance should be focused at releases of possible derivatives where these can be identified and where it can be established that impacts related to the Art. 6(1) criteria may be associated with such releases.

  Where releases of the substance and of its derivatives can be excluded, a “short-cut” may be taken in terms of assessing possible exposures and risks, seeing as these would not be expected where releases do not occur. In this case, the assessment documentation should specify that exposures, respectively risks are not expected as the substances and/or its derivatives do not remain in the EEE and thus releases, which could lead to exposures and to actual impacts, are not expected.

Sources of information (P III Steps 2a and 2b)

Information sources that can be used to obtain data on treatment and emissions for estimations:

- Information already collected in previous steps
- Chemical Safety Reports (if available und data appropriate for quantitative release) from ECHA or the registrant;
- Studies and research

- ECHA guidance documents[115]:
  - Environmental exposure estimation (R16)
  - Estimation of exposure from waste life (R18)
- Information and data from EUROSTAT;

Facts about relevant waste streams and treatment processes as well as the outcome of release estimations will be documented in Chapter 5 of the Dossier.

3.6. P III Step 3 Exposure estimation during use and/or WEEE treatment

The **aim** of this step is to determine human and environmental exposure to the substance during use and/or during the relevant WEEE treatment processes (see P III Step 1b and P III Step 2).

Approach: Existing information on human and environmental exposure related to the relevant WEEE treatment processes shall be used to estimate the range of possible exposures. Where data is available, exposure estimations shall be performed using suitable models (e.g. ECETOX-TRA, EUSES).

Examples of effects of substances used in EEE potentially leading to impacts on human health and/or the environment include (not exhaustive):

- Leaching of substances when the WEEE-components end up in landfills (e.g. metals and BFRs), leading to contamination of soil, surface water and ground water;
- Emissions of particle bound substances (e.g. Ba oxide; phosphor coatings; BFRs as TBBPA, HBCDD; metals such as Be, As or Ni) via fine dust during collection, transport, dismantling, shredding and mechanical treatment;
- Effects on humans caused by inhalation of dust or contaminated air during shredding and dismantling processes;
- Effects on humans caused by skin contact and/or inhalation of workers during manual dismantling of WEEE;
- Emissions of substances not being destroyed or immobilised during thermal processes (heavy metals, phthalates);
- Negative impacts may arise due to derivatives of a substance that are generated during waste treatment. For example, halogenated substances (e.g. PVC-plastics and BFRs) are dioxin precursors in thermal processes (considering that other substances such as Cu and Sb are very potent catalysts in the transformation reactions). These lead to risks for human health and the environment when WEEE materials are incinerated without using best available techniques, which is the case also in several countries within the EU; and
- Emissions of volatile substances (e.g. Hg) from broken components during collection, transport, dismantling, shredding and mechanical treatment.

Information required

Available and relevant data regarding exposure (e.g. monitoring data; population group, exposure time, exposure concentration) have to be collected. Literature on human and environmental expo-

[115] See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

sure to a specific substance as a result of waste management should be summarised. On the basis of the release estimates calculated in P III Step 1b and P III Step 2, exposure concentrations for end-users for the environment and for workers shall be calculated.

In case the operational conditions vary considerably, different scenarios should be analysed. Existing risk reduction measures and their impact on possible exposure to the substance of concern will be described.

For substance groups, including elements and their compounds, possible differences in expected exposure severity should be discussed in relation to differences in associated hazards of group members. This is to allow concluding at later stages if the rational for a group restriction is justified (i.e. that impacts related to the Article 6(1) criteria are expected to be similar).

The following information, structured as described below, is required:

- Exposure of end-users (EEE during use)
- Occupational exposure of workers (EEE waste processing plants)
- Exposure of neighbouring residents (EEE waste processing plants)
- Exposure of adjacent environment (EEE during use, EEE waste processing plants)

Result/Expected Outcome: Exposure levels for the environment, workers and neighbouring residents shall be summarised.

Sources of information

- Information on releases of substances from waste management is available for some substances and elements under the European Release and Transfer Register (E-PRTR) on releases[116].
- Information on releases of substances is available from the European Information Platform for Chemical Monitoring (IPCHEM). This is “the European Commission’s reference access point for searching, accessing and retrieving chemical occurrence data collected and managed in Europe”. Data is available for four categories: Environmental monitoring, Human Bio-Monitoring, Food and Feed, Products and Indoor Air[117].
- European Centre for Ecotoxicology and Toxicology Chemicals[118]: provides a Targeted Risk Assessment (TRA) tool to determine the exposure of workers and consumers and environmental exposure, based on different exposure scenarios.
- EUSES for environmental exposure estimation[119]
- Further information sources which might provide relevant information are listed in P III Step 1c (information sources related to human health) and in P III Step 1d (information sources related to risks for the environment)
- Stakeholder consultation

This information (if measured data are available) will be documented in Chapter 6 of the Annex II Dossier and is part of the evaluation of exposures during use and during waste management operations.

[116] See: https://prtr.eea.europa.eu/#/home

[117] See: https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html

[118] See: http://www.ecetoc.org/tra

[119] See: https://ec.europa.eu/jrc/en/scientific-tool/european-union-system-evaluation-substances

3.7. P III Step 4 Evaluation of impacts

In addition to the negative impacts of the substances during use and during waste management operations of EEE (P III Step 4a), risks for workers (P III Step 4b) and for the environment (P III Step 4c) related to these life cycle phases should be assessed.

For substance groups, including elements and their compounds, possible differences in expected exposure severity should be discussed in relation to differences in associated hazards of group members. This is to allow concluding at later stages if the rational for a group restriction is justified (i.e. that impacts related to the Article 6(1) criteria are expected to be similar).

3.8. P III Step 4a) Evaluation of risks for end-users of EEE as specified by Article 6(1)(b) (first part)[120]

The **aim** of this step is to characterise the risks which might arise due to direct or indirect contact with the substance during the use of EEE.

Approach: The information collected in previous steps (e.g., evidence as to exposure during normal and non-normal use, threshold levels, toxicological reference values, endpoints of concern, exposure data) will be considered to describe the expected risk. Exposure levels above reference values indicate that there is cause of concern and that the risk is not controlled.

Objectives:

- A qualitative risk characterisation if no threshold level is available;
- If appropriate data are available, a quantitative assessment should be performed for each exposure pattern of a given exposure scenario (comparison of exposure with estimated safe exposure levels);
- If appropriate data are available, it will be examined if there is an unacceptable exposure of end-users to the substance during normal and non-normal use, also specifying the likelihood of occurrence of the exposure and its range.

Result/Expected Outcome: The risk characterisation for human health will determine if, in the defined exposure scenarios, risks to human health are to be expected for end-users of EEE. If monitoring data of sufficient quality (relevant and reliable) are available, the risk characterisation will be based on measured data. It should be assessed if there is a margin of safety which is considered to be sufficient. The data source for exposure assessment will be explained in order to identify uncertainties and underlying assumptions. For the purpose of the assessment it shall be considered if the substance/substance group is comparably easily releasable during use due to the following reasons:

- The substance is used in or as a liquid (under ambient conditions) in EEE
- The substance is in particulate form in EEE
- The substance is highly volatile (under ambient conditions) when used in EEE
- Evidence exists that the potential for release of the substance/substance group in the use phase is significant and that such release may result in adverse impacts on health and or on the

[120] Article 6(1)(b)(first part): “could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance”;

environment. For example, the risk of breakage of mercury containing discharge lamps and of resulting emissions is considered to be significant.

Sources of information

- for details see P III Step 1a)-1c), 2 and 3
- ECHA guidance documents[121]:
  - Characterisation of dose [concentration] - response for human health (R8)
  - Consumer exposure assessment (R15)

The results of this step are documented in Chapter 7.1 of the Dossier.

3.9. P III Step 4b) Evaluation of negative impacts on WEEE management as specified by Article 6(1)a and 6(1)(b)(second part)[122]

The **aim** of this step is to assess whether a substance or group of substances could have a negative impact during WEEE management operations, e.g. on the possibilities for preparing for the reuse of WEEE or for the recycling of materials from WEEE.

Approach: The information collected in previous steps (e.g., evidence on exposure during WEEE management operations, evidence on obstacles for preparing WEEE for reuse or for recycling of materials from WEEE) will be considered to describe the expected impacts. Relevant negative impacts on any possible step within the overall treatment process of WEEE have to be considered.

Result/Expected Outcome:

The evaluation should assess whether a substance or group of substances could have negative impacts during WEEE management operations, e.g. on the possibilities for preparing for the reuse of WEEE or for the recycling of materials from WEEE. It shall be considered that relevant negative impacts on WEEE management exist, if at least one of the following **criteria** applies:

- Evidence exists that the presence of the substance in WEEE hinders recycling and/or recovery as it has adverse effects on recycling / recovery processes. For this purpose, lower recycling/recovery rates shall be considered where e.g. the presence of the substance makes recycling/recovery processes impossible or so expensive that a treatment option lower in the waste treatment hierarchy has to be chosen
- Evidence exists that large amounts of the substance are not eliminated or collected for safe disposal during treatment processes, but contaminate the recycled material (metals, plastics, glass) and thus remain in the recycling loop. As a consequence:
  - Use of respective recycled content (secondary materials) is limited to certain application areas or completely prohibited; or

[121] See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

[122] Article 6(1)(a) could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;
(b)(second part): “could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;”

  - The hazardous substance / substance group may be distributed across various types of recycled materials such as metals, plastics, glass or building material and subsequently in the environment.

- Evidence exists that the presence of the substance in WEEE results in a large amount of material from the overall treatment process having to be treated as hazardous waste.
- Evidence exists that hazardous degradation/transformation products are formed during WEEE management (including thermal processes (combustion, milling), mechanical, chemical and biological processes (mechanical biological treatment, landfilling) and that these result in impacts on human and/or environmental health.

Sources of information

- Information on WEEE treatment (e.g. information available from the WEEE forum and in the context of ongoing activities on the standardisation of minimum treatment standards for WEEE treatment (CENELEC)).
- Information on any processes where WEEE or materials derived from WEEE are treated (in particular BREFs for waste treatment industries, glass production, storage and handling, non-ferrous metals industries, iron and steel production, waste incineration, polymers)
- Stakeholder consultation (waste treatment sector)

The findings/results of this step will be documented in Chapter 7.2 of the Dossier.

3.10. P III Step 4c) Evaluation of risks for workers (Article 6(1)(c)) and neighbouring residents (Article 6(1)(b))[123]

The **aim** of this step is to characterise the risks which might arise due to direct or indirect contact with the substance during the EEE waste management processes.

Approach: The information collected in previous steps (e.g., threshold levels, toxicological reference values, endpoints of concern, exposure data) will be considered to describe the expected risk. Exposure levels above reference values indicate that there is cause of concern and that the risk is not controlled.

Objectives:

- A qualitative risk characterisation if no threshold level is available
- If appropriate data are available, a quantitative assessment should be performed for each exposure pattern from a given exposure scenario (comparison of exposure with estimated safe exposure levels
- If appropriate data are available, it will be examined if there is an unacceptable exposure of workers involved in WEEE operations
- If appropriate data are available, it will be examined if neighbouring residents are at risk (e.g. due to persistent or volatile properties of substances)

[123] Article 6(1)(b) could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;
Article 6(1)(c) could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;

Result/Expected Outcome: The risk characterisation for human health will determine if, in the defined exposure scenarios, risks to human health are to be expected for workers and neighbouring residents. If monitoring data of sufficient quality (relevant and reliable) are available, the risk characterisation will be based on measured data. It should be assessed if there is a margin of safety which is considered to be sufficient. The data source for exposure assessment will be explained in order to identify uncertainties and underlying assumptions. It shall be considered that negative impacts on workers or on neighbouring residents exist if at least one of the following **criteria** applies:

- Evidence exists of exposure of workers to substance or substance group and of subsequent negative impacts on worker health.
- Evidence that the substance/substance group was measured at significantly elevated levels in the environment (air, water, soil, biota) near WEEE treatment installations / locations. Evidence of elevated levels measured in the environment shall generally be considered significant when end-point related limit values are exceeded (i.e. DMELs, PNEC, etc.) and when this can be tied to emissions from the presence of the substance in WEEE. Consideration should determine if harm may occur or not as a result of elevated levels and so whether a restriction should be considered if control measures (such as workplace exposure limits, which are applicable at recycling sites) are not effective at preventing harm to humans or to the environment.

Sources of information

- for details see P III Step 1a)-1c), 2 and 3
- ECHA guidance documents[124]:
  - Characterisation of dose [concentration] - response for human health (R8)
  - Occupational exposure assessment (R14)

The results of this step are documented in Chapter 7.3 of the Dossier.

3.11. P III Step 4d) Evaluation of the risk for the environment (Article 6(1)(a) and/or b)[125]

The **aim** of this step is to assess the environmental risks associated with waste management operations.

Approach/Criteria: Environmental concentrations near EEE processing plants (if available) and Predicted Environmental Concentrations (PECs) as calculated and described in previous steps will be compared with Predicted No Effect Concentrations (PNECs) in order to evaluate the expected risk for the environment. If the PEC values are above PNECS a risk for the environment cannot be excluded. A qualitative assessment will be performed in case there are PBT and vPvB substances for which no PNEC can be derived.

[124] See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

[125] Article 6(1)(a) could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;
(b) could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;

Result/Expected Outcome: The risk characterisation for the environment will determine if any risks for the environment are to be expected in the defined exposure scenarios. The data source for exposure assessment will be detailed in order to identify and document uncertainties and underlying assumptions. It shall be considered that negative impacts on the environment from WEEE management locations exist if at least the following **criterion** applies:

- Evidence that the substance/substance group was measured at significantly elevated levels in the environment (air, water, soil, biota) near WEEE treatment installations / locations. Evidence of elevated levels measured in the environment shall generally be considered significant when end-point related limit values are exceeded (i.e. DMELs, PNEC, etc.) and when this can be tied to emissions from the presence of the substance in WEEE. Consideration should determine if harm to the environment may occur or not as a result of elevated levels and so whether a restriction should be considered if control measures (e.g. emission mitigation and end-of-pipe measures) are not effective at preventing harm to the environment.

Sources of information

- See sources given in 1d, 2, 3,
- ECHA guidance documents[126]: Characterisation of dose [concentration] – response for environment (R10).

The results of this step are documented in Chapter 7.4 of the Dossier.

- P III Step 5 Evaluation of the availability of substitutes and alternative technologies and information on their hazardous properties

If the results of P III Step 4 show that there is either a negative impact on WEEE management or a risk for human health or the environment during use or during WEEE management, it should be investigated if suitable[127] substitutes or alternative technologies are available.

Approach: Information should be compiled on possible alternatives for the substance under assessment (substitute substances or alternative technologies). Information should allow understanding the range of applicability of possible substitute substances/alternative technologies, the level of development of substitute substances/alternative technologies in terms of maturity for application as replacements and the potential of substitute substances/alternative technologies to themselves be associated with negative impacts on the environment.

For substance groups, including elements and their compounds, this chapter should include not just information on alternatives that are not part of the group, but also on the likelihood of group members to be applied as substitutes for each other, seeing as this is often the rational for group restriction, where one member may constitute a substitute for another. In such cases, the substitution of one member through another would constitute a regrettable substitution as impacts in the use and/or waste phase are expected to be of a similar order.

Information required

As a first step, a summary of available alternatives shall be compiled referring both to technological alternatives (elimination) and to substance alternatives (substitution). For each alternative, the

[126] See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

[127] Technically feasible and commercially available within a certain time period

range of application for which it can be used as a replacement should be detailed to allow an understanding of the scope of applications for which alternatives exist or are in development stages. The stage of maturity as an alternative should further be specified (e.g. already applied in a certain application range; applied in certain cases; applied by certain manufacturers; in development stages), as well as the reliability of the alternative. Though in some cases it may become clear that an alternative does not provide sufficient reliability for a certain application, this may differ for other applications and could also be a focus for further research of the alternative. In this sense, the compilation should provide information as to the actual applicability of an alternative as a replacement, however not excluding information on alternatives found to be less suitable.

Information from this step should be documented in Chapter 8.1 of the Dossier.

As a second step, information on the hazardous properties of available substitute substances/alternative technologies is to be investigated. The hazardous properties of alternatives should be briefly described, including data availability and possible data gaps. Should a substance be determined to be persistent and bio-accumulative, but to lack classifications related to toxicity, available results of animal testing should be reviewed to consider if the substance could be toxic. This is of particular relevance for new substances where hazard classification is still in process. The considered alternative options have to be compared with each other and with the substance of concern in terms of their hazardous properties regarding the environment or human health.[128]

To establish the hazardousness of substitute substances/alternative technologies, information from the substance inventory developed in P I and P II is to be considered. In this respect it is important to note that a substance may have been given a low priority on the basis of it not being used in EEE. Should the substance have a hazard classification, this should be taken into consideration in order to derive if a restriction of the substance under assessment could motivate a phase-in of a substance also considered hazardous (regrettable substitution). Should this be the case, existing information on hazards and expected volumes of use should be documented to allow consideration in P III Step 7 whether an assessment of such potential alternatives is needed to allow simultaneous restriction of the substance and its potential alternatives that exhibit hazardous properties.

Where alternatives are themselves already subject to restrictions, they should also be specified as unsuitable replacements.

Information from this step should be documented in Chapter 8.2 of the Dossier.

Sources of information

- See sources given in P III Step 1c-d
- Support database
- Available studies on alternatives
- Stakeholder consultation
- Further information on how to assess alternatives is available on EPA's Design for the Environment (DfE) programme[129].

[128] U.S, EPA Design for the Environment Programme Alternatives Assessment Criteria for Hazard Evaluation. Version 2.0. August 2011

[129] https://www.epa.gov/saferchoice/design-environment-alternatives-assessments

A summary of alternatives found to be mature and acceptable in terms of hazardous properties should be detailed in Section 8.3 of the Dossier. This section should also detail uncertainties of the results.

3.12. P III Step 6 Socio-economic impact analysis

The **aim** of this step is to assess whether the costs of a restriction scenario are proportionate to the benefits to the environment and to health expected thereof.

The **approach** presented here follows the recommendations of the ECHA guidance documents "Guidance on socio-economic analysis - Restrictions" and "on the preparation of socio-economic analysis as part of an application for authorisation"[130]. However, the analysis shall predominantly rely on information and data from available socio-economic analyses. Given the targeted approach of an assessment for a RoHS restriction, quantitative impacts shall be specified where data is available from prior studies or from stakeholders (monetary as also non-monetary as available). Estimations of additional impacts or analysis of the certainty of existing estimations shall be performed on a qualitative basis. Where relevant, it should be specified across what period economic impacts are expected to occur (one time investments, operational costs, substitution in short term/long term, etc.).

Information required

The positive and negative socio-economic impacts of a restriction of the substance of concern shall be estimated by presenting the expected impacts of a RoHS restriction scenario. In cases where a restriction under REACH has been proposed, the differences between the RoHS and the REACH restriction scenarios in expected impacts should be analysed (costs for implementation versus benefits in terms of protection of the environment and of health) at least on a qualitative basis.

The following impact categories should be analysed (list is not exhaustive - further categories should be considered on a case-by-case basis):

- Impacts on manufacture of the substance (manufacture of the chemical sector in the EU and outside the EU), including impacts on
  - Costs of manufacture (of the substance and of substitutes);
  - Potential turnover);
  - Administration costs;
  - Unemployment and scar effects;
  - Impacts on SMEs;

[130] See: ECHA guidance documents on SEA:
- General: https://echa.europa.eu/support/socio-economic-analysis-in-reach
- Restrictions:https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d
- Authorisations: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e

- Impacts on manufacture of EEE (manufacture of OEMs and the supply chain in the EU and outside the EU), including impacts on
  - Costs of manufacture (including benefits for manufacturers that have already substituted);
  - Impact on innovation;
  - Impact on raw material utilisation;
  - Potential turnover;
  - Administration costs;
  - Unemployment and scar effects;
  - Impact on trade, including international trade;
  - Impacts on SMEs;
  - Impacts on non-EEE manufacturers and users (in cases where equipment similar to EEE may be out of scope;

  Where relevant, supply stability of substitute materials (technologies), and raw material availability should be taken into consideration. Where substitutes are not sufficiently mature, the time required for R&D as well as possible costs should be estimated on the basis of available data.
- For industrial and private end-users of EEE:
  - estimation of increase/decrease in product costs;
  - effect on product lifetime, functionality and usability;
  - Impact on the quality of products;
  - Impact on safety of the public
  - For industrial consumers:
  - Estimation of consequences on competitiveness and jobs
- For waste management:
  - Impacts relating to the decrease of hazardous substances in generated WEEE;
  - Impact on amount of waste generated;
  - Necessity to adapt waste management processes;
  - Estimation of adaptation costs and cost savings (by less harmful alternatives);
  - Estimation of additional revenues from recycling, if a less harmful alternative allows more/easier recycling;
  - Effects on turnover;
  - Effects on employment.

All of the individual categories over the life cycle, which may have an impact are summed up to provide the total socio-economic effect of a substance restriction in terms of:

- costs;
- competitiveness of the EU economy;

- employment;
- compatibility of EEE;
- impacts on environment and health.

Within the various categories, the distribution of costs and benefits between various actors (for example between different consumers, different manufactures, etc.) should also be considered and documented.

Sources of information

In addition to the **information** collected in previous steps, the following sources of information are suggested:

- Socio-economic assessment performed under REACH, RARs (if available and appropriate);
- Use of socio-economic assessment performed by other institutions;
- ECHA guidance: Guidance on the preparation of socio-economic analysis as part of an application for authorisation and for restriction proposals[131].
- Stakeholder consultation.

The results of the socio-economic impact analysis of a potential restriction are documented in Chapter 9 of the Dossier. This section should also detail uncertainties of the results.

3.13. P III Step 7 Decision on inclusion and rationale

The **aim** of this step is to decide whether a restriction of a substance/substance group under RoHS would be the most appropriate measure to combat negative impacts during use and during WEEE management operations on human health and the environment.

To reach this decision, a case-by-case **approach** has to be applied which shall consider the following aspects:

A recommendation for restricting a substance under RoHS should be considered where a risk for the environment or for human health during use or during WEEE treatment has been identified or can be assumed based on related estimates (see P III Step 4a - d). Where there is an uncertainty of data, the precautionary principle shall be taken into account. The application of the precautionary principle is related to whether or not the risk is managed, i.e., the range of possible impacts related to the use of a substance is acceptable. The precautionary principle is to be considered in the justification of a restriction if there are well-founded indications that a risk is not adequately managed but data gaps (e.g. regarding route and range of exposure) do not allow the estimation of impacts. If the lack of data does not allow estimating the nature of possible impacts (e.g., substance suspected of hazard but still under verification) a decision is to be postponed until such data gaps can be closed. For further guidance on data quality and dealing with data gaps see appendix A.7.

[131] ECHA guidance documents on SEA:

- General: https://echa.europa.eu/support/socio-economic-analysis-in-reach
- Restrictions:https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d
- Authorisations: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e

The rationale behind an inclusion of the substance into Annex II of RoHS as an appropriate risk management option – or a justification why it is not - shall take into account the following aspects:

Hazardous potential

- The nature and reversibility of the adverse effect;

Identified Exposure

- The amount of substance released / the range of subsequent impacts;
  - The estimated number of exposed users or exposed workers;
  - The environment compartment to be exposed;
  - Expected exposure from WEEE that is not properly collected and treated;

Estimated risk

- The number of waste treatment processes from which the risks arise:

  For processes performed at a large number of installations/locations spread all over the EU (and third countries), restrictions under RoHS are appropriate. The same is true for waste treatment processes which can be carried out legally under a wide range of conditions, influencing the release rates of hazardous substances. For processes performed at only a small number of installations, other risk management measures at process or plant level should also be considered, including e.g. adaptations of waste legislation and occupational safety and health legislation, BAT definitions, enforcement actions.

- The severity and extent of the risk identified;
- Uncertainties within the risk assessment approach;

Impact on users and workers

The extent to which users/workers are exposed to emissions of the substance during use /during the waste phase respectively, resulting in negative impacts on their health.

Impact on the environment

The extent to which the environment is exposed to emissions of the substance as a result of its use in EEE, during the use and waste phase and the range of subsequent impacts.

Impact on waste management

- The extent to which material recycling/recovery rates are reduced[132];
- The extent to which recycled materials are contaminated with the hazardous substance / group of substances;
- The amount of hazardous waste which is generated in the course of processing WEEE;

Available Alternatives

- The availability of substitutes/alternatives with a less negative impact related to use and to WEEE management;

[132] In particular if the recycling/recovery rate required under EU legislation is not achieved.

  - Technical feasibility of the alternative substance;
  - A less hazardous toxicological profile of the alternative substance.

- The availability of substitutes/alternatives with similar or higher impacts related to use and to WEEE management and their potential of leading to “regrettable” substitution;

Socio-economic impact analysis

- The socio-economic impacts (see P III Step 6, Section 3.12);
- The proportionality of costs of a restriction in comparison to the expected benefits of restriction;
- Uncertainties of the results and possible consequences of any wrong conclusions which are drawn from the assessment.

In the case of an assessment of a substance group, including elements and their compounds, the discussion of results should show that possible differences in expected impacts related to certain group members would not affect the fulfilment of the Article 6(1) criteria, i.e., the justification for restriction of the group. Should this not be the case, it should be considered if restriction of a sub-selection of the group members would be justified and subsequently the scope of the group to be restricted is to be adjusted.

The decision to recommend a substance or substance group for inclusion in Annex II of RoHS is to be documented in Chapter 9 of the RoHS-Dossier and shall include:

- The substance /substance group to be restricted (CAS number to be specified if relevant);
- Conditions of the restriction:
  - A recommendation on the threshold limit value (% by weight in the homogenous material) above which the substance/substance groups should not be present in the homogenous material once a restriction is in force. The limit value should be determined in relation to the level of presence in EEE and/or WEEE that could lead to negative impacts on the environment and/or health (i.e. exposures).
  - The scope of the restriction in terms of EEE Annex I categories and the transition period to be provided for different categories. The period recommended for transition should take into consideration:
    - the time needed for stakeholders to conclude on the presence of the substance in EEE relevant to them;
    - the time needed for stakeholders to verify the applicability of available substitutes; and
    - the time needed for stakeholders to request exemptions and for these to be processed by the Commission (decision) in cases justified as per Article 5 of the Directive.
  - It should also be detailed whether certain EEE is to be excluded from the scope of the restriction in light of parallel legislation with a more stringent restriction[133].
  - Whether EEE in scope of the RoHS Directive is to be excluded from the scope of other existing EU legislation (e.g. restrictions listed under Annex XVII of REACH, granted authorisations listed under Annex XIV of REACH).

[133] As for example in Delegated Directive 2015/863: “*The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006*.”

– Whether exemptions are to be granted for equipment benefiting from a REACH Annex XIV authorisation or whether such equipment should be granted a longer transition period.

APPENDIX

A.1 Information sources used for the 2013 inventory of substances in EEE" (PART I, Step 1)

This annex is reproduced from AUBA (2013). Links have been updated in a few cases.

For the inventory of substances used in EEE that has been established during the first review of RoHS Annex II in 2013, information from the following databases has been extracted:

- Substances listed in the IEC 62474 Database „Declarable Substances" (IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry): http://std.iec.ch/iec62474
- ZVEI-Umbrella specifications: https://www.zvei.org/en/association/divisions/electronic-components-and-systems-division/material-data-declaration-on-product-level-and-the-umbrella-specification-based-on-product-families-as-an-efficient-example/

Information both on main components as well as on minor components of several components of EEE are available from product data sheets for product families, so-called "umbrella specifications". These data sheets were developed by manufacturers of components organised in the Electronic Components Division within the German Electrical and Electronic Manufacturers Association (ZVEI) and aim to comply with the request of customers for detailed material specifications on individual electronic components, semiconductors, passive components, printed circuit boards, and electromechanical components.

For this study, 60 product data sheets published at the ZVEI-website at December 2012 were used.

- Information on substance uses as available from registration dossiers: sub- stances with the use descriptor "SU16" "Manufacture of computer, electronic and optical products, electrical equipment" if available from ECHA
- Information on substance uses (Nace-codes C26 "Manufacture of computer, electronic and optical products" and C27 "Manufacture of computer, electronic and optical products"[134]) as available from the Nordic Product Register (SPIN – substances in preparations in nordic countries-register)- http://spin2000.net/

Information from the following studies was used:

- Inventory of Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, not regulated by the RoHS Directive
- The inventory of potentially problematic substances contained in EEE comprises 64 substances, including hazardous substances as well as non-hazardous substances, which may cause problems in WEEE-management.
- Monitoring results of Umweltbundesamt (2011): Karzinogene, mutagene, reproduktionstoxische (CMR) und andere problematische Stoffe in Produkten. Identifikation relevanter Stoffe und Er-

[134] Relevant uses to be selected.

zeugnisse, Überprüfung durch Messungen, Regelungsbedarf im Chemikalienrecht. ISSN 1862-480

  - The study provides information on hazardous substances in products. Annex 4.B summarizes information on substances analysed in EEE (various information sources).

- Monitoring results SENS, SWICO & SLRS (2008): PCB in Kleinkondensatoren aus Elektro- und Elektronikaltgeräten. Schlussbericht.

About 15 hazardous substances were analysed in capacitors derived from small EEE.

- Review on hazardous substances in EEE provided by DANISH EPA (2012)

Greening of electronics – The list consists of 25 substances.

A.1.1 Data sources on use of nanomaterials

The following list of sources can be consulted:

- The Europa web-platform on nanomaterials provides general information: http://ec.europa.eu/research/industrial_technologies/nanoscience-and-technologies_en.html
- Second Regulatory Review on Nanomaterials {COM(2012) 572 final} The document covers nanomaterials within the scope of the Commission Recommendation 2011/696/EU on the definition of nanomaterial: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52012DC0572
- Commission staff working paper on Types and uses of nanomaterials, including safety aspects accompanying the Communication from the Commission on the Second Regulatory Review on Nanomaterials https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012SC0288

An EU project launched by the Commission in 2011 on occupational risks of nano-materials, and other recent research, including on the fate of nanomaterials in the environment and in waste, will provide more insight for further legislative guidance and risk assessment work[135],[136].

The International Organisation for Standardisation published a specific standard (ISO/TR 13121:2011) that offers guidance on the information needed to make sound risk evaluations and risk management decisions.

Current studies on nano-waste[137],[138].

- OECD: http://www.oecd.org/sti/sci-tech/oecdworkingpartyonnanotechnology.htm

[135] Commission staff working paper. ´Types and uses of nanomaterials, including safety aspects Ac- companying the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Second Regulatory Review on Nanomaterials {COM(2012) 572 final}

[136] Communication from the commission to the European parliament, the council and the European economic and social committee. Second Regulatory Review on Nanomaterials. Brussels 03.10.2012

[137] Bio Intelligence Service (2011). Study on coherence of waste legislation, Final report prepared for the European Commission

[138] Musee, N.,2011, Nanowastes and the environment: Potential new waste management paradigm. Environment International. 37: 112-128

- ECHA: https://echa.europa.eu/regulations/nanomaterials
- France has implemented a national nanomaterial register to which nanomaterial producers, importers, distributers or formulators are obliged to register: https://www.r-nano.fr/

Furthermore, following databases from different institutions (e.g. consumer organisations) have been set up, but have major drawbacks to identify the use of nanomaterials in consumer products including EEE, because the information is often based on not verified producer declaration. On the other hand, many products containing nanomaterials might not be included in these databases, as the producers are not declaring the containment of nanomaterials:

- The ANEC/BEUC 2010 inventory is an inventory of nanotechnology based consumer products established by European consumer organisations. The Microsoft Excel Table is available on the BEUC website (http://www.beuc.eu/safety/nanotechnology).
- The DTU Environment, the Danish Ecological Council and Danish Consumer Council have set up a nanomaterial data-base, including so far more than 3,000 products: http://nanodb.dk/en/about-us/
- A German inventory of nanotechnology based consumer products built up by BUND (Bund für Umwelt und Naturschutz Deutschland) is available online: https://www.bund.net/chemie/nanotechnologie/nanoprodukte-im-alltag/nanoproduktdatenbank/
- The Woodrow Wilson database is a U.S. inventory of nanotechnology based consumer products. Although the origin of the inventory is in the United States, it is applicable for global use. (http://www.nanotechproject.org/cpi/)
- Information on the application fields of nanomaterials, relevant health and environment aspects as well as facts on risk management and safety aspects can be found in the DaNa2.0 (Data and knowledge on Nanomaterials) database (https://www.nanopartikel.info/en/)

A.2 Template for collecting information of use of substances in EEE through stakeholder consultation in P1 Step 1b

Substance identity				**Uses in EEE**					**RoHS Status**	**Hazard group**	**Use relevance**	**REACh relevance**	**Overall priority**	**Previous comme**	**Estimated volume of use in EEE in the EU**									**Waste / use phase / comments**
CAS No	EC No	Name	Group (if applicable)	Please specify the known uses of the substance in EEE					Currently under assessment or previously assessed under RoHS	Based on evidence that the substance/ substance group has relevant hazard properties (Human health & environment)	Evidence for high volumes of use and/or used used as nanomaterial in EEE	Restriction under REACh Annex XVII including some EEE, or proposed + listed in Annex XIV or proposed		Stakeholder comments received in the previous stakeholder consultation	Please specify estimated range of use in EEE in the EU in tonnes per annum									Please provide information on possible use phase / waste management impacts acc. to RoHS Art. 6(1). Please also provide other relevant comments on specific substances here.
				Category	Main function / us	Additive use / Reactive use?	Presence in EEE plausible?	Substitute for another listed substance? Please specify.							0-1 t/a	1-10 t/a	10-100 t/a	100-1000 t/a	>1000 t/a	Phased-out	No knowledge	If you represent a manufacturer (OEM, supplier) please specify the range of your use related to EEE manufacture	Used as nanomaterial in EEE	
7440-02-0	231-111-4	Nickel (Ni)	Element	Metal compound	NA		Yes			Group I	WAHR	WAHR	Group I											
1304-56-9	215-133-1	Beryllium oxide		Metal compound	Ceramic capacitors		Yes		Yes	Group I	WAHR		Group I											
7440-41-7	231-150-7	Beryllium (Be)	Element	Metal compound	Alloys		Yes		Yes	Group I	WAHR		Group I											
1313-99-1	215-215-7	Nickel monoxide		Metal compound	NA		Yes			Group I	Nano		Group I											
1314-13-2	215-222-5	Zinc oxide		Metal compound	NA		Yes			Group I	Nano		Group I											

A.3 Template for collecting information from stakeholders for re-fined prioritisation of high priority substances as described in P II Step 2

The format below was developed in the course of a study prepared by Baron et al. (2014) and is provided here as an illustration. An example of the excel format can be viewed here: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/Questionaire_Background_Info_Substances_prioritisation.xlsx.

Stakeholder consultation concerning a "Study for the review of the list of restricted substances under RoHS 2 – Analysis of impacts from a possible restriction of several new substances under RoHS 2"

Questionnaire: Initially compiled information and areas where further input is requested

Contribution submitted by:	Organisation name:	
	Organisation type:	
Date:		
Contact Person:	Name:	
	Telephone:	
	Email:	

Please note that references have been removed for the sake of clarity, however the provided information is based on public information. References can be provided upon request.

Substance	CAS-Nr	EC-Nr	Uses (General)	Uses EEE	Is this substance in use in additional applications?	Is substitution underway for one of these applications (please specify with which alternative chemical substance)?	Quantities in use (general)	Quantities in use (EEE)	Do you agree with the provided information? Do you assume the actual uses to be higher or lower?	If not, please estimate the quantity range in which this substance is in use (in general and/or in EEE).	Please explain the basis for quantity usage estimations and provide references or further data if relevant	Further Comments and/or references
Diisobutylphthalate (DIBP)	84-69-5	201-553-2	DIBP is used as plasticiser for specific applications, for example in PVC, and frequently as a gelling aid in combination with other plasticisers and as plasticiser for nitrocellulose, cellulose ether and polyacrylate and polyacetate dispersions. These are used in paints, lacquers, varnishes, paper, pulp and boards, as adhesives, binding agents, softeners and viscosity adjusters. DIBP is also used in coatings, e.g. antislip coatings, and in epoxy repair mortars. As a plasticiser in dispersion glues and printing inks DIBP is applied in paper and packaging for	The available information does not mention EEE applications, though it is possible that DIBP is used as a plasticiser in PVC and other ploymers used for manufacture of cable insulation.			Information from the year 2000 indicates the manufacture and/or use of DIBP in Europe to be in the range of 10,000 to 50,000 t/a.	No reliable data available				
Di-(2-ethylhexyl)phthalate (DEHP)	117-81-7	204-211-0	DEHP is predominantly used (up to 97%) as a plasticiser in polymer products (mainly PVC)	The predominant use of DEHP in EEE is in flexible PVC in cables and wires. Minor uses of DEHP in ceramics for electronics or as dielectric fluids in capacitors.			In 2007 approximately - 340,000 tonnes/year were manufactured in the EU. The Net use of DEHP in the EU was approximately 280,000 tonnes/year in 2007.	EEE volume in the EU approximately 20,000 t/y				
Benzyl butyl phthalate (BBP)	85-68-7	201-622-7	BBP is used as a plasticiser in minor concentrations in flexible polymers (e.g. PVC) as well as in some non-polymers (e.g., adhesives, paints, sealants, printing inks). BBP is mainly used as plasticiser in PVC flooring.	The usage in EEE has not been confirmed. However, BBP may be present in following applications which may sometimes be applied in EEE: synthetic leather, coated textile, flexible or rigid PVC sheets, printing inks, sealants and adhesives. These applications might be used in various product types including electric devices.			The overall production in the EU in 2007 was below 18,000 t/y.	EEE volume approximately 2,000 t/a of BBP in EU				

A.4 Alignment of electrical and electronic appliances to WEEE categories

Below the alignment of electrical and electronic appliances to the individual WEEE categories according to Annex III and Annex IV of the WEEE-Directive (2012/19/EU) is provided taking into account treatment options.

The listing in itself is neither exhaustive nor does it inform whether a particular appliance is in the scope of RoHS.

1. Temperature exchange equipment

Temperature exchange equipment/Cooling and freezing equipment: Refrigerators, Freezers, Equipment which automatically delivers cold products, Air conditioning equipment

Temperature exchange equipment/Others: Dehumidifying equipment, Heat pumps, Radiators containing oil and other temperature exchange equipment using fluids other than water for the temperature exchange

2. Screens, monitors, and equipment containing screens having a surface greater than 100 cm^2

Screens, Televisions, LCD photo frames, Monitors, Laptops, Notebooks.

3. Lamps

Straight fluorescent lamps, Compact fluorescent lamps, Fluorescent lamps, High intensity discharge lamps - including pressure sodium lamps and metal halide lamps, Low pressure sodium lamps, LED.

4. Large equipment

Large equipment household: Washing machines, Clothes dryers, Dish washing machines, Cookers, Electric stoves, Electric hot plates, Luminaires, Equipment reproducing sound or images, Musical equipment (excluding pipe organs in- stalled in churches), Appliances for knitting and weaving,

Large equipment/others: Large computer-mainframes, Large printing machines, Copying equipment, Large coin slot machines, Large medical devices, Large monitoring and control instruments, Large appliances which automatically deliver products and money, Photovoltaic panels.

5. Small equipment

Vacuum cleaners, Carpet sweepers, Appliances for sewing, Luminaires, Micro- waves, Ventilation equipment, Irons, Toasters, Electric knives, Electric kettles, Clocks and Watches, Electric shavers, Scales, Appliances for hair and body care, Calculators, Radio sets, Video cameras, Video recorders, Hi-fi equipment, Musical instruments, Equipment reproducing sound or images, Electrical and electronic toys, Sports equipment, Computers for biking, diving, running, rowing, etc., Smoke detectors, Heating regulators, Thermostats, Small Electrical and electronic tools, Small medical devices, Small Monitoring and control instruments, Small Appliances which automatically deliver products, Small equipment with integrated photovoltaic panels.

6. Small IT and telecommunication equipment (no external dimension more than 50 cm)

Mobile phones, GPS, Pocket calculators, Routers, Personal computers, Printers, Telephones.

To understand how the scopes of the directives align to the various EEE categories, the following list specifies the RoHS categories and under which WEEE categories they are understood to fall. This list is not exhaustive.

- RoHS Cat. 1: Large household appliances:
  - some of the equipment under this category is expected to fall under WEEE Cat. 1: temperature exchange equipment, such as refrigerators, freezers, equipment which automatically delivers cold products, air conditioning equipment.
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such as washing machines, clothes dryers, dish washing machines, cookers, electric stoves, electric hot plates,
- RoHS Cat. 2: Small household appliances.
  - some of the equipment under this category is expected to fall under WEEE Cat. 5. Small equipment, such as vacuum cleaners, carpet sweepers, appliances for sewing, microwaves, ventilation equipment, irons, toasters, electric knives, electric kettles, clocks and watches, electric shavers, sales, appliances for hair and body care, calculators, radio sets,
- RoHS Cat. 3: IT and telecommunications equipment -
  - some of the equipment under this category is expected to be covered under WEEE Cat. 2: screens, monitors, and equipment containing screens having a surface greater than 100 $cm^{2,}$ such as screens, televisions, LCD photo frames, monitors, laptops, notebooks.
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such as large computer-mainframes, large printing machines, copying equipment.
  - some of the equipment under this category is expected to fall under WEEE Cat. 6. Small IT and telecommunication equipment (no external dimension more than 50 cm) such as mobile phones, GPS, pocket calculators, routers, personal computers, printers, telephones.
- RoHS Cat. 4: Consumer equipment -
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such as equipment reproducing sound or images, musical equipment.
- RoHS Cat. 5: Lighting equipment
  - light sources falling under this category fall under the WEEE Cat. 3: Lamps. According to Article 2(3)(c) of WEEE, the directive does not apply to filament bulbs.
  - luminaires under this category are expected to fall under WEEE Cat. 4: Large equipment or Cat. 5. Small equipment - depending on the size of the luminaire.
- RoHS Cat. 6: Electrical and electronic tools.
- RoHS Cat. 7: Toys, leisure and sports equipment -
  - some of the equipment under this category is expected to fall under WEEE Cat. 5. Small equipment, such as electrical and electronic toys, sports equipment, computers for biking, diving, running, rowing, etc.,
- RoHS Cat. 8: Medical devices -
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such as large medical devices.

  - some of the equipment under this category is expected to fall under WEEE Cat. 5. Small equipment, such as small medical devices.
  - according to WEEE Article 2(4)(g), “medical devices and in vitro diagnostic medical devices, where such devices are expected to be infective prior to end of life, and active implantable medical devices” are excluded from the scope of WEEE.
- RoHS Cat. 9: Monitoring and control instruments including industrial monitoring and control instruments -
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such large monitoring and control instruments.
  - some of the equipment under this category is expected to fall under WEEE Cat. 5. Small equipment, such as small monitoring and control instruments,
- RoHS Cat. 10. Automatic dispensers -
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such as large appliances which automatically deliver products and money.
  - some of the equipment under this category is expected to fall under WEEE Cat. 5. Small equipment, such as small appliances which automatically deliver products
- RoHS Cat. 11. Other EEE not covered by any of the categories above.

A.5 Information on WEEE management in the EU

The following section has been based on the AUBA 2013 methodology in structure and updated as far as new data were available.

The following information and sources has been compiled to assist the assessment of substance in relation to possible impacts of substances during the waste management of EEE.

A.5.1 Amounts of EEE put on the European market

Below the amounts of EEE put on the EU market divided by EEE categories according to WEEE Annex I (transitional period) in 2014 (last non-provisional data) and in 2016 (most recent provisional Eurostat estimation) according to Eurostat[139] are provided.

EEE category	**Products put on the market (t) for 2014**	**Products put on the market (t) 2016** - *provisional data, Eurostat estimate*
Automatic dispensers	72.404	71.655
Consumer equipment and photovoltaic panels	783.854	878.168
Electrical and electronic tools	555.788	624.977
Gas discharge lamps	84.613	71.333
IT and telecommunications equipment	1.250.096	1.148.155
Large household appliances	4.742.498	5.273.012
Lighting equipment	393.906	492.726
Medical devices	101.612	108.011
Monitoring and control instruments	142.959	179.233
Small household appliances	906.484	979.871
Toys, leisure and sports equip-	226.729	267.701
Total *…amounts collected / put on the market	9.260.943	10.094.842

[139] See Waste electrical and electronic equipment (WEEE) by waste management operations [env_waselee], last update: 27-03-2019 under http://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do

A.5.2 Information on material composition of WEEE

The following tables provide information on the material composition of individual categories/types of WEEE. Information has been taken from Tables 30-35 in the final report of the "Study on WEEE recovery targets, preparation for re-use targets and on the method for calculation of the recovery targets", prepared by BiPro, BIO by Deloitte (BIO) and the United Nations University (UNU) and published by the Commission in April 2015[140].

Material composition and compliance aspects for Category 1: Temperature exchange equipment

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	57.7%	
Copper (Cu)	5.2%	
Aluminium (Al)	2.7%	
Plastics	24.7%	Usually without Brominated Flame Retardants (BFRs)
Glass	0.0%	
Gold (Au)	0.000006%	
Silver (Au)	0.000002%	
Palladium (Pd)	0.0%	
Other	9.7%	CFC/HCFC as well as contaminated oil, PCB capacitors, PUR foam are the main hazardous substances to dispose of according to Annex VI

[140] See study under: http://ec.europa.eu/environment/waste/weee/pdf/16.%20Final%20report_approved.pdf

Material composition and compliance aspects for Category 2: Screens, monitors, and equipment containing screens having a surface greater than 100 cm^2

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	25.8%	
Copper (Cu)	3%	
Aluminium (Al)	2.8%	
Plastics	24.5%	A share of the plastics fraction might contain BFRs and should be removed according to Annex VII requirements. BFR mainly contained in TV housing and monitor & TV sets (Wager et al. 2010).
Glass	29.6%	
Gold (Au)	0.005024%	
Silver (Au)	0.002150%	
Palladium (Pd)	0.000968%	
Other	14.29%	Hazardous components listed in Annex VII should be disposed of accordingly. For this category mercury contained in backlights and LCDs are main elements of concerns.

Material composition and compliance aspects for Category 3: Lamps

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	0%	
Copper (Cu)	0%	
Aluminium (Al)	12.5%	
Plastics	10.9%	Usually without Brominated Flame Retardants (BFRs)
Glass	66.70%	
Gold (Au)	0.0%	
Silver (Au)	0.0%	
Palladium (Pd)	0.0%	
Other	9.9%	Hazardous components listed in Annex VII should be disposed of accordingly. For this category, mercury and other heavy metals are the main elements of concern.

Material composition and compliance aspects for Category 4: Large equipment

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	53.6%	
Copper (Cu)	2%	
Aluminium (Al)	7.8%	
Plastics	10.4%	Usually without Brominated Flame Retardants (BFRs)
Glass	1.5%	Mainly from PV panels
Gold (Au)	0.005986%	
Silver (Au)	0.000003%	
Palladium (Pd)	0.0%	
Other	24.69%	Hazardous components listed in Annex VII should be disposed of accordingly.

Material composition and compliance aspects for Category 5: Small equipment

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	46%	
Copper (Cu)	8.8%	
Aluminium (Al)	4.3%	
Plastics	26.3%	Approximately 30% might contain BFRs. Particularly in IT housings [Waeger et al. 2010]. This fraction should be handled appropriately.
Glass	0.0%	Mainly from PV panels
Gold (Au)	0.001629%	
Silver (Au)	0.000368%	
Palladium (Pd)	0.000102%	
Other	14.6%	Hazardous components listed in Annex VII should be disposed of accordingly. Appliances of this category might include batteries, PCB containing and other capacitors and toner cartridges.

Material composition and compliance aspects for Category 6: Small IT and telecommunication equipment (no external dimension more than 50 cm)

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	39%	
Copper (Cu)	45.5%	
Aluminium (Al)	0%	
Plastics	35.8%	Might contain BFRs. Particularly in IT housings [Waeger et al. 2010].
Glass	12.89%	Mainly from PV panels
Gold (Au)	0.009017%	
Silver (Au)	0.002539%	
Palladium (Pd)	0.000678%	

Materials	Percentage of total weight in %	Comments on compliance
Other	2%	Hazardous components listed in Annex VII should be disposed of accordingly. For this category might include batteries, PCB containing and other capacitors and toner cartridges.

A.5.3 Information on treatment processes applied

Management of WEEE in many cases consists of several steps before individual material streams are re-used, recycled or disposed of.

For the initial treatment of particular WEEE categories including Cat 1 “Temperature exchange equipment”, Cat 2 “Screens, Monitors”, Cat 3 “Lamps”, Cat 6 “Small IT and telecommunication equipment” dedicated treatment processes are applied to a large extent.

Other WEEE categories, such as large household appliances and small appliances, are generically subjected to manual dismantling and treatment in shredder.

These initial processes aim at separation of different waste streams. Depollution measures lead to hazardous waste streams. Manual or mechanical separation and sorting steps result in waste streams for recycling and recovery and in residues for disposal (incineration or landfill).

When the substance is exclusively used in appliances belonging to a particular category these dedicated treatment processes should be considered.

Furthermore the treatment processes applied to individual waste streams derived from initial WEEE treatment have to be considered. It is assumed, that several material streams, such as waste plastics, glass, metals, electronic components, etc. can be assessed generically for all types of WEEE. In addition to the final treatment process (recycling, recovery, incineration, landfilling) also intermediate treatment steps are possible.

In particular for substances which are widely used in EEE but connected with a particular material, such as substances used as flame retardants in plastics, the evaluation of individual material streams is recommended.

In addition, treatment operations for those waste streams (MSW, metal scrap) where WEEE, which is not separately collected, ends up, have to be considered.

Below, the main processes are described briefly including information on the fate of substances during the processes, information on installations and release factors, where available.

A.5.3.1 Collection and transport of WEEE and storage of WEEE and secondary wastes

It is assumed that collection, transport and storage of WEEE do not considerably differ for different types of appliances and respectively for WEEE-categories. Furthermore, differences between separate collection and collection as part of other waste streams (MSW or metal scrap) are considered to be of minor relevance.

Emissions to air:

Emissions to air may occur because of damaging of WEEE components containing volatile substances or because of evaporation of volatile components due to storage for longer periods under hotter conditions. Evaporations depend on the volatility of the substance.

Emissions to soil and water

Wastes stored outside may release substances, which are less bound to the materials, through rainwater run-off to water and soil. Of particular relevance are substances which are used as or in a liquid (e.g. compressor oils or electrolytes) or as powders.

A.5.3.2 Shredding and automated sorting of WEEE

Shredding and automated sorting is applied to all types of WEEE and many types of secondary wastes such as cables, electronic components, mixed plastics, etc. and diverse intermediate waste fractions.

Shredding may be performed in large ELV shredders, special shredders dedicated to particular types of WEEE or to secondary wastes (e.g. horizontal cross flow shredders or cable shredders) or encapsulated shredders.

Often shredding is combined with automated sorting techniques.

Emissions to air:

The substance contained in the shredded material can evaporate, if it is not firmly bound to the materials, or it can be emitted to air as part of dust particles. In most cases evaporation will be much less relevant than emission of dust.

Evaporations depend on the volatility of the substance; emissions with dust on the properties of the dust particles (particle size and density).

Emissions to soil and water are considered to be of minor relevance for most shredding processes.

Resulting waste streams include:

- Ferrous metals
- Non-ferrous metals
- Plastics
- Glass
- Powders
- Mixed shredder residues
- Residues from air treatment (filter dust)
- Particular intermediate waste fractions may be subjected to several shred- ding processes.

Number of installations:

Shredders of metal (mixed scrap) waste - About 350 mixed scrap shredders are operating in Europe in 2014. Mixed scrap shredders are generally capable of processing between 25 and 400

tonnes of metal waste per hour. Most of these shredders are located in the open air, not enclosed within buildings. (WASTE BREF Draft 2017[141])

WEEE shredders - various categories of WEEE are processed in shredders. For WEEE waste streams containing e.g. volatile fluorocarbons (VFCs), volatile hydrocarbons (VHCs), or mercury, closed shredders are in use. A majority of the WEEE shredders installed in the last years treat equipment such as cooling and refrigerating appliances containing hydrofluorocarbons and are generally capable of processing automatically 35 to 75 devices per hour in a two steps process: First cooling circuits of temperature exchange equipment are treated after which oils and VFCs are removed. Following the devices are shredded into smaller material components (ferrous scrap, mixed non-ferrous scrap, foam, and plastics) and VFC and VHC blowing agents are removed and treated separately. Specific WEEE shredders are also installed for large domestic appliances; cathode ray tube (CRT) equipment; flat panel displays; and lamps. (WASTE BREF Draft 2017)

ELV-shredders: 21037

Operation days:

(330 d)

Generic release factors for shredders

Parameter	Default	Reasoning
RF air	0.1	For materials with low weight, such as paper, plastics, minerals
	0.05	For materials with medium weight, such as rubber
	0.01	For materials with high weight, such as metals
RF water	minor	Mostly no water con- tact
RF soil	minor	Processing does not give rise to release to soil

[141] Best Available Techniques (BAT) Reference Document for Waste Treatment, Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control) JOINT RESEARCH CENTRE Directorate Growth and Innovation Unit Circular Economy and Industrial Leadership European IPPC Bureau Final Draft (October 2017), European Integrated Pollution Prevention and Control Bureau (EIPPCB) at the European Commission's Joint Research Centre, available under: http://eippcb.jrc.ec.europa.eu/reference/BREF/WT/WT_Final_Draft1017.pdf

Specific transfer factors to dust (mechanical treatment of WEEE) (Source: BUWAL 2004 cited by AUBA (2013))

TF	Substances
0.1	Al
0.14	Pb
0.01	Cr
0,01	Cu
0.01	Hg
0.07	Sb
0.13	Cd
0.01	Fe
0.02	Ni
0.25	Zn
0.12	Sn
0.08	Br
0.1	PentaBDE
0.04	HBCD
0.04	DecaBDE
0.03	Cl
0.04	P
0.03	TBBPA
0.03	OctaBDE
0.15	PCB Sum

Concentrations of substances in dust from mechanical treatment of WEEE (Source: BUWAL 2004 cited by AUBA (2013))

Concentration (mg/kg)	Substance
20000	Al
5900	Pb
740	Cr
6000	Cu
1.7	Hg
1700	Sb
340	Cd

Concentration (mg/kg)	Substance
69000	Fe
2300	Ni
18700	Zn
4300	Sn
3400	Br
49	PentaBDE
10	HBCD
290	DecaBDE
4600	Cl
200	P
700	TBBPA
230	OctaBDE
27	PCB Sum

A.5.3.3 Manual Diamantring

Manual dismantling is relevant for all types of WEEE except Cat 3 (lamps).

Emissions to air

The substance contained in components of the dismantled WEEE can evaporate, if they are not firmly bound to the materials. Where drillers, saws, etc. are used to support dismantling of appliances, also emissions with dust particles are relevant.

Emissions to soil and water are considered to be of minor relevance for most dismantling activities. Emissions, however, can occur, e.g. from leakage of waste oil etc.

For manual dismantling also skin contact of the workers with the substance is of relevance.

Resulting waste streams include:

- Ferrous metals
- Non-ferrous metals
- Plastics
- Glass
- Electronic components

A.6 Guidance on groups of similar substances

This guidance is based on discussions of the Commission expert group accompanying future substance reviews under Directive 2011/65/EU and a proposal prepared as guidance on the definition of groups of similar substances in which some adjustments have been made.

A.6.1 Introduction

Article 6(1) of the RoHS Directive (2011/65/EU) requires the European Commission to consider reviews and amendments of the list of restricted substances in Annex II. The directive gives the possibility to review and assess both single substances as well as groups of similar substances.

The term ‘grouping’ or ‘substance grouping’ is interpreted to describe the general approach for considering more than one substance at the same time in an assessment. Assessing a group of substances could in some cases provide an alternative to the individual assessment of substances, mainly in order to maximise efficiency.

This annex thus aims to provide implementing guidance, describing an approach that is to be applied in the grouping of substances under RoHS, to simplify where possible the assessment process. It is intended as an indicative list of guiding criteria for the selection of substances that can be better assessed together.

A.6.2 Grouping of substances under RoHS

Under RoHS, a group of substances subject to assessment for potential restriction in EEE should be composed of substances sharing one or a combination of the following similarities:

- Common structure, functional group(s) constituents or chemical classes;
- Common (eco-)toxicological effects, hazard classification or toxicokinetics;
- Common physico-chemical properties;
- Common mode or mechanism of action;
- Common adverse outcome pathway;
- Common environmental fate/behaviour;
- Likelihood of common precursors and/or breakdown products via physical or biological processes that result in similar substances;
- Constant pattern or trend across the group in the potency of the properties;
- Comparable type and duration of exposure due to either the use of the EEE or the management operations of the related WEEE;
- Similar or same purpose/use/function in specific applications
- Presence in EEE, or reasonable expectation of presence in EEE according to the substance’s characteristics, for the same purpose/use/function;

The above list is not exhaustive, but rather provides example criteria that can be used to group substances for assessment and potential restriction. The listed criteria can in some cases be used alone, but in general, the more criteria apply, the more robust the definition of the group. Selection

of substances for grouped assessment depends on many criteria and each group needs to be considered on a case-by-case basis. Some general guidance is detailed below.

Table 3-4: Guidance on the application of substance grouping criteria

Criterion	Implications regarding the possibility for group assessment
Common structure, functional group(s), constituents or chemical classes	This alone will usually not be sufficient because typically in groups defined on the basis of common functionality, there will be too many substances with a very large variation in properties, behaviours and applications, so that the assessment as a group would be impractical. However, this can be used with other criteria to define a group.
Common (eco-)toxicological effects, hazard classification or toxicokinetics;	These are useful criteria as they limit a group assessment to substances that potentially have a similar negative health or environmental impact. Furthermore, in order to possibly establish a single threshold for the group, it should be considered if the concerned effects of the substances are additive or synergetic (for which case the threshold shall define the maximum total concentration of all members of the group of substance present in the homogenous material).
Similar physico-chemical properties	This criterion will usually not suffice for definition of a group on its own, but it could be useful in combination with other substance's properties, use or behaviours. For example, substances with similar vapour pressure may result in similar levels of exposure to workers.
Common mode or mechanism of action	This important criterion could contribute to a better definition of the group.
Common adverse outcome pathway	This important criterion could contribute to a better definition of the group.
Likelihood of common precursors and/or breakdown products via physical or biological processes that result in similar substances	If all substances in the group can be transformed to a similar extent at end of life into the same types of hazardous substances that are known to pose a risk to health or the environment, then they could be assessed as a group. However, substances that readily produce hazardous by-products should be assessed separately from substances that form these substances only under rare conditions.
Constant pattern or trend in the potency of the properties across the group	Predictable trends of properties that depend on structural features (e.g. alkyl chain length) within a group might be a way to determine which substances to include in a group.
Similar or same purpose/ use/function in specific applications	This criterion will usually not suffice for definition of a group on its own, but can be used to refine it. For example, if several similar substances could be used for the same application in EEE and are interchangeable and appear to be equally harmful, then it would seem sensible to consider them as a group.
Presence in EEE, or reasonable expectation of presence in EEE according to the substance's characteristics, for the same purpose/use/function	This criterion will usually not suffice for definition of a group on its own, but it could be useful in combination with other substance's properties, use or behaviours. For example, a substance not used in EEE, but similar to another one used in EEE can be assessed within the same group of the second substance if there is likelihood that the first substance is used to replace the second one in EEE.

One example of a grouping approach, is to look at the structural criterion in combination with other criteria, such as those related to the properties, effects, behaviour or mode of action of the grouped substances. In this case, groups of substances are selected based on the hypothesis that structural changes across the group will produce changes that would affect the whole spectrum of properties in consistent and coherent trends.

Another example is a group of substances having the same hazard classification (e.g. reproductive toxins), similar exposure levels (i.e. users and workers would be exposed to the same amount irrespective of which substance is used) and/or they are interchangeable in use so that one can be substituted for another. Substances with different hazard classifications or likely to have very different exposure levels may need to be assessed separately because their potential health and environmental impacts will be very different. However, some substances have not been fully tested so have not yet been classified. Therefore, substances with similar structure that are likely to have similar hazard classifications could be included in a group for assessment. Furthermore substances that have similar but not identical classifications, such as reproductive toxins category 1A and 1B, and where exposure levels are not the same, might be considered for inclusion in one group for assessment if the effects of hazard classification and exposure result in similar negative health or environmental effects (i.e. also as a means of preventing regrettable substitution).

Before a group of substances can be assessed for potential restriction under RoHS, the following information should be documented to explain how the group of similar substances was derived:

- All members of the group are as far as possible[142], properly identified by a CAS name or number, an EC name and/or number, and/or one or more equivalent identifiers;
- All relevant criteria are considered, described, and documented, including assumption and/or information used to fill information gaps, as relevant;
- The applicability domain of the group is clearly defined (i.e. the similarity requirements to set the boundaries that are used as inclusion/exclusion criteria of the group) and justified, to allow substances to be considered in the future as members of the group.

It is of particular importance to describe and document the common elements of a group, together with the variation within the group. When differences between the members of the group exist so that the degree of similarity or commonality is challenged or appears less evident, such differences must be clearly described. Among possible example of such variations/differences, the following examples are worth mentioning:

- an effect which varies in intensity across the group, such that some members of the group meet the criteria for one hazard classification for the particular endpoint, whereas other members of the group meet the criteria for another;
- the presence of a breakpoint indicating a change in the mode of action or the effect of a consistent tendency across the group, e.g. a peak in activity or a breakpoint in a trend;
- a trend analysis that may apply to a subgroup but not to the whole group.

When the difference/variation does not negate the commonality for that criterion, then grouped assessment is confirmed as the right approach. On the contrary, when a difference/variation ne-

[142] In some cases, for example where a grouping is based on similar structures, some members of a group may be theoretical (assumed not to have been synthesised) and thus to lack common identifiers, these shall be specified based on structure and other typical characteristics to allow understanding the justification for inclusion in the group.

gates the commonality for that criterion, then the grouped assessment may be determined as an inappropriate approach from the perspective of the criterion concerned.

Ultimately, decisions on whether to consider substances separately or as a group must be made on a case-by-case basis. It will be necessary to consider whether the members of a group are sufficiently similar to determine if it will be beneficial to assess these as a group or separately.

If, for example, structure similarity is applied as a criterion, in practice it may be possible to identify the trends and changes for some but not all of the properties of potential interest in a given group. Likewise, significant differences in structure or composition, leading to significant changes in properties, inconsistent or incoherent trends, and/or different classifications, might indicate that the grouped approach is unlikely to be robust and efficient enough and that a substance-specific assessment is more appropriate.

Ideally, the robustness and validity of a group of substances should be confirmed or refuted as early as possible in the grouping exercise, in order to avoid an inefficient subsequent assessment.

A.6.3 Assessments of groups

Developing a group could be the result of an iterative process and subject to adjustment as more information becomes available on substances that could be added to the group or removed from the group, during the assessment of the group. Thus during the assessment process, a given group of substances could be split into smaller groups, and substances could be added to it or removed from it in light of evidence obtained (e.g. if this shows that an included substance is very different to other members of the group and so requires separate assessment).

Where during an assessment one or more additional substances are scrutinised on the basis of the grouping criteria listed above and applicable to the group concerned, the substance could be:

- included in the group and in the related assessment; or
- kept out of the group, in which case the substance would need to be separately assessed.

If a substance is considered for inclusion in an existing group, it will be necessary to evaluate both the data for this substance in light of the group assessment, as well as the group assessment in light of the data for the additional substance. If the initial group assessment is sufficiently robust, the additional data is unlikely to alter the conclusions of the initial assessment.

The use of a group approach should, - as for the single substance approach, - identify and characterise (qualitatively or quantitatively) the negative impacts that should be tackled by a restriction under RoHS.

Grouping of substances has also been considered in other regulatory frameworks and international fora where further guidance is available:

- REACH: Section 1.5 of Annex XI;
- ECHA: Pages 65-71 of the ECHA Guidance on information requirements and substance safety assessment (Chapter R.6: QSARs and grouping of substances) (May 2008); and
- OECD: Pages 11-25 of the OECD Guidance on grouping of chemicals (Second edition, April 2014).

A.7 Guidance on data quality and dealing with data gaps

This guidance is based on discussions of the Commission expert group accompanying future substance reviews under Directive 2011/65/EU and a proposal prepared as guidance on data quality and dealing with data gaps, in which some revisions have been performed.

When do the recommended data quality requirements apply?

The methodology described in the manual consists of three parts. The first two parts (see Chapter 1 on Identification of substances and Chapter 2 on Prioritisation of substances) are aimed at the prioritisation of substances which will be assessed in the last part (see Chapter 3 on Detailed assessment of substances). The issue of data quality and data gaps is mainly relevant for the implementation of Part three. Therefore, the assessment in stage three is dealt with in this section.

Is there any additional guidance available?

Article 6(1) further specifies that the review shall use publicly available knowledge obtained from the application of chemical legislation such as REACH. Though this is not understood to mean that other sources should not be used, it suggests that the review is to be based on publicly available data. 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.

What is the main purpose to define data quality?

The most important reason is to avoid that poor quality data are used to show that a restriction is justified or is not justified. The assessment should collect and review all available data and

- only base decisions on results that are non-controversial within the research community; and
- assess thoroughly research that gives unusual and inconsistent data compared to the non-controversial data and document such uncertainties within the assessment dossier.

Inconsistent data may be correct and usable, but it may also be wrong due to incorrect/unrealistic testing conditions. If certain data is controversial, but it cannot be proved wrong, it may be used to indicate the need for further research to allow the closing of a certain gap needed for coming to a decision.

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.

What data can be used to fulfil the quality requirements?

Where available, data generated through other legislation related to chemicals and particularly through the REACH (Registration dossier, CORAP evaluation, Annex XV dossiers, authorisation dossiers, etc.) are recommended as a first choice. 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 governmental agencies, and also of non-EU governmental agencies (US EPA; etc.), statistics (EUROSTAT but also EU national), studies from recyclers, economic reports, market analysis from manufacturers and authorities, etc. Publicly available information should be preferred where possible.

Should data still be missing after the stakeholder consultation stage, it is recommended to widen the search for information, through requesting input from further / other stakeholders and to consider expanding the search beyond publicly available publications.

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 data may be due to the fact that it is not known, 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 business confidential information (BCI). Documentation of the fact that more data are available could be considered, but such data should not be used to justify a certain view.

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 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 of 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 abso-

lute minimum. In particular multiple assumptions could significantly increase the uncertainty of results and these should be noted and the consequence of uncertainties discussed. 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 to be taken with full awareness of all uncertainties and possible consequences.

Furthermore, if the final assessment is inconclusive due to lack of data, it could be recommended to revisit the assessment within a few years, when such data has been generated (e.g. where the knowledge base is expected to expand through ongoing studies). Alternatively, areas requiring further research should be outlined, also specifying how such research can be expected to contribute to the conclusion of the assessment. On this basis, the Commission shall be able to determine the timing for a reassessment as well as to consider the preparation of relevant studies.

To ensure that data gaps and how they are dealt with is documented, the following aspects should be clearly presented within the assessment report (dossier):

all information that could be gathered,

- all information that had ultimately not been available,
- all assumptions used, and for each assumption its rationale,
- all conclusions that have been drawn **including the indication of uncertainties and possible consequences thereof**.

References:

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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.

A.8 Summary of Contribution submitted to Stakeholder Consultation on the RoHS Substance Methodology

A.8.1 List of contributing stakeholders:

A stakeholder consultation was held on the RoHS draft methodology for substance identification. Prioritisation and assessment between 26 October 2018 to 21 December 2018. The following stakeholders submitted (non-confidential) contributions to the stakeholder consultation:

> Contribution of **RINA Consulting** (formerly EdifERA and ERA Technology Ltd), submitted on 07.12.2018: PDF

> Contribution of **COCIR (European Association of the Radiological, Radiotherapy and Healthcare IT Industry)**, submitted on 14.12.2018: PDF

> Contribution of **ZVEI (Zentralverband Elektrotechnik- und Elektroindustrie**), submitted on 19.12.2018: PDF

> Contribution of **AmCham EU (American Chamber of Commerce to the European Union)**, submitted on 20.12.2018: PDF

> Contribution of **EUROMOT (the European Association of Internal Combustion Engine Manufacturers)** and **AEM (US Association of Equipment Manufacturers**), submitted on 20.12.2018: XLSX

> Contribution of **Digital Europe**, submitted on 20.12.2018: XLSX

> Contribution of **MedTech Europe**, submitted on 20.12.2018: PDF

> Contribution of **The European Semiconductor Industry Association (ESIA)**, submitted on 20.12.2018: PDF

> Contribution of **the Industry Associations DIGITALEUROPE, ESIA, IPC, JBCE, ITI, KEA, SEMI and ZVEI**, submitted on 21.12.2018: PDF

> Contribution of the **Beryllium Science and Technology Association (BeST)**, submitted on 21.12.2018: PDF

> Contribution of **the associations BeST, mmta, i2a, IMAT**, submitted on 21.12.2018: PDF

> Contribution of several **Industry Stakeholders**, submitted on 21.12.2018: PDF

> Contribution of **Japanese electric and electronic (E&E) industrial associations**, submitted on 21.12.2018:

>> General comments: PDF

>> Attachment 2 detailed comments on methodology: XLSX

>> Attachment 3 as draft Appendix on substitute: PDF

>> Attachment 4 as draft Appendix on group of substance: PDF

>> Attachment 5 as draft Appendix on data gap: PDF

> Contribution of **JBCE – Japan Business Council in Europe**, submitted on 21.12.2018: PDF

> Contribution of **Test and Measurement Coalition (TMC)**, submitted on 21.12.2018: PDF

> Contribution of **Campine**, submitted on 21.12.2018: PDF

> Contribution of the **Swedish Chemicals Agency (KEMI)**, submitted on 21.12.2018: PDF

> Contribution of the **European Chemical Industry Council - Cefic aisbl and Eurometaux,** submitted on 21.12.2018: XLSX

> Contribution of **Orgalime**, submitted on 21.12.2018: PDF

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Baron, Y.; Blepp, M.; Gensch, C.-O. & Moch, K. (2014). Study for the review of the list of restricted substances under RoHS 2 - Analysis of impacts from a possible restriction of several new substances under RoHS 2: Under the Framework Contract led by Eunomia Ltd.: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation. http://rohs.exemptions.oeko.info/.

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