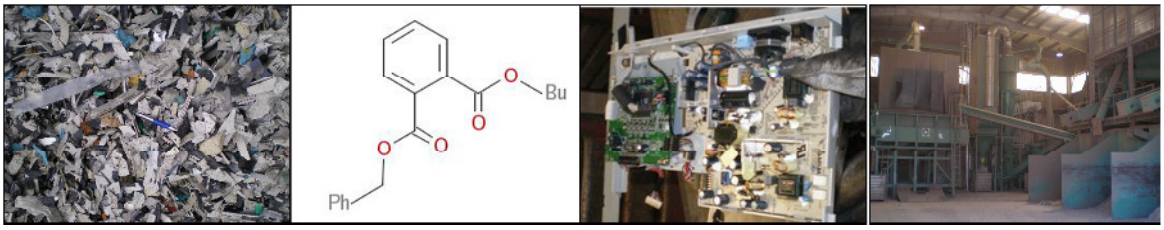
ENVIRONMENT AGENCY AUSTRIA umweltbundesamt

Study for the Review of the List of Restricted Substances under RoHS2

Reference: ENV.C.2/ETU/2012/0021

Final Report



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2 EXECUTIVE SUMMARY

2.1 Introduction

Hazardous substances in EEE

Electrical and electronic equipment (EEE) contains an increasing variety of organic and inorganic chemical substances. Some of these substances have properties which are hazardous to human health and/or the environment.

RoHS Directive

According to the RoHS Directive (2002/95/EC) the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in EEE has been banned/restricted since 2006. In 2011 the recast of the Directive (RoHS2) came into force. It aims inter alia 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 (Annex II to the Directive). In particular 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 WEEE.

Review of restricted substances under RoHS2

Article 6 of RoHS2 calls for a review of the list of restricted substances by the European Commission:

- before 22 July 2014;
- periodically thereafter on its own initiative or
- following the submission of a proposal by a Member State.

Requirements for the review of restricted substances

Article 6 (1) of RoHS2 requires that the review of the list of restricted substances in Annex II shall be based on a “thorough assessment”. Furthermore the Article requires that the review and amendment of the list of hazardous substances shall be coherent with other legislation related to chemicals in particular with REACH (the system of Registration, Evaluation, Authorisation and Restriction of Chemicals introduced by Regulation (EC) No 1907/2006) and its Annexes XIV and XVII. The review shall use publicly available knowledge derived from this legislation. Interested parties, including economic operators, recyclers, treatment operators, environmental organizations and employee and consumer associations shall be consulted during the review of the list of restricted substances.

2.2 Objectives of the project

In 2012 the European Commission DG Environment launched the present study with the 2 main objectives:

- to develop a methodology to identify and assess substances based on the criteria in Recital 10 and Article 6(1) and 6(2) of RoHS2
- to assess the substances addressed in Recital 10 of RoHS2 with a view to their future restriction.

To fulfill the above listed objectives cooperation and consultation with stakeholders was to be organized. Contribution by stakeholders were gathered by

public internet consultation and meetings among a selected group of stakeholders.

2.3 Main project outcomes

The main outcomes of the project are:

- A manual on the developed "Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive";
- An inventory of substances used in EEE;
- A list of substances ranked according to their priority for a detailed assessment with the view of a potential restriction under RoHS
- Detailed assessments of those substances, which should be considered as a priority for the first review according to Recital 10 of RoHS2[1] including a recommendation whether or not to restrict a given substance

2.3.1 Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive

The method developed consists of three parts:

- Identification of substances
- Pre-assessment of substances
- Detailed assessment of substances

PART I: Identification of substances

Aim

The aim of Part I is to identify all substances in EEE which may cause risks for the environment and workers during WEEE management or have any other negative impacts on waste management, as specified by RoHS2, Article 6.

Inventory and substance information

First an inventory of substances used in EEE has to be created. Existing databases and computer based tools shall be used to establish a comprehensive database with information on the substances concerned (substance properties and waste aspects). In the framework of the current project a comprehensive substance inventory was compiled (see Chapter 6.2.1). For future reviews of the list of restricted substances in EEE, thus, the current inventory will have to be updated. Finally, chemicals are selected by applying defined criteria (hazardous properties, evidence that the substance is relevant with regard to RoHS Article 6 (1) a, b, and c [WEEE management]).

Substance properties

Table 1 gives an overview of the selection criteria with regard to hazardous properties.

[1] HBCDD, DEHP, BBP and DBP

Table 1: Criteria regarding hazardous properties

The substance is/shows:
listed in Annex VI CLP / fulfils criteria of Annex VI
Carcinogenic OR mutagenic OR reprotoxic [Categories 1A and 1B and 2]
PBT (persistent, bio-accumulative, toxic)
PB (persistent, bio-accumulative)
SVHC = substance of very high concern under REACH
defined as endocrine disruptor, category 1, (EC[2])
radioactive

Waste relevance

With regard to RoHS Article 6 (1) a, b, and c (WEEE management) substances / substance groups including substances of very small size used in EEE are selected where indication is given that they:

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

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 WEEE under current operational conditions;

c) could lead to unacceptable exposure of workers involved in WEEE collection or treatment processes;

PART II: Pre-assessment

Aim

Part II aims at narrowing down the list of identified substances, which may have negative impacts on human health, the environment or WEEE management as specified by RoHS II Article 6 (1) a, b, and c by a comparably easy and fast procedure. It further 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).

Legal status

First, substances already **restricted** in a wider context covering also EEE are **excluded**.

Grouping system

Secondly, a prioritization of substances is carried out by **grouping** substances on the basis of an assessment of:

- their hazardous properties and
- their negative impacts during WEEE management (=waste relevance) as specified by Article 6 (1) a, b, and c

Hazardous properties

The grouping system for hazardous properties is on the one hand based on the hazard categories according to the CLP regulation and on the other hand on the criteria for PBT/vPvB properties as laid down in Annex XIII of REACH regulation. In addition, properties according to the criteria of substances of very high concern (SVHC) are considered.

[2] http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm

Relevance for waste management

To evaluate the relevance for waste management the following attributes are evaluated in detail.

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

- There is evidence that the substance hinders recycling or recovery as it has adverse effects on recycling / recovery processes (examples are Pb in glass fractions, halogenated polymers in fractions to be used for energy recovery).
- There is evidence that large proportions of the substance[3] remain in the recycling loop and are not discharged during the treatment processes and collected for subsequent safe disposal. As a consequence 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.

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

- There is evidence that the substance was measured at significantly elevated levels in the environment (air, water, soil, biota) near WEEE treatment installations / locations
- There is evidence that hazardous[4] degradation/transformation products are formed during WEEE management (including thermal processes (combustion, milling), mechanical, chemical and biological processes (MBT, landfilling)
- The substance is used as a nanomaterial in EEE and there are concerns about negative effects on human health or the environment
- The substance is comparably easily releasable

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

- There is evidence that negative health impacts during WEEE management occur
- The substance was found at significantly elevated levels in humans near WEEE treatment plants / locations.

Overall priority of a substance

The overall priority of a substance or substance group is determined by how often a certain priority group occurs Table 7 . There are three priority groups for human health & environmental concerns (red, orange and yellow) and three waste criteria (each red and not coloured).

[3] Provided that the substance has inherent hazardous properties

[4] 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

Table 2: Overview of priority categories

Overall priority of substances / substance groups	I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII	XIII	XIV
Human Health & Environment														
Waste Crit. 6.1.a														
Waste Crit. 6.1.b														
Waste Crit. 6.1.c														

PART III: Detailed assessment of substances / substance groups

Aim

The aim of the detailed assessment is to conclude whether a substance or substance group should be recommended for restriction under RoHS2 or not.

Furthermore, the purpose of the detailed assessment is to fulfil the information requirements of Article 6 of ROHS2.

Contents

The assessment consists of:

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

Criteria

A recommendation for a restriction under RoHS shall be considered when:

- the substance / substance group has 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

  OR

- the substance / substance group gives 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

  OR

- the substances / substance group leads to unacceptable exposure of workers involved in the waste EEE collection or treatment processes

The chart below (Figure 2) provides an overview of the individual steps of the methodology.

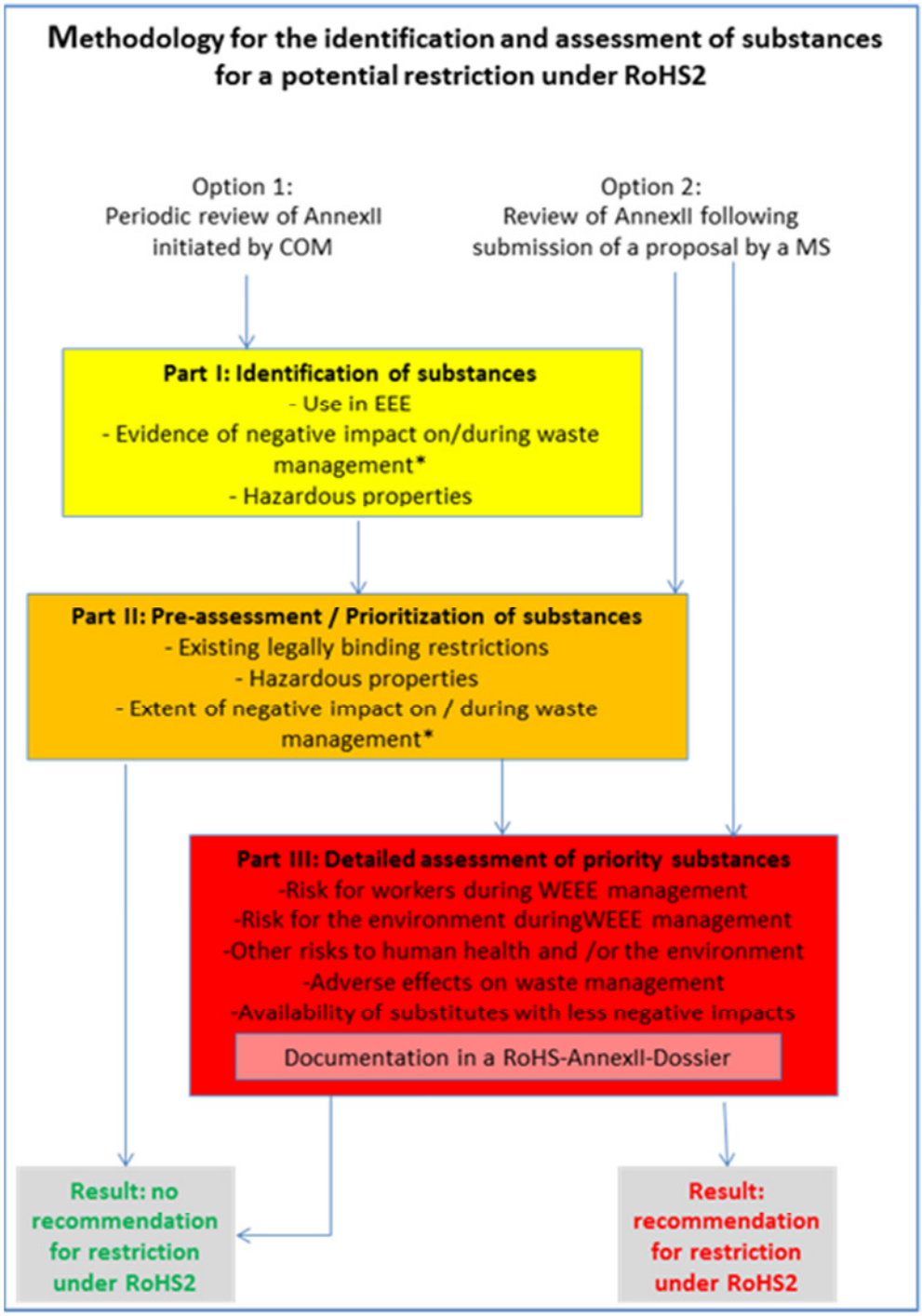

*Figure 1: Overview of the methodology (*as specified by Article 6 (1) a, b, c of RoHS2)*

2.3.2 Inventory of substances used in EEE

The final inventory of substances used in EEE consists of **738** substance entries. It includes 31 substances, which have already been restricted and 27 substances where the substance´s presence in EEE has been classified as "possible", "not known" or "unlikely". In addition there are more than thirty entries in the substance inventory which are not classified by CAS, including e.g. nano-applications of substances.

Information contained in the EEE substance inventory

The EEE substance inventory contains the following information:

- Name of the substance
- CAS and EC number of the substance, where available
- Information on the likeliness of the substance´s presence in EEE

Furthermore, the substances are classified by category (acids, elements metal, metal compound, dyes, polymers, additives etc.) and their main function in EEE (stabilizer, flame retardant etc.).

2.3.3 Priority list of substances ranked according to the substance´s priority for a detailed assessment with the view of a potential restriction under RoHS

The priority list consists of **56 substances** and their overall priority category. In addition it includes 11 elements and the following substance groups: phthalates, brominated flame retardants, chlorinated flame retardants and chloroalkanes.

Ranking of priority substances

The following ranking of substances with regard to their priority for further assessment under RoHS was obtained:

Highest priority

Eight substances were identified to be of highest priority:

- the 4 phthalates Di-(2-ethylhexyl)phthalate (**DEHP**), Di-n-butyl phthalate (**DBP**), Butyl benzyl phthalate (**BBP**) and Diisobutyl phthalate (**DiBP**)
- the chlorinated flame retardant **tris(2-chloroethyl)phosphate**
- the 2 brominated flame retardants Hexabromocyclododecane (**HBCDD**) and 2,3-dibromo-1-propanol and
- **Dibromoneopentyl-glycol**[5]

Second highest priority

Four substances were identified to be of the second highest priority:

- **antimony trioxide**
- diethyl phthalate (**DEP**)
- Tetrabromobisphenol A (**TBBPA**) and
- **medium-chain chlorinated paraffins**

[5] however, indication that use amounts are low

The polymer **PVC** was classified to be of the third highest priority, in particular because of its high waste relevance.

Third highest priority

Five substances were identified to be of the fourth highest priority:

Fourth highest priority

- the Be-(compounds): **beryllium metal** and **beryllium oxide** (BeO)
- the Ni-compounds: **nickel sulphate** and **nickel sulfamate** (=Nickel bis sulfamidate) and
- **Indium phosphide**

Four substances were identified to be of the fifth highest priority:

Fifth highest priority

- the two As-compounds **di-arsenic pentoxide**; (i.e. Arsenic pentoxide; Arsenic oxide) and **di-arsenic trioxide** (i.e. Arsenic trioxide)
- the two Co-compounds cobalt dichloride and cobalt sulfate

Two substances were identified to be of the sixth highest priority: **cobalt metal** and **nonylpheno**l.

Sixth highest priority

Beside the name of the substance / substance category, CAS and EC numbers, information on the present SVHC status of the substance[6], information on the hazardous properties for human health and environment based on the CLP classification system and on criteria defined within REACH (status January 2013), information whether a substance/substance group fulfils the 3 criteria specified in Article 6 (1) of RoHS2 the overall priority category of a particular substance is given.

Information contained in the Priority List

2.3.4 Detailed assessment of HBCDD, DEHP, BBP and DBP

For the substances assessed in detail within this project the following is concluded:

HBCDD is recommended for restriction under RoHS as a **risk for the environment** is expected from both shredding of WEEE and recycling of HBCDD containing HIPS from WEEE, is expected. Risks for the aquatic compartment and for secondary poisoning were identified. Based on exposure estimates for workers involved in the recycling of HBCDD containing plastics performed with the ECETOC TRA targeted risk assessment tool a **risk to human health** of workers cannot be precluded. Generally, HBCDD has been included as POP to the International Stockholm Convention and is as such subject to minimization on a global scale due to risks identified for human health and the environment.

Risks for the environment

The investigated **phthalates** are recommended for restriction under RoHS too.

A **risk for the environment** is expected due to treatment of **DEHP** containing WEEE in shredders, due to shredding of cables and recycling of PVC derived

[6] Status June 28, 2013

from WEEE. There is cause for concern regarding the risk for secondary poisoning of mammalians and birds.

DBP is very toxic to higher plants. Effects on common European species[7] have already been detected at DBP concentrations in the air of 0.1 µg/m^3 (mean EC_{10}[8] concentrations 0.12 - 4.48 µg/m^3). ECETOC modelling data predict concentrations of 0.1-0.7 µg/m^3 at shredding facilities. EUSES modelling data for environmental exposure generated within this project are lower (0.02 to 0.03 µg/m^3). However, it cannot be excluded that concentrations at shredding facilities, especially at high temperatures exceed the PNEC of 0.1 µg/m^3.

For **BBP** no risk for the environment from shredding of WEEE was identified.

Risks for Human Health

The European risk assessment report on **DEHP** concluded that there is a need for limiting the risks from the use of DEHP at workplaces. Several risk reduction measures have been taken so far. For **waste treatment activities** only limited information on working conditions and risk for workers is available. Single measurements at shredding facilities conducted by Plastics Recyclers Europe (EuPR) found exposure concentrations below the relevant reference values DNEC and DNEL with short exceedances during specific tasks (i.e. loading activities)[9]. These measurements, although limited, are in line with the results of the ECETOC modelling for shredder facilities during the activities in this project. It can be concluded, that specific tasks in shredding and recycling facilities may lead to exposure concentrations above the reference value (DNEC) derived by the Risk Assessment Committee (RAC) of the European Chemicals Agency. Therefore it can be concluded that a **health risk for workers from DEHP cannot be excluded**. Risk assessments based on exposure estimates for **DBP** and **BBP** indicate that no risk for human health of workers at recycling facilities is expected.

There is increasing evidence and requests from various scientists and institutions[10] that for similarly acting chemicals (such as certain phthalates, e.g.: DEHP, DBP and BBP) **a cumulative risk assessment** should be performed. Combination effects of chemicals have also been addressed by the European Commission and the European Council[11]. Taking into account that the effects of the reprotoxic phthalates are cumulative and taking into account the precautionary principle as requested by RoHS it is recommended to restrict all assessed phthalates in EEE.

Waste management

All four substances have additional negative impacts on **waste management.** These include in particular reduced recycling possibilities for WEEE plastics due to the use prohibitions and restrictions of these substances and the generation

[7] including bean, cabbage, spruce, white clover, plantain and common velvet grass
[8] Effective concentration 10%:
[9] FoBig, 2013
[10] SCHER, SCCS, SCENIHR, 2012, NRC 2008; Kortenkamp 2009; Wittasek, 2011
[11] http://ec.europa.eu/environment/chemicals/effects/effects_en.htm

of considerable amounts of hazardous wastes. In addition, HBCDD is expected to remain a long time in the recycling loop.

Alternatives

Furthermore for all of the investigated substances **alternatives** with less negative properties are available and technically and economically feasible.

Socio-economic impacts

The description of socio-economic impacts of a ban of the 4 substances did not reveal exorbitantly high costs, whereas the above mentioned negative impacts can be reduced.

2.4 General conclusion and outlook

Conclusions from the stakeholder involvement

Stakeholders involved in the project provided valuable scientific and technical information. Concerning the development of the method and its initial application it became apparent that fundamentally different viewpoints concerning the implementation of Article 6 of RoHS2 exist.

During the current RoHS project the Commission Services definitely clarified that a “thorough assessment” of substances as requested by the RoHS-Directive is not to be performed the same way as a substance assessment under REACH. The outcome of a substance assessment under RoHS has to be robust and science based but quantitative impact assessments are not obligatory. In particular, the provisions of Article 6 (2) of RoHS2 need to be considered in the assessment.

Conclusions drawn from the initial application of the developed method

From **developing** the method and **applying it for the first time** during the present project, the following conclusions can be drawn:

- Little **information** may be available on the **actual quantities of the substances used in EEE entering the European market**. Therefore plausible ranges of use quantities and contents in electrical & electronic appliances shall be estimated.
- **Little comprehensive information** is currently available on **WEEE treatment** in Europe. It is expected that for future substance assessments more detailed data will be available from the BAT-Reference Document for the Waste Treatment Industries, which is currently under revision. Where no data are available scenarios based on best possible estimates have to be established and used for the substance assessments.
- Applying the developed methodology revealed, that the chosen approach for risk assessment is suitable to **estimate an unacceptable exposure of workers** and **concerns for the environment**.

  Within this project commonly used and accepted tools[12]for exposure and risk assessment of chemicals and biocides were applied. However exposure scenarios of waste treatment processes have not been integrated in these tools yet. As a consequence of the above mentioned lack of detailed information about WEEE treatment, the exposure scenarios for the substance

[12] EUSES: European Union Substance Evaluation System, ECETOC TRA: European Centre for Ecotoxicology and Toxicology of Chemicals Targeted Risk Assessment

assessments in this project were approximated using exposure scenarios for most applicable industrial processes as available from the REACH implementation process.

Proposal for the ongoing review of the list of restricted substances under RoHS

Beyond the technical aspects of identifying and assessing substances under RoHS it is proposed to consider the following aspects when reviewing Annex II to RoHS2 in future.

- The periodic review on the Commission´s initiative should be performed **every 4 years.** This is in concordance with the approach for the adaptation to the scientific and technical progress regarding exemptions from RoHS restrictions.
- **An additional review** may be performed when Member States submit restriction proposals before mid-term between two reviews.

Proposed steps in a review

Within each review cycle the following steps should be taken:

- Up-date of the substance inventory, the list of substances which may cause risks for the environment or workers during WEEE management or have any other negative impacts on waste management and - if necessary - the ranking of substances regarding to their priority for a detailed assessment.

  This includes an up-date of the status of harmonised classification[13] and self-classifications[14]. Furthermore, up-to date information on potential negative effects of nano-materials used in EEE[15] has to be considered.
- Estimation of the **use quantities** of the substances / elements / substance groups on the **priority list** and evaluation of the availability of **substitutes** for these substances before deciding which substances will be assessed in detail.
- If a prioritized substance representative of a group of substances with structural similarities (and/or identical physical and chemical properties, similarities in the toxicological profile) and if, moreover, those groups of substances, co-occur in WEEE and have an negative impact at the WEEE process and/or represent a risk to environmental or human health a **grouping approach** should ideally be performed.
- When a **risk during WEEE treatment was identified** for a substance in the detailed assessment, all substances in the same priority group and in the next lower group should be immediately assessed in detail during the same assessment cycle.
- For substances where **no risk** was identified in a detailed assessment but where **increasing quantities in EEE are likely** to occur in future, e.g. because they substitute other, meanwhile restricted, substances, the actual use amounts should be evaluated in the next assessment cycle.

[13] ATP update

[14] CLP-inventory

[15] Several substances are used at very small size or with a very small internal or surface structure (nano-materials) are used in EEE. There is an on-going discussion whether release during waste treatment of products containing nano-materials could lead to unacceptable exposure concnetrations.

- For substances where a restriction in EEE was not recommended/decided because of **unavailability of less hazardous alternatives**, these preconditions should also be verified during the following assessment cycle.

Future activities by the Commission in the on-going review process of Annex II

The Commission Services plan to establish a **working group** consisting of maximum 12 members including most active stakeholders from Member States, NGOs, consultancies and industry. The working group will accompany the on-going process of reviewing Annex II of RoHS2. Tasks of the working group will include an adjustment of the RoHS review process to developments under REACH and other pieces of chemical legislation (including an exchange with ECHA and its scientific bodies) and strategies for handling lacks of essential data.

3 INTRODUCTION

3.1 Background and aim of the project

Electrical and electronic equipment (EEE) contains an increasing variety of organic and inorganic chemical substances. Some of these substances have properties which are hazardous to human health and/or the environment.

Restriction of hazardous substances in EEE (RoHS)

According to the RoHS Directive (2002/95/EC), the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in EEE has been banned/restricted since 2006. Maximum concentration values by weight in homogeneous materials were specified[16]. 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.

Recast of the RoHS Directive

In 2008 a proposal for a recast of the RoHS Directive was made[17]. The recast (RoHS 2 Directive) came into force in July 2011. 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 WEEE.

Another objective of the recast of the RoHS Directive is to harmonize 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 REACH (Regulation (EC) No 1907/2006) and provisions related to the management of WEEE; in particular the WEEE Directive (2012/19/EU).

Review of restricted substances under RoHS2

Article 6 of RoHS2 calls for a review of the list of restricted substances by the European Commission:

- before 22 July 2014;
- periodically thereafter on its own initiative or
- following the submission of a proposal by a Member State.

Requirements for the review of restricted substances

Article 6 (1) of RoHS 2 requires that the review of the list of restricted substances in Annex II shall be based on a "thorough assessment" without specifying the methodology[18].

According to Article 6 (1) of RoHS 2, the review and amendment of the list of hazardous substances shall be coherent with other legislation related to chemi-

[16] Decision 2005/618/EC

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

[18] In the proposal for the recast of RoHS, the application of a methodology based on the process set out in Articles 69 to 72 of REACH had been proposed for reviewing the list of restricted substances

cals in particular with REACH (the system of Registration, Evaluation, Authorisation and Restriction of Chemicals introduced by Regulation (EC) No 1907/2006) and its Annexes XIV and XVII. The review shall use publicly available knowledge derived from this 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:

- could have a negative impact during WEEE management operations, including on the possibilities for preparing for the reuse of WEEE or for recycling of materials from WEEE;
- 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 WEEE under current operational conditions;
- could lead to unacceptable exposure of workers involved in the WEEE collection or treatment processes;
- could be replaced by substitutes or alternative technologies which have less negative impacts.

Stakeholder involvement

Furthermore RoHS2 specifies that interested parties, including economic operators, recyclers, treatment operators, environmental organizations and employee and consumer associations shall be consulted during the review of the list of restricted substances.

Requirements for MS-Proposals

Article 6 (2) of RoHS2 lays down the minimum information, which has to be contained in Member State proposals to review and amend the list of restricted substances:

- precise and clear wording of the proposed restriction;
- references and scientific evidence for the restriction;
- information on the use of the substance or the group of similar substances in EEE;
- information on detrimental effects and exposure in particular during WEEE management operations;
- information on possible substitutes and other alternatives, their availability and reliability;
- justification for considering a Union-wide restriction as the most appropriate measure;
- socio-economic assessment.

Substances regulated under REACH

When assessing substances under RoHS, Annexes XVII and XIV of REACH are of particular relevance.

Annex XVII of REACH lists substances (on its own, in a mixture or in an article) for which manufacture, placing on the market or use is limited or banned in the

European Union. Each entry shows the substance or group of substances or the mixture, and the conditions of their restriction.

Articles 69-73 of REACH describe the process for introducing new and amending current restrictions.

A Member State, or the European Chemicals Agency (ECHA) upon request by the European Commission, can propose restrictions. A proposal that is considered to be in line with the requirements of Annex XV to REACH is subject to a 6 months public consultation. ECHA's Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC) provide their opinions on the proposal. It is a Commission decision to amend Annex XVII to REACH ('Comitology': regulatory procedure with scrutiny)."

Annex XIV to REACH (List of Substances Subject to Authorisation) establishes a list of substances which may only be used after authorisation has been granted by the European Commission. The scientific committees of ECHA, RAC and SEAC, give their opinion on each Authorisation application. Authorisation will only be granted if the applicant demonstrates that the risk to human health or the environment from the continued use of the substance is adequately controlled or the socio-economic benefits outweigh the risks.

Article 57 of REACH lays down the criteria for substances which may be subject to authorisation:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with CLP Regulation (EC) No 1272/2008 (CMR substances)
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII
- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances, e.g. endocrine disrupting properties

Authorization

Article 58 of REACH sets out the conditions and criteria under which a substance shall be included in Annex XIV (e.g. priority is to be given to PBT and vPvB substances, hazardous substances of wide dispersion and hazardous substances of high volumes). After a two-step regulatory process, substances of very high concern (SVHCs) may be included in the Authorisation List and become subject to authorisation. These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation.

Article 59 lays down the procedure under which a substance is included in Annex XIV and subject to authorisation.

The general approach for prioritization of substances of very high concern (SVHCs) for inclusion in the list of substances subject to authorization under REACH is mainly based on intrinsic properties, uses and volumes (ECHA, 2010[19]). With the Roadmap for the identification of SVHCs identification and im-

[19] http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list

plementation of REACH risk management measures from now until 2020 the European Commission laid down its objective to include all relevant currently known SVHCs in the candidate list by 2020. The Roadmap is based on the Risk Management Options (RMO) approach. Consistent with the principles of better regulation, the RMO identifies the best regulatory option to manage the risk, either within REACH (authorisation, restriction or substance evaluation) or outside of REACH (with another legislation)[20]

Relation between RoHS and REACH

The REACH regulation "registration, evaluation, authorization and restriction of chemical substances" regulates chemical substances on their own, in mixtures or in articles. Recital 14 of RoHS states that information, generated by REACH, should be used by the relevant actors in the application and implementation of appropriate Community legislation, for example that covering products.

RoHS is a sector specific directive stipulating rules on the restriction of certain hazardous substances in EEE. There is neither a legal mandate nor an obligation to copy the procedure of substance restriction under REACH and involve ECHA and its scientific committees (RAC, SEAC). However, information generated by REACH will be used for the restriction process under RoHS. As outlined above it can be expected that also inclusion in ROHS2 can be selected as the appropriate RMO for specific SVHC substances.

Priority substances to be considered for restriction under RoHS 2

During the preparation of ROHS2, an extension of the list of restricted substances was discussed.

Preparatory studies, in particular the review of restricted substances under RoHS (Öko-Institut, 2008), revealed that further relevant hazardous substances are used in EEE. 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 (TBBP-A) and Hexabromocyclododecane (HBCDD) and the phtalates Bis (2-ehtylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) were identified as high priority substances.

However, due to insufficient data on environmental, economic and social impacts, in particular on possible substitutes, the extension of the list of restricted substances was deferred until the reviews under Article 6 of RoHS 2.

According to Recital 10 of RoHS 2 the use of the following substances should be considered as a priority for the first review:

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

These substances have meanwhile been included in Annex XIV to REACH and are therefore subject to authorisation. The latest application date for DEHP,

[20] (Council of the European Union, 2013 http://register.consilium.europa.eu/pdf/en/13/st05/st05867.en13.pdf.

BBP and DBP was 21 August 2013. The latest application date for HBCDD is 21 February 2014.

Once new scientific evidence is available, it will be necessary to investigate, whether other hazardous substances, especially those which were subject to previous assessments[21] should also be included in the list of restricted substances. Recital 10 of RoHS also refers to the precautionary principle:

Precautionary principle

"The measures are necessary to achieve the chosen level of protection of human health and the environment, with due respect for the precautionary principle, and having regard to the risks which the absence of measures would be likely to create in the Union."

In the communication from the Commission of the European Communities COM (2000) 1 final the Commission´s approach towards applying the precautionary principle is outlined. 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, and 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, and that scientific evaluation does not allow the risk to be determined with sufficient certainty (COM 2000 1 final). Within the methodology described in this manual the precautionary principle shall be applied according to the basic principles of proportionality, consistency, responsibility, taking into account costs and benefits. Decisions taken might be subject for review in case of availability of additional data as laid down in the Commission's communication

Weight of evidence

The so called weight of evidence 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 shall be given appropriate weight. It shall be documented and justified in a clear and transparent manner. Under REACH, the so-called weight of evidence approach is a component of the decision-making procedure and thus an important part of the chemical safety assessment. It is described more precisely in the practical guide: "How to report weight of evidence?" (ECHA, 2010) as well as in Annex I of the CLP regulation (EC) No 1272/2008. It is also outlined in the general approach for prioritisation of SVHC substances for inclusion in the list of substances subject to authorisation (ECHA, 2010). It is as well described in the memorandum of the Scientific Committees on Emerging and Newly Identified Health Risks (SCENIHR, 2012[22]). The principles of weighing of evidence shall be considered in order to draw conclusions of restriction on substances under RoHS2.

Comitology procedure

According to Article 6 (3) of RoHS 2 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.

Aim of the project

In 2012 the European Commission launched the present study with the 2 main objectives:

[21] = Öko-institut study, 2008

[22] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_s_001.pdf

- to develop a methodology to identify and assess substances based on the criteria in Recital 10 and Article 6(1) and 6(2) of RoHS2
- to assess the substances addressed in Recital 10 of RoHS2 with a view to their future restriction.

To fulfill the above listed objectives cooperation and consultation with stakeholders were organized. Contribution by stakeholders will be gathered by public internet consultations and meetings among a selected group of stakeholders.

3.2 Implementation of the project

The project was launched in November 2012. The duration of the project was originally foreseen to be 1 year and – due to intensive stakeholder contribution - was finally extended for an additional month.

The overall work was divided into 4 work packages according to the project schedule below (Table 3).

Table 3:Project schedule

No.	**Work package** / **Task** / **Duration**	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
1	Develop a methodology to identify and assess substances												
1.1	Review and analysis of selection & assessment criteria and of restrictions												
1.2	Methodology for identifying candidates												
1.3	Methodology for the pre-assessment of the candidates												
1.4	Methodology for the assessment of selected candidates												
1.5	Manual for future reviews												
2	Apply the methodology to selected substances												
2.1	Identification of candidates												
2.2	Pre-assessment												
2.3	Assessment of selected substances												
2.4	Recommendation for future restriction												
3	Stakeholder consultation												
3.1	Review of stakeholder candidates												
3.2	Stakeholder meetings												
3.3	Project website												
3.4	Internet consultation												
4	Accompanying tasks												
4.1	Meetings with Commission	X		X	S	X	S				S	X	
4.2	Reporting to Commission			O			O			O		O	O
4.3	Project management												

X…Meeting with Commission staff; S...Stakeholder Meeting; O...Reporting deliverable.

4 OVERVIEW OF PROJECT DELIVERABLES

The following deliverables, which are described in detail below, were prepared within the project:

- A manual on the developed “Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive”;
- An inventory of substances used in EEE;
- A list of substances in EEE which may cause risks for the environment or workers during WEEE management or have any other negative impacts on waste management;
- A list of substances ranked according to their priority for a detailed assessment with the view of a potential restriction under RoHS;
- Detailed assessments (RoHS-AnnexII-Dossiers) of HBCDD, DEHP, BBP and DBP including a recommendation whether or not to restrict a given substance and the underlying justification
- A project web-site providing information on internet consultations and stakeholder meeting and interim results **http://ec.europa.eu/environment/waste/rohs_eee/review/index_en.htm**, **http://www.umweltbundesamt.at/rohs2**
- Documentation and analysis of stakeholder contributions received during the 4 internet consultations performed;
- Materials (presentations, background papers) for and documentation (minutes) of 3 stakeholder meetings.

5 METHODOLOGY FOR IDENTIFICATION AND ASSESSMENT OF SUBSTANCES FOR INCLUSION IN THE LIST OF RESTRICTED SUBSTANCES (ANNEX II) UNDER THE ROHS2 DIRECTIVE

5.1 Description of how the methodology was elaborated

Methodology approach

First a general methodology approach was developed. The proposal was published on the project website on 20 February 2013 and put up for discussion at the first stakeholder meeting held on 13 March 2013 and during the 2nd internet consultation (20 Feb – 10 March 2013). An overview of the most important comments received during the 2nd internet consultation is provided in Chapter 9.1.2.

Manual, first draft

Taking into account the comments received a first draft of a manual describing the methodology was elaborated and published on the project website on 7 May 2013. The first draft of the manual was put up for discussion during the 3rd internet consultation (7 May – 10 June 2013) and during the second stakeholder meeting held on 14 May in Brussels. An overview of the comments received during the 3rd internet consultation and the 2nd meeting are provided in Chapter 9 and Chapter 13.9.1, Annex.

Manual, second draft

A second draft of the manual, taking into account the comments received, was published on the project web-site in June 2013.

Manual, final

The final version of the manual was prepared in parallel to the present report and is attached as a separate document.

5.2 Result: Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive

According to RoHS2 the focus of the developed methodology lies on the impacts on human health and the environment during waste treatment and further negative impacts on waste management.

The method consists of three parts:

- Identification of substances
- Pre-assessment of substances
- Detailed assessment of substances

Below the methodology is summarized. The manual describing the methodology in detail and the template “RoHS2-AnnexII-Dossier” for documentation of the results of the detailed assessment are provided as separate documents (see Annex, Chapter 13.1 and Chapter 13.2).

PART I: Identification

Aim

The aim of Part I is to identify all substances in EEE which may cause 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) requests to take special account of whether a substance, including substances of very small size, 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"*

Inventory

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 and waste aspects). In the framework of the current project a comprehensive substance inventory was compiled (see Chapter 6.2.1). For future reviews of the list of restricted substances in EEE, thus, the current inventory will have to be updated.

Finally, chemicals are selected by applying defined criteria (hazardous properties, evidence that the substance is relevant with regard to RoHS Article 6 (1) a, b, and c [WEEE management]).

Substance properties

Table 1 gives an overview of the selection criteria with regard to hazardous properties.

Table 4: Criteria regarding substance properties

The substance is/shows:
listed in Annex VI CLP / fulfils criteria of Annex VI
Carcinogenic OR mutagenic OR reprotoxic [Categories 1A and 1B and 2]
PBT (persistent, bio-accumulative, toxic)
PB (persistent, bio-accumulative)
SVHC = substance of very high concern under REACH
defined as endocrine disruptor, category 1, (EC[23])
radioactive

Waste relevance

With regard to RoHS Article 6 (1) a, b, and c (WEEE management) substances / substance groups including substances of very small size used in EEE are selected where indication[24] is given that they:

[23] http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm

[24] *The following sources of information may be used:*

- could have a negative impact during WEEE management operations, including the possibilities for preparing for reuse of WEEE or for recycling of materials from WEEE;
- 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 WEEE under current operational conditions;
- could lead to unacceptable exposure of workers involved in WEEE collection or treatment processes;

- Studies & investigations on WEEE treatment[24]
- 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
- Perform a stakeholder consultation (in particular waste treatment sector)

PART II: Pre-assessment:

Aim

Part II aims at narrowing down the list of identified substances, which may have negative impacts on human health, the environment or WEEE management as specified by RoHS II Article 6 (1) a, b, and c by a comparably easy and fast procedure. It further 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).

Approach

First, substances already restricted in a wider context covering also EEE are **excluded**.

Grouping system

Secondly, a prioritization of substances is carried out by **grouping** substances on the basis of an assessment of:

- their hazardous properties and
- their negative impacts during WEEE management (=waste relevance) as specified by Article 6 (1) a, b, and c:

  a) "*Substances / substance groups that 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) "*Substances / substance groups that 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) *"substances / substance groups could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes"*

Hazardous properties

The grouping system for hazardous properties is on the one hand 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. In addition, properties according to the criteria of substances of very high concern (SVHC) are considered.

The allocation of a substance / substance group regarding its hazardous properties (human health & environment) is determined as described in Table 5 below. The allocation to the individual Hazard groups (Human health and environment) is described in detail in the methodology manual.

Table 5: Hazard Groups (Human Health & Environment)

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)

Relevance for waste management

The **relevance of a substance** / **substance group for waste management** is determined as described in Table 6 below.

Table 6: Waste Relevance

Waste Relevance
One of the criteria of Article 6 (1) a, b, c is fulfilled
No Waste Relevance
None of the criteria of Article 6 (1) a, b, c is fulfilled

To evaluate the relevance for waste management the following attributes are evaluated in detail.

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

- There is evidence that the substance hinders recycling or recovery as it has adverse effects on recycling / recovery processes (examples are Pb in glass fractions, halogenated polymers in fractions to be used for energy recovery).
- There is evidence that large proportions of the substance[25] remain in the recycling loop and are not discharged during the treatment processes and collected for subsequent safe disposal. As a consequence 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.

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

- There is evidence that the substance was measured at significantly elevated levels in the environment (air, water, soil, biota) near WEEE treatment installations / locations
- There is evidence that hazardous[26] degradation/transformation products are formed during WEEE management (including thermal processes (combustion, milling), mechanical, chemical and biological processes (MBT, landfilling)
- The substance is used as a nanomaterial in EEE and there are concerns about negative effects on human health or the environment[27]

[25] Provided that the substance has inherent hazardous properties

[26] 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

[27] According to the ROHS Directive special account shall be given to nanomaterials. Various uses 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.

Due to the lack of knowledge on the fate and behaviour of nanoparticles in the environment and the human body the precautionary principle shall be applied and information on whether a specific substance is used as nanomaterial shall be documented at this stage. The information whether the substance is used as nanomaterial should be available at the registered substances database of ECHA (**http://echa.europa.eu/web/guest/information-on-**

- The substance is comparably easily releasable due to following reasons
  - The substance is used in or as a liquid in EEE
  - The substance is used in powders
  - The substance is highly volatile

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

- There is evidence that negative health impacts during WEEE management occur
- The substance was found at significantly elevated levels in humans near WEEE treatment plants / locations.

Overall priority of a substance

The overall priority of a substance or substance group is determined by how often a certain priority group occurs. There are three priority groups for human health & environmental (red, orange and yellow) and three waste criteria (each red and not).

Substances are classified as the highest priority where all 3 waste criteria are fulfilled and the human health & environmental hazards are of high priority (red).

Substances, where all 3 waste criteria are fulfilled and the human health & environmental hazards are of medium priority (orange), are classified as second highest priority.

Substances, where all 3 waste 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 waste criteria are fulfilled, are classified as fourth highest priority.

Further priority / colour combinations are displayed in Table 7 below.

Table 7: Overview on priority categories

Overall priority of substances / substance groups	I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII	XIII	XIV
Human Health & Environment														
Waste Crit. 6.1.a														
Waste Crit. 6.1.b														
Waste Crit. 6.1.c														

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”.

Volumes used in EEE and substitutes

For a further differentiation of substances which were considered to be of the same (high) priority using these attributes, volumes used in EEE[28] and the availability of substitutes shall be evaluated[29].

PART III: Detailed assessment of substances / substance groups

Aim

The aim of the detailed assessment is to conclude whether a substance or substance group[30] should be recommended for restriction under RoHS2 or not.

Furthermore, the purpose of the detailed assessment is to fulfil the information requirements of Article 6 of ROHS2.

Contents

The assessment consists of:

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

Criteria

A recommendation for a restriction under RoHS shall be considered when:

- the substance / substance group has 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

  OR
- the substance / substance group gives 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

  OR
- the substances / substance group leads to unacceptable exposure of workers involved in the waste EEE collection or treatment processes

RoHS2-AnnexII-Dossier

For documentation a template forma was developed, which is provided as a separate document "*RoHS2-AnnexII-Dossier.docx*" attached to this report.

[28] Contained in EEE put on the European market

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

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

Overview

The chart below (Figure 2) provides an overview of the individual steps of the methodology.

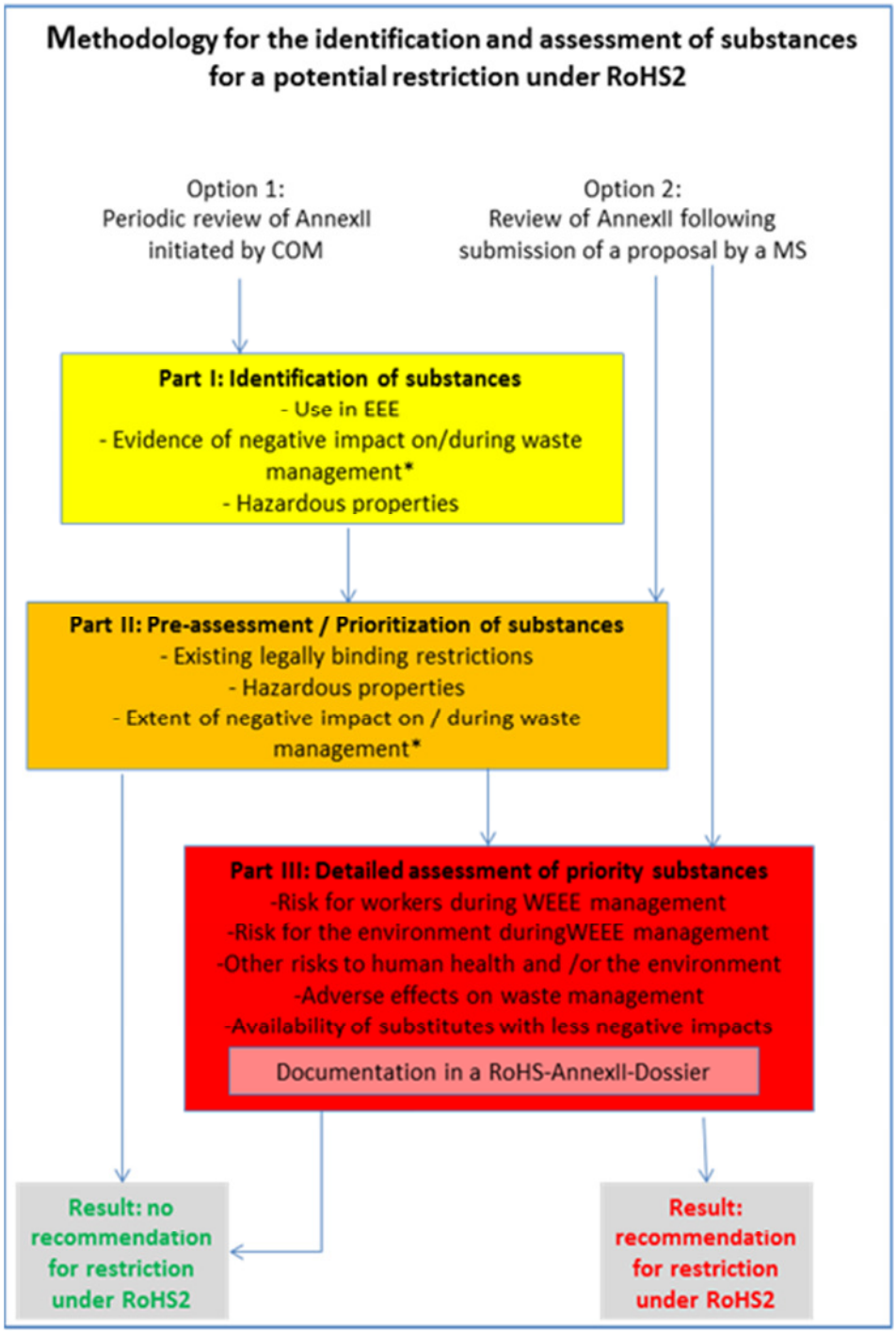

*Figure 2: Overview of the methodology (*as specified by Article 6 (1) a, b, c of RoHS2)*

6 IDENTIFICATION OF SUBSTANCES WHICH MAY CAUSE RISKS FOR THE ENVIRONMENT OR WORKERS DURING WEEE MANAGEMENT OR HAVE ANY OTHER NEGATIVE IMPACTS ON WASTE MANAGEMENT

6.1 Description of the application of Part I of the developed methodology

6.1.1 Application of Step I 1) "Creation of an inventory of substances used in EEE"

Databases, literature

In order to establish an inventory of substances used in EEE as a first step information from various databases and published literature was compiled.

Databases used to compile the EEE-substance-inventory:

- 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 on both the main components and the 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 meet 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 in December 2012 were used.

- Information on the use of substances available from the ECHA dissemination site[31] based on the registration of substances: substances with the use descriptor "SU16" "Manufacture of computer, electronic and optical products, electrical equipment".
- Information on substance uses (Nace-codes C26 "Manufacture of computer, electronic and optical products" and C27 "Manufacture of computer, electronic and optical products" [32]) as available from the Nordic Product Register (SPIN – substances in preparations in Nordic countries- register)- http://90.184.2.100/DotNetNuke/default.aspx

[31] link: http://echa.europa.eu/information-on-chemicals/
[32] Relevant uses to be selected

In addition information from the following **studies/reports etc.** was used:

- Inventory of ÖKO-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. The study provides information on hazardous substances in products. Annex 4.B summarizes information on substances analyzed in EEE (various information sources).
- Monitoring results in WEEE: SENS, SWICO & SLRS, (2008): PCB IN KLEINKONDENSATOREN AUS ELEKTRO- UND ELEKTRONIKALTGERÄTEN. SCHLUSSBERICHT. About 15 hazardous substances were analyzed in capacitors derived from small EEE.
- Review of hazardous substances in EEE provided by the DANISH EPA (2012) GREENING OF ELECTRONICS. The list consists of 25 substances.
- Substances listed by the Berkeley Center for Green Chemistry (2012). Identification of substances of concern during informal recycling of electronics.
- Information on radioactive substances used in lamps: European Lamp Companies Federation (2009): Ionizing Substances in Lighting Products.
- Information on nanomaterials used in EEE: from the 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; http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_com(2012)_572.pdf and from the COMMISSION STAFF WORKING PAPER ON TYPES AND USES OF NANOMATERIALS, INCLUDING SAFETY ASPECTS ACCOMPANYING 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} http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials__staff_working_paper_accompanying_com(2012)_572.pdf
- UBA-De reports on assessment criteria for substitutions of flame retardants (Umweltbundesamt De, 2000)
- Screening of scientific literature
- Screening of industry websites

Process chemicals

Some of the lists used to establish the EEE substance inventory contain not only substances present in the final product, but also such which are used during the production process of EEE. Examples are the SPIN-database or the IEC 62474 Database „Declarable Substances“.

Therefore the list compiled on the basis of the above mentioned sources was manually screened for those substances, whose presence in EEE is not plausible, e.g. solvents.

Stakeholder contribution to the substance inventory

The resulting draft inventory of approximately 700 entries (of which 126 were classified as unlikely to occur in EEE) was then put up for discussion among stakeholders participating in the 2nd stakeholder meeting. The following information was provided by stakeholders:

- additional substances present in EEE
- indications of substances whose presence in EEE is unlikely
- information on the amount of substances in individual EEE components
- information on the specific function of individual substances in EEE

The contributions were received from:

- ChemSec - the International Chemical Secretariat
- KEMI – Swedish Chemicals Agency
- Digitaleurope and TechAmerica Europe
- EFRA - European Flame Retardants Association
- NIA – Nanotechnology Industry Association
- Pinfa – Phosphorus, Inorganic & Nitrogen Flame Retardants Association
- TriQuint Semiconductor, Inc.
- Hewlett Packard
- International Campaign for Responsible Technology

The comments were considered as follows:

- Additional substances in EEE provided by the stakeholders were added to the inventory
- Where conflicting comments on the substance´s presence in EEE were received or where the comments contradicted documented evidence, the substance was kept in the inventory.
- Where one or more comments were received saying that presence of the substance in EEE was implausible, the substance was removed from the inventory
- Substances or substance groups where stakeholders said that they were not present in EEE, because they had already been restricted by RoHS, REACH etc., were not removed from the inventory but marked accordingly[33].

The additional substances provided by the International Campaign for Responsible Technology were not added to the inventory, as they contain also process chemicals, which would require an additional plausibility check. However, these additional 76 substances are provided as a separate list (sheet "*Addition ICRT*" in "*EEE-substance-inventory.xls*").

[33] i.e. 31 substances of the inventory

6.1.2 Application of Step I 2a) "Selection of substances used in EEE which are hazardous" and of Step I 2b) "Selection of substances used in EEE which are of concern during WEEE management (Article 6 (1) a, b, c)"

In order to obtain a list of substances which may cause risks for the environment or workers during WEEE management or have any other negative impacts on waste management the following steps were taken:

Hazardous properties

First, the substance inventory was narrowed down to substances fulfilling the following criteria based on the regulatory status of January 2013 (as specified in the methodology manual).

The substance is/shows:

- listed in Annex VI CLP / fulfils criteria of Annex VI
- carcinogenic OR mutagenic OR reprotoxic [Categories 1A and 1B and 2]
- PBT (persistent, bio-accumulative, toxic)
- PB (persistent, bio-accumulative)
- SVHC = substance of very high concern under REACH
- defined as endocrine disruptor, category 1, (EC[34])
- radioactive

Indication for waste relevance

In addition, substances were selected where there is evidence that they:

- could have a negative impact during WEEE management operations, including the possibilities for preparing for reuse of WEEE or for recycling of materials from WEEE;
- 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 WEEE under current operational conditions;
- could lead to unacceptable exposure of workers involved in WEEE collection or treatment processes;

Therefore review literature focusing on hazardous components in EEE and WEEE treatment was screened; including ÖKOINSTITUT (2008), SWEDISH EPA (2011), DEPA (2012) and BERKLEY CENTER FOR GREEN CHEMISTRY (2012).

[34] http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htmECEC

6.2 Results

6.2.1 Inventory of substances used in EEE

Substance entries

The final inventory of substances used in EEE consists of **738** substance entries. It includes also 31 substances, which have already been restricted and 27 substances where the substance´s presence in EEE has been classified as "possible", "not known" or "unlikely"[35]. 31 of the entries in the substance inventory are not classified by CAS, including e.g. nano-applications of substances.

Information contained in the EEE substance inventory

The EEE substance inventory contains the following information:

- Name of the substance
- CAS and EC number of the substance, where available
- Information on the likeliness of the substance´s presence in EEE

Furthermore, the substances are classified by category (acids, elements metal, metal compound, dyes, polymers, additives etc.) and their main function in EEE (stabilizer, flame retardant etc.).

The inventory is provided as a separate document "*EEE-substance-inventory.xls*".

6.2.2 List of substances which may cause risks for the environment or workers during WEEE management or have any other negative impacts on waste management

The final list of substances which may cause risks for the environment or workers during WEEE management or have any other negative impacts on waste management is provided as a filtered sheet "*Subst. which may cause risk*" in the separate document "*EEE-substance-inventory.xls*".

In total 151 substances were identified.

[35] In total 224 substances had been removed from the original list of substances

7 PRE-ASSESSMENT OF IDENTIFIED SUBSTANCES

7.1 Description of the application of Part II of the developed methodology

7.1.1 Selection of priority substances

In order to identify substances / substance groups of highest priority for a detailed assessment the following targeted approach was followed:

1) All substances categorized as Human Health Hazard Group I and either as Environmental Hazard Group I or II[36] were selected from the "*RoHS-working-list*".

2) In addition, all substances / substance groups for which all 3 waste criteria (*Article 6, RoHS2)* are fulfilled were selected. Therefore the same information sources were used that had been drawn upon for establishing the "*RoHS-working-list*" (see Chapter 6.1.2).

3) For those substances or substance groups, which were selected due to the latter criterion, but for which no harmonized classification (CLP) existed, self-classifications by notifiers regarding human health and environmental hazard properties were screened.

Brominated flame retardants fulfil all three waste criteria. Thus, in addition to the substances being harmonised classified, self-classifications of notifiers in the C&L inventory were screened for further flame retardants[37]. Only those flame retardants, which were - according to the self-classification – classified in the highest hazard group (red) either regarding human health or the environment, were added to the "*Priority list*". As different self-classifications of a chemical might be notified in the C&L inventory, the most conservative classifications for the same endpoint (e.g., if both Carc 1A and 1B were notified, only Carc 1A was considered) were taken into account for the prioritization of the compound for the present project.

For substance groups, including elements with a high waste relevance the most hazardous representative of the group shall determine the hazard properties (human health and environment) of the substance group in the context of the pre-assessment[38].

7.1.2 Ranking of priority substances

In accordance with the developed methodology the overall priority for each substance or substance group has been determined by how often a certain priority

[36] Due to the limited number of fully assessed PBT (persistent, bioaccumulative and toxic) substances which fulfil the (criterion for Environmental Hazard group I) the Environmental Hazard Group II was selected too. Substances, which are used as radioactive isotopes in EEE were selected too, although the hazard grouping system is not directly applicable to them.

[37] e.g. Öko-Institut 2008; ad hoc internet search strategy

[38] This approach shall be applied for prioritizing substance groups. A differentiated approach will be required in the context of the detailed assessment.

group occured. There are three human health hazards & environmental hazards (red, orange and yellow) and three waste criteria.

- Substances where all 3 waste criteria are fulfilled and the human health & environmental hazards are of high priority (red) are classified as the highest priority (I).
- Substances, where all 3 waste criteria are fulfilled and the human health & environmental hazards are of medium priority (orange), are classified as second highest priority (II).
- Substances, where all 3 waste criteria are fulfilled and the human health & environmental hazards are of lower priority (yellow), are classified as third highest priority (III).
- Substances, where the human health & environmental hazards are of high priority (red) and 2 of the 3 waste criteria are fulfilled, are classified as fourth highest priority (IV).

Further priority (colour) combinations are displayed in Table 8 below.

Table 8: Overview of overall priority categories

Overall priority of substances / substance groups	I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII	XIII	XIV
Human Health & Environment														
Waste Crit. 6.1.a														
Waste Crit. 6.1.b														
Waste Crit. 6.1.c														

7.1.3 Evaluation of the legal restriction status

The substance entries on the priority list established as described in Chapter 7.1.1 were screened regarding regulations under the EU POPs Regulation, the Stockholm Convention and existing restrictions under REACH (Annex VII) covering EEE.

Three substance entries were **removed** from the priority list: hexachlorobenzene, because it is already in the Stockholm Convention; tributyltin oxide, because it is restricted according to REACH and short chain chlorinated paraffins because they have been added in the POPs Regulation.

7.2 Result: A priority list of substances ranked according to the substance´s priority for a detailed assessment with the view of a potential restriction under RoHS

The priority list consists of **56 substances**[39] and their overall priority category. In addition it includes 11 elements and the following substance groups: phthalates, brominated flame retardants, chlorinated flame retardants and chloroalkanes. For elements and substance groups starting points for estimating the priority are given.

Ranking of priority substances

The following ranking of substances with regard to their priority for further assessment under RoHS was obtained:

Highest priority

Eight substances were identified to be of highest priority:

- the 4 phthalates Di-(2-ethylhexyl)phthalate (**DEHP**), Di-n-butyl phthalate (**DBP**), Butyl benzyl phthalate (**BBP**) and Diisobutyl phthalate (**DiBP**)
- the chlorinated flame retardant **tris(2-chloroethyl)phosphate**
- the 2 brominated flame retardants Hexabromocyclododecane (**HBCDD**) and 2,3-dibromo-1-propanol
- and Dibromoneopentyl-glycol[40]

Second highest priority

Four substances were identified to be of the second highest priority:

- antimony trioxide
- diethyl phthalate (**DEP**)
- Tetrabromobisphenol A (**TBBPA**)
- and medium-chain chlorinated paraffins

Third highest priority

The polymer **PVC** was classified to be of the third highest priority, in particular because of its high waste relevance.

Fourth highest priority

Five substances were identified to be of the fourth highest priority:

- the Be-(compounds): **beryllium metal** and **beryllium oxide** (BeO)
- the Ni-compounds: **nickel sulphate** and **nickel sulfamate** (=Nickel bis sulfamidate)
- and **indium phosphide**

Fifth highest priority

Four substances were identified to be of the fifth highest priority:

- the two As-compounds **di-arsenic pentoxide**; (i.e. Arsenic pentoxide; Arsenic oxide) and **di-arsenic trioxide** (i.e. Arsenic trioxide)

[39] 12 metal compounds, 3 inorganic compounds, 5 phtalates, 3 phenolic compounds, 1 chlorinated and 4 brominated flame retardants, 1 chloroalkanes, 4 phosphates, 11 polymers, 5 radioactive substances and 7 other substances

[40] however, indication that use amounts are low

- the two Co-compounds **cobalt dichloride** and **cobalt sulfate**

Sixth highest priority

Two substances were identified to be of the sixth highest priority:

- **cobalt metal** and
- **nonylphenol**

The overall priority category for the remaining substances can be found in the ranked priority list, which is provided as a separate document ("*Priority list.xls*").

Information contained in the Priority List

The priority list contains the following information:

- Name of the substance / substance category
- CAS and EC number of the substance
- Information on the present SVHC status of the substance[41]
- Information on the hazardous properties for Human Health and Environment based on the CLP classification system and on criteria defined within REACH (status January 2013)
- Information and evidence whether a substance/substance group fulfils the 3 criteria specified in Article 6 (1) of RoHS2, namely:

  a) "Substances / substance groups that 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) "Substances / substance groups that 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) "substances / substance groups that could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes"
- The reference for evaluation of the waste criteria

In addition, the human health & environment hazard group (Group 1 = red, Group 2 = orange, Group 3 = yellow) as well as the fulfilment of the three waste criteria (red) are provided.

Finally, the overall priority category (I, II, III etc.) of a particular substance is given.

[41] Status June 28, 2013

8 DETAILED ASSESSMENT OF SUBSTANCES

According to the project specifications those substances, which - according to Recital 10 of RoHS2 – should be considered a priority for the first review of Annex II, were assessed in detail:

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

These substances were also classified to be of highest priority in line with the developed pre-assessment methodology (see Chapter 7.2)

8.1 Detailed assessment of HBCDD

Below the main aspects and results of the detailed assessment are summarized. The full assessment is provided as a separate document attached to this report "*RoHS_AnnexII_Dossier_HBCDD.docx*".

Hazardous potential

Nature and reversibility of the adverse effect

HBCDD is persistent and undergoes long range transport; it accumulates in the food chain, is reprotoxic and accumulates in human breast milk.

HBCDD releases from WEEE treatment

WEEE treatment compared to the treatment of other post-consumer wastes

The relevant releases of HBCDD from shredding of WEEE and recycling of HIPS parts derived from WEEE are releases to the air. The same is true for the treatment of other post-consumer wastes[42].

The RAR for HBCDD (EC, 2008a) identifies EPS and XPS insulation boards as the most relevant post-consumer waste streams. About the actual releases of HBCDD from the demolition of buildings, which depend very much on the techniques used for demolition, there is generally a big uncertainty. Nevertheless, rough estimates of HBCDD releases from insulation boards are provided by the RAR. Based on an annual consumption of 8,000 tonnes of such insulation boards in the EU, releases during waste management are estimated to account for **108 kg/a** of a 30% share of boards being recycled after manual removal from buildings, plus an estimated **5,600 kg/a** resulting from the demolition of buildings containing the remaining 70% of EPS/XPS boards. Releases from further waste management operations have not been estimated.

[42] In general, RAR HBCDD provides little information on releases of HBCDD-containing products once they have become waste.

In a scenario where emissions of dust at shredder plants are prevented to a high extent, HBCDD releases via particulates from WEEE treatment are comparably low: **43 kg/a**.

In a scenario where only limited measures for preventing dust emissions from shredder plants are taken, the estimated releases from mechanical treatment of WEEE are **413 kg/a**, which is considerably higher than the emissions from manually removed EPS/XPS boards.

Taking into account that material streams derived from WEEE may be subjected to mechanical treatment processes several times during the overall treatment chain, it is expected that the actual releases might even be higher.

HBCDD releases to air and waste water from the recycling of WEEE-HIPS parts (each approximately **25.7 kg/a**) are estimated to be lower than releases from the mechanical treatment of WEEE.

In any case, overall releases from WEEE treatment (compare **Fehler! Verweisquelle konnte nicht gefunden werden.**) are expected to be much lower than the estimated releases from EPS/XPS containing demolition boards (**5,780 kg/a** from the recycling and demolition of buildings in a worst case scenario).

Releases from WEEE treatment compared to total HBCDD releases

Compared to releases of HBCDD to air other than those resulting from waste management activities (as estimated in the RAR for HBCDD, i.e. **508 kg/a**; see Table 9 below) the releases from WEEE treatment are either of the same order of magnitude (**420 kg/a**) or lower by one order of magnitude (**50 kg/a**) where measures for the prevention of dust emissions have been implemented.

Releases into waste water from WEEE treatment are expected to be of little relevance (19 kg/a) compared to the total HBCDD releases to waste water (6,251 kg/a) and surface water (1,933) as estimated in the RAR (see Table 9 below).

In addition, releases of HBCDD are also expected from landfills, incineration plants and uncontrolled treatment of WEEE.

Table 9: Summary of HBCDD releases (Source: Table 3-34 of the RAR for HBCDD, EC, 2008a)

	Total (kg/year)			Continental (kg/year)			Regional (kg/year)		
Life-cycle stage	**Air**	**Waste-water**	**Surface-water**	**Air**	**Waste-water**	**Surface-water**	**Air**	**Waste-water**	**Surface-water**
Production	2.0	0.73	0	0	0	0	2.0	0.73	0
Micronising	0.3	0	0	0	0	0	0.3	0	0
Formulation EPS and HIPS	19.5	48	212	19.1	48	99	0.4	0	113.4
Formulation XPS	11.3	71.2	8.5	5.7	35.6	4.3	5.7	35.6	4.3
Formulation polymer dispersion (for textiles)	6.8	220	55	4.5	146	37	2.3	74	18
Industrial use EPS	102	82	20.4	92	74	18	10.2	8.2	2
Industrial use HIPS	6.3	5.0	1.3	5.7	4.5	1.2	0.63	0.5	0.13
Industrial use XPS (compound)	100	27	7	80	21.6	5.6	20	5.4	1.4
Industrial use XPS (powder)	23.6	26.4	6.6	21.5	9.5	2.4	2.1	16.9	4.2
Industrial use textile (backcoating)	0.64	5653	1413	0.32	2826	706	0.32	2826	706
Professional use insulation boards (at building sites)	182	0	182	164	0	164	18	0	18
Service Life Textiles (washing)	0	10.5	0	0	7.9	0	0	2.6	0
Service Life Textiles (wear)	0	107	27	0	80	20	0	27	7
Service Life EPS&XPS	54	0	0	48.6	0	0	5.4	0	0
Total emissions	508	6251	1933	441	3253	1058	67.4	2997	874
kg/day*	1.39	17.1	5.29	1.21	8.9	2.89	0.18	8.21	2.39

*These emissions are used in the EUSES model for the estimation of the regional and continental background

Human health risk

Workers in plastics recycling

Workers are expected to be **at risk** in facilities where HBCDD containing plastic parts from WEEE are recycled.

Based on an estimated number of 50 installations where HBCDD containing plastics are processed/recycled[43], and taking into account an average of 25 employees in the plastics processing sector, the number of workers at risk is estimated to be 1,250.

Workers in mechanical treatment of WEEE

Shredding, applied outdoors, is considered to present a lower health risk. However, workers might be at risk because they are exposed to a mixture of hazardous substances contained in shredder dust. Even if the risk characterization ratio is below 1, the safety margin is in some cases below a factor of ten.

Based on an estimated number of 450 installations in the EU where WEEE and materials derived thereof are treated mechanically[44], and assuming 5 to 15 workers per installation[45], the estimated range of workers exposed to HBCDD releases ranges between 2,250 to 6,750.

A considerably higher risk is expected to arise from **uncontrolled treatment in third countries**. Residents in the neighbourhood of waste treatment sites are also at risk due from **hazardous degradation and incineration products**. Especially risks to unborn and breast-fed babies have been identified and health effects have been reported.

Environmental exposure

Environmental exposure from the shredding of WEEE and recycling of HIPS was estimated on the basis of the calculated HBCDD releases using the EUSES. 2.1 system for the evaluation of substances. Compared to other industrial processes, local HBCDD concentrations at sites where WEEE is shredded and HIPS recycled are **more than one order of magnitude higher** than background concentrations.

Monitoring data from third countries demonstrate the **long-lasting contamination** of the environment from WEEE treatment.

Risk for the environment

A risk to the aquatic compartment has been identified in the shredding of WEEE[46] and the recycling of HIPS[47], **as well as a risk of secondary poison-**

[43] Basis for the assumption: IPTS (2013): an overall quantity of 50,000 plastics-converters processes 46 Mio tonnes of plastics → average treatment capacity: 1,000 t/a. Amount of HIPS resulting from the dismantling of WEEE: appr. 50,000 t/a of HIPS → 50 plants involved.

[44] The estimation is based on the following: 220 (EC, 2012b) to 232 (IPTS, 2007) large-scale shredder plants are operated in the EU. According to information available from Austria (Umweltbundesamt, 2008) and France (contribution to a stakeholder consultation, the WEEE Forum), there are at least as many mechanical treatment plants for WEEE as large scale shredders. According to the estimates of other stakeholders, there are at least 100 installations. The total number of mechanical treatment plants has therefore been estimated at 450.

[45] Estimate based on Umweltbundesamt (2008)

[46] Involved number of sites: at least 450

[47] Involved number of sites: 50

ing of the aquatic, marine and terrestrial compartment. There is a major concern that the accumulation of such substances in the food chain will lead to adverse effects in the long term. Especially top **predators are at risk** from the burden of persistent organic pollutants. In the environment HBCDD is part of a mixture of persistent organic pollutants which is toxic in many cases and endangers especially **sensitive and endangered species** and affects **sensitive stages of development**.

Main influencing factors within the assessment

There are 2 major factors influencing the result of the risk assessment:

- The annual quantities of HBCDD actually contained in the WEEE collected are influenced by various factors, including the actual quantity of HBCDD put on the European market via EEE, the lifespan of EEE and the actual WEEE amounts collected.
- To what extent measures for preventing diffuse emissions have been applied when handling materials derived from shredded WEEE is considered to have a considerable impact on the estimated HBCDD emissions. However, there is no information available on the actual implementation of such measures.

Within the risk assessment approach the two evaluation tools ECETOC TRA and EUSES have been used. As these have not yet been adapted to the evaluation of waste exposure scenarios because no process categories, emission tables and special scenarios have been integrated, appropriate scenarios have been developed; emissions and releases calculated and used as input parameters for EUSES.

Impact on waste management

The extent to which material recycling/recovery is affected:

Under current operational conditions the presence of Br is determined to decide whether it is allowed to recycle WEEE plastics or not. HBCDD thus reduces the possibilities for WEEE plastics recycling as it is not distinguishable with routine detection methods from other brominated flame retardants.

The extent to which HBCDD remains in the recycling loop

There are indications that within the EU not all plastics containing HBCDD are separated before the plastics are subjected to material recycling although this is required pursuant to the WEEE-Directive[48]. It is known that such shipments take place under the guise of the Green List.

The amount of hazardous waste which is generated in the course of processing WEEE

Wastes with a HBCDD content of 0.5% are considered hazardous. Assuming a separation of all plastics containing more than 0.5% HBCDD, the amounts of

[48] (enforcement experiences in the context of transboundary waste shipment, Austrian analyses of plastic fractions from dismantling of TV and monitors; personal communication Austrian MoE)

HBCDD used in EEE would lead to an annual quantity of up to 20,000 tonnes of hazardous plastics waste.

Other negative impacts on waste management

In waste incineration plants HBCDD containing plastics contribute to corrosion and the possibilities for use in industrial co-incineration are lower.

Available Alternatives

The availability of substitutes/alternatives with less negative properties

Substitutes for HBCDD in HIPS and alternatives for HIPS in EEE are both available. They include also substances which are less hazardous than HBCDD, in particular p-based flame retardants.

Technical and economic feasibility of the alternative substance

Since HBCDD is not widely used in HIPS (only 5%), it is assumed that using the alternative flame retardants on the market is technically and economically feasible (UNEP, 2011).

Socio-economic impacts

In total, the ban on HBCDD creates no additional costs when compared to a non-ban scenario (which requires investments in emission reduction measures), while creating substantial additional benefits for health, environment and the economy.

The costs of a potential restriction of HBCDD (higher material costs and investments in new moldings for the producers) in EEE are estimated to be no higher than those for non-action (i.e. costs for additional emission reduction measures). The overall effect on jobs is expected to be neutral in both scenarios.

With respect to the benefits to be achieved, there is a major difference between the two scenarios. While the implementation of emission reduction measures in scenario A provides only for a better protection of workers in the environment around the flame retardant / plastic production sites in Europe a ban on HBCDD (scenario B) generates the following additional benefits:

- Globally reduced environmental and health impacts during HBCDD and plastics production
- Reduced environmental and health impacts during use and especially waste phase
- Reduced corrosion of waste incineration plants
- Increased recycling potential of plastics

Conclusion:

It is recommended **that HBCDD should be included in Annex II** to the RoHS Directive. A restriction of HBCDD under RoHS is considered to be an appropriate measure to reduce any negative effects during or on WEEE management because:

- a **risk for the environment** from the shredding of WEEE and the recycling of HBCDD containing HIPS is expected: for the aquatic compartment and in the form of secondary poisoning
- a **risk to human health of workers** involved in the recycling of HBCDD containing plastics is expected
- a **risk for residents in the neighborhood** is expected, especially in third countries
- the overall releases from relevant WEEE treatment are a relevant contributor to the total HBCDD releases to air
- there are **several negative impacts on waste management** (reduced recycling possibilities for WEEE plastics, generation of considerable amounts of hazardous wastes and a long life-time in the recycling loop)
- **alternatives** with less negative properties are available (in particular P-based flame retardants) and their use is technically and economically feasible
- the description of the **socio-economic impacts** shows that the additional costs for producers of chemicals and EEE are compensated by several benefits (such as the reduced risks and the less negative impacts on waste management as a consequence of a restriction of HBCDD in EEE).

For the **maximum concentration of HBCDD to be tolerated in homogenous materials in EEE** it is proposed to set the same value as defined for POPs waste in Annex IV to the EU POPs Regulation (850/2004/EC) for most POPs, i.e. 0.005 %.

8.2 Detailed assessment of DEHP

Below the main aspects and results of the detailed assessment are summarized. The full assessment is provided as a separate document attached to this report "RoHS_AnnexII_Dossier_DEHP.docx".

Hazardous potential

Nature and reversibility of the adverse effects

Substance of very high concern

DEHP is a substance of very high concern because of its toxicity to the reproductive system, the kidney and the liver. Data from animal studies and occupational exposure clearly demonstrate its adverse effects. Especially the effects on unborn babies are of major concern as they are believed to be long lasting effects.

DEHP releases during WEEE treatment

WEEE treatment compared to other waste treatment processes

The majority of environmental releases of DEHP from relevant WEEE treatment processes[49] are releases to **air**. The total annual releases are estimated to be **0.9 to 6.8** tonnes. A minor part is released to **waste water** (**235 kg/a**) [50].

The RAR for DEHP (EC, 2008) estimates releases from paper recycling, car shredders, incineration and municipal landfills. In addition, releases from products which remain in the environment after their use are estimated.

In a scenario where emissions of particulates at shredder plants and cable shredders are successfully prevented, DEHP releases to air from WEEE treatments (**0.9 t/a**) are lower compared to releases to air from other waste treatment and disposal processes (**20 t/a**). However, in a scenario where only a few measures for preventing dust emissions from shredders are taken, the WEEE treatment processes contribute with **6.8 t/a** DEHP considerably to these releases.

Given that the WEEE material streams are mechanically treated several times during the whole treatment process, it is expected that the actual releases might even be higher.

The RAR identifies landfills as the most relevant waste treatment process with respect to DEHP releases to water (**15 t/a**). Estimated releases from WEEE treatment are comparably low (**0.2 t/a**). Also, the contribution of disposed of WEEE to DEHP releases from landfills is low. According to COWI (2009), the overall DEHP input into landfills is 195,000 t/a. DEHP entering landfills via WEEE is estimated to be approximately 5,360 t/a.

Releases from WEEE treatment compared to total DEHP releases

Independent of the extent to which emission prevention measures have been implemented at WEEE treatment plants, the contribution of the WEEE treatment processes to the overall releases of DEHP to air (546 t/a, see Table 10 below) is low. In addition, releases of DEHP are also expected from landfills, incineration plants and uncontrolled treatment of WEEE.

[49] i.e. treatment of WEEE in shredders, cable shredders and recycling of PVC

[50] In general, RAR DEHP provides little information on releases of DEHP containing products once they have become waste.

Table 10: Summary of total DEHP emissions (Source: Table 3.37 of the RAR for DEHP, EC, 2008)

Life-cycle stages	Emission Air	Distribution Waste Water[1]	in Urban 0-5 cm	tonnes Soil[3] >5 cm	/year Total
1a production	2	682	7	0	691
1b transportation	0	50	0	0	50
Polymers:					
2a-g Polymer-proc/form	197	197	0	0	394
Non-polymers:					
3a Sealant-formulation	28	111	1	0	140
3b Sealant-processing	1	0	56	0	57
4a Paint-formulation	4	14	0.1	0	18
4b Paint-processing	0	1	7	0	9
5a Ink-formulation	4	17	0.2	0	21
5b Ink-processing	83	0.8	2	0	86
6 Ceramic-formulation	0.1	0.6	0	0	1
Total / industrial uses	**319**	**1,074**	**74**	**0**	**1,467**
7 Polymer-Indoor use	181	1,316	0	0	1,497
7 Polymer-Outdoor use	6	688	642	5,760	7,096
7 Non-pol. Indoor use	18	314	0	0	333
7 Non-pol. Outdoor use	2	157	157	0	316
Total / end-product uses	**207**	**2,475**	**799**	**5,760**	**9,241**
8a Paper recycling	0	9.9	0	0	10
8b Car shredder	5.5	0	62	0	67.5
8c Incineration stations	5.5	0	0	0	5.5
8d Municipal land-fill	0	15	0	0	15
8e Waste / environment[2]	9	2,413	7,240	8,185	17,847
Total / disposal	**20**	**2,438**	**7,302**	**8,185**	**17,945**
Total:	**546**	**5,987**	**8,175**	**13,945**	**28,653**

1) Emission to waste waster except for scenarios 7/out door and 8e (see text for more details)
2) Waste remaining in the environment. Only the contribution from out-door use.
3) Soil buried cables in "urban/Ind. Soil" (>5 cm).

Exposure of workers

Workers in mechanical treatment of WEEE

Based on an estimated number of 450 installations in the EU where WEEE and materials derived thereof are treated mechanically[51] and assuming 5 to 15 workers per installation[52], the estimated range of workers exposed to DEHP releases ranges between 2,250 to 6,750.

Workers in plastics recycling

Based on an estimated number of 9 installations where recycled PVC is formulated from WEEE and 9 installations where recycled PVC is further processed and made into articles, and taking into account an average of 25 employees in the plastics processing sector, the number of workers affected by DEHP exposure is estimated to be 450.

Human health risk

The European risk assessment report on DEHP concludes that there is a need for limiting the risks from use of DEHP at workplaces. Several risk reduction measures have been taken so far. For waste treatment activities only limited information on working conditions and risks for workers is available. Single measurements at shredding facilities operated by Plastics Recyclers Europe found concentrations below the DNEC and DNEL with short exceedances during specific tasks (i.e. loading activities (FoBig, 2013)). These measurements, although limited, are in line with the results of ECETOC modelling for shredder facilities. It can be concluded that specific working tasks in shredding and recycling facilities may lead to exposure concentrations above the reference value (DNEC) derived by the Risk Assessment Committee (RAC) of the European Chemicals Agency. Therefore, it can be assumed that a possible health risk for workers cannot be excluded.

Under comparably unsafe working conditions, e.g. in third countries, a risk from DEHP exposure expected for workers and residents in the neighbourhood is even more likely. These health effects include: repeated dose toxicity effects on kidney and testes, as well as effects on fertility and development. Future generations might be affected.

An assessment of endocrine disruptors within the regulatory framework of the European Union is currently under discussion. As it is not possible to establish a threshold for the adverse effects of genotoxic carcinogens, the possibility of establishing such a threshold for endocrine disrupters is under debate. Therefore, releases of and exposure to endocrine disrupters such as DEHP should be minimized.

[51] This estimate is based on the following information: 220 (EC, 2012b) to 232 (IPTS, 2007) large-scale shredder plants are operated in the EU. According to information available from Austria (Umweltbundesamt, 2008) and France (contribution to stakeholder consultation, WEEE Forum) there are at least as many mechanical treatment plants for WEEE as there are other large-scale shredders. Other stakeholders who participated in the project estimated that there were at least 100 installations. The total number of mechanical treatment plants was therefore estimated to be 450.

[52] Estimation based on Umweltbundesamt (2008)

Environmental exposure

DEHP is a widespread environmental pollutant, found in the food chain and in the human diet. Environmental exposure resulting from the mechanical treatment of WEEE and recycling of WEEE plastics has been estimated using the *EUSES. 2.1 system* for the evaluation of substances. Environmental monitoring data on WEEE sites in Europe are lacking. Monitoring data on comparable industrial processes show elevated concentrations of DEHP in the surrounding environment. Studies conducted in specific non-European countries have shown environmental contamination with DEHP near WEEE treatment sites. DEHP degrades slowly and has a potential for bioaccumulation.

Risk for the environment

The predicted environmental concentrations in earthworms - even if overestimated by the EUSES system - predict a risk to mammalians and birds due to secondary poisoning; this is in line with other industrial processes where DEHP is used.

Main influencing factors within the risk assessment

There are 3 major factors influencing the result of the risk assessment:

- The annual quantities of DEHP contained in the collected WEEE depend on: the actual DEHP quantities put on the European market via EEE, the lifespan of EEE, the actual WEEE collection rate.
- The degree to which measures for preventing dust emissions are applied when handling materials derived from shredded WEEE affects the estimated DEHP releases considerably. However, there is no information available on the actual implementation of such measures.
- The risk for workers depends on the use of local exhaust ventilation and whether personal protective equipment is used, e.g. gloves. Data on the actual working conditions at WEEE treatment plants are sparse.

The environmental exposure estimate is based on EUSES which (as yet) does not address waste treatment specifically. Thus, appropriate scenarios were defined, and emissions and releases were calculated and used as input parameters.

Impact on waste management

The extent to which material recycling/recovery is affected

Taking into account the regulations pertaining to the use of DEHP (e.g. under REACH) it is expected that the recycling possibilities for PVC will be reduced due to the presence of DEHP in WEEE plastics.

The extent to which DEHP remains in the recycling loop

Currently recycled PVC is used for the production of low value articles (shoe soles, hoses etc.). Thus it is not expected that DEHP will stay in the recycling loop for long.

The amount of hazardous waste which is generated in the course of processing WEEE

Wastes with a DEHP content of 0.5% are considered hazardous. Assuming a separating and shredding rate of 80% for all WEEE cables, the estimated amount of hazardous waste generated per year is 110,000 tonnes[53].

Available Alternatives

Detailed assessments on possible alternatives were carried out recently (Maag et al.; 2010, COWI; 2009, ECHA; 2013). Besides the hazard profiles of such substitutes, their use and technical feasibility were also determined. The results of these assessments show that the substitution of DEHP by less harmful substances (e.g. ASE, DINCH) is possible and already being done. The use of DEHP in EEE is not considered to be essential. However, some niche applications cannot be ruled out.

Socio-economic impacts

In total, a ban on DEHP in EEE would create limited additional costs while creating substantial additional benefits for health, environment and the economy.

The overall impact on jobs/employment is expected to be small. While some jobs are expected to be lost in industries where EEE is used (due to a marginal increase in prices for EEE), some new jobs are likely to be created in the production of alternative plasticisers and in the environmental (chemical analysis) sector.

With respect to the benefits, however, the impact of a DEHP ban is expected to be substantial:

- Increase in the competitive position of an environmentally friendly industry
- Global reduction of environmental and health impacts from DEHP and plastics production
- Reduction of the environmental and health impact from the use of DEHP-containing EEE and especially of impacts arising during the waste and recycling phase

[53] 60,000 tonnes of cable and 40,000 tonnes of plastic fractions resulting from the mechanical treatment of cables.

Conclusion:

It is recommended **that DEHP should be included in Annex II** to the RoHS-Directive. A restriction of DEHP under RoHS is considered to be an appropriate measure to reduce any negative effects arising from - or on - WEEE management because:

- A risk for the environment (secondary poisoning of mammalians and birds) must be expected from the relevant WEEE treatment processes (i.e. the handling of materials at shredder sites, shredding of cables and recycling of PVC derived from WEEE). Occupational exposure estimates for workers in WEEE treatment plants indicate that exceedances of safe exposure levels derived by the risk assessment committee of the European Chemicals Agency are possible. Therefore, a risk for workers cannot be excluded.
- DEHP **releases** from sites for the mechanical treatment of WEEE and cables and from PVC recycling are relevant contributors to the overall releases to air from treatment of DEHP containing wastes in a scenario where measures for preventing dust emissions are insufficient.
- There are considerable **negative impacts on waste management** (reduced recycling possibilities due to regulations for DEHP, generation of considerable amounts of hazardous waste).
- alternatives with less negative properties **are available and technically and economically feasible** (e.g. ASE or DINCH)
- the **socio-economic impact analysis** indicates that a restriction of DEHP would have several benefits, including reduced risks and a less negative impact on waste management. Additional costs would be incurred in some sectors, i.e. by producers of chemicals and in the production of EEE.

The proposed **maximum concentration value of DEHP to be tolerated** in EEE is **0.1 weight % per homogenous material**. Given the level of risk identified when assuming a DEHP concentration in PVC of a few % it can be expected that a maximum concentration of 0.1 weight % will lead to significantly reduced risks.

- alternatives with less negative properties **are available and technically and economically feasible** (e.g. ASE or DINCH)
- the **socio-economic impact analysis** indicates, that a restriction of DEHP would have several benefits, including reduced risks and less negative impacts on waste management. Additional costs would be incurred in some sectors, i.e. producers of chemicals and production of EEE.

The proposed **maximum concentration value of DEHP to be tolerated** in EEE is **0.1 weight % per homogenous material**. Given the level of risk identified when assuming a DEHP concentration in PVC of a few % it can be expected that a maximum concentration of 0.1 weight % will lead to significantly reduced risks.

8.3 Detailed assessment of DBP

Below the main aspects and results of the detailed assessment are summarized. The full assessment is provided as a separate document attached to this report “RoHS_AnnexII_Dossier_DBP.docx”.

Hazardous potential

Nature and reversibility of the adverse effects:

Substance of very high concern

DBP is a substance of very high concern and classified as toxic to reproduction, based on evidence for adverse effects on the reproductive organs in rodents which are attributed to an anti-androgenic mode of action. A risk for workers was identified for DBP for industrial processes in Europe 2003, with concerns for general systemic toxicity as a consequence of repeated dermal exposure arising from aerosol forming activities, as well as concerns for adverse local effects in the respiratory tract as a consequence of repeated inhalation exposure,.

DBP releases from WEEE treatment

WEEE treatment compared to other waste treatment processes

The majority of environmental releases of DBP from relevant WEEE treatment processes[54] are releases to **air**. Annual releases are estimated to be **0.15 to 1.4** tonnes.

COWI (2009) presents release estimates for the incineration and landfilling of solid waste:

Table 11: Releases of DBP from main solid waste operations (Source: COWI, 2009, Table 2-12)

	Tonnage (t/y)	Releases to the environment, t/y		
		Air	Soil	Waste water
Incineration	2,200	0.9	0.0	0
Landfilling	5,500	0.0	0.2	14
Total		0.9	0.2	14

In a scenario where emissions of particulates at shredder plants are successfully prevented, DBP releases to air from WEEE treatment **(0.15 t /a)** are estimated to be lower than releases to air from waste incineration. However, in a scenario where insufficient measures for preventing dust emissions from shredders are taken, the releases from WEEE treatment (**1.4 t/a**) are considered to be higher than the releases to air by waste treatments (0.9 t/a)

Given that material streams derived from WEEE may be subjected to mechanical treatment several times during the whole treatment process, it is assumed that the actual releases might even be higher.

In addition, DBP is assumed to be emitted from landfills, incineration plants and uncontrolled treatment of WEEE.

[54] i.e. treatment of WEEE at shredder sites

Exposure of workers

Based on an estimated number of 450 installations in the EU where WEEE and materials derived thereof are treated mechanically[55] and assuming 5 to 15 workers per installation[56], the estimated range of workers exposed to DBP releases ranges between 2,250 to 6,750.

Human health risk

Based on the assumptions underlying this assessment, there is no expected health risk for workers from DBP exposure at WEEE shredding plants.

The EU-RAR identifies a risk for workers, with concerns for general systemic toxicity as a consequence of repeated dermal exposure arising from aerosol forming activities, as well as concerns for adverse local effects in the respiratory tract as a consequence of repeated inhalation exposure in all occupational exposure scenarios.

Therefore, under comparably unsafer working conditions, e.g. in third countries, a risk from DBP exposure can be expected. Also, residents in the neighbourhood are likely to be exposed and, therefore, at risk.

An assessment of endocrine disruptors within the regulatory framework of the European Union is currently under discussion. As it is not possible to establish a threshold for adverse effects of genotoxic carcinogens, the possibility for establishing such a threshold for endocrine disruptors is under debate. Therefore, releases of and exposure to endocrine disrupters such as DBP should be minimized. Further, the European Commission states in its conclusions about the combination effects of mixtures submitted to the European Council that particular attention should be paid to mixtures for which one or more components are assumed to have no threshold for its/their effects (EC 2012). Therefore, the precautionary principle as referred to in the ROHS Directive should be applied and the risk of similarly acting phthalates should be addressed.

Environmental exposure

Based on the assumptions underlying the present assessment, the environmental exposure to DBP at sites where WEEE is shredded is estimated to be low. However, monitoring data are missing.

Risk for the environment

According to the euses modeling within this assessment no risk for the environment due to DBP exposure from sites for WEEE shredding is expected.Within the EU-RAR a PNEC plant-air of 0.1 µg/m^3 was defined. The calculated PEC for the air compartment is 0.03 µg/m^3; the derived PEC/PNEC is 0.3. However taking into account the results of the ECETOC TRA occupational exposure modelling concentrations could reach and exceed the PNEC for higher plants and lead to a risk for the environment.

[55] The estimate is based on the following: 220 (EC, 2012b) to 232 (IPTS, 2007) large-scale shredder plants are operated in the EU. According to information available from Austria (Umweltbundesamt, 2008) and France (contribution to stakeholder consultation, WEEE Forum), there are at least as many mechanical treatment plants for WEEE as there are large-scale shredders. Other stakeholders participating in the project estimated that there were at least 100 installations. The total number of mechanical treatment plants was therefore estimated to be 450.

[56] Estimate based on Umweltbundesamt (2008)

Main influencing factors within the risk assessment

There are 2 major factors influencing the result of the risk assessment::

- The annual quantities of DBP contained in the collected WEEE depend on: the actual DBP quantities put on the European market via EEE, the lifespan of EEE, the actual WEEE collection rates.
- The extent to which measures are applied for preventing dust emissions when handling materials derived from shredded WEEE affects the estimated DBP releases considerably. However, there is no information available on the actual implementation of such measures.

The environmental exposure estimate is based on EUSES which (as yet) does not address waste treatment specifically. Thus, appropriate scenarios were defined, and emissions and releases were calculated and used as input parameters.

Impact on waste management

The extent to which material recycling/recovery is affected

Taking into account the regulations pertaining to the use of DBP (e.g. under REACH), it is expected that the recycling possibilities for plastics containing DBP will be reduced due to the presence of DBP in plastics derived from WEEE.

The extent to which DBP remains in the recycling loop

Under current operational conditions PVC is used for the production of low value articles (shoe soles, hoses etc.). Thus it is not expected that DBP contained in PVC will stay in the recycling loop for long.

The amount of hazardous waste which is generated in the course of processing WEEE

Wastes with a DBP content of 0.5% are considered hazardous in accordance with the European list of waste (fulfilment of criterion H10, reprotoxic[57]).

As there is no information on the amounts of DBP actually contained in individual material streams resulting from the treatment of WEEE, no estimate can be produced of how much hazardous waste can be prevented through a restriction of DBP in EEE.

Available Alternatives

Detailed assessments on possible alternatives were carried out recently (Maag et al.; 2010, COWI; 2009, ECHA; 2013, DEPA, 2010). Besides the hazard profiles of such substitutes, their use and technical feasibility were also determined. The results of these assessments show that the substitution of DBP by less harmful substances (e.g. ASE, DINCH) is possible and already being done. The use of DBP in EEE is not considered to be essential. However, some niche applications cannot be ruled out.

[57] According to 2000/532/EC one or more substance(s) toxic for reproduction of category 1 or 2 classified as R60, R61 at a total concentration ≥ 0,5 % mean(s) that H10 is fulfilled

Socio-economic impacts

In total, a ban on DBP in EEE would create limited additional costs (an estimated 2 million € annually) while creating additional benefits for health, environment and the economy.

The overall impact on jobs/employment is expected to be very small. While a few jobs are expected to be lost in industries where EEE is used (caused by a marginal increase in prices for EEE), some new jobs are likely to be created in the production of alternative plasticisers and in the environmental (chemical analysis) sector.

With respect to the benefits, however, the impact of a DBP ban is expected to be substantial (as compared to a scenario where considerable amounts of DBP continue to be used in EEE):

- Increase in the competitive position of an environmentally friendly industry
- Global reduction of environmental and health impacts from DBP and plastics production

Conclusion:

It is recommended that DBP should be included in Annex II to the RoHS-Directive. A restriction of DBP under RoHS is considered to be an appropriate measure to reduce any negative effects on WEEE management because:

- There are negative **impacts on waste management**, namely the reduced recycling possibilities because of the restriction of the use and manufacture of DBP in the EU under REACH.
- The **releases** from sites where WEEE are shredded are relevant contributors to the overall DBP releases from solid waste processing if measures for preventing dust emissions are insufficient.
- **Alternatives** with less negative properties are available and technically and economically feasible (e.g. ASE or DINCH)
- The description of the **socio-economic impacts** indicates that a restriction of DEHP would have several benefits, including reduced risks and a less negative impact on waste management. Additional costs would be incurred in some sectors, i.e. by producers of chemicals and in the production of EEE.

The proposed **maximum concentration value of DBP per homogenous material** to be tolerated in EEE is **0.1 weight %**. Given the level of risk identified when assuming a DEHP[58] concentration in PVC of at least one percent it can be expected that a maximum concentration of 0.1 weight% will lead to significantly reduced risks.

[58] A substance of equivalent concern

8.4 Detailed assessment of BBP

Below the main aspects and results of the detailed assessment are summarized. The full assessment is provided as a separate document attached to this report "RoHS_AnnexII_Dossier_BBP.docx".

Hazardous potential

Nature and reversibility of the adverse effects:

Substance of very high concern

BBP is a substance of very high concern because of the effects it has on fertility, the reproductive organs, development and endocrine activity. It has been found to adversely affect the reproductive organs in experimental animal studies. Furthermore, the substance has been found to be a developmental toxicant. The adverse effects reported in the animal studies include decreased anogenital distance, increases in male offspring with reproductive tract malformations, as well as effects on testicular migration.

The amount of BBP released during WEEE treatment

WEEE treatment compared to other waste treatment processes

The majority of environmental releases of BBP from relevant WEEE treatment processes[59] are releases to **air**. Annual releases are estimated to be **0.06 – 0.56** tonnes.

COWI (2009) provides a summary of the total releases of BBP in Europe during individual life-cycle stages (see Table 12): BBP releases from WEEE shredder sites were found to be a major source of emissions to air from the treatment of wastes. The estimated releases to air from WEEE treatment (**0.06 to 0.56 t/a**) are higher than releases from other disposal operations (**0.02 t/a**), even in a scenario where adequate measures for the prevention of dust emissions are taken (**0.06 t/a**).

Given that material streams derived from WEEE may be subjected to mechanical treatment several times during the whole treatment process, the actual releases are assumed to be even higher.

Furthermore, additional amounts of BBP are assumed to be emitted from landfills (predominantly to waste water), incineration plants (predominantly to air) and uncontrolled treatment of WEEE.

Releases from WEEE treatment compared to total BBP releases

Compared to the total releases of BBP to air (50 t/a) in Europe, releases from sites where WEEE is shredded are low.

[59] i.e. treatment of WEEE in shredders and handling of the shredded material

Table 12: Total releases of BBP (Source: COWI, 2009, Table 0-1)

Activity	Tonnage handled	Emission to (t/y):		
	t/y	Air	Soil	Waste water
EU manufacture of BBP	20,000	0.1	n.d.	220
Transportation of substance from manufacturing	20,000	0	0	1
Formulation	2,800	1	0.3	4
Processing	8,000	19	5.3	10
End-product uses	8,000	29	4.0	121
Disposal	7,740	0.02	0.2	1
Total releases (round)		50	10	360

Exposure of workers

Based on an estimated number of 450 installations in the EU where WEEE and materials derived thereof are treated mechanically[60] and assuming 5 to 15 workers per installation[61], the estimated range of workers exposed to BBP releases ranges between 2,250 to 6,750.

Based on the assumptions underlying this assessment, the exposure of workers to BBP in shredder plants for WEEE is low. However, monitoring data are missing. Health inspections should clarify if and to what extent workers in shredder plants are exposed to BBP.

Human health risk

Based on the assumptions underlying this assessment there is no expected health risk for workers from BBP exposure at WEEE shredding plants.

However, under comparably unsafe working conditions, e.g. in third countries, a risk from BBP exposure can be expected. Also residents in the neighborhood are likely to be exposed and, therefore, at risk.

An assessment of endocrine disruptors within the regulatory framework of the European Union is currently under discussion. As it is not possible to establish a threshold for the adverse effects of genotoxic carcinogens, the possibility for establishing such a threshold for endocrine disruptors is under debate. Therefore, releases of and exposure to endocrine disrupters such as BBP should be minimized.

Environmental exposure

Based on the assumptions underlying this assessment, the environmental exposure to BBP from WEEE treatment activities at shredder sites is low. However, monitoring data are missing.

[60] The estimate is based on the following: 220 (EC, 2012b) to 232 (IPTS, 2007) large-scale shredder plants are operated in the EU. According to information available from Austria (Umweltbundesamt, 2008) and France (contribution to stakeholder consultation, WEEE Forum) there are at least as many mechanical treatment plants for WEEE as there are large-scale shredders. Other stakeholders who participated in the project estimated that there were at least 100 installations. The total number of mechanical treatment plants was therefore estimated to be 450.

[61] Estimate based on Umweltbundesamt (2008)

Risk for the environment

Based on the assumptions underlying this assessment there is no expected risk for the environment from BBP exposure.

Main influencing factors within the risk assessment

There are 2 major factors influencing the result of the risk assessment:

- The annual quantities of BBP contained in the collected WEEE depend on: the actual BBP quantities put on the European market via EEE, the lifespan of EEE, the actual WEEE collection rate.
- The extent to which measures are applied for preventing diffuse emissions at WEEE shredder sites affects the estimated BBP releases considerably. However, there is no information available on the actual implementation of such measures.

The environmental exposure estimate is based on EUSES, which (as yet) does not address waste treatment specifically. Thus, appropriate scenarios were defined, and emissions and releases were calculated and used as input parameters.

Impact on waste management

The extent to which material recycling/recovery is affected:

Taking into account the regulations pertaining to the use of BBP (e.g. under REACH) it is expected that the recycling possibilities for plastics containing BBP will be reduced due to the presence of BBP in plastics derived from WEEE.

The extent to which BBP remains in the recycling loop

Under current operational conditions PVC is used for the production of low value articles (shoe soles, hoses etc.). Thus it is not assumed that BBP contained in PVC will stay in the recycling loop for long.

The amount of hazardous waste which is generated in the course of processing WEEE

Wastes with a BBP content of 0.5% are considered to be hazardous in accordance with the European list of waste (fulfilment of criterion H10, reprotoxic[62]).

As there is no information on the amounts of BBP actually contained in particular material streams resulting from the treatment of WEEE, no estimate can be produced of how much hazardous waste can be prevented through a potential restriction of BBP in EEE.

[62] *According to 2000/532/EC, one or more substance(s) toxic for reproduction of category 1 or 2 classified as R60, R61 at a total concentration ≥ 0.5 % mean(s) that H10 is fulfilled*

Available Alternatives

Detailed assessments of possible alternatives were carried out recently (Maag et al.; 2010, COWI; 2009, ECHA; 2013, DEPA, 2010). Besides the hazard profiles of such substitutes, their use and technical feasibility were also assessed. The results of these assessments show that the substitution of BBP by less harmful substances (e.g. GTA) is possible and already takes place. The use of BBP in EEE is not considered to be essential. However, some niche applications cannot be ruled out.

Socio-economic impacts

In total, a ban on BBP in EEE would create limited additional costs (an estimated 1.4 million € annually) while creating additional benefits for health, environment and the economy.

The overall impact on jobs/employment is expected to be very small. While a few jobs are expected to be lost in industries where EEE is used (due to a marginal increase in prices for EEE), some new jobs are likely to be created in the production of alternative plasticisers and in the environmental (chemical analysis) sector.

With respect to the benefits, however, the impact of a BBP ban is expected to be substantial (as compared to a scenario where considerable amounts of BBP continue to be used in EEE):

- Increase in the competitive position of an environmentally friendly industry
- Global reduction of environmental and health impacts from BBP and plastics production

The socio-economic impacts are based on a worst case scenario which shows the costs of replacing BBP in a scenario where substantial amounts of BBP are used in European EEE.

Conclusion:

It is recommended **that BBP should be included in Annex II** to the RoHS Directive. A restriction of BBP under RoHS is considered to be an appropriate measure to reduce any negative effects arising from - or on - WEEE management because:

- There are **negative impacts on waste management**, namely the reduced recycling possibilities because of the restrictions of the use and manufacture of BBP in the EU under REACH.
- **BBP releases** to air from sites where WEEE is shredded are higher compared to BBP releases from any other disposal operation.
- **Alternatives** with less negative properties are available and technically and economically feasible (e.g. GTA)
- The socio-economic impact analysis indicates that a restriction of BBP would have **several benefits**, including reduced risks and a less negative impact on waste management. Additional costs would be incurred in some sectors, i.e. by producers of chemicals and in the production of EEE.

The proposed **maximum concentration value of BBP per homogenous material** to be tolerated in EEE is **0.1 weight %**. Given the level of risk identified when assuming a DEHP[63] concentration in PVC of about one %, it can be expected that a maximum concentration of 0.1 weight % will lead to significantly reduced risks.

[63] A substance of equivalent concern

9 STAKEHOLDER CONSULTATION

9.1 Internet Consultation

After the project was launched more than 500 stakeholders were contacted via email to inform as many stakeholders as possible about the ongoing review process of Annex II to the RoHS Directive. The following types of stakeholders were contacted:

- Member States / EC representatives
  - RoHS Key Officials
  - RoHS Enforcement Network
  - TAC Waste Framework Directive
  - TAC RoHS-Directive/WEEE-Directive (provided by EC / DG Environment)
  - ECHA Member States Committee
  - RAC Risk Assessment Committee
  - TWG for BREF Document (BAT) on Waste Treatment Industries
- NGOs/Industry
  - Consultancies
  - EEE industry
  - EEE industry associations
  - NGOs
  - Recyclers & waste treatment operators
  - Recyclers & waste treatment operators associations
  - Research industry & universities
- Persons and institutions which were involved in previous consultations of the ROHS directive and other akin regulations (provided by EC / DG Environment)

9.1.1 1st internet consultation

The 1st internet consultation was conducted from 20 January 2013 to 10 February 2013. It was aimed at the development of an identification methodology. A questionnaire was provided with the following main question: Which substances or compounds which are hazardous to human health and the environment (e.g. classified according to Reg. 1272/2008/EC, identified as PBT or vPvB) are used in electrical and electronic appliances?

For each substance or compound the following information was requested:

- Name of substance
- CAS number
- Other specifications
- Use in electrical and electronic appliances
  - Type of use (widespread or special application / single type)
  - Used in which type of component or application
  - Function of the substance

  - Type of appliance
- Comments

Out of 543 stakeholders that were contacted the following responded to the questionnaire:

Table 13: Feedback to the questionnaire

Denmark – Danish Ministry of the Environment
Apple
Daikin Europe
Electrolux
ERA Technology
Japan Plasticizer Industry Association
JBCE - Japanese Business Council in Europe
OSRAM (Lamps and lighting systems)
Panasonic
Schott AG (Glass industry)
TechAmerica Europe & DigitalEurope

**...Representing the Test & Measurement Coalition and Molecular Weight Group Manufacturers (LMW)

9.1.2 2nd internet consultation

During the 2nd stakeholder consultation the **methodology approach for the identification and assessment of substances** for a potential restriction under RoHS 2 was put up for discussion. The 2nd internet consultation was conducted from 20 February 2013 to 13 March 2013.

Generic comments on the review process regarded:

- The involvement of ECHA and related committees / same procedure as for restriction under REACH?
- The question of who will assess, how often etc.
- Recommendations for better implementation of REACH (Commission´s SVHC roadmap)
- Recommendations for better implementation of waste & worker´s health legislation

The most relevant comments regarding the identification of substances were:

- The term “candidate substances” may give rise to misunderstandings due to its use under REACH
- Additional sources such as IEC, SPIN database were proposed
- Waste aspects should be given more weight in the identification
- Frequency of listings as an assessment criteria
- Grouping of substances

The most relevant comments regarding the pre-assessment of substances were:

- Consideration of existing/expected regulations, e.g. POP
- How to consider nano-materials
- Voluntary restrictions; Use pattern not appropriate
- Take into account existing scoring systems for hazards (e.g. Green screen)
- Integration of biomonitoring data

The most relevant comments regarding the detailed assessment of substances were:

- Importance of “coherence” with REACH
- Full assessment of all substitutes / alternatives was seen to necessary
- Consider provisions of waste legislation and occupational health

Table 13 summarizes the stakeholder contribution during the 2nd internet consultation. The comments were published on the project website.

Table 14: Feedback during 2nd stakeholder consultation

Member States / EC representatives
Danish Ministry of the Environment (.pdf)
Norwegian Ministry of the Environment (.pdf)
Swedish Chemicals Agency (.pdf)
NGOs and Consultancies
ChemSec (.xls, .pdf)
ERA Technology (.xls)
Industry
AmCham EU - American Chamber of Commerce to the EU (.pdf)
BASF Group (.xls)
CECED - European Committee of Domestic Equipment Manufacturers ()
DIGITALEUROPE; TechAmerica Europe (.pdf, .pdf)
Diodes Zetex Semiconductors (.xls)
EDMA - European Diagnostic Manufacturers Association; Eucomed Medical Technology; ORGALIME - The European Engineering Industries Association (.xls, .pdf, .pdf)
EFRA - European Flame Retardants Association; CEFIC - European Chemical Industry Council (.pdf)
ESIA - European Semiconductor Industry Association (.pdf)
Eurometaux - European Association of Metals (.pdf)
Hewlett-Packard Company (.pdf)
IPC - Association Connecting Electronics Industries (.pdf, .doc)
JBCE - Japanese Business Council in Europe (.pdf)
JPIA - Japan Plasticizer Industry Association (.xls)
Low Molecule Weight Phthalates Coalition (.pdf, .pdf)
NIA - Nanotechnology Industries Association (.pdf)
ORGALIME - The European Engineering Industries Association; CEFIC - European Chemical Industry Council (.pdf)
PlasticsEurope; PlasticsEurope Deutschland (.pdf, .pdf)
SEMI (.xls, .doc)
Test & Measurement Coalition, representing cat. 9 industrial products (.pdf, .pdf)
TIE - Toy Industries of Europe (.xls)

9.1.3 3rd internet consultation

During the 3rd stakeholder consultation the draft methodology manual was put up for discussion.

In total 19 stakeholders provided comments (the main contents are listed in Chapter 9.1.2).

9.1.4 4th internet consultation

During the 4th stakeholder consultation the **results of the detailed assessments of HBCDD, DEHP, BBP and DBP** (RoHS-AnnexII-Dossiers) were put up for discussion. The consultation period lasted from 22 October to 25 November, 2013.

In total 33 contributions were received. Many comments were of a general nature. A comparably small number of specific pieces of information about the assessed substances was provided. Furthermore, several statements were received that data is insufficient or wrong, however, without providing the requested robust information.

Below, please find a summary of the most important comments.

Specific information provided

The following specific data and information was provided:

- Information on the concentrations of phthalates in soft PVC waste (DEHP: 7.5%, BBP and DBP: 0.1%).
- European figures for 2010 for the plastics demand of the E&E sector per plastic type (9.7% PS, 4.3 % PVC)
- Exposure measurements of workers at sites where cables resp. PVC derived thereof are treated (shredding/sorting and recycling)
- Information on the share of DEHP containing PVC in cables (80%) and other parts (20%)
- A risk assessment report was provided for DEHP issued by the Japanese National Institute of Advanced Industrial Science and Technology (AIST)
- National data on the amounts of PVC derived from recycled cables (80%) and on the numbers of waste treatment plants.
- Information on treatment options (processes) for plastics waste.

Comments on the assessments

The following information used in the assessments was stated to be wrong, too unspecific, or not robust enough:

- The use amounts of the substances assumed for the assessments. It was pointed out that the estimates used were based on out-dated data, which did not take into account the recent developments caused by REACH. For example, it was stated that the share of HIPS in EEE containing HBCDD in Europe was less than 5% (as used for the assessment). Several stakeholders said that the use amounts were actually lower for all four substances. Especially a confirmation of the use of BBP and DBP in EEE was claimed. However, the information provided was not underpinned by robust data on EEE brought onto the European market.
- Costs of a ban for EEE-producers. It was stated that a restriction would lead to considerable costs for EEE producers because
  - The alternatives may change life-time and other technical characteristics of the EEE products
- One should consider the costs to prove that the components of the EEE-products are free from the substance to be banned
- Costs for developing, testing and approving alternative substances should be taken into account.

However, no estimates for these costs were provided.

Comments on the methodology

The following comments were made on **aspects**, which are evaluated within the **detailed assessments**:

- A full assessment of alternatives including LCA, and an explanation of burden-shifting etc. was requested
- A description of uncertainties of the results was requested
- A quantification of the materials that are "actually" not recycled due to the presence of the substance in question (e.g. on account of the REACH regulation).
- A justification why a European Union-wide restriction is the appropriate measure
- A justification that the suggested maximum concentration reduces the risk
- A quantification of the benefits within the description of the socio-economic analysis

The following **approaches chosen for the detailed assessment** were criticized:

- Sub-optimal working conditions at waste treatment sites should be considered as well (It was stated that compliance with OHS-regulation should be assumed at waste treatment sites. (e.g. that gloves and masks would be worn in any case, where necessary)).
- Using of information from studies performed in non-EU countries as an indication of a potential risk from the substance of concern.

It was claimed that the **criteria which eventually lead to a decision on a recommendation for a restriction** of a substance are not adequately explained in the manual. The manual was amended accordingly.

Comments on the outcomes of applying the developed methodology

The following comments were made on **substance prioritization**:

- The groups brominated and chlorinated flame retardants as well as PVC are under discussion for a potential restriction in EEE and some industry stakeholders do not appreciate that these groups were not part of the ones being assessed in detail during the project, as they would have preferred to eliminate the uncertainties about that.
- The information used for prioritization is not sufficient (actual impacts should be relevant ranking criteria).

It was claimed that for **Category 8 and 9** appliances longer periods for application of a ban will be needed.

Generic comments on the project/consultation process

The following generic comments on the project / consultation process were made:

- Too little time was foreseen for the stakeholder consultations during the project (several months were suggested)

9.2 Stakeholder Meetings

Three stakeholder meetings initiated by the project team were performed during the project. They were held in Brussels on March 13, May 14 and October 28. The minutes of all meetings are provided in the Annex (Chapter 13.9)

In addition, Umweltbundesamt organized additional meetings with stakeholders during which several project relevant issues were discussed in detail. The list below gives an overview of these meetings.

Table 15: Additional stakeholder meetings held at Umweltbundesamt

Initiator / Date of meeting	**Participants**	**Topics**
ZVEI / 29.4.2013	Eilken Bodu, Brenner Axel, Koring Andre, Thomas Fischer, Richard Lax, Uwe Blumenstein	Special issues regarding regulation of chemicals under REACH and RoHS
Hewlett Packard / 13.06.2013	Telephone conversation with Pieter Paul Laenen, Helen Holder, Ray Moskaluk	Activities of HP related to substitution of hazardous compounds in EEE
CEFIC / 7.5.2013	Timmermans Liesbeth, Karall Julianna, Kohl Florian	Discussion of special issues of the methodology
Plastics Europe / 22.07.2013	Arjen Sevenster, Geoffrey Tilleux, Heinz Schratt	soft PVC recycling, DEHP authorization / recyclers concerns life cycle stages covered, elements for evaluation, timing and consequences for the recycling industry, identification of specific information needed by Umweltbundesamt in the frame of the assessment
Plastics Europe / 20.11.2013	Geoffrey Tilleux, Klaus Schneider	Exposure measurements regarding DEHP performed by plastic recyclers in the context of a foreseen authorization under REACH for DEHP in recyclates

In addition information on the project was provided in the context of an invitation by FEEI – the Association of the Austrian Electrical and Electronics Industries at the Austrian Chamber of Commerce on March 18, 2013 and the German Fraunhofer Institut in Berlin on June 11, 2013.

9.3 Project website

The project website was included in the RoHS section of the Europa website hosted by the Commission. Static pages were produced / maintained by Umweltbundesamt and approved / launched by the Commission.

http://ec.europa.eu/environment/waste/rohs_eee/review/index_en.htm

Download documents and additional information for the stakeholder consultation process (internet consultations and stakeholder meetings) was/is provided at the Umweltbundesamt website:

http://www.umweltbundesamt.at/rohs2

The main contents of the website are:

- Home (Welcome)
- Introduction (Information on the overall project issue)
- News (Changes of the website, Launches of consultation procedures)
- Project overview (Detailed workplan)
- Project schedule (Milestones and overall project schedule)
- Public consultation (background material and documentation)
- Stakeholder meetings (presentations, minutes)
- Interim and Final Results (reports, substance lists, dossiers)

10 OVERALL CONCLUSION / OUTLOOK

Motivation

The activities described in this project report were conducted in the context of the **first review of Annex II** to the RoHS2-Directive on the Commission´s initiative, which is requested to be completed by June 2014.

Assignment of the project outcomes

The developed **methodology** and the **manual,** respectively, are intended as guidance for the Commission Services to be used in any future review of the list of restricted substances in EEE. This includes both reviews on the Commission´s initiative and reviews initiated by submission of restriction proposals by Member States. In addition, the "***EEE-substance-inventory"*** containing more than 700 substances, the "***list of substances which may cause risks for the environment or workers during WEEE management or have any other negative impacts on waste management***" (=result of substance identification) and the "***list of substances ranked according to their priority for a detailed assessment with the view of a potential restriction under RoHS***" (= result of pre-assessment of substances) are destined to be used as starting points in future reviews on the Commission´s initiative.

Member States may use the **manual** too, when they intend to make a restriction proposal.

The **detailed assessments of the 4 substances** (HBCDD, DEHP, BBP and DBP) prepared during this project - in particular the rationale as to why a Union-wide restriction should be considered - provide the basis for an amendment to Annex II to the RoHS Directive by the Commission Services in 2014.

Conclusions from the stakeholder involvement

The consultation process accompanying the development of the method and its initial application revealed that there are several aspects where fundamentally **different viewpoints** concerning the **implementation of Article 6 of RoHS2** exist between different stakeholders**.** The key issues can be summarized as follows:

The RoHS Directive sets rather generic provisions as to how to review the list of restricted substances. Thus it turned out to be difficult to find a common understanding of the **differentiation between the method, describing how to perform a "thorough assessment" of substances, and the procedural aspects of the political process** of **amending Annex II of RoHS**.

In-depth discussions regarding the **scope of a "thorough assessment"** of substances as requested by Article 6 of the RoHS Directive and the interpretation of the term "**coherence with REACH**" in this context took place.

Several industry stakeholders expected that the principles established for substance assessment under REACH would be transferred to RoHS assessments in a rather unmodified way. That includes quality requirements for the information used, e.g. used data are up-to-date, quantification of impacts, assessment of socio-economic impacts and alternatives as well as a scientific review processes. Furthermore, the corresponding institutional set-up in particular the role of the scientific bodies of the European Chemicals Agency ECHA is specified in detail.

During the current RoHS project the Commission Services definitely clarified that a "thorough assessment" of substances as requested by the RoHS-

Directive is not to be performed the same way as a substance assessment under REACH. The outcome of a substance assessment under RoHS has to be robust and science based but quantitative impact assessments are not obligatory. There is also no legal basis within RoHS to demand a full socio-economic-analysis, but a description of the impacts has to be made. The provisions of Article 6 (2) need to be considered in the assessment.

Conclusions drawn from the initial application of the developed method

From **developing** the method and **applying it for the first time** during the present project, the following conclusions can be drawn:

- Little **information** may be available on the **actual quantities of the substances used in EEE entering the European market**. One reason is, that a large proportion of EEE, respectively its components, is produced outside the EU, where even less information about the use of particular chemicals is available than in the EU. Another reason is, that available use data may not reflect recent changes in substances´ markets, e.g. caused by changes in the chemicals legislation.

  Options to overcome these constraints are estimating plausible ranges of use quantities and chemical analyses of electrical & electronic appliances.
- **Little comprehensive information** is currently available on **WEEE treatment** in Europe; including the overall number of particular installations, information about releases of the substances of concern, detailed descriptions of the exposure of workers or exposure measurements at WEEE treatment plants. The latest EU-wide[64] study compiling information on WEEE treatment dates from 2007[65].

  It is expected that for the next cycle of substance assessments some of these data will be available from the BAT-Reference Document for the Waste Treatment Industries (BREF WTI), which is currently under revision. Treatment of metal wastes including WEEE in shredders was so far not included in the document. Since the latest amendment of the list of industrial activities by the IED-Directive, however, it is. Where no data are available scenarios based on best possible estimates have to be established and used for the substance assessments.
- Applying the developed methodology revealed, that the chosen approach for risk assessment is suitable to **estimate an unacceptable exposure of workers** and **concerns for the environment**.

  A risk assessment of a chemical is based on a hazard assessment and an exposure assessment. For an exposure assessment usually defined exposure scenarios are used. In the course of the implementation of REACH tools for estimating exposure concentrations based on these scenarios were developed. Within this project the ECETOC TRA (targeted risk assessment) tool[66] was used to assess human exposure and the EUSES 2.1.model was used to calculate predicted environmental concentrations. These tools are commonly used and accepted for exposure and risk assessment of chemi-

[64] EU-15

[65] HUISMAN, J. ET AL. (2007): 2008 Review of Directive 2002/96 on Waste Electrical and Electronic Equipment (WEEE).

[66] http://www.ecetoc.org/tra

cals and biocides. However exposure scenarios of waste treatment processes have not been integrated in these tools yet. As a consequence of the above mentioned lack of detailed information about WEEE treatment, the exposure scenarios for the substance assessments in this project were approximated using exposure scenarios for most applicable industrial processes as available from the REACH implementation process.

- **Measures to deal with particular hazardous substances** may be discussed under **several pieces of chemical legislation**. The fact, that a substance is a candidate for a future regulation under the POPs-Regulation, REACH or any other law does not mean that a restriction under RoHS should not be considered. A restriction under RoHS will also apply to imported EEE, whereas a ban of manufacturing and using a substance in the EU according to Annex XIV, REACH, for example, does not affect imported goods.

Conclusions drawn from the substance assessments

For the particular substances (HBCDD, DEHP, BBP and DBP) assessed in detail within this project the following is concluded:

Risks for the environment

HBCDD is recommended for restriction under RoHS as a **risk for the environment** is expected from both shredding of WEEE and recycling of HBCDD containing HIPS from WEEE, is expected. Risks for the aquatic compartment and for secondary poisoning were identified. Based on exposure estimates for workers involved in the recycling of HBCDD containing plastics performed with the ECETOC TRA targeted risk assessment tool a **risk to human health** of workers cannot be precluded. Generally, HBCDD has been included as POP to the International Stockholm Convention and is as such subject to minimization on a global scale due to risks identified for human health and the environment.

The investigated **phthalates** are recommended for restriction under RoHS too.

A **risk for the environment** is expected due to treatment of **DEHP** containing WEEE in shredders, due to shredding of cables and recycling of PVC derived from WEEE. There is cause for concern regarding the risk for secondary poisoning of mammalians and birds.

DBP is very toxic to higher plants. Effects on common European species[67] have already been detected at DBP concentrations in the air of 0.1 µg/m^3 (mean EC_{10}[68] concentrations 0.12 - 4.48 µg/m^3). ECETOC modelling data predict concentrations of 0.1-0.7 µg/m^3 at shredding facilities. EUSES modelling data for environmental exposure generated within this project are lower (0.02 to 0.03 µg/m^3). However, it cannot be excluded that concentrations at shredding facilities, especially at high temperatures exceed the PNEC of 0.1 µg/m^3.

For **BBP** no risk for the environment from shredding of WEEE was identified.

Risks for Human Health

The European risk assessment report on **DEHP** concluded that there is a need for limiting the risks from the use of DEHP at workplaces. Several risk reduction

[67] including bean, cabbage, spruce, white clover, plantain and common velvet grass
[68] Effective concentration 10%:

measures have been taken so far. For **waste treatment activities** only limited information on working conditions and risk for workers is available. Single measurements at shredding facilities conducted by Plastics Recyclers Europe (EuPR) found exposure concentrations below the relevant reference values DNEC and DNEL with short exceedances during specific tasks (i.e. loading activities)[69]. These measurements, although limited, are in line with the results of the ECETOC modelling for shredder facilities during the activities in this project. It can be concluded, that specific tasks in shredding and recycling facilities may lead to exposure concentrations above the reference value (DNEC) derived by the Risk Assessment Committee (RAC) of the European Chemicals Agency. Therefore it can be concluded that a **health risk for workers from DEHP cannot be excluded**. Risk assessments based on exposure estimates for **DBP** and **BBP** indicate that no risk for human health of workers at recycling facilities is expected.

There is increasing evidence and requests from various scientists and institutions[70] that for similarly acting chemicals (such as certain phthalates, e.g.: DEHP, DBP and BBP) **a cumulative risk assessment** should be performed. Combination effects of chemicals have also been addressed by the European Commission and the European Council[71]. Taking into account that the effects of the reprotoxic phthalates are cumulative and taking into account the precautionary principle as requested by RoHS it is recommended to restrict all assessed phthalates in EEE.

Waste management

All four substances have additional negative impacts on **waste management.** These include in particular reduced recycling possibilities for WEEE plastics due to the use prohibitions and restrictions of these substances and the generation of considerable amounts of hazardous wastes. In addition, HBCDD is expected to remain a long time in the recycling loop.

Alternatives

Furthermore for all of the investigated substances **alternatives** with less negative properties are available and technically and economically feasible.

Socio-economic impacts

The description of socio-economic impacts of a ban of the 4 substances did not reveal exorbitantly high costs, whereas the above mentioned negative impacts can be reduced.

[69] FoBig, 2013
[70] SCHER, SCCS, SCENIHR, 2012, NRC 2008; Kortenkamp 2009; Wittasek, 2011
[71] http://ec.europa.eu/environment/chemicals/effects/effects_en.htm

Proposal for the on-going review of the list of restricted substances under RoHS

Beyond the technical aspects of identifying and assessing substances under RoHS it is proposed to consider the following aspects when reviewing Annex II to RoHS2 in future.

- The periodic review on the Commission´s initiative should be performed **every 4 years**.

  This is in concordance with the approach for the adaptation to the scientific and technical progress regarding exemptions from RoHS restrictions and was supported by a majority of stakeholders involved in the project.
- If Member States submit restriction proposals before mid-term between two reviews an **additional review** shall be performed. Restriction proposals submitted after mid-term should be integrated within the regular periodic reviews.

Proposed steps

Within each review cycle the following steps should be taken:

- Up-date of the substance inventory, the list of substances which may cause risks for the environment or workers during WEEE management or have any other negative impacts on waste management and - if necessary - the ranking of substances regarding to their priority for a detailed assessment.

  This includes in particular an up-date of the status of harmonised classification[72] and self-classifications[73]. Further up-to date information on potential negative effects of nano-materials used in EEE[74] has to be considered.
- Estimation of the **use quantities** of the substances / elements / substance groups on the **priority list** and evaluation of the availability of **substitutes** for these substances before deciding which substances will be assessed in detail.
- If a prioritized substance representative of a group of substances with structural similarities (and/or identical physical and chemical properties, similarities in the toxicological profile) and if, moreover, those groups of substances, co-occur in WEEE and have an negative impact at the WEEE process and/or represent a risk to environmental or human health a **grouping approach** should ideally be performed.
- When a **risk during WEEE treatment was identified** for a substance in the detailed assessment, all substances in the same priority group and in the next lower group should be immediately assessed in detail during the same assessment cycle.
- For substances where **no risk** was identified in a detailed assessment but where **increasing quantities in EEE are likely** to occur in future, e.g. because they substitute other, meanwhile restricted, substances, the actual use amounts should be evaluated in the next assessment cycle.
- For substances where a restriction in EEE was not recommended/decided because of **unavailability of less hazardous alternatives**, these preconditions should also be verified during the following assessment cycle.

[72] ATP update

[73] CLP-inventory

[74] Several substances are used at very small size or with a very small internal or surface structure (nano-materials) are used in EEE. There is an on-going discussion whether release during waste treatment of products containing nano-materials could lead to unacceptable exposure concnetrations.

- The experiences from the current project indicate that **sufficient time for stakeholder consultation** in the context of detailed assessments should be foreseen.

Future activities by the Commission in the on-going review process of Annex II

The Commission Services plan to establish a **working group** consisting of maximum 12 members including most active stakeholders from Member States, NGOs, consultancies and industry. The working group will accompany the on-going process of reviewing Annex II of RoHS2. Tasks of the working group will include an adjustment of the RoHS review process to developments under REACH and other pieces of chemical legislation (including an exchange with ECHA and its scientific bodies) and strategies for handling lacks of essential data.

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12 ABBREVIATIONS

ABS .....Acrylonitrile butadiene styrene

AEL.....Acceptable exposure level

ASE .....Alkylsulphonic phenylester

ATP .....Adaptation to Technical Progress to the CLP Regulation

BAT AEL.....BAT associated emission level

BAT .....Best available technology

BBP .....Butyl benzyl phthalate

BCF .....Bio-concentration factor

BMD .....Bench mark dose

BREF WTI .....Reference document on best available techniques for the waste treatments industries

BREF.....Best available technology references document

bw.....Body weight

CAS.....Chemical Abstract Service

CLP .....Classification and Labelling regime

CMR .....Carcinogenic, Mutagenic and toxic to Reproduction

COP.....Conference of parties

CRT .....Cathode ray tube

CSR.....Chemical safety report

DBP.....Dibutyl phthalate

DBT .....Dibutyl terephthalate

DecaBDE .....Decabrominated diphenylether

DEHP .....Bis (2-ehtylhexyl) phthalate

DEP.....diethyl phthalate

DGD .....Dipropylene glycol dibenzoate

DIDP.....Di-disodecyl phthalate

DINCH.....Di-isononyl-cyclohexane-1,2dicarboxylate

DINP.....Di-isononyl phthalate

DMEL .....Derived minimum exposure level

DNEC…….Derived no effect concentration

DNEL.....Derived no effect level

dw.....Dry weight

ECETOC TRA ....European Centre for Ecotoxicology and Toxicology of Chemicals: (industry association for developing science in human and environmental risk assessment of chemicals) Targeted Risk Assessment

ECHA ..... European Chemicals Agency

EEE ..... Electrical and electronic equipment

EPS ..... Expandable Polystyrene

EUSES ..... The European Union System for the Evaluation of Substances

GD ..... Gestational day

GTA ..... Glycerol Triacetate

HBCDD ..... Hexabromocyclododecane (same as HBCD)

HDPE ..... High density polyethylene

HIPS ..... High impact polystyrene

IED ..... Industry Emissions Directive

IT ..... Information technology

Koc ..... organic carbon normalised distribution coefficient

LD ..... Lethal dose

LEV ..... local exhaust ventilation

LOAEL(s) ..... Lowest observed adverse effect levels

Log KoW ..... ratio of concentrations of a compound in water and octanol; measure of lipophilicity.

MBT ..... mechanical-biological treatment

MOS ..... Margin of safety

MSW ..... Municipal solid waste

NOAEC ..... No observable adverse effect concentration

NOAEL ..... No observable adverse effect level

OEL ..... Occupational exposure level

PAE ..... Phthalic acid esters

PBDF, PBDD ..... Polybrominated dibenzofurans/dioxins

PBT ..... Persistent, bioaccumulative and toxic

PC ..... Polycarbonate

PCB ..... printed circuit board

PCDF, PCDD ..... Polychlorinated dibenzofurans/dioxins

PE ..... Polyethylene

PEC ..... Predicted effect concentration

PM ..... Particular matter

PND ..... Postnatal day

PNEC ..... Predicted no effect concentration

POD ..... Point of departure

POP ..... Persistent organic pollutant

PP.....Polypropylene

PPE .....Polyphenylene ether

PVC .....Polyvinyl chloride

QSAR .....Quantitative Structure-Activity Relationship

RAC.....Risk assessment committee

RAR.....Risk assessment report

RCR.....Risk characterisation ratio

REACH .....Registration, Evaluation, Authorisation and Restriction of Chemicals

RFair.....Release factor to air

RoHS.....Restriction of Hazardous Substances

SAN.....Styrene acrylonitrile

SCCP .....Scientific Committee on Consumer Products

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

SMEs .....Small and medium sized enterprises

STOT RE.....specific target organ toxicity: repeated exposure

STP .....sewage treatment plant

SVHC .....Substance of Very High Concern

TBBPA.....Tetrabromobisphenol A

TDI.....Tolerable daily intake

vPvB .....very Persistent and very Biooaccumulative

WEEE .....Waste electrical and electronic equipment

WPP .....Waste processing plant

XPS .....Extruded polystyrene

XRF .....X-ray fluorescence screening

13 ANNEX

13.1 Manual on the Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive

Separate document

13.2 ROHS Annex II dossier - Template

Separate document

13.3 Inventory of substances used in EEE

Separate document

13.4 Priority List

Separate document

13.5 ROHS Annex II dossier – HBCDD (detailed assessment)

Separate document

13.6 ROHS Annex II dossier – DEHP (detailed assessment)

Separate document

13.7 ROHS Annex II dossier – BBP (detailed assessment)

Separate document

13.8 ROHS Annex II dossier – DBP (detailed assessment)

Separate document

13.9 Minutes of the stakeholder meetings

13.9.1 Minutes of the 1st stakeholder meeting

The meeting was held on Wednesday, 13 March 2013 in Brussels, Rue de la Science 15, 1040 Brussels, room 00/NYERERE.

Aim of the meeting was the presentation and discussion of the proposed methodology for the identification and assessment of substances for a potential restriction under RoHS2. A list of participants is provided at the bottom of this document.

The topics of the agenda were presented and discussed in the following order:

1) Introduction/Background on RoHS2
2) Overview presentation of the project
3) Presentation of the proposed identification methodology
4) Presentation of the proposed pre-assessment methodology
5) Presentation of the proposed assessment methodology and the proposed RoHS-Annex II-Dossier
6) Outlook (next steps and up-coming events)

The minutes of the meeting and the presentations held by Umweltbundesamt are available at:
http://www.umweltbundesamt.at/rohs2

1 Introduction/Background on RoHS2 (Commission)

A description of the legal procedure of reviewing and amending Annex II of RoHS2 and the context of the ongoing study was given by the Commission (Mr Eberl):

The legal instrument for amending Annex II pursuant to Article 6(3) is a delegated act. Due to the requirements for the procedure of delegated acts a comprehensive impact assessment of substance restrictions is not required. A Member States expert group for RoHS delegated acts was already registered when the first series of amendments to Annexes III and IV (exemptions) was launched in 2012. When preparing a proposal for an amendment of Annex II the Commission has to consult the respective expert group. It is possible to restrict one or several substances in one delegated act.

Depending on the findings of the ongoing study, in particular taking into account recommendations for the restriction of individual substances, the Commission will table a legal proposal for an amendment of Annex II of RoHS2. A draft delegated act is then presented to the Member States expert group. After inter-service consultation the delegated act will be adopted by the Commission. If the

European Parliament and the Council do not revoke the amendment within 2 (or 4) months, the measure has been accepted and will be published in the Official Journal.

2 Overview presentation of the project (Umweltbundesamt)

The project, in particular the project objectives, schedule, expected outcomes and opportunities for stakeholder contribution were presented by Ms Karigl.

Discussion of Top 1 + 2:

Information exchange between MS expert group and TAC

It was explained by the Commission, that there are no specific rules for the exchange of information between the MS expert group and the TAC. Nevertheless, there is a personnel overlap between the two groups, and the TAC will be notified of all COM activities regarding delegated acts.

Context between and the methodology to be developed in this study and the RoHS2-Directive

It was clarified that the methodology will not be incorporated into Directive 2011/65/EU, but shall serve as guidance for any review of Annex II (list of restricted substances) of the Directive. The Directive does not elaborate on the assessment of substances after the submission of restriction proposals by Member States, but the methodology developed in this study should provide the rules for any review.

Coherence RoHS/REACH

The meaning of “coherence of RoHS and REACH” as requested in Article 6 RoHS2 was discussed:

It was clarified that there is neither a legal mandate nor an obligation to copy the procedure of substance restriction under REACH, including the institutions involved. The responsible body for the assessment of substances with a view to a potential inclusion in Annex II of RoHS2 is the Commission. For future reviews, in the opinion of the Commission the only option is that a consultant is commissioned to perform the scientific part of the assessment by applying an agreed methodology.

It was further clarified that there is no legal requirement that ECHA and its committees play a role under RoHS. An informal involvement of ECHA is beneficial and also takes place in the present study.

Under REACH, industry has to prove that there is no risk arising from a substance to be placed on the market, whereas the restriction of a substance under RoHS2 by the Commission has to be based on an assessment showing that the

use of the substance in EEE may cause a risk or other negative impacts during end-of-life management of EEE.

It was mentioned that it would be advantageous for developing and applying the methodology to consider current developments in REACH. This is already foreseen within the proposed assessment procedure.

3 Presentation of the proposed identification methodology (Umweltbundesamt)

The draft identification methodology was presented by Ms Uhl.

Discussion related to Top 3:

Data sources

It was suggested to use the databases provided by the Joint Industry Guide and IEC (International Electrotechnical Commission) for establishing the inventory of substances in EEE and to focus attention on up-dating used data during future reviews. It was clarified that the information on the use of particular substances as contained in registration dossiers under REACH are not publicly available and can thus not be used for the identification of substances used in EEE. Additional lists delivered by stakeholders to increase the quality of the database are welcome, updating regarding new and relevant data is foreseen to be a part of the methodology.

Criteria for identification

One comment on the identification method was, that the end-of-life phase should already be considered at this early stage of the methodology. Substances which lead to dangerous degradation products during WEEE management can be added within this step by including additional lists. It was further recommended by stakeholders that company restriction lists should be used carefully, as substances banned on these lists do not necessarily pose a risk but may be banned for other reasons, e.g. product quality, marketing etc. Only substances which are voluntarily restricted due to hazardous properties will be further assessed; this will be specified in the refined methodology.

It was suggested that the number of listings should not be taken as a criterion for the identification of relevant substances. Within the proposed methodology it is foreseen that the number of listings is only taken as an additional indicator, and not as identification criterion.

Further aspects

Grouping of identified substances for their combined assessment was discussed in detail. It was mentioned that the restriction of substance groups may help avoiding that similar substances will be listed one by one, leading to exceeding administrative efforts. It is also in line with RoHS to assess substance

groups collectively. On the other hand, it was stated that in some cases grouping will lead to listing of harmless substances which deal as alternatives to harmful substances within one group (e.g. phthalates).

It was agreed that grouping of substances will be considered when fine-tuning the methodology, as far as appropriate, due to the requirements of ROHS2.

It was discussed whether the substance evaluation process under REACH may result in a risk management measure in RoHS. As RoHS and REACH do not refer to each other it is not foreseen in the context of the substance evaluation process under REACH to cover restrictions in RoHS.

4 Presentation of the proposed pre-assessment methodology (Umweltbundesamt)

The draft pre-assessment methodology was presented by Ms Cladrowa.

Discussion related to Top 4:

Consideration of nano-materials

The approach how to consider nano-materials under RoHS was discussed in detail. It was mentioned that substance classification under CLP does not take into account the use of a substance as a nano-material. Nano application per se provides no evidence for hazardous properties and should therefore not be part of the scoring system. It was further discussed that methodologies for testing nano-materials are currently under development. The consultant stated that only in case there is evidence for the release of nano-particles at the waste phase, and potential danger to human health and/or the environment has been identified, nano-application will lead to scoring.

As far as nano-materials are explicitly mentioned in ROHS2 (“including materials of very small size”), nano-materials have to be considered. It was agreed that the responsible desk officer of the Commission will be contacted by Umweltbundesamt to provide recent literature and data on nano-materials.

Criteria applied for prioritization of substances

Prioritization of substances is mainly based on harmonised classification of substances according to CLP, but also additional criteria such as endocrine disrupting properties will be taken into account.

The proposed scoring system was discussed. Higher scores for carcinogenicity were suggested. It was clarified that the proposed scores have to be seen as a starting point for discussion and will be adapted during methodology refinement.

It was asked if a scoring system for a similar topic was known, but so far there was no experience in the auditory.

5 Presentation of the proposed assessment methodology (Umweltbundesamt)

The draft assessment methodology was presented by Ms Uhl.

Discussion related to Top 5:

Criteria applied for the risk assessment

When using monitoring data for risk assessment, other applications of the substance than use in EEE should be taken into account.

Evaluation of substitutes

Evaluation of substitutes was discussed in detail. It was mentioned that a complete LCA may be required for all possible substitutes. However, it was agreed that there are limits for the assessment under RoHS and the focus of this Directive is explicitly on the end-of-life stage.

It was clarified that the existence of proper substitutes is not a pre-requisite for a possible new substance restriction under RoHS, since there is a mechanism for exemptions from restriction.

Consideration of waste management under uncontrolled conditions

Consideration of waste management under sub-optimum conditions was discussed in detail. Whereas one view was to concentrate on proper waste management only, the other view was that uncontrolled handling in third countries is the reality and should be taken into account. It was suggested that at least severe acute effects (lethality, skin burn, etc.) should be taken into account.

General comments on the overall methodology

Stakeholders suggested to rely on data and methods developed under REACH. Indeed it is foreseen to use available data and methods, but, as foreseen under ROHS, to focus on the waste stage.

There was a general agreement that the methodology for identification and assessment of substances should be risk-based. The key issue of the assessment methodology is to clearly describe the negative impacts of a substance which justifies the restriction under RoHS.

The question was raised whether the quantity of flame retardants in materials should be evaluated with regard to its technical justification. There was an agreement that addressing this topic scientifically would exceed the scope of the project.

It was proposed to use results of a current EU project on flame retardants “enfiro”.

Scope / system boundaries of the methodology:

It was clarified that the criteria mentioned in RoHS2 Article 6 (1) a, b, c refer to the end-of-life stage only (not to the use phase). Risks occurring during the use phase of EEE should be dealt within the context of regulation of chemical and product safety.

Other topics discussed

It was suggested to consider the efforts necessary for compliance testing, for industry and authorities, when recommending a substance for restriction.

There were concerns that further substance restrictions will lead to a flood of exemptions, and how to handle them.

6 Conclusion and Outlook

Participants of the meeting agreed to the overall approach for the methodology for the identification and assessment of substances for potential restriction under RoHS2.

Umweltbundesamt will fine-tune the methodology and prepare a draft manual by May 2013 taking into account stakeholder contributions.

The draft manual will be presented on the project web-site by May 2013.

All comments received in the context of the second stakeholder consultation will be published at the project web-site, provided that the respective stakeholder agrees.

Topic of the second stakeholder meeting in May 2013 will be a discussion of the draft methodology manual.

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13.9.1 Minutes of the 2nd stakeholder meeting

The meeting was held on Tuesday, 14 May 2013 in Brussels, Avenue de Beaulieu 5, 1160 Brussels, Room 00/C.

Aim of the meeting was the presentation and discussion of the draft manual on a methodology for the identification and assessment of substances for a potential restriction under RoHS2. A list of participants is provided at the bottom of this document.

The topics of the agenda were presented and discussed in the following order:

1) Overview presentation on actual status of the project progress (objectives, approach, schedule, milestones, first outcomes)

2) Summary of the received comments on the draft methodology approach

3) Presentation of the draft methodology manual: identification of substances
4) Presentation of the draft methodology manual: pre-assessment methodology
5) Presentation of the draft methodology manual: assessment methodology
6) Outlook (next steps and up-coming events)

The minutes of the meeting and the presentations held by Umweltbundesamt are available at: http://www.umweltbundesamt.at/rohs2

1 Overview presentation of the actual status of the project (Umweltbundesamt)

The project objectives, status in the schedule, and achieved and coming milestones were presented.

2 Summary of the received comments on the draft methodology approach

An overview on the third stakeholder consultation was provided. This included affiliation of stakeholders contributing during the 2nd stakeholder consultation and a compilation of the most frequent comments grouped by “generic comments” and annotations related to identification, pre-assessment and detailed assessment and their related response.

Introductory and generic discussion of the project and its outcomes:

Procedure of Review of Annex II

The procedure of reviewing Annex II of RoHS2 was discussed in detail.

There was a general agreement that the manual describes the methodology for identification and assessment of substances under RoHS2 but does not cover general procedural aspects of a review of Annex II.

Regarding the responsibility for evaluating substances for a potential restriction under RoHS the Commission clarified that the addressee of the manual is the Commission. The manual will be used:

- for substance assessments during periodic reviews of Annex II
- to assess restriction proposals according to Article 6 (2) RoHS submitted by Member States

Member States may use it when they intend to make a restriction proposal, however there is no legal obligation to do so.

Furthermore, proposals were made by stakeholders on how to conduct future reviews of Annex II in a practicable way that avoids re-assessment of substanc-

es in inappropriate time intervals. Some stakeholders suggested that the Commission should initiate a review of Annex II every 4 years, and an optional 2 year review taking into account proposals that have been submitted before mid-term by Member States.

(Legal) consequences of the outcomes of pre-assessment and detailed assessment in the context of RoHS

The question was raised, what are the consequences when a substance was not identified as high priority substance during pre-assessment or was not (yet) recommended for restriction after a detailed assessment. There was a common understanding, that a distinct time period where the substance will not be re-evaluated is necessary to provide predictable conditions for industry. The Commission stated that a re-evaluation is possible if new scientific evidence or new information on alternatives would become available.

It was further clarified by the Commission, that the Commission has a legal mandate to ban a substance when there is a considerable risk during waste management due to its use in EEE.

(Legal) consequences of the outcomes of substance evaluations under REACH

Furthermore, it was discussed whether there are consequences for the review process of RoHS 2 Annex II, if the restriction of a substance is rejected under REACH – either by ECHA committees or the Commission. There was a common understanding, that there is no legal consequence. From the technical and scientific point of view it was stated, that although a restriction proposal may be rejected under REACH, a restriction due to negative impacts during WEEE management and risk during the waste phase of EEE is possible. Furthermore restrictions may become possible with availability of substitutes/alternative technologies with less negative impact.

Consideration of uncontrolled treatment and illegal shipment

The question how the treatment of (illegally shipped) WEEE under uncontrolled conditions should be considered in the assessment was discussed in detail. In the opinion of the Commission and a large majority of participants at the meeting, substance restrictions under RoHS are not the appropriate measure to solve the problem of inadequate WEEE treatment in third world countries. It was stated that the most important measure to solve the problem would be better enforcement of the Waste Shipment Regulation. It was further mentioned that also Annex VI of the recast of the WEEE Directive addresses this problem. However, there was also an opinion given by an NGO, that treatment of WEEE outside Europe should receive much attention in the assessment. Although the focus will therefore be on legal waste treatment scenarios, the Commission suggested a case-by-case robustness check of the results.

Waste management conditions

For assessing the impact of particular substances during WEEE management, the current operational conditions are considered. These are not necessarily BAT.

3 Presentation of the draft methodology manual - identification of substances

The draft identification methodology was presented, as well as preliminary results of applying it (list of substances used in EEE, list of substances identified to be of relevance in terms of Article 6 (1) points a) to d)).

Discussion related to Top 3:

Hazardous substances to be assessed under RoHS

There was an opinion among industry stakeholders that a substance has to have hazardous properties according to a classification, such as the CLP Regulation. The RoHS Directive neither provides a definition of the term “hazardous” nor a binding reference, but it provides the criteria listed in Article 6 (1) points a) to c)), to be taken into account. In the opinion of the Commission substances are hazardous in the context of RoHS, when one of these criteria applies.

As an outcome of the discussion it was decided to include a explanation for “hazardous” in the Manual, specifying the term “hazardous” in the context of RoHS.

Wording: Substances used in EEE, which cause problems during WEEE management

In the current draft of the manual – for reasons of easy reading – the term substances “causing problems during WEEE management” was used. It was agreed that a reference to the criteria listed in Article 6 (1) a) to c) RoHS would facilitate unambiguous understanding and increase transparency of the methodology.

Specification of requirements for information sources

The methodology foresees literature search at all three steps (identification, preassessment and detailed assessment). Whereas in the identification step various types of literature may be used (including e.g. newspaper articles) are appropriate, the detailed assessment has to focus on scientific literature as a first choice.

Suggestions for improvements of the workflow chart

For better understanding of the chart which explains the workflow of identification of substances two amendments were proposed. The term “potential” in the explanation of the arrow from Step I 2a will be deleted as it is misleading as well as the arrow from Step I 2a to I 2b.

Wording: Substances "used in EEE"

Industry stakeholders pointed out, that the term substances "used in EEE" might be misleading as only substances contained in the final product – not substances used in the production process – should be identified. It was clarified that the aim of identification is to identify substances contained in EEE. However, substances which may form different reaction products and might release hazardous substances should be considered.

4 Presentation of the draft methodology manual – pre-assessment

The draft pre-assessment methodology was presented as well as some examples of applying the scoring system to selected substances (examples from the Öko-Institut report).

Discussion related to Top 4:

Hazardous properties

There was a common understanding that the allocation of scores for hazardous properties (human health and environment) was both appropriate from a scientific point of view as well as coherent with principles applied in REACH. Concerning endocrine disrupting properties, Umweltbundesamt reported that Europe-wide agreed criteria will be published by the end of 2013 and that there might be only two categories. Therefore, the category 3 is seen as preliminary and questionable.

It was suggested by the Commission to indicate also the preliminary character of categories one and two of endocrine disruptors" as long as there is no harmonised classification of substances according to the newly developed criteria. (Category 1, 2)

"Potential problems during waste management"

Furthermore, there was a common understanding, that a more detailed is needed how attributes are allocated to the individual criteria listed in Article 6 (1) a-c. The reasoning for allocation of scores should be described more in detail in the manual. Especially Article 6 (1) a (could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE) should be addressed adequately.

Some MS suggested that attributes for negative impacts on WEEE management could be: diffuse release, no recycling, captured in dust, large volumes or ability to form dust.

The approach how to consider nano-materials was discussed again in the second meeting. Stakeholders agreed with the changed approach that nano-materials should receive high priority during pre-assessment only when there is

concern of risk during waste management – and not by the sole fact that the substance is present as a nano-material in EEE.

Overall scoring system

It was discussed whether a traffic light system would have benefits compared to the currently proposed scoring system using numeric values. Furthermore, more details on the algorithm for determining the overall priority was demanded.

The question was raised whether the category “waste problem” should receive higher scores compared to the hazardous properties of a substance.

It was suggested by a MS to consider the availability of substitutes/alternatives. The efforts and data sources required to evaluate the existence of appropriate alternatives were discussed in detail. While MS suggested a search in the Subsport portal industry stakeholders suggested to use data available from documents produced during the REACH process.

The requirement for a strategy for missing data when applying the scoring system was discussed.

As an outcome of the discussion it was decided to refine the scoring system considering a traffic light approach explaining the rationale of prioritization more in detail.

5 Presentation of the draft methodology manual – detailed assessment

The draft assessment methodology was presented.

Discussion related to Top 5:

Wording: “Risk assessment”

There was a discussion on the term “risk assessment” and “risk characterisation” in the context of the methodology developed. MS raised concerns, that the terms would suggest an approach identical with the extensive investigations and comprehensive assessment of substances under REACH, which is not required by RoHS.

As an outcome of the discussion it was agreed to consider replacing the terms “risk assessment” and “risk characterisation” (e.g. by “risk estimation”) or to provide unambiguous definitions.

Determination of relevant waste management processes

There was a general agreement among the participants, that only processes, where a considerable share of the substance input into the process is caused by WEEE, are relevant for an assessment under RoHS.

Estimation of releases from WEEE treatment processes

The availability of appropriate information on substance releases during waste treatment processes was discussed in detail. There were concerns raised by industry stakeholders how the assessment will be performed in case of missing information, which was observed during the Öko-Institut assessment for several substances.

Taking into account the likelihood of unavailability of measured releases of specific substances, in the manual a top-down approach was chosen as guidance for estimating releases: Where no measured release data are available, the application of release factors for comparable substances and for particular materials containing the substance should be used for estimation of releases. For the current draft of the manual, release factors for WEEE relevant processes were compiled in an Annex, e.g. release factors for dust from shredders as provided by the ECHA-Guidance, Chapter R.18.

Negative impacts on waste management

The question whether the need of more sophisticated/expensive technologies is a relevant criterion was discussed controversially among industry stakeholders. Whereas some were of the opinion that expensive technologies are a considerable negative impact on WEEE management, others were of the opinion that costs do not matter in this context.

As an outcome of the discussion it was agreed, that the individual attributes for evaluation of negative impacts on WEEE management should be explained more in detail, taking into account the criteria listed in Article 6 (1) a) to c).

Assessment of substance groups

The possibility to assess substance groups was discussed. If it is reasonable to assess a substance group, e.g. due to their use as a chemical mixture, as laid down in the Directive also substance groups can be assessed. Hazardous model compounds shall be chosen to evaluate the hazard of the group (pre-assessment).

Stakeholder involvement in the detailed assessment of substances

The way how producers/users can/should contribute to the detailed assessment of substances was discussed. It was clarified, that producers/users should be asked to provide data (preferably registration dossiers and/or Chemical Safety Reports).

Furthermore, draft results of the assessment will be put up for discussion.

6 Conclusion and Outlook

Participants of the meeting agreed in general to the manual on the methodology for the identification and assessment of substances for potential restriction under RoHS2.

Umweltbundesamt will refine several aspects (see points above) of the methodology considering also stakeholder comments on the draft manual as received by 10th of June 2013.

All comments received in the context of the third stakeholder consultation will be published at the project web-site, provided that the respective stakeholder agrees.

Participants are especially invited to comment on their understanding of the Article 6 (1) criteria, and to provide specific questions, benchmarks etc. to be used especially for evaluating Article 6 (1) a) related impacts ("*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*").

Umweltbundesamt will apply the refined pre-assessment methodology to the identified substances to determine substances of highest priority by mid of June and the Commission will then decide which substances will be subjected to a detailed assessment during the present project. The Commission´s decision will be published on the project web-site.

Registrants of the selected substances will be asked to provide any available data which could be used during the detailed assessment of WEEE treatment.

Topic of the third stakeholder meeting in Sept/Oct 2013 will be a discussion of the draft assessment results of the selected substances.

List of participants:

Institution / Name
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Austrian Economic Chamber - Thomas Fischer
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BeST - Beryllium Science & Technology Association - Heleen Vollers
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CEFIC - European Chemical Industry Council - Maggie Saykali
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13.9.1 Minutes of the 3rd stakeholder meeting

Minutes

Third stakeholder meeting

"Study for the Review of the List of Restricted Substances under RoHS2"

Prepared by Umweltbundesamt

The meeting was held on Monday, 28 October 2013 in Brussels, Avenue de Beaulieu 5, 1160 Brussels, Room 5/0/C.

Aim of the meeting was to discuss the outcomes of applying the developed methodology, i.e. a list of substances ranked according to the substance´s priority for a detailed assessment with the view of a restriction in EEE and detailed assessments of 4 substances (HBCDD, DEHP, BBP, DBP). A list of participants is provided at the bottom of this document.

The topics of the agenda were presented and discussed in the following order:

1) Overview on project activities
2) Detailed assessment of selected substances / Details how the methodology was applied
3) Detailed assessment of selected substances (HBCDD)
4) Next steps during the project and plans of the Commission regarding future steps in the context of the review of Annex II to RoHS

Due to intensive discussions on the foreseen presentations on the detailed assessment of DEHP, DBP and BBP and on the pre-assessment of substances were not held. However the presentations – together with these minutes – are available at:

http://www.umweltbundesamt.at/rohs2

The meeting was held on Monday, 28 October 2013 in Brussels, Avenue de Beaulieu 5, 1160 Brussels, Room 5/0/C.

A list of participants is provided at the bottom of this document.

Aim of the meeting was to discuss the outcomes of applying the developed methodology, i.e.:

Pre-assessment: a list of substances ranked according to the substance´s priority for a detailed assessment with the view of a restriction in EEE and

Detailed assessments of 4 substances (HBCDD, DEHP, BBP, DBP).

The topics of the agenda were presented and discussed in the following order:

5) Overview on project activities
6) Detailed assessment of selected substances / details how the methodology was applied
7) Detailed assessment of selected substances (HBCDD)
8) Next steps during the project and plans of the Commission regarding future steps in the context of the review of Annex II to RoHS

Due to intensive discussions on the methodology and the detailed assessment of HBCDD it was not possible to present the assessments of DEHP, DBP and BBP and the result of pre-assessment of substances. The presentations – together with these minutes – are available at:

http://www.umweltbundesamt.at/rohs2

Resume

Detailed assessment of selected substances:

The deadline for commenting on the draft ROHS-AnnexII-Dossiers for HBCDD, DEHP, BBP and DBP will be extended to **November 25**.

The i**nformation** used for the detailed assessments was derived from a thorough literature collection, in particular considering information available from activities under REACH, risk assessment reports, information on BAT in waste treatment and also information obtained by stakeholders. If stakeholders have **more detailed and/or up-to date information** the consultant kindly asks to provide information on the key issues as provided in the Annex to this minutes.

In general, **opposite opinions on several issues remained among stakeholders, resp. Commission Services** during the meeting:

- Member states mentioned that the method is very useful and fulfils the re-

quirement of coherence with REACH very well by applying ECHA guidance's and tools.

- Industry pointed out that it is of high importance that, when the assessment is carried out by different consultants, consistent results are achieved. Improvements concerning specific details were requested.
- The criterion "impact on recycling" was discussed thoroughly. There are different points of views whether the presence of a substance, whose use is restricted by any legislation, constitutes a negative impact on the possibilities of recycling per se. Some industry stakeholders are of the opinion that only technical difficulties or additional costs are to be seen as a negative impact on recycling and highlighted the need of resource efficiency. Other stakeholders pointed out that removing hazardous substances is of higher priority compared to material recycling. This is also the view of the consultant.
- Intensive discussions concerned the topic of grouping of substances. NGOs recommend giving higher priority to PVC and brominated flame retardants due to the generation of hazardous combustion products, including POPs and the relevance for third countries. POPs should be minimized on a global scale. Industry stakeholders discussed this topic controversially. PVC and several brominated flame retardants as a group were identified by applying the pre-assessment methodology to be of comparably high priority for a detailed assessment. A detailed group assessment of a limited number of similar substances is in principle possible, although for practical reasons prioritization and assessment in this project were based on properties of individual substances. The Commission stated that it is not envisaged to restrict all brominated flame retardants as a group.
- Some stakeholders claimed that the origin of information used in the detailed assessments (exposure scenarios for assessing risks during WEEE treatment, alternatives and socio-economic impacts) should be made clearer. Stakeholders addressed the question of sensitivity and uncertainty. The consultant points out that the rationale of each dossier contains a description of main influencing factors.

  It was clarified by the Commission Services that the "*thorough assessment*" of substances as requested by the RoHS-Directive does not have to be performed in the same way as a substance assessment under REACH. The outcome of a substance assessment under RoHS2 has to be robust and science based but quantitative assessments are not obligatory. There is also no legal basis within ROHS to demand a full socio economic analysis. Besides, measures implemented by way of delegated acts - being the case when reviewing Annex II to RoHS2 - do not require a full impact assessment. However the provisions of Article 6 (2) need to be considered in the assessment.
- Some stakeholders are of the opinion that a restriction under RoHS has no added value for those substances which are already on Annex XIV or XVII of REACH.

  However, it has to be considered that a restriction according to Annex XIV REACH does not affect imported EEE, only a restriction under RoHS will lead to a substantial reduction of hazardous substances in wastes from electrical appliances. The same is true, as long the possibility of an authorization for the substance in the EU exists.

Several questions and opinions on the overall consultation process in the context of reviewing the list of hazardous substances appeared. It was agreed that the final project report will contain a short section "**Guidance for the periodical review of Annex II ROHS2**" providing suggestions for the procedural aspects in addition to the Methodology Manual.

The Commission Services announced their plans to establish a **working group** of maximum 12 members (most active stakeholders from MS, NGOs, consultancies and industry). The purpose of the working group should be to accompany the continuing process of reviewing Annex II of RoHS2. Details are not yet available.

Annex:

Up-date of key data for detailed assessments of HBCDD, DEHP, BBP, DBP

The information used for the detailed assessments was derived from a thorough literature collection, in particular considering information available from activities under REACH, risk assessment reports, information on BAT in waste treatment and also information obtained by stakeholders.If stakeholders have more detailed and/or up-to date information the consultant kindly asks to provide information on:

- Amount of HBCDD, DEHP, BBP, DBP imported as part of EEE in tonnes/year
- Amount of HBCDD, DEHP, BBP, DBP used in EEE produced within the EU in tonnes/year
- Costs for European EEE producers when switching from plastics containing from HBCDD, DEHP, BBP, DBP to their alternatives in € plus an explanation what causes these costs
- Life time range of moulds for EEE housings
- Number of sites where WEEE are treated mechanically other than in large-scale metal ELV shredders in the EU
- Actual releases of HBCDD, DEHP, BBP, DBP from shredding of WEEE in large-scale metal shredders (and other mechanical treatments)
- Number of sites where cables are shredded (mechanically treated) in the EU
- Actual releases of DEHP, BBP and DBP from mechanical treatment (shredding) of cables
- Amounts or shares of PVC derived from WEEE cables, that are recycled/landfilled/incinerated (*total soft PVC recycling of cables in 2010: 79,300 t)*
- Amounts or shares of PVC derived from other WEEE parts, that are recycled/landfilled/incinerated
- Number of installations performing recycling of PVC derived from WEEE cables (or other PVC parts) in the EU
- Actual releases of DEHP, BBP and DBP from recycling (formulation and use of PVC)
- Amount or share of HIPS derived from WEEE that is recycled.
- Number of plants where HIPS from WEEE is recycled (mechanical treatment, formulation use of the polymer
- Actual releases of HBCDD from recycling (mechanical treatment formulation and use of the polymer)
- Workplace exposure data (monitoring data preferred):
- Information on exposure to HBCDD, DEHP, BBP and DBP of workers at sites where WEEE are treated mechanically (e.g., measured data, assumptions, bio-monitoring data)?
- Information on exposure to DEHP, BBP and DBP of workers at sites where cables are treated mechanically (e.g., measured data, assumptions, bio-monitoring data)?
- Information on exposure to DEHP, BBP and DBP of workers at sites where

PVC from WEEE cables is recycled (e.g., measured data, assumptions, bio-monitoring data)?
- Data on workers health within recycling facilities where HIPS and PVC from WEEE are processed
- Processes and conditions for recycling processes of HIPS and PVC as input parameters to be used in ECETOC TRA
- Data on environmental concentration of areas near sites, where WEEE are shredded, with respect to DEHP, BBP and DBP
- Data on environmental concentration of areas near sites, where cables are shredded, with respect to DEHP, BBP and DBP
- Data on environmental concentration of areas near sites, where PVC from WEEE is recycled, with respect to DEHP, BBP and DBP
- Amounts of BBP and DBP contained in EEE resp. Concentrations of BBP and DBP in WEEE WEEE-cables

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