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Draft 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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Disclaimer

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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 manual published in 2013 by the Austrian Umweltbundesamt (AUBA 2013). In parallel to its preparation the inventory of substance relevant for future assessment is being updated and seven substances, specified by the terms of reference of this study, are being assessed based on the methodology detailed herein. Based on this experience, the methodology and the information made available for using it shall be further refined where relevant.

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 legislation 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.

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)[1] in EEE has been banned/restricted since 2006. Maximum concentration values by weight in homogeneous materials were specified[2]. 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[3]. 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 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 Umwelt Bundesamt (AUBA 2013). This document has been revised in relation to various developments in policy and is now being published for consultation with stakeholders.

[1] 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.

[2] Decision 2005/618/EC

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

Please note

The following two divergent formatting styles are 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.

For the purpose of the consultation with stakeholders, in cases where particular information is sought or where clarifications are needed, questions have been built into the manual.

Question for Stakeholders participating in the stakeholder consultation are formatted as blue text and presented in boxes.

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[4]) and hexabromocyclododecane (EU RAR 2007b[5]) 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[6]) 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).

[4] 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.

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

[6] 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).

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).

In the course of the AUBA review, an inventory of substances of relevance for EEE was also generated[7] 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)[8], 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;

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

8 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)

(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 design 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 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.

It is also worth mentioning the Communication on the interface between chemical, product and waste legislation published by the European Commission in 2018 (COM 2018 32 final).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 be-

ing 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 harmonized 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.

How these issues can be overcome and possible actions that the Commission can initiate are specified.

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.
			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 Art. 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[9].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 (Art. 69). However, looking at the RoHS Article 6(1) criteria suggests that it suffices for a substance

[9] 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.

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.

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, where for example a risk exists but for example there is no data as to actual exposure. If REACH restricts a certain substance in all applications, RoHS should not promote exemptions that may lead to the increased use of such a substance (for example as a substitute). 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. This does not give priority to such information and data 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 "Introduction", 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 prioritization 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[10] mentioned in Article 6(1), the grouping of similar substances[11] 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 list of restricted substances as well as during implementation, e.g. to ensure market surveillance. It might become evident to form groups of substances e.g. in line with a simultaneous presence of substances (e.g., UVBC[12] substances) and/or same behaviour of individual group members 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 show similar trends in their physico-chemical properties, and even more important, 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.

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

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

[12] Unknown or variable composition, complex reaction products or biological material substances

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, the environment or resource efficiency during use and/or during WEEE management[13] and how to assess them to justify a potential restriction under RoHS.

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. 14);
- A review following submission of a restriction proposal by a Member State.

In addition, the manual may be used as guidance by Member States when they intend to prepare a restriction proposal.

II.IV Overview of the methodology

The methodology described in this manual consists of three parts:

- PART I: Identification of substances[14] used 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);
- PART II: Pre-assessment: Prioritization 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)
- PART III: Detailed assessment of high priority substances with a view to a potential restriction under RoHS.

PART I serves as a screening step in order to identify all substances used 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).

First an inventory of substances used in EEE is created. Existing databases and computer based tools are then used to establish a comprehensive database with information on the substances concerned (substance properties, use and waste aspects). Finally, chemicals are selected by applying defined criteria (hazardous properties, evidence that the substance is relevant with regard to RoHS Article 6(1) [EEE use and WEEE management]). The information collected is used for further substance assessment and considerations.

Part II aims at narrowing down the list of substances used 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), through a comparably easy and fast procedure. Substances which are most likely to be of highest concern regarding their potential negative impacts

[13] 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.

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

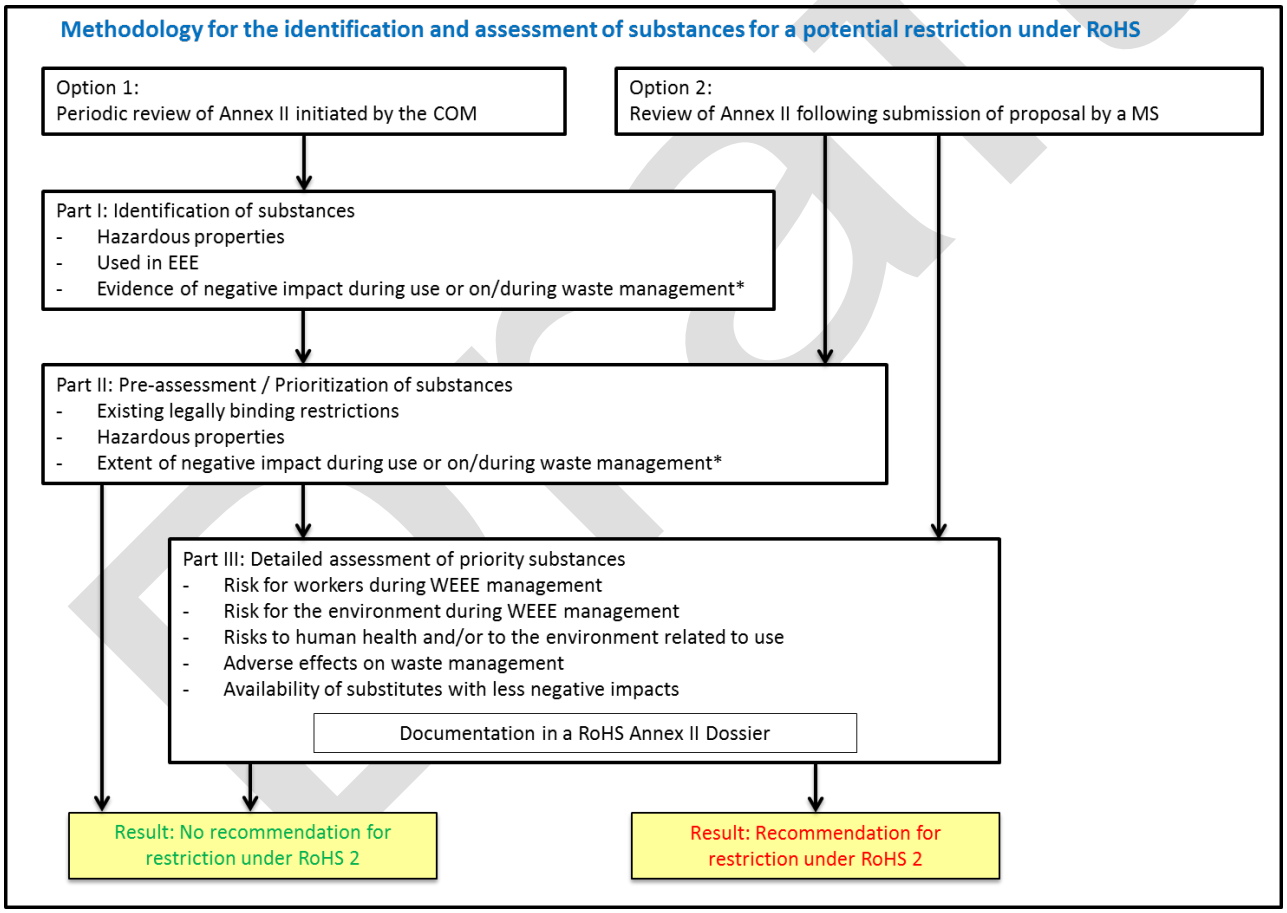
on human health, the environment or resource efficiency and thus most urgently require a detailed assessment under RoHS shall be identified. This is done through taking consideration of legal status of the substance, hazard classifications and potential for the Article 6(1) criteria to be fulfilled. After substances have been identified based on selection criteria (initial prioritization) a refinement of the substances of high priority is performed to further refine the selection.

PART III is a detailed assessment of a substance/substance group, with regard to the specifications of Article 6, 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 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.

Figure 1-1 provides an overview of the overall methodology described in detail in this manual.

Figure 1-1: 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[15] or risks for the environment and workers during WEEE management or have any other negative impacts on waste management, as specified by RoHS2, 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 standardized 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.

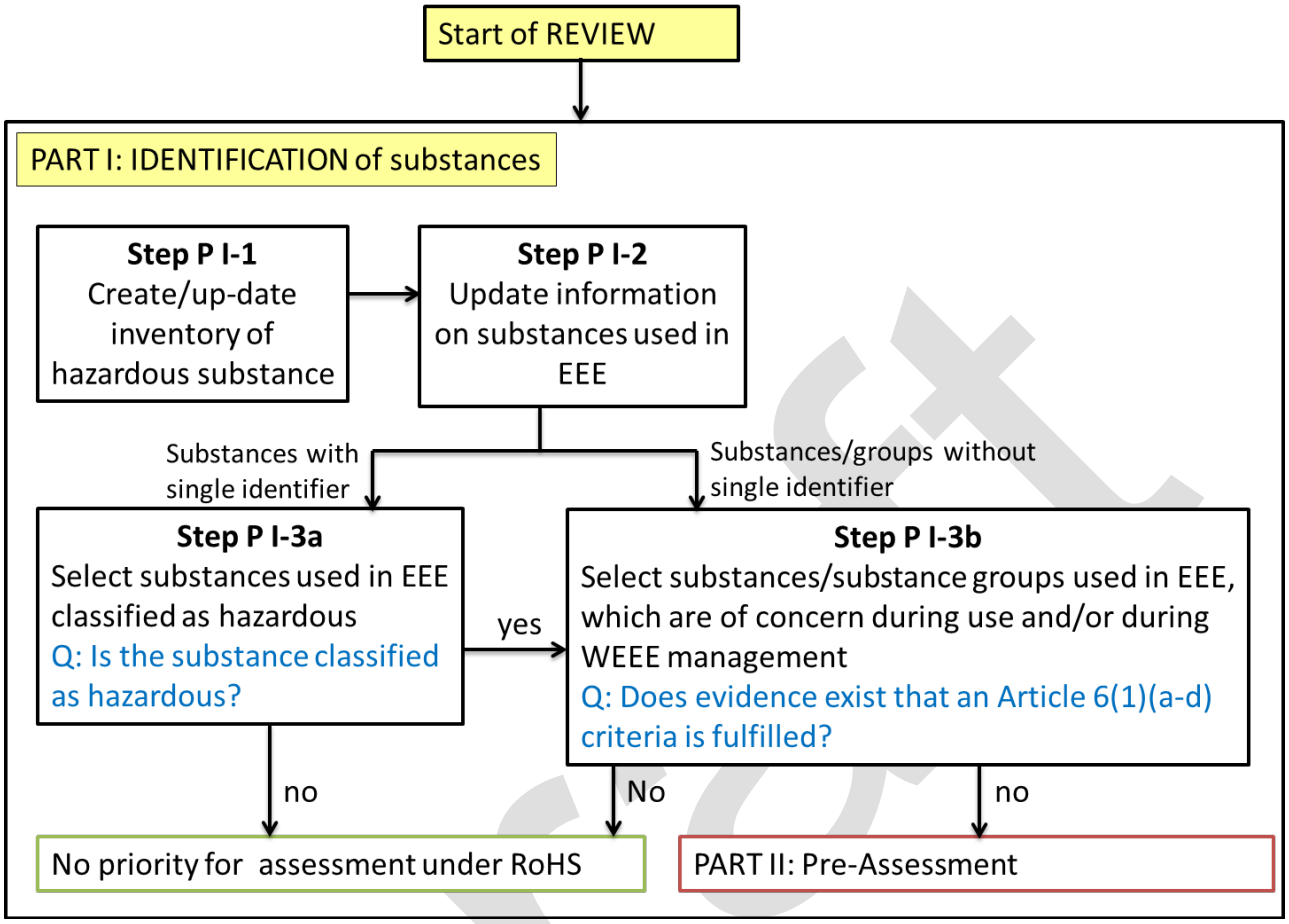
The identification of potentially RoHS-relevant substances used in EEE involves three major tasks:

- Creation of an inventory of substances classified or suspected as hazardous (Step P I-1)
- Creation of an inventory of substances used in EEE (Step P I-2)
- Evaluation of the relevance of a given substance for further assessment (Step P I-3):
  - Selection of substances used in EEE which were identified as hazardous (Step P I-3a)
  - Selection of substances, where there is evidence that they have negative impacts during use and/or on or during WEEE management (Step P I-3b)

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

[15] 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.

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



Note: The term hazardous substance generally refers to substances classified as hazardous under the CLP Regulation. Nonetheless, some substances, when present in waste, may result in the waste being classified as hazardous waste. Though this could also be considered for the purpose of Step P I-3a, it is related to the waste phase and is thus (where relevant) to be considered under Step P I-3b (for example Art. 6(1)(a) - "*could have a negative impact on during EEE waste management operations, including on the possibilities for preparing for the reuse* [...] *or for recycling* [...]"

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. The inventory established in 2013 (AUBA) provides a first basis to be updated in the following periodic review. 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 prioritization 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.
- 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.

1.1. Step P I-1) Compile inventory of substances which are hazardous

Approach/Criteria: To establish the initial inventory, substances classified or suspected of having hazardous properties shall be compiled, 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 PB and/or vPvB properties and/or a potential for endocrine disruption and/or are radioactive 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.

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 Art. 3(5); CLP Art. 3(11)). As polymers are considered to be substances it stands to reason that they could be considered for restriction under RoHS.

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 properties [identified in accordance with article 57(f) of REACH]
Radioactive
Suspected as any of the above

Source: Adapted with revisions from AUBA (2013)

Database on substance information: In order to generate a list of relevant substances, information on the substance identity (name, CAS and EC identifiers) as well as on the identified or suspected priorities is to be compiled. A differentiation between identified properties (e.g., classification) and between suspected properties shall be applied to allow selecting substances identified as having hazardous properties at later stages. Exploration of the data can be easily 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 compiled.

Databases on hazardous substances on one side, as well as governmental lists on European, national and international level as well as lists from non-governmental organizations 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.

- 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[16]. 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”[17]. The list currently contains 191[18] substances, 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)[19]. There are currently 43 substances on the Authorisation List[20], 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[21].

- 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.[22] There are currently 68[23] substances listed on the list of restrictions.

- PBT properties

Data and results of the PBT working group of ECHA shall be considered for future reviews[24]. Furthermore, results of PBT/vPvB assessments performed under the previous EU chemicals legisla-

16 https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp
17 http://echa.europa.eu/candidate-list-table
18 Last viewed on 20.07.2018
19 https://echa.europa.eu/authorisation-list
20 Last viewed on 17.10.2018
21 https://echa.europa.eu/previous-recommendations
22 The list of restriction is available under https://echa.europa.eu/substances-restricted-under-reach
23 Last viewed on 20.07.2018
24 https://echa.europa.eu/de/pbt-expert-group)

tion can be found on the ECHA website[25]. 127[26] substances are included in this data base, though not all have been found to comply with PBT or vPvB criteria.

- 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[27].

- Endocrine disruptors

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 (in force since 10 May 2018) and the Biocidal Products (BP) Regulation (EU) 528/2012 (in force since 7 December 2017). Where the criteria are fulfilled, a substance is considered to have endocrine disruptive properties. In the PPP and BP legislations, a substance is considered endocrine disruptive if all criteria are fulfilled, "*unless there is evidence demonstrating that the adverse effects identified are not relevant to humans*". This means that endocrine effects in these legislations are only considered where they may affect humans. The REACH legislation (Article 57(f)), however, 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.

For the purpose of determining whether substances in the inventory have endocrine disrupting properties, the available data gained within the European Endocrine disrupters strategy shall be taken into account. In total, more than 500 substances have been evaluated with regard to their endocrine disrupting properties.[28]

Data and results of the Endocrine Disruptor working group of ECHA shall also be considered for future reviews.[29]

- 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 considered hazardous and could be regulated in the future. 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 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

[25] https://echa.europa.eu/information-on-chemicals/pbt-vpvb-assessments-under-the-previous-eu-chemicals-legislation

[26] Last viewed on 26.07.2018

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

[28] Currently, there is no newer data base for substances considered as having endocrine disrupting properties, i.e. meeting the scientific criteria under the PPP and BP legislations. When such a data base is established, it should be updated as the source for determining this property for substances in the inventory. http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm

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

damage to health and environment (such as substances with endocrine disrupting properties). The rational for including substances in the SIN List is based on a scientific review and the reasons for the addition of substances to the list are specified. [30] 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.

Question for Stakeholders participating in the stakeholder consultation:
Please specify additional lists of relevance for specifying substances identified or suspected of having hazardous properties.

1.2. Step P I-2) Create/Update the existing inventory of substances used in EEE

Approach/Information:

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 used 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 prioritization. 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.

Step P I-1a) Up-date new information available from the following databases:

The initial inventory is to be updated in relation to new information regarding substances already listed and also in relation to substances newly identified as relevant. For the purpose of this update 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[31]. Three categories are specified in this respect:
  - Criteria 1: Currently Regulated;
  - Criteria 2: For assessment;
  - Criteria 3: For information only.
- ZVEI-Umbrella specifications[32]:
- Information on substance uses as available from the registration process under REACH: substances with the use descriptors[33] SU 2a (Mining, (without offshore industries)), SU 9 (Manufacture of fine chemicals), SU 11 (Manufacture of rubber products), SU 12 (Manufacture of plastics products, including compounding and conversion), SU 15 (Manufacture of fabricated metal

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

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

[32] 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/

[33] Not only clear EEE descriptors are included but also descriptors of materials commonly applied in EEE.

products, except machinery and equipment), SU 16 “Manufacture of computer, electronic and optical products, electrical equipment” (to be specified in search under Uses and exposures>Sector of use)[34].

- Information on substance uses (Nace-codes C26 “Manufacture of computer, electronic and optical products” and C27 “Manufacture of computer, electronic and optical products”[35]) as available from the Nordic Product Register (SPIN – substances in preparations in Nordic countries - register)[36];
- Information from requests for new RoHS exemptions / renewal of exemptions / withdrawal of exemptions, in which potential substitutes are addressed.

Step P I-1b) Supplement the existing 2013 inventory with information from additional up-to-date information sources

- Studies and other information on substances used in EEE
- Investigations/studies on substances found in WEEE[37]
- Stakeholder consultation on substances used in EEE (focus on EEE producers) and/or substances found in WEEE[38] (focus on NGOs, scientific bodies, waste management operators, etc.). The stakeholder consultation should be used to collect initial information as to the volume range of use of substances included in the inventory of substances. This should be performed by providing the list of substances included in the inventory and requesting stakeholders to specify the use in relation to a number of volume ranges. See Annex 0 for template.

In addition, due to the requirements of RoHS, special attention shall be given to adding information on the use of nanomaterials in EEE. According to the RoHS Directive, special account shall be given to nanomaterials[39]. General information on nanomaterials can be found on the Europa website on nanotechnologies[40].

In 2012, the EU 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.[41] This document is accompanied by a Commission Staff Working Paper on nanomateri-

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

[35] Relevant uses to be selected

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

[37] Such information needs to be considered with caution. Presence of a substance in WEEE is evidence to its past use in EEE. Use of substances in EEE at present may have been subject to changes (phase-out, elimination through design changes) and thus presence in WEEE should only be considered indicative of possible current use.

[38] Information on occurrence of substances in waste is to be evaluated with caution, particularly in relation to substances found in products with longer lifetimes. Though such data can be considered indicative as to which substances are present in products of relevance to the waste stream, in practice such data contends evidence of the products placed on the market in the past that may or may not still be placed on the market at present. In some cases, substances may have been substituted in new products (manufacture or use phase), while products arriving at end-of-life in the waste stream will reflect designs to have been placed on the market in the past.

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

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

als, which provides an overview of available information on nanomaterials on the market, their types and uses, as well as on safety aspects[42].

Additional information on data sources on the use of nanomaterials is provided in Annex A.1.1.

Question for Stakeholders participating in the stakeholder consultation:

Please specify additional lists of relevance for specifying substances used or suspected of being used in EEE.

Step P I-1c) 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[43]. 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 derivatives[44] 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 prioritization and how this information should be considered in an assessment of the substance or of substances for which it may be a substitute.

1.3. Step P I-3a) Select substances used in EEE which are hazardous

Approach/ Criteria: In order to select those substances with the highest potential of causing adverse effects, information on the hazardous properties of substances collected in Step P I-1 shall be screened to allow a selection of the substances identified with hazardous properties.

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

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

[44] An example is AsO3, where – even if not contained in a glass matrix as AsO3 - in cases of use, contained compounds may be released during the crushing or milling of glass.

1.4. Step P I-3b) Select substances used in EEE which are of concern during use or during WEEE management (Article 6 (1) a, b, c, d)

Step P I-3b **aims** to select substances / substance groups including substances of very small size used in EEE, where there is evidence that they fulfil the Article 6(1)(a-d) criteria (see "Background", Section II.I)

Step P I-3b is applied to:

i. substances / substance groups without a single identifier (CAS No.) where no hazard assessment according to Step P I-3a could be carried out; and

ii. substances / substance groups, which were classified as non-hazardous in Step P I-1 (or only suspected as hazardous).

The following **sources of information** should be screened:

- Studies & investigations on substances present in EEE[45]
- Studies & investigations on WEEE treatment[46]
- Technical standards for waste treatment (e.g. BREFs (waste treatment industries, non-ferrous metals, ferrous metals, polymers, glass, etc.), standards dedicated to WEEE treatment, e.g. standards being currently prepared under CENELEC, respectively WEEELabex standards prepared by the WEEE-Forum, national standards)
- Pollutants inventories
- Direct stakeholder consultations (e.g. with the waste treatment sector)[47]

Possible adverse effects of substances during the use phase: In some cases, a substance may be released into the environment from EEE during the use phase, i.e. in an uncontrolled or diffuse release. This is understood to refer to possible releases related to the intended use of a substance, but also to non-intended use. Examples of effects of substances applied in EEE potentially causing risks for human health and the environment during use include (not exhaustive):

- Release of a substance as a result of intended use (for example in the case of substances with high volatility, or substances that are not chemically bound to the material matrix in which they are contained such as phthalates released from plastics during the use phase);
- Release of a substance during improper use or accident, particular when such use is probable (for example, release from an EEE exposed to heat or to fire such as dioxins released during a fire from objects containing flame retardants, or mercury release related to breakage of discharge lamps);

Possible adverse effects of substances during WEEE treatment: Management of WEEE consists of several steps before individual material streams are re-used, recycled, recovered or dis-

[45] During the review of RoHS Annex II in 2018, the following sources were evaluated regarding their suitability for identification within Step 2b: DANISH EPA 2012; KEMI 2011; (Groß et al. 2008); Berkley Center for Green Chemistry 2012. During the second review of the RoHS Annex II in 2018, the following sources were also consulted: To be completed after the inventory has been revised.

[46] For the first review of RoHS Annex II in 2013, the following sources were evaluated regarding their suitability for identification within Step 2b: DANISH EPA 2012; KEMI 2011; (Groß et al. 2008); Berkley Center for Green Chemistry 2012. During the second review of the RoHS Annex II in 2018, the following sources were also consulted: To be completed after the inventory has been revised.

[47] For example through the European Electronics Recyclers Association.

posed of. It includes collection, transport, storage and treatment of separately collected WEEE. Dedicated treatment processes have been developed for specific types of WEEE. A significant amount of WEEE is not collected separately and ends up e.g. in residual waste, or is disposed (illegally) in the environment. 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[48]. A compilation of treatment processes applied for WEEE is provided in PART III, Step 2a, see Section 3.5.

Examples of effects of substances used in EEE potentially causing risks for human health and the environment and which may require special emission control and treatment measures during WEEE management are (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.

[48] For example, West-African countries are known to be major destinations for used EEE and WEEE exports from the EU. With regard to cables, this situation is of particular concern because non-compliant management sometimes involves the open burning of cables to liberate the metal wires (mostly from copper) from their insulation material. The practice of open cable burning has been observed in many countries, but in particular in countries with a strong dominance of informal sector recycling such as Ghana and Nigeria in West-Africa (Manhart et al. 2011; Prakash & Manhart 2010; Atiemo et al. 2016).

2. Part II) PRE-ASSESSMENT OF SUBSTANCES

Pre-assessment of the identified relevant substances **aims** at determining which substances / substance groups should most urgently be subjected to a detailed assessment for a potential restriction under RoHS (see Part III). The process described in this section aims at establishing a sub-selection of the substances initially identified for the inventory. The exclusion of a substance from the inventory at this stage (or allocation of a lower priority for its review) is applied during a certain revision of the substance inventory, however, does not remove the substance 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.

Approach:

Step P II-1: Substances already restricted in a wider context covering also EEE, or those that will be restricted soon, are to be excluded.

Step P II-2: A prioritization of substances is to be carried out by grouping substances on the basis of possible impacts (health, environment) to arise during use or during WEEE management as specified by Article 6 (1). An assessment of the hazardous properties of substances shall support this prioritization in terms of existing hazardous classifications providing indication as to the possible type of impacts to arise (on human health, on the environment) and as to their severity. Should the same impacts be associated with a number of similar substances, resulting in an identical initial prioritization, the comparison of classifications as detailed below shall allow the prioritisation within the group of substances.

INTERPRETATION:

Though in practice it is expected that substances fulfilling Article 6(1) criteria shall be classified as hazardous, in theory it is possible that in some cases available information and data shall indicate fulfilment of the criteria for a substance that has not yet been classified. In this sense, fulfilment of the Article 6(1)(a-d) criteria is interpreted to have precedence over the status of hazardous classification, provided that available data and information support the occurrence of a potential impact of relevance.

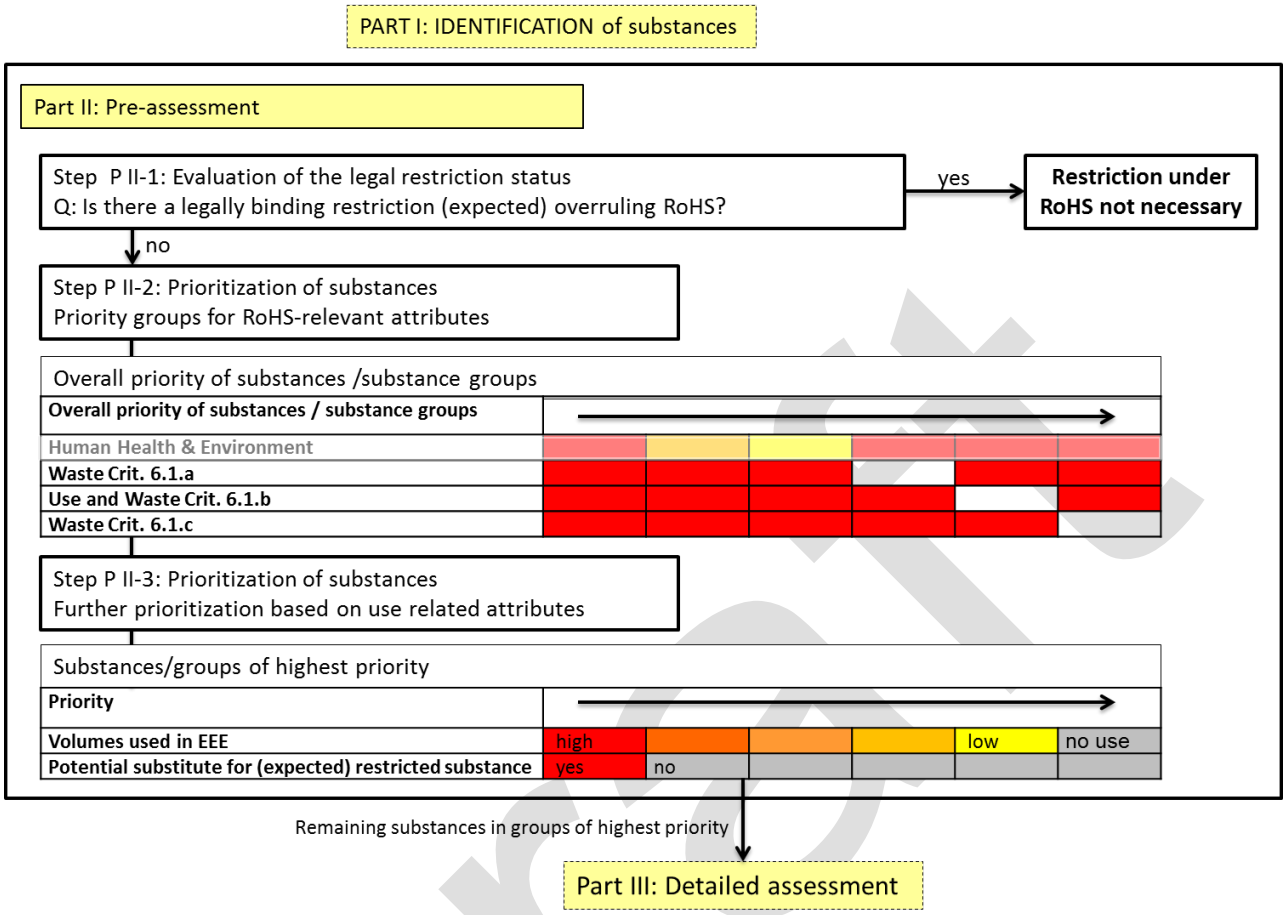
Step P II-3: To further differentiate between substances which were considered to be of the same (high) priority using these attributes, volumes used in EEE[49] and the potential for being used as a substitute for a substance already restricted or proposed for restriction shall be evaluated[50].

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

[49] Contained in EEE placed on the Union market

[50] Not an in-depth analysis is requested at this stage, but a screening of easily available information.

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



Source: Adapted with revisions from AUBA (2013)

2.1. Step P II-1) Evaluation of the legal restriction status

The **aim** of step P II-1 is to exclude substances, where a restriction under RoHS is not required, as the substance is already restricted in other pieces of legislation or where a legally binding restriction is expected in the foreseeable future.

Criteria: The substance is excluded if it is:

- Prohibited and/or restricted in accordance with the POPs Regulation (EC) No 850/2004 and its amendments
- 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].

[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

  - 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]

2.2. Step P II-2) Prioritization 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, the environment or resource efficiency during use and/or WEEE management.

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

- Hazardous properties / Human Health & Environment
- Use or waste relevance according to :
  - Article 6 (1)(a), RoHS
  - Article 6 (1)(b), RoHS
  - Article 6 (1)(c), RoHS

The requirements of Article 6(1)(d) with regard to substitutes or alternative technologies are not included in this step, as it is assumed that for most substances, information shall not be accessible without performing an in-depth analysis. Should information available from a first screening suggest that substitutes or alternative technologies exist that result in lower impacts, this would be covered for the sake of prioritisation through the reference to Article 6(1)(a-c) and is thus considered sufficient at this stage.

1) Hazardous properties

On the one hand, the grouping system for hazardous properties is based on the hazard categories according to CLP and on the other hand, on the criteria for PBT/vPvB properties as laid down in Annex XIII of REACH. As mentioned in “Background”, Section II.I, Annex III of the WFD also specifies properties of waste which render it hazardous. In addition, properties according to the criteria of substances of very high concern (SVHC) are considered.

In general, the CLP hazard categories (1, 1A, 1B) as well as substances identified as SVHC substances according to REACH are considered to represent the most severe effects within a specific hazard class, whereas category 4 stands for the least severe hazard of the specific hazard class. Within the two main hazard categories, i.e. Human Health Hazards and Environmental Hazards, three groups each have been defined. The hazardous properties prioritisation is specified below:

[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

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

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

Table 2-1: Human Health Hazard Groups

Human Health Hazard – Group I
Carcinogenic OR reprotoxic OR mutagenic (Category 1A)
Carcinogenic OR reprotoxic OR mutagenic (Category 1B)
Endocrine disruptive
Respiratory sensitization (Category 1)
STOT-SE, STOT-RE (specific target organ toxicity at single and repeated exposure) (Category 1)
Acute toxic (Category 1)
Human Health Hazard – Group II
Skin sensitization (Category 1, 2)
Skin corrosion/irritation (Category 1A, 1B, 1C, 2)
Serious eye damage/eye irritation (Category 1, 2)
Carcinogenic OR reprotoxic OR mutagenic (Category 2)
Acute toxic (Category 2)
Respiratory sensitization (Category 2)
STOT-SE, STOT-RE (specific target organ toxicity at single and repeated exposure) (Category 2)
Human Health Hazard – Group III
STOT-SE (specific target organ toxicity at single exposure Category 3)
Acute toxic (Category 3 and 4)

Source: Adapted and revised from AUBA (2013)

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

The allocation of individual substance properties to 3 environmental health hazard groups is provided in Table 2-2 below. 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, for example:

- Results of the PBT- working group at ECHA[54];
- Evaluations of UNEP, UNECE and POP-RC[55];
- The European Commission's Joint Research Centre (JRC) Risk assessment reports/Existing substances information system/PBT assessment[56]:
- US National Library of Medicine, Toxicology Data Network (Toxnet)[57]

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

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

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

Table 2-2: 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
Environmental Hazard Group II
PB (persistent and bio-accumulative)
Hazardous to the aquatic environment (Chronic Category 1, 2)
Hazardous to the aquatic environment (Acute Category 1)
Environmental Hazard Group III
Hazardous to the aquatic environment (Chronic category 3, 4)
Persistent (REACH criterion)
Bioaccumulative (REACH criterion)

Source: Adapted and revised from AUBA (2013)

Radioactive Substances

Radioactive substances are not covered by REACH and CLP. In order to categorize them into human health and environmental hazard groups, the hazardous potential shall be looked up and attributed to the specific groups.

Information sources:

- International Agency for the Research on Cancer: IARC database[58].
- IARC monograph, volume 78 ionizing radiation part 2 describes the carcinogenic risks of selected radionuclides[59]: and radiation (Volume 100D):
- IAEA: International Atomic Energy Agency[60]:
- US-Environmental Protection agency (US EPA)[61]:

The overall relevance of a substance / substance group regarding its hazardous properties (human health & environment) is determined as described in Table 2-3 below.

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

[58] See: http://monographs.iarc.fr/index.php; http://monographs.iarc.fr/ENG/Monographs/vol100D/mono100D.pdf

[59] See: http://monographs.iarc.fr/ENG/Monographs/vol78/mono78.pdf

[60] See: http://www.iaea.org

[61] See: http://www.epa.gov/radiation/source-reduction-management/radionuclides.html

Table 2-3: 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)

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.

2) Use and waste relevance

For evaluating the relevance of a substance / substance group during use and/or during WEEE management the grouping system described as follows shall be applied.

The grouping is based on the fulfilment of the criteria specified in Article 6(1)(a-c) of RoHS regarding substances / substance groups.

The information collected under Part I, Step P I-2b, shall be analysed systematically to determine whether the above mentioned criteria are met:

Criterion a) is fulfilled if one of the following facts is true:

- Evidence exists that the substance hinders recycling or recovery as it has adverse effects on recycling / recovery processes (examples are Pb in glass fractions, or halogenated polymers in fractions to be used for energy recovery)
- Evidence exists that large proportions of the substance[62] remain in the recycling loop and is/are not discharged during the treatment processes and collected for subsequent safe disposal. As a consequence:
  - Use of respective recycled content (secondary materials) is limited to certain application areas or completely prohibited; or
  - The hazardous substance / substance group may be distributed across various types of recycled materials such as metals, plastics, glass or building material and finally in the environment.

[62] Provided that the substance has inherent hazardous properties.

Criterion b) is fulfilled if one of the following applies:

- The substance/substance group is comparably easily releasable during use or during waste management due to 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

Question for Stakeholders participating in the stakeholder consultation:

Please submit reference to legislation and/or to standards where thresholds are defined for the criteria mentioned, e.g. under what circumstances and measurement conditions would the volatility of a substance potentially lead to emissions from an article in which it is contained (including non-intended use such as in case of breakage)?

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

Question for Stakeholders participating in the stakeholder consultation:

Please indicate criteria for specifying when a potential for release is to be considered significant.

- Evidence that the substance/substance group was measured at significantly elevated levels in the environment (air, water, soil, biota) in urban areas and/or near WEEE treatment installations / locations. For example, there is evidence related to elevated levels of certain POPs in urban areas (Bogdal et al. 2014), some of which are or have been used in the past in EEE.

Question for Stakeholders participating in the stakeholder consultation:

Evidence of elevated levels measured in the environment shall be considered significant when end-point related limit values are exceeded (i.e. DMELs, PNEC, etc.). Do you support this specification - please explain your views and provide supporting data to explain them if relevant.

- Evidence exists that hazardous[63] degradation/transformation products are formed during WEEE management (including thermal processes (combustion, milling), mechanical, chemical and biological processes (mechanical biological treatment, landfilling)
- The substance is used as a nanomaterial in EEE and concerns have been expressed by relevant authorities (see references in Step P 1-1b and in the Appendix, Section A.1.1) about negative effects on human health or the environment: Due to the lack of knowledge on the fate and behaviour of nanoparticles in the environment and the human body the precautionary principle

[63] To determine substances of highest relevance transformation/degradation products with the properties of Human Health Hazard Group I and/or Environmental Hazard Group I should be considered.

shall be applied and information if a specific substance is used as nano-material shall be documented at this stage. [64]

Criterion c) is fulfilled if one of the following facts is true:

- Evidence exists that negative health impacts during WEEE management occur
- The substance was found at significantly elevated levels in humans in proximity of WEEE treatment plants / locations

The relevance of a substance / substance group for waste management is determined as described in Table 5 below.

Table 2-4: Waste Relevance

Waste Relevance
One or more of the criteria of Article 6(1)(a-c) are fulfilled
No waste relevance
None of the criteria of Article 6 (1) a, b, c is fulfilled

Source: Adapted from AUBA (2013)

3) Prioritization due to restriction under REACH

If the substance is listed in Annex XVII[65] (restriction on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles) under REACH and the restriction covers applications in EEE or if such a restriction has been proposed, the substance shall be prioritized 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 restrictions under REACH and RoHS to be amended in proximity.

4) Grouping of substances / chemical category approach

Grouping of substances may be relevant e.g. in line with a simultaneous presence of substances (e.g. UVBC[66] substances) and/or same behaviour of individual group members within the 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 Annex 5.7.

It is important that, following the precautionary principle, the most hazardous group member will be taken into consideration for the prioritization of substances (Step P II-2-5).

[64] The information if the substance is used as nanomaterial should be available at the registered substances database of ECHA (http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances). Under the chapter physico-chemical properties of a specific substance, information about the use as nanomaterial should be documented under the subchapter “particle size distribution, granulometry”. Potential information sources on nanomaterials are provided in the Appendix, Section A.1.1.

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

[66] Unknown or Variable composition, Complex reaction products or Biological material substances.

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

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

To determine the overall priority of a substance, the data compiled for it is to be reviewed and categorized. Based on the colour coding specified in Table 2-3 and Table 2-4, fulfilment of the various criteria shall result in priority groups being associated with the relevant colour coding for the (health and environmental) hazard groups and for fulfilment of the use and waste related Article 6(1)(a-c) criteria. As explained above, where the Article 6(1)(a-c) criteria are concerned, each of these is perceived separately as either fulfilled or not and where relevant specified as such (red colour coding or no colour, respectively). Depending on the hazard classifications of a substance, it shall be specified in hazard group 1 (highest hazard priority - red), group 2 (moderate hazard priority - orange) or group 3 (low hazard priority - yellow). If the substance is not classified, it shall not be specified a hazard group (i.e. no colour). In this sense the Article 6(1)(a-c) criteria have a higher weight than the hazard priority. This is justified with the understanding that if multiple criteria are fulfilled, related impacts can be expected to be of a wider range and of higher severity, whereas a substance may be classified with certain hazards, without being expected to result in impacts in the use and waste phase. The prioritization at this stage is performed to allow a differentiation between substances that should be assessed earlier than others, whereas during the actual assessment the actual range and severity of possible impacts shall be investigated in more detail. In this sense the prioritization should not be seen as an actual assessment of possible impacts but rather of the potential for various impacts to incur.

The awarded colour coding is to be compiled and the overall priority determined based on Table 2-5 below. The overall priority of a substance or substance group is defined by the frequency of particular priority groups (colours) for human health hazards & environmental hazards and for the three waste criteria.

Table 2-5: Overview of possible colour combinations for the highest overall priority categories

Overall priority of substances / substance groups	I	IIa	IIb	IIc	IIIa	IIIb	IIIc	IV	Va	Vb	Vc	VIa	VIb	VIc
Human Health & Environment														
Waste Crit. 6.1.a														
Waste Crit. 6.1.b														
Waste Crit. 6.1.c														

Overall priority of substances / substance groups	VII	VIIIa	VIIIb	VIIIc	IXa	IXb	IXc	X and below
Human Health & Environment								
Waste Crit. 6.1.a								Other combinations
Waste Crit. 6.1.b								
Waste Crit. 6.1.c								

Source: Adapted and revised from AUBA (2013)

Substances are classified as the highest priority where all 3 Article 6(1)(a-c) criteria are fulfilled and the human health & environmental hazards are of high priority (red).

Substances, where all 3 Article 6(1)(a-c) criteria are fulfilled and the human health & environmental hazards are of medium priority (orange), are classified as second highest priority.

Substances, where all 3 Article 6(1)(a-c) criteria are fulfilled and the human health & environmental hazards are of lower priority (yellow), are classified as third highest priority.

Substances, where the human health & environmental hazards are of high priority (red) and 2 of the 3 Article 6(1)(a-c) criteria are fulfilled, are classified as fourth highest priority.

Further priority (colour) combinations are displayed in Table 2-5 above.

Where Article 6(1)(a-c) criteria are fulfilled (one/multiple), however human health & environmental hazards have not been identified; a restriction could hypothetically be justified. 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 a pre-condition to fulfilment of Article 6(1)(a-c) would be that human health or environmental hazards are associated with the substance/substance group.

For a further differentiation of substances / substance groups of equally (high) priority the volumes used in EEE and the availability of substitutes shall be evaluated.

Information on the volumes of the substance / substance groups used in EEE entering the Union market gathered through the stakeholder consultation held in step P I-1b (see Section 1.1) should be juxtaposed against the initial prioritisation to create an internal prioritization within the priority sub-groups.

Substitutes for substances that are already restricted shall be investigated based on a screening of easily available information on substitutes (e.g. Subsport-portal). Substances included in the priority groups I to V (see Table 2-5) that are found to be potential substitutes for substances restricted or proposed for restriction shall be moved to the priority group I.

6) Targeted approach for refined prioritisation of high priority substances

For substances / substance groups of the highest priority, additional information shall be compiled to allow a refined prioritisation according to the following approach:

1. Select all substances from the highest priority groups, creating a so called "RoHS-working-list"[67].

2. For these substances, information shall be collected from publicly available sources and compiled into a tabulation[68] 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:

[67] 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)

[68] 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.

- Substance identity (Name, CAS and EC identifiers);
- 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);

3. The tabulation shall be supplemented with questions for stakeholders (see template provided in the Appendix, Section A.3). A stakeholder consultation shall be held to collect additional information on the substances. Stakeholders shall be asked to use the excel format to provide information for all substances subject to the refined prioritization, though provision of additional data and information shall also be possible.

4. 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; and
- References.

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 prioritization and general aspects of relevance and including a usage magnitude ranking and recommendations for each substance[69].

[69] 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[70] should be recommended for restriction under RoHS2 or not.

The decision on which substances are to undergo a detailed assessment is to be taken by the Commission. Prioritization of substances, performed according to Part II, shall feed into such decisions. Nonetheless, the Commission may decide to prioritize 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 of which a substance or a group of substances need to fulfil at least one to justify a restriction under the Directive (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 are fulfilled, justifying an exemption. The following guidance has furthermore 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)

Additionally, in some cases, it may be relevant to specify equipment groups or sub-groups to be excluded from the scope of the restriction[71]. In others, it may be relevant to specify an equipment

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

[71] 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.

group or sub-group and/or a material for which the restriction shall apply at a later date, pending to a review of scientific and technical progress[72].

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

If relevant, distinction should be made as to the certainty of information provided by various references – harmonized classifications for example shall be assumed to have a higher certainty than self-classifications[73] made by suppliers in safety data sheets. Various sources may also differ in their certainty and this should be taken into consideration and communicated where relevant. For the purpose of evaluating the certainty of various sources, the so called weight of evidence approach may be applied[74]. 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 consider whether certain sources should be considered to have a higher weight than others in light of their higher certainty.

"(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).

[72] 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). A further possibility would be when the substance is present in secondary materials used in manufacture, and the benefit of further use of this resource has been shown to exceed the possible costs related to the impact of its presence in EEE.

[73] 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.

[74] 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 potential 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):

- 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);

Question for Stakeholders participating in the stakeholder consultation:

For the purpose of specifying an exhaustive list of socio-economic impacts to be considered, please specify categories that should be taken into consideration.

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[75] shall be taken into account. International guide-

[75] 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

lines and recommendations and other relevant available scientific and technical information, shall be considered.

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 nutshell"[76]. Further in depth guidance documents are provided on the ECHA website[77].

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:

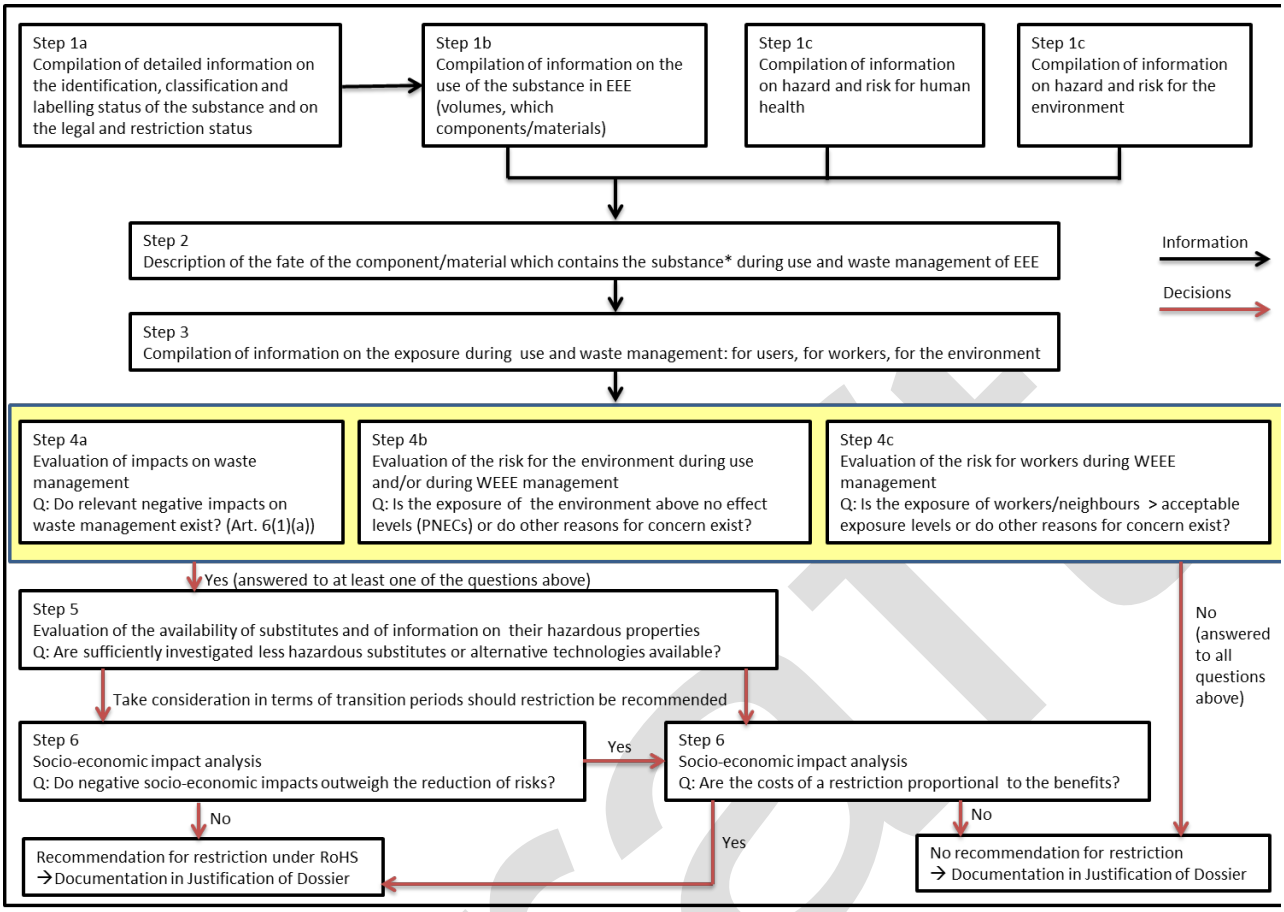
- information is to be collected and documented in the dossier in relation to:
  - the substance identification, classification and labelling and legal status (Figure 3-1, step 1a);
  - the substances use in EEE (typical function and applications, volumes of use) (Figure 3-1, step 1b);
  - the hazard risk of the substance for health (Figure 3-1, step 1c);
  - the hazard risk of the substance for the environment (Figure 3-1, step 1);
  - 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 potential for 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.

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

[77] 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.

3.1. Step P III-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
  - Name, other identifiers and composition of the substance
  - Physico-chemical properties
- Classification:
  - Harmonized 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 harmonized 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 all 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. The information related to the parameters above is to be compiled for all group members for which 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, no further assessment will be performed. Respectively, if restriction under one of these regulations is expected in the near future, the assessment should also be discontinued.

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 environmental 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)[78]
- ECHA substance information system[79].
- European Union law and other documents considered to be public are provided on EUR-Lex homepage[80].

[78] See: https://echa.europa.eu/information-on-chemicals/cl-inventory-database

[79] See: http://echa.europa.eu/information-on-chemicals

[80] See: https://eur-lex.europa.eu/homepage.html

- Stockholm Convention website[81]
- Montreal Protocol website[82].

Further information sources:

- eChemPortal of the OECD[83].
- ChemIDplus of the U.S. National Library of Medicine[84]
- Subsport[85] (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. Step P III-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 step P III-3 "Determination of the relevant waste streams and treatment processes and release estimation " and step P III-5 "Substitutes".

Information required

- Compile information on the appliances in which the substance is used: This information is needed in order to determine relevant waste streams (WEEE categories) (see Step P III A 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 plasticizer, flame retardant, etc.) or the properties that it enables in EEE is also to be compiled.
- 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 an exposure estimation in Step P III-3 (see Section 3.6).

For substance groups, including elements and their compounds, information related to the parameters above is to be compiled for all group members for which data is available.

[81] See: http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx
[82] See: http://ozone.unep.org/montreal-protocol-substances-deplete-ozone-layer/32506
[83] See: https://www.echemportal.org/echemportal/index.action
[84] See: https://chem.nlm.nih.gov/chemidplus/
[85] See: www.subsport.eu

Possible sources of information

- Information from substance registration dossiers
- Studies and working papers
- Product and material databases (for details see Step P III-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. Step P III-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 potential of the substance and potential 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 is to be compiled for all group members for which data is available. 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

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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[86] (e.g. R7[87], R8[88])
- 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)[89]
- European Food Safety Authority (EFSA)[90]

International sources:

- eChem Portal of OECD[91]
- OECD QSAR toolbox[92]
- WHO Library information system (WHOLIS)[93]
- International Agency of Research on Cancer (IARC)[94]
- International Program of Chemical Safety (IPCS)[95]
- POPRC: Persistent Organic Pollutants Review Committee[96]
- UNEP United Nations Environmental Programme[97]
- UNECE United Nations EconomicCommission for Europe[98]

86 See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.
87 Guidance on Information Requirements and Chemical Safety Assessment
88 Characterisation of dose [concentration] - response for human health
89 See: https://osha.europa.eu/en
90 See: http://www.efsa.europa.eu/
91 See: http://www.oecd.org/
92 See: http://www.qsartoolbox.org/
93 See: http://www.who.int/library/en/
94 See: http://www.iarc.fr/
95 See: http://www.inchem.org/
96 See: http://www.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx
97 See: http://www.unep.org/
98 See: http://www.unece.org/

Member States:

- Gefahrenstoffinformationssystem (GESTIS) der deutschen gesetzlichen Unfallversicherung[99],
- ANSES (French Agency for Food, Environmental and Occupational Health & Safety[100], INERIS (French National Institute for Industrial Environment and Risks[101] and INRS (French National Institute for Research and Occupational Health and Safety[102].
- RIVM (National Institute for Public Health and the Environment, Netherlands[103]

Non EU countries and other sources:

- Agency of Toxic Substances and Disease Registry (ATSDR) of the U.S. Department of Health and Human Services[104]
- Chemical Carcinogenesis Research Information System (CCRIS) of the US National library of medicine[105]
- Integrated Risk Information System (IRIS) of the US National library of medicine[106]
- Toxicology Data Network (ToxNet) of the US National library of medicine[107]
- National Institute of Technology and Evaluation (NITE); Japan[108]
- Scientific literature (e.g., PubMed, Web of Knowledge)[109]
- European Centre for Ecotoxicology and Toxicology of Substances (ECETOC)[110]

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

3.4. Step P III-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 potential 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.

99 See: http://gestis.itrust.de/nxt/gateway.dll/gestis_de/000000.xml?f=templates$fn=default.htm$vid=gestisdeu:sdbdeu$3.0
100 See: https://www.anses.fr/en
101 See: https://www.ineris.fr/fr
102 See: http://en.inrs.fr/
103 See: https://www.rivm.nl/en/
104 See: https://www.atsdr.cdc.gov/
105 See: https://toxnet.nlm.nih.gov/newtoxnet/ccris.htm
106 See: https://www.epa.gov/iris
107 See: https://toxnet.nlm.nih.gov/
108 See: https://www.nite.go.jp/index-e.html
109 See: https://www.ncbi.nlm.nih.gov/pubmed/
110 See: http://www.ecetoc.org/

- 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 characterization. Potential PBT properties shall be documented.

For substance groups, including elements and their compounds, information is to be compiled for all group members for which data is available. 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 step P III-1c (see Section 3.3).

Additional information sources:

- Syracuse Research Cooperation (SRC); Environmental fate database[111].
- ECHA guidance documents[112]:
  - 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.

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

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

3.5. Step P III-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 potential release of the substance and to give guidance on how to perform the relevant release estimations. 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.

Step P III-2a) Determine which treatment processes does 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 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.

A significant share of WEEE is not collected by the foreseen systems so that average collection rates have been below 40% in the majority of EU member states in 2015[113]. Therefore, also processes applied in the treatment of waste streams, where the non-appropriately collected WEEE typically end up, i.e. mainly land-filling, incineration and mechanical treatment and sorting, have to be considered.

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 Step A1b “Information on the use of the substance”)
  - information on the WEEE categories in which the substance 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 Step P III-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:

[113] 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.

- 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 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, an estimation shall be attempted based on existing knowledge acquired during the first parts of the assessment. 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 vary between WEEE categories.
- The treatment options vary between individual WEEE categories. Certain WEEE categories, such as gas discharge lamps, screens and cooling and freezing appliances, undergo dedicated treatment processes under special conditions as a first treatment step.

The following table provides guidance on the **initial treatment** processes, which are applied according to the WEEE category in which the substance is found.

[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.

Table 3-1: Initial treatment processes for WEEE

Initial treatment process	The substance is present in appliances belonging to					
	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)

Treatment of secondary waste: The following table provides guidance on 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.

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	Elec-tronic compo-po-nents	Cables	Glass	Pow-ders	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)

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Step P III-2b) Determination for which processes exposure assessments shall be performed

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 about which processes are dedicated 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*	
Storage of secondary wastes*	
Dedicated treatment processes for cooling & freezing appliances, screens, lamps	Landfilling of residual waste containing WEEE
Manual dismantling of WEEE	Mechanical treatment of residual waste
Shredding (and automated sorting) of WEEE	Incineration of residual waste
Shredding/sorting of cables	Shredding/sorting of metals
Shredding/sorting of electronic components	
Shredding/sorting of plastics	
Recycling of plastics	Recycling of ferrous metals
	Recycling of non-ferrous metals
	Recycling of glass
	Recycling as construction material
	Landfilling of residues from WEEE treatment
	(Co-)Incineration of residues
Uncontrolled treatment in third countries**	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 (since the data quality may be insufficient for a 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 to allow estimation, 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 availa-

ble data). On the basis of these assumptions, estimation shall be carried out, specifying 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 qualitative assessment of substance release 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 has to 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).

Sources of information (Steps P III-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)

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.

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

3.6. Step P III-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 step P III-1b and step P III-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).

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

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

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

- European Centre for Ecotoxicology and Toxicology Chemicals[116]: 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[117]
- Further information sources which might provide relevant information are listed in step P III-1c (information sources related to human health) and in step P III-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: http://www.ecetoc.org/tra

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

3.7. Step P III-4) Evaluation of impacts

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

3.8. Step P III-4a) Evaluation of risks for end-users of EEE

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 potential 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 shall 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 shall 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.

Sources of information

- for details see step 1a)-1c), 2 and 3
- ECHA guidance documents[118]:
  - 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.

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

3.9. Step P III-4b) Evaluation of negative impacts on WEEE management as specified by Article 6(1)a

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.

Relevant negative impacts on any possible step within the overall treatment process of WEEE have to be considered.

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 (lower recycling/recovery rates because 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.
- Evidence exists that the presence of the substance in WEEE results in a large amount of material resulting from the overall treatment process having to be treated as hazardous waste.

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. Step P III-4c) Evaluation of risks for workers and neighbouring residents

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 potential 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 shall 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)

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 shall 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.

Sources of information

- for details see step 1a)-1c), 2 and 3
- ECHA guidance documents[119]:
  - 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. Step P III-4d) Evaluation of the risk for the environment

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 a potential 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.

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 explained in order to identify and document uncertainties and underlying assumptions.

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

Sources of information

- See sources given in 1d, 2, 3,
- ECHA guidance documents[120]: Characterisation of dose [concentration] – response for environment (R10).

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

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

If the results of 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[121] substitutes or alternative technologies are available.

Approach: Information is to 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.

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 range of application for which it can be used as a replacement is to 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 potential of available substitute substances/alternative technologies is to be investigated. The hazard potential of alternatives is to be briefly described, including data availability and potential data gaps. 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.[122]

To establish the hazard potential 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 im-

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

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

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

portant 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 must 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 step P III-7 whether an assessment of such potential alternatives is needed to allow simultaneous restriction of the substance and its potential alternatives that exhibit hazardous potential.

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 step 1c-d
- Subsport 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[123].

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.

3.13. Step P III-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 "on the preparation of socio-economic analysis as part of an application for authorisation" and "Guidance on socio-economic analysis - Restrictions"[124]. 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. 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 impacts are expected to occur (one time investments, operational costs, substitution in short term/long term, etc.).

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

[124] See:

- ECHA – European Chemicals Agency (2011): Guidance on the preparation of socio-economic analysis as part of an application for authorisation. ECHA-11-G-02-EN. echa.europa.eu/documents/; and
- ECHA – European Chemicals Agency (2008) Guidance on socio-economic analysis - Restrictions. https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d

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Information required

The positive and negative socio-economic impacts of a restriction of the substance of concern shall be quantified 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 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);
  - Potential turnover ;
  - Administration costs;
  - Unemployment and scar effects;

  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;
  - For industrial consumers:
  - estimation of consequences on competitiveness and jobs
- For waste management:
  - 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[125].
- 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.

3.14. Step P III-7) Decision on inclusion and rationale

The **aim** of this 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 Step P III 4a - d). Where there is an uncertainty of data, the precautionary principle should be taken into account.

[125] 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;
  - Potential for 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 waste management

- The extent to which material recycling/recovery rates are reduced[126];
- 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;
  - 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 Step P III-6, Section 3.13).

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

- Uncertainties of the results and possible consequences of any wrong conclusions which are drawn from the assessment

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;
- 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 scope of the restriction in terms of EEE Annex I categories and the transition period to be provided for different categories. 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.
  - If the presence of the substance or substance group (respectively one of its members) in secondary materials is to be tolerated (in all or in specific EEE applications of such materials), the terms of restriction of the substance or substance groups in secondary materials should be defined through an exemption.. The exemption would first come into scope at the end of the transition period (previously 4 years and above granted) with a duration of 5 years. It is noted that the transition period may differ between Annex I categories and thus category specific validity periods may need to be specified for the exemption. A revaluation of the further need for the exemption, if applied for, could be performed shortly before the end of the 5 year period, adapting the conditions of exemption if necessary. It should also be noted that should such exemptions become common (in light of circular economy efforts), that a certification system would be needed to document the use of secondary materials contaminated with restricted substances so as to avoid misuse of the exemption.

    The restriction dossier could already propose the conditions of the exemption, if these can be clarified. This would give stakeholders certainty and motivate the use of secondary materials. In this case, the following details should be specified: formulation of the specific conditions of exemption, including as relevant detail of tolerated substance thresholds (limit values) and EEE application areas (if relevant).[127].
  - 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).
  - 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.

[127] Once a restriction of the substance is to be announced, at the latest once it comes into force, a decrease in the amount of the substance (or substance group) being placed on the market through EEE can be expected. Depending on the lifetime of relevant products, this decrease shall later also become noticeable in waste material streams. It is thus expected that with time, the threshold of tolerated substance could be reduced and that the special exemption conditions shall no longer be needed once elevated levels are not expected in waste. The update of such elements ^ is integrated into the exemption evaluation process..

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).

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/iec62474.nsf/MainFrameset
- ZVEI-Umbrella specifications: http://www.zvei.org/Verband/Fachverbaende/ElectronicComponentsandSystems/Seiten/Umbrella-Specifications.aspx

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 organized 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"[128]) as available from the Nordic Product Register (SPIN – substances in preparations in nordic countries-register)- http://90.184.2.100/DotNetNuke/default.aspx

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

[128] Relevant uses to be selected.

  - The study provides information on hazardous substances in products. Annex 4.B summarizes information on substances analyzed 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[129],[130].

The International Organization for Standardization 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[131],[132].

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

[129] 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}

[130] 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

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

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

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 into 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 build-up 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, including so far more than 3,000 products data-base: 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 an 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 Step P1-1b

cas	ec-no	name	Estimated volume of use in EEE in the EU								Nano materials
			Please sepcify estimated range of use in tonnes per annum							If you represent a manufacturer (OEM, supplier) please specify the range of use of your EEE related manufacture	Please specify if the substance is applied as a nano-material in EEE relevant applications
			0-1 t/a	1-10 t/a	10-100 t/a	100-1000 t/a	>1000 t/a	Phased-out	No knowledge of use		
85-68-7	201-622-7	BBP; benzyl butyl phthalate									
117-81-7	204-211-0	Di-(2-ethylhexyl)phthalate (DEHP)									
7440-43-9	231-152-8	cadmium (pyrophoric)									
84-74-2	201-557-4	Di-n-butylphthalate (DBP)									
85535-84-8	287-476-5	alkanes, C10-13, chloro; chlorinated paraffins, C10-13									

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

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A.5 Information on WEEE management in the EU

Chapter to be added following assessment of the seven substances #

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 (e.g. all congeners of polybrominated diphenyl ethers (PBDE))	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[133], 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 negates the commonality for that criterion, then the grouped assessment may be determined as an inappropriate approach from the perspective of the criterion concerned.

[133] 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 synthesized) 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.

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 characterize (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).

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