



Report on the Identification and Prioritisation of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive

**Study to support the review of the list of restricted
substances and to assess a new exemption request under
RoHS (RoHS Pack 15 - Task 3, draft final)**

*Under the Framework Contract: Assistance to the Commission
on technical, socio-economic and cost-benefit assessments
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Abbreviations and Definitions

AUBA	Austrian Umweltbundesamt GmbH
CAS	Chemical Abstracts Service
CLP	Classification and Labelling Regulation
CMR	Carcinogenic, mutagenic, toxic for reproduction - A substance that is classified as car-cinogenic category 1 or 2, and/or mutagenic category 1 or 2, and/or toxic for reproduc-tion category 1 or 2
ECHA	European Chemicals Agency
EEE	Electrical and electronic equipment, which according to RoHS Article 3(1) means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such cur-rents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current;
IEC	International Electrotechnical Commission
PBT	Persistent, bioaccumulative and toxic - A substance that fulfils the persistence, bioac-cumulation and toxicity criteria set out in Annex XVIII of REACH
POP	Persistent organic pollutants
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 De-cember 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, establishing a European Chemicals Agency
RoHS	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
SCIP	A database for information on Substances of Concern In articles and in Products
SPIN	Substances in Preparations in Nordic Countries
SU	Description of use
vPvB	Very persistent, very bioaccumulative - A substance that fulfils the very persistent and very bioaccumulative criteria set out in Annex XVIII of REACH
ZVEI	Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (German Electrical and Electronic Manufacturers' Association)

1. Summary

This report describes activities carried out in the scope of the project Identification and Prioritisation of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS Directive. All activities are based on the Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive (dated 26.09.2019), here after "the manual".

The report describes the work carried out in accordance with the following parts of the manual:

- PART I: Identification of substances used and/or present in EEE, which may have negative impacts on human health, the environment or resource efficiency during use and/or during WEEE management according to RoHS Article 6(1). The existing inventory of a previous study was used as a basis to be updated. Existing databases and computer based tools were then used to establish a comprehensive database with information on the substances concerned, with a focus on hazard properties (human health and environmental hazards) and use aspects (typical applications, volumes of use). This work resulted in an inventory of 897 substances that were indicated to be present in EEE or used during the manufacturing of EEE. Those substances were then pre-assessed according to a range of criteria to provide a first indication regarding the substances priority for further assessment, resulting in 10 groups, from group I (priority for further assessment, 57 substances) to group X (no priority for further assessment).
- PART II: Prioritisation of substances used in EEE, which may most likely have negative impacts on human health, the environment or resource efficiency during use and/or during WEEE management according to RoHS Article 6(1). This part was applied to a sub-selection of the substances identified in P I, understood to have the highest priority for further assessment according to the guidance in P III of the manual. Information was collected and reviewed on volumes of use and on typical applications in EEE. Based on this information and the hazard properties of the substance, a sorting and clustering of the prioritised substances was carried out, resulting in five clusters of substances (clusters I a) to I e)). The seven substances in cluster I a) are of the highest hazard group and were indicated to be used in high volumes or as nano-material or were indicated to be potential substitutes for substances listed under Annex II of the RoHS Directive or substances that are currently under assessment for a possible inclusion in Annex II. The further clusters of substances incrementally fulfil fewer criteria.

The following documents were produced that constitute the results of this work:

- Pre-prioritised substance inventory: A spreadsheet format list containing more than 900 substances that are indicated to be present in EEE or used in the manufacture of EEE, including information on their identity (CAS number, EC number, substance name), their legal status under various directives and regulations (CLP, REACH, RoHS, POPs Regulation, among others), their hazardous properties (CMR, PBT/vPvB, endocrine disrupting properties, etc.), and their

volumes of use in EEE. The substances in this list have been pre-prioritised in accordance with criteria described in the manual, into ten priority groups, with group I associated with the highest and group X with the lowest priority (refer to manual P I Step 2: Priority pre-assessment of inventory sub-stances).

- List of prioritised substances: A spreadsheet format list containing 44 substances from the priority group I of the Pre-prioritised substance inventory mentioned above, complemented with information on their use (applications) in general and in EEE as well as their volumes of use in general and in EEE, where such information was available. Substances on this list were further sorted into five clusters to improve the clarity of results.

Three stakeholder consultations were conducted to request additional information from participating organisations, with a focus on applications of substances in EEE and volumes of use (quantities) of substances in EEE in the EU. While many organisations contributed information on applications of substances, and some information on the amount of specific substances used in articles manufactured by those organisations, no data could be retrieved regarding the amount or order of magnitude of substances in EEE in total in the EU. Limited information could be retrieved from the Urban Mine Platform . Additional data on presence in articles may be in the future available through the SCIP data base and other future initiatives.

2. About this document

This document describes the steps that were carried out according to the methodology manual. The manual describes the approach and provides instructions on how to carry out the compilation of an inventory and prioritisation of substances. This document describes the results of applying this methodology in the course of this study and deviations from it, where applicable. To increase the readability of this document, parts of the methodology manual have been copied in for the convenience of having the description of the approach and the results in one place. Paragraphs copied from the manual are formatted in italics.

3. Part I IDENTIFICATION OF SUBSTANCES

The aim of Part I is to identify all substances in EEE, which may cause risks for the environment during use¹ or risks for the environment and workers during WEEE management or have any other negative impacts during waste management, as specified by RoHS 2, Article 6.

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

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

- *Creation of an inventory of substances (P I Step 1):*
 - *Updating information on substances classified or suspected as hazardous (P I Step 1a);*
 - *Updating information on substances used and/or present² in EEE (P I Step 1b);*
- *Pre-assessment of priority of substances listed in the inventory (P I Step 2):*
 - *First run of the pre-assessment to establish classification of substances to priority groups (P I Step 2a);*
 - *Stakeholder consultation for collecting information on substances in the inventory with focus on the substances in the highest priorities (P I Step 2b);*
- *Update information in the inventory and re-run pre-assessment to conclude on substances in highest priorities³ to be subject refined prioritisation in P II (P I Step 3).*

An inventory of substances used in EEE was established during the first review of Annex II of RoHS in 2013-2014. The inventory established in 2013 AUBA⁴ (Karigl et al. 2014) provides a first basis to be updated in the following periodic reviews. Each further revision should use the initial inventory of the last revision as a first basis to be

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

² Substances used in manufacture of EEE may or may not be present in the final product. Similarly, substances present in EEE may or may not have been applied in this form in the manufacture. The inventory shall update information on substances used in manufacture and on substances present in EEE, specifying presence where this data is found to allow a differentiation at later stages.

³ The number of substance (priority classes) to be subjected to the prioritisation of P II shall be discussed and approved with the EC, also depending on the study scope.

⁴ Abbreviation for Austrian Umweltbundesamt GmbH (AUBA)

updated, adding and updating existing data before applying the various selection and prioritisation stages.

3.1. P I Step 1: Compile inventory of substances

The final inventory from the previous study (Karigl et al. 2014) was used as a first basis and was updated where relevant in relation to additional substances present in EEE or used in the manufacturing of EEE (e.g. new substances). Additional substances or substance groups (hereafter: substances) were added to the inventory from the following sources:

- IEC 62474 Database „Declarable substance groups and declarable substances“ (IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry)⁵:
 - 77 additional entries were added to the inventory.
- ZVEI umbrella specifications could not be consulted as they are no longer updated and were no longer available online. Therefore, no new information has become available after the initial study by AUBA (Karigl et al. 2014) from this source. Instead, material data sheets from TDK/Epcos on a range of passive electronic components, including capacitors, inductors, and sensors were evaluated (see next bullet).
- 791 Material Data Sheets showing typical compositions of specific electronic product groups published by TDK Electronics⁶:
 - 72 substances were identified; of those, 44 were already contained in the EEE inventory;
 - 28 additional substances were added to the inventory.
- Requests for new RoHS exemptions / renewal of exemptions / withdrawal of exemptions, in which potential substitutes were specified. No additional substances were identified for addition to the inventory.
- The following reports/studies were evaluated:
 - Bundesamt für Umwelt: “Substance flows in Swiss e-waste” (BAFU 2017)
 - DANISH EPA: “Hazardous substances in plastic” (Hansen et al. 2014)
 - DANISH EPA: “Survey of brominated flame retardants” (Lassen et al. 2014)
 - DANISH EPA: “Shredder residues: Problematic substances in relation to resource recovery” (Hyks et al. 2014)
 - DANISH EPA: “Environmental and health screening profiles of phosphorous flame retardants” (Lassen et al. 2016)

⁵ Refer to Website of the IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry: <http://std.iec.ch/iec62474> [accessed on 25th February.2020]

⁶ Material Data Sheets published by TDK Electronics: <https://www.tdk-electronics.tdk.com/en/176050/company/environmental-protection/material-data-sheets> [accessed on 20th July 2018]

- DANISH EPA: “Category approach for selected brominated flame retardants” (Wedebye et al. 2016)
- DANISH EPA: “Pre-screening of REACH registration dossiers for 9 brominated flame retardants” (Nielsen et al 2016)
- Nordic Council of Ministers: “Hazardous substances in plastics” (Stenmarck et al. 2017)
- Oeko-Institut: “Study for the Review of the List of Restricted Substances under RoHS2” (Gensch et al. 2014)
- Oeko-Institut: “Evaluation of small brominated alkyl alcohols for a possible RoHS restriction” (Baron et al. 2017)
- RISE: “Mapping and Evaluation of some Restricted Chemical Substances in Recycled Plastics Originating from ELV and WEEE Collected in Europe” (Andersson et al. 2019)
- Swico, SENS, SLRS Report: “Fachbericht 2017” (Böni et al. 2017)

The reports/studies listed above, found to be relevant to EEE, were scanned for lists of hazardous substances or other references to hazardous substances present in EEE or used in the manufacturing of EEE.

- 90 different substances are described in the reports/studies, 50 of which were already contained in the inventory; 40 additional substance were identified
- 5 of those 40 substances were contained in the AUBA list “substances removed”⁷. These substances were nevertheless added to the inventory, as it could not be excluded that new information had become available since the previous study was carried out.
- The 40 substances/groups were added to the inventory as separate entries, which resulted in the addition of 73 substances with unique CAS numbers in total, as members of substance groups were listed individually.

Discussion of the feasibility of an alternative approach for updating the EEE inventory

An alternative approach to updating the initial EEE inventory was investigated but not found to be feasible. The approach was to compile a new inventory from relevant sources rather than to incrementally update the AUBA inventory. The sources would have been substance lists specific for EEE (IEC 62474, SPIN), REACH registered substances with specific use descriptors (to be specified in search under Uses and

⁷ The finale EEE inventory produced by AUBA (Karigl et al. 2014) contained a separate list of substances that had been removed from the inventory before its finalization, as information had become available indicating a substance would not be relevant for an inventory listing hazardous substances understood to be present in EEE.

exposures>Sector of use), as well as relevant studies/reports. However, there were two main issues with this approach:

- The number of substances in the sources was enormous, and considered too large to be workable, particularly in stakeholder processes;
- The sources often do not differentiate between substances present in EEE and substances used in the manufacture of EEE or intermediates.

To illustrate the first issue, Table 3-1 lists the number of substances listed in each source. It was decided that a substance inventory with several thousand entries was not a workable approach. Additionally, none of the listed sources indicate whether a substance is merely used in production of EEE but is not contained in the final article (e.g. solvents). Consequently, it was decided to incrementally update the AUBA EEE inventory instead, as described above.

Table 3-1: Sources considered in the alternative approach to updating the EEE sub-stance inventory and number of entries

Source	Number of unique entries
REACH substances with use descriptor SU 2a "Mining, (without offshore industries)"	573
REACH substances with use descriptor SU 9 "Manufacture of fine chemicals"	8888
REACH substances with use descriptor SU 11 "Manufacture of rubber products"	1463
REACH substances with use descriptor SU 12 "Manufacture of plastics products, including compounding and conversion"	2643
REACH substances with use descriptor SU 15 "Manufacture of fabricated metal products, except machinery and equipment"	1109
REACH substances with use descriptor SU 16 "Manufacture of computer, electronic and optical products, electrical equipment"	1197
SPIN database substances with Nace Code 26 "Manufacture of computer, electronic and optical products"	665
SPIN database substances with Nace Code 27 "Manufacture of electrical equipment"	478

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

Data on hazardous properties of all substances in the inventory was updated by consulting the sources prescribed in the methodology manual, listed in Table 3-2.

Table 3-2: Criteria for the identification of candidates in the inventory master list as hazardous

<i>The substance is/shows...</i>
Listed in Annex VI CLP (or fulfils the criteria that would justify a listing in Annex VI CLP)
Carcinogenic OR mutagenic OR reprotoxic [Categories 1A and 1B and 2]
PBT (persistent, bio-accumulative, toxic)

The substance is/shows...
vPvB (very persistent, very bio-accumulative)
PB (persistent, bio-accumulative)
Listed as substance of very high concern (SVHC) under REACH
Subject to authorisation (Annex XIV) under REACH
Subject to restriction (Annex XVII) under REACH
Considered to have endocrine disrupting and/or other properties identified in accordance with Article 57(f) of
Suspected as any of the above (based on CoRAP; SIN List)
Listed under the ECHA public activities coordination tool (PACT)
Substances used as nanomaterial in EEE

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

The list updated through Step 1a was further updated in relation to available information as to the use and/or presence of the substance in EEE. For the purpose of this step, the following lists and sources were consulted:

- Substances listed in the IEC 62474 Database „Declarable substance groups and declarable substances“. It is understood that substances or substance groups are added to the list of declarable substances on the basis for example of regulatory requirements or requirements of industry standards that set reporting thresholds⁸. The following information was extracted:
 - Information on typical applications of substances in EEE was added to the EEE inventory;
 - Presence in EEE was considered plausible, if a substance was listed in the IEC 62474 Database.
- TDK/Epcos Material Data Sheets:
 - Presence in EEE for listed substances is considered plausible.
- Substances with the use descriptor SU 16 “Manufacture of computer, electronic and optical products, electrical equipment“:
 - Substances listed with this use descriptor are considered to possibly be present in EEE, as the source does not differentiate between substances used during manufacturing and substances contained in final articles.
- Information from requests for new RoHS exemptions / renewal of exemptions / withdrawal of exemptions, in which potential substitutes are addressed.

⁸ For further details see: <http://std.iec.ch/iec62474/iec62474.nsf/MainFrameset> [accessed 20th July 2018]

Volumes of use

Little information is publicly available on the volumes of use of specific substances in EEE within the EU. Various sources of information were checked in terms of their relevance for the purpose of this study:

- Volumes of use from the REACH registration process (tonnage bands) is not useful for the current task due to the following reasons:
 - The tonnage bands refer to a substance being manufactured in the EU or imported into the EU. The data does not account for volumes of a substances imported as constituent of articles that are manufactured overseas and imported into the EU. As the majority of EEE are produced outside the EU (Asia), the REACH registered volume data do not account for substances contained in the vast majority of EEE in the EU.
 - In correspondence with ECHA⁹ it was confirmed that although registrants do provide indications regarding downstream uses of manufactured or imported substances (sectors, processes, products), there is no data to indicate amounts of a specific substance in specific product categories (such as EEE). Registrants do not provide indications on the share of the substances in different sectors. Additionally, registrants typically do not have data on the total amount of a substance as a constituent of products (see bullet point above).
- Literature, reports:
 - Previously used literature and reports (including literature listed in chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**) have been checked for data on the amount of specific substances in EEE in the EU. No references could be identified that provide such specific data.
- The Urban Mine Platform¹⁰ that was generated as a part of a European research project (ProSUM¹¹) and provides projected data of volumes of materials and elements within EEE placed on the European market by year was checked for relevant information. Data was extracted on listed materials and elements. However, only relevant materials and elements are referred to in the platform, while specific flame retardants or phthalates are not accounted for.
- Data on volumes of use in EEE were requested in all stakeholder consultations within the project. A few contributions included indications on the volume of specific substances used in EEE, the frame of reference for provided data was generally specific to the contributing organisation. This did not allow projections from one manufacturer to the entirety of EEE included in the scope of RoHS.

⁹ Personal communication on 30. July 2019

¹⁰ <http://www.urbanmineplatform.eu/composition/eee/elements> [last accessed on 19th February 2020]

¹¹ H2020 project "Prospecting Secondary raw materials in the Urban mine and Mining wastes" (ProSUM) project website: <http://www.prosumproject.eu/> [last accessed on 19th February 2020]

- Direct correspondence with selected stakeholders (incl. ZVEI) did not result in further data on the volumes of specific substances used in EEE in the EU.

3.1.2. Stakeholder Consultation 2018-2

A first stakeholder consultation with relation to the substance inventory was carried out between 26th October 2018 and 21st December 2018¹². The substance inventory at the time comprised 815 entries and included the following information, where available:

- Substance identity (CAS No., EC No., Name, Group);
- Source of information (e.g. IEC 62474);
- Uses in EEE (category, main function, additive or reactive use);
- Nanomaterial;
- Estimated volume of use in EEE in the EU (in tonnage bands).

A guidance document included questions to stakeholders pertaining to verifying and complementing the information provided in the inventory.

Contributions were received from 9 organisations or groups of organisations¹³. Contributions directly related to the questions asked in relation to the EEE inventory have been summarised in Table 3-3, including the actions that were taken accordingly. Further contributions were focused on the Substance Methodology and were not considered in the further development of the inventory.

Table 3-3: Stakeholder comments received and actions taken

Stakeholder	Comments directly related to the questions asked in relation to the substance inventory	Action taken
Alliance Elektronique – ACSIEL	Provision of list containing 5 substances, 2 of which were new additions to the inventory	Added 2 new entries to the inventory
EUROMOT and AEM	Provision of Excel file with 23 substances incl. use examples for engines (engine BOM). All 23 substances were already	Added additional information on use of substances in EEE

¹² <https://rohs.exemptions.oeko.info/index.php?id=302> [last accessed 19th April 2020]

¹³ <https://rohs.exemptions.oeko.info/index.php?id=304> [last accessed 19th February 2020]

Stakeholder	Comments directly related to the questions asked in relation to the substance inventory	Action taken
	contained in the EEE inventory	
PI Ceramic GmbH	Provision of data on 11 substances; all 11 substances already in inventory; provision of data on volume of use in piezo electronic components	Data on volumes of use added to the EEE inventory
ZVEI	Marking of duplicate entries in EEE inventory; marked substances as intermediates (not present in EEE due to reactivity)	Duplicates were removed; substances pointed out as intermediates were marked as such in the EEE inventory

In summary, after the stakeholder consultation, 2 additional entries were added to the inventory. 16 entries were removed from the inventory as they were duplicates. 12 substances were marked as “intermediates” following stakeholder feedback.

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

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

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

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

Criteria: The substance is excluded if it is:

- *Restricted or to be restricted (within duration of the transition period) under the RoHS Directive.*
- *Restricted in accordance with the REACH Regulation (Annex XVII), provided that the scope of the restriction would make a RoHS restriction redundant;*

- *Prohibited and/or restricted in accordance with the POPs Regulation (EC) No 850/2004 and its amendments, provided that the scope of the decision (exemptions/acceptable uses) would make a RoHS restriction redundant;*
- *A decision to list the substance (or substance group) in Annex A (elimination) and/or Annex B (restriction) of the Stockholm Convention has been taken by the Conference of the Parties (COP) and its implementation is pending, provided that the scope of the decision (exemptions/acceptable uses) would make a RoHS restriction redundant¹⁴*
- *Covered by the Montreal Protocol, the Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, and the F-gas Regulation (EC) No 842/2006¹⁵.*

Out of the 897 substances contained in the substance inventory, 44 entries were removed after above steps were completed.

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

The aim of step 2 is to identify those substances or groups of substances which are of highest concern regarding their potential negative impact on human health and/or the environment during use and/or WEEE management. In order to prioritise substances, a grouping system based on the assessment of the following three attributes was applied in accordance to the manual:

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

1) Hazardous properties

The results of the categorisation of substances into hazard groups in accordance with the manual are shown in **Fehler! Verweisquelle konnte nicht gefunden werden.**

¹⁴ See further information under:

- Convention text and amendments: <http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx> [last accessed on 19th February 2020]
- Reports and decisions of the COP: <http://chm.pops.int/TheConvention/ConferenceoftheParties/ReportsandDecisions/tabid/208/Default.aspx> [last accessed on 19th February 2020]

¹⁵ See: <http://ozone.unep.org/montreal-protocol-substances-deplete-ozone-layer/32506> [last accessed on 19th February 2020]

below. Please note that substances may both fulfil human hazard and environmental hazard criteria and may therefore be accounted for in both parts of the table.

Table 3-4: Number of substances in each hazard group

Hazard group	# of substances
Human Health Hazard	
- Group I	123
- Group II	38
- Group III	78
Environmental Hazard	
- Group I	92
- Group II	3
- Group III	19
No relevant hazard criteria	640

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

In certain cases a substance may be addressed under the REACH Regulation (Authorisation, Restriction) or regulation may be under consideration. On the basis of the Common Understanding (COM 2014), and to ensure coherence with REACH, in such cases, it shall be of a higher priority to assess whether such substances when used and/or present in EEE fulfil the RoHS Article 6(1) criteria and whether a RoHS restriction would achieve a higher level of protection than the REACH route. Therefore, where a substance is listed in Annex XIV and/or in Annex XVII of the REACH Regulation or if such a listing is under consideration, a RoHS assessment should be prioritised for this purpose and would result in the substance being moved to Group I in relation to its hazard group prioritisation (i.e. red colour).

- Criterion A was found to be true for 52 substances in the EEE inventory. These were all grouped into the overall priority group I.

2) Use relevance

Methodology

Where information indicates use and/or presence of the substance /substance group in EEE in high volumes it is assumed to indicate a higher potential for the criteria

specified in Article 6(1) of RoHS to be fulfilled. Thus for the following grouping system, the information required under P I, Step 1b, shall be analysed systematically and shall constitute the following criterion:

- *Criterion B: There is evidence that the substance/ substance group is used and/or present in EEE in high volumes;*
- *For the purpose of determining this criterion, the REACH registration volume principles are to be used. High volume of a substance is to be assumed when*
- *the annual use is ≥ 1 tonne for substances exhibiting CMR properties; or*
- *the annual use is ≥ 100 tonnes for substances classified as very toxic to aquatic organisms; or*
- *the annual use is ≥ 1000 tonnes for all other substances.*

Additionally, criterion B is to be considered fulfilled when a substance may be used in nanomaterial form in certain EEE applications, despite its EEE use volume being below the above specified thresholds.

Results

Criterion B was found to be true for 43 substances in the EEE inventory.

3) Determination of the overall priority of substances / substance groups

Methodology

The pre-prioritisation was carried out in accordance with the manual as shown in Table 3-5.

Table 3-5: Overview of possible colour combinations for the highest overall priority categories

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

Results

Prioritisation resulted in the following distribution of substances into the ten priority groups (number of substances in brackets):

- Group I (57)
- Group II (1)
- Group III (111)
- Group IV (27)

- Group V (1)
- Group VI (3)
- Group VII (61)
- Group VIII (22)
- Group IX (32)
- Group X (538)

3.2.3. P I Step 2b): Stakeholder Consultation 2019-3

A second stakeholder consultation with relation to the substance inventory was carried out between 26th September 2019 and 7th November 2019. The pre-prioritized substance inventory at the time comprised 853 entries and included the following information:

- Substance identity (CAS No., EC No., Name, Group)
- Uses in EEE (category, main function, additive or reactive use, indication whether presence in EEE considered plausible, indication whether substance is a substitute for another listed substance)
- RoHS status (currently under assessment or previously assessed under RoHS)
- Hazard group (combined results for human health and environmental hazard properties)
- Use relevance (high volumes of use and/or used as nanomaterial in EEE)
- REACH relevance (listed or proposed for listing under REACH Annex XIV or XVII)
- Resulting overall priority (Groups I – X)
- Previously received stakeholder comments
- Estimated volume of use in EEE in the EU (in tonnage bands)
- Waste / use phase / comments (requesting information on possible use phase / waste management impacts acc. RoHS Art. 6(1); other comments)

A guidance document included questions to stakeholders pertaining to verifying and complementing the information provided in the inventory. Stakeholders were requested to provide additional information, with the aim of either:

- Providing evidence that a substance in the highest priorities should have a lower priority based on new evidence related to, e.g. a lower volume of use or no use in EEE;
- Providing evidence that a substance in a lower priority group should have a higher priority, based on new evidence related to, e.g. a high volume of use in EEE

Comments were received from 12 organisations or groups of organisations¹⁶. The following comments were directly related to the substance inventory:

- five substances were identified as already restricted under RoHS and were consequently removed from the inventory
- one substance was identified as currently restricted under the POPs Regulation and was consequently removed from the inventory
- Several substances were highlighted as not present in EEE, and were consequently marked as such
- Five phthalates were incorrectly grouped in hazard group I due to an error in the algorithm for automated grouping, which was corrected. Those five phthalates are no longer in group I but sorted into their various correct groups.

Additionally, stakeholders provided volumes of use for a few substances and indicated more substances that are used during manufacturing but are not present in the final EEE. This was noted in the inventory.

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

Methodology

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

Substances in the highest priority groups shall be put on a short list, creating a so called "RoHS-Working-List"¹⁷. This list shall be subjected to the prioritisation in P II.

Results

At the time this step was finalised, the assessment of the seven substances (or substance groups) to be performed as part of this study had not concluded yet.

¹⁶ <https://rohs.exemptions.oeko.info/index.php?id=339> [last accessed on 19th February 2020]

¹⁷ The groups for which the refinement is to be performed shall be discussed and approved with the Commission. The selection can be performed automatically using the features of the established substance database (RoHS-working-list.xls)

Therefore, this step was carried out according to the information on possible substitutes contained in the draft substance dossiers.

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

Methodology

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

For all substances from the highest priority groups, information shall be collected from publicly available sources and compiled into a tabulation. The tabulation should include the information for each substance regarding the following parameters and topics:

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

Results

The following 43 substances comprised the group of the highest priority substances:

- Boric acid
- 1-bromopropane
- Bis(2-methoxyethyl) ether (Diglyme)
- Tris(2-chloroethyl)phosphate (TECP)
- Bis(2-methoxyethyl) phthalate
- C,C'-azodi(formamide) (ADCA)
- N,N-dimethylacetamide (DMAC)
- Diarsenic pentoxide; Arsenic pentoxide; Arsenic oxide
- Diboron trioxide
- Disodium tetraborate, anhydrous
- Dipentyl phthalate (DPP)

- Nickel monoxide
- Zinc oxide
- Diarsenic trioxide; Arsenic trioxide
- Tris(2-chloro-1-methylethyl)phosphate (TCCP)
- Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)
- Hexahydro-4-methylphthalic anhydride
- Henicosafleuroundecanoic acid
- Trixylyl phosphate (TXP)
- Hexahydromethylphthalic anhydride
- 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)
- Tricosafleurododecanoic acid
- Perfluorodecanoic acid (PFDA)
- 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)
- Perfluorononan-1-oic-acid (PFNA)
- Heptacosafleurotetradecanoic acid
- 2-benzotriazol-2-yl-4,6-di-tert-butylphenol
- 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)
- Hexahydro-1-methylphthalic anhydride
- Formaldehyde
- [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride
- Hexahydro-3-methylphthalic anhydride
- N,N-dimethylformamide (DMF)
- 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)
- 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DIDP)
- 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear
- 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters
- 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)
- Perfluorotridecanoic acid
- Nickel (Ni)
- Cyclohexane-1,2-dicarboxylic anhydride
- 1-methyl-2-pyrrolidinone (NMP)
- reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)

4.1. Stakeholder Consultation 2019-4

A third stakeholder consultation with relation to the substance inventory was held from 5th December 2019 until 13th February 2020¹⁸. The purpose of this consultation was to collect input concerning quantitative usage data for the 43 priority substances in EEE identified in the highest priority group of the substance inventory (i.e., the prioritised shortlist).

The prioritized shortlist included the following information:

- Substance identity (CAS No., EC No., Name, Group)
- Description of the known uses (applications) and volumes of use (quantities) in general
- Description of the known uses (applications) and volumes of use (quantities) in EEE
- Indication whether substance is used as nanomaterial in EEE

A guidance document included questions to stakeholders pertaining to verifying and complementing the information provided in the prioritised shortlist. The main purpose of this consultation was to collect input concerning quantitative usage data for the 43 priority substances in EEE identified in the highest priority group of the substance inventory. Where this was not possible, estimations on the range of use was requested, with a view to a refined prioritisation for future review cycles. Stakeholders were also asked to specify whether they supported the information compiled and to contribute information as to possible impacts that the presence of the substance may cause during use and/or waste management (relating to RoHS Article 6(1) criteria).

Comments were received from 4 organisations¹⁸:

- Nickel Institute
- Wirtschaftsverband Stahl- und Metallverarbeitung e.V. (WSM)
- MedTech Europe
- Japan Electronics and Information Technology Industries Association (JEITA)

Contributions directly related to the questions asked in relation to the prioritised shortlist have been summarized in Table 4-1, also listing the actions that were taken accordingly. Other received contributions were more focused on the Substance Methodology and are thus not listed here.

¹⁸ <https://rohs.exemptions.oeko.info/index.php?id=347> [last accessed on 19th February 2020]

Table 4-1: Stakeholder comments received, and actions taken

Stakeholder	Comments directly related to the questions asked in relation to the substance inventory	Action taken
Nickel Institute	Additional information on general uses of nickel	Added to the information on nickel
MedTech Europe	Additional information on main uses, presence in EEE, REACH SVHC status, and further comments for all substances in the priority list	Relevant information was added
JEITA	Additional information on main uses, presence in EEE, REACH SVHC status, and further comments for all substances in the priority list	Relevant information was added

Further comments pointed out:

- A lack of transparency in the hazard grouping of substances;
- A previous study by the Danish EPA was quoted to state "Nickel in stainless steel is generally not a concern";
- Germany regulates nickel via a national German OEL for nickel at 0.030 mg Ni/m³ (respirable fraction) and 0.006 Ni/m³ (alveolar fraction) under the German Technical Regulation for Hazardous Substances (TRGS) 900 "Occupational Exposure Limits";
- ECHA RAC recommended a rounded value of 0.005 mg Ni/m³ as an OEL for the respirable fraction of nickel metal in March 2018.

4.2. Finalization and clustering of substances

Taking into account stakeholder contributions, the final results of the prioritisation were generated. In this step, a last modification to the list of substances was necessary as detailed below.

Three substances were added, that were falsely eliminated from the list in a previous step¹⁹:

- Di-"isodecyl" phthalate (DIDP) (CAS Nr.: 26761-40-0)
- Di-"isononyl" phthalate (DINP) (CAS Nr.: 28553-12-0)
- Di-n-octyl phthalate (DnOP) (CAS Nr.: 117-84-0)

As the substance 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (CAS Nr.: 68515-49-1) was already contained in the inventory and is considered fully interchangeable with DIDP²⁰, both substances were merged into a single entry in the list.

One substance was removed, that was previously falsely listed as used as nanomaterial in EEE (this changed resulted in its reclassification into group III):

- reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)

The final RoHS Working List therefore contains 44 entries (substances / substance groups). The substances were clustered into five groups to provide more structure to the list. A further prioritisation of substances on the list according to the methodology was only possible to a limited degree, as usage data (volumes of use; use as nanomaterial) for the substances was absent in the majority of cases.

For the sorting and clustering, the following criteria were accounted for:

- Hazard group
- High volume of use and/or use as nanomaterial
- Indication that substance is a potential substitute for substances that are listed on RoHS Annex II or are under assessment for possible inclusion on RoHS Annex II
- Indication that substance is a potential substitute for another substance on the list (to facilitate parallel assessments);
- Indication that substance may possibly not be present in EEE²¹;

Usage data was available only for three substances/groups (with one of the individual substances being in scope of one group of substances included therein). The relevance

¹⁹ Elimination from the RoHS Working List due to low hazard grouping; however, relevance under REACH (Criterion A) required reinstating substances when this became clear

²⁰ <https://echa.europa.eu/documents/10162/b66cca3a-5303-455b-8355-63bf741e263b> [last accessed on 17th April 2020)

²¹ In cases where substances were indicated to not be present in EEE, for instance according to IEC 62474 or statements by contributing stakeholders. Those indications were, however, not considered sufficient to remove substances from the list as it could not be ensured that such statements were representative for EEE of various sectors and manufacturers.

of this differentiator should be checked in relation to the availability of data in the future (for example, additional data on presence in articles may be available through the SCIP data base and other future initiatives).

The result of the sorting and clustering is listed in the following. More details on each substance are included in the RoHS Working List.

It should be noted that the inclusion of a substance in the below list does not presume a recommendation for the inclusion in Annex II of the RoHS Directive. The inclusion in the below list indicates that a substance is of the highest priority for a detailed assessment according to the methodology manual. Only the detailed assessment (Part III of the methodology manual) may result in a recommendation to restrict a substance for the use in EEE under RoHS Annex II.

Cluster I a)

Cluster I a) comprises substances of the highest hazard group, for which data indicated a high volume of use, the use as nanomaterial in EEE, or a substitution potential for other RoHS-relevant substances, thereby fulfilling several criteria that point to their high relevance for a detailed assessment.

CAS No	EC No	Name
7440-02-0	231-111-4	Nickel
1313-99-1	215-215-7	Nickel monoxide
1314-13-2	215-222-5	Zinc oxide
25155-23-1	246-677-8	Trixylyl phosphate (TXP)
68515-42-4	271-084-6	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)
28553-12-0	249-079-5	Di-"isononyl" phthalate (DINP)
26761-40-0; 68515-49-1	247-977-1; 271-091-4	Di-"isodecyl" phthalate (DIDP)

Cluster I b)

Cluster I b) comprises substances of the highest hazard group, or substances that were indicated to be substitutes for other substances in this cluster (to facilitate parallel assessments).

CAS No	EC No	Name
3864-99-1	223-383-8	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)

36437-37-3	253-037-1	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)
3846-71-7	223-346-6	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)
25973-55-1	247-384-8	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)
131-18-0	205-017-9	Dipentyl phthalate (DPP)
71888-89-6	276-158-1	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich = Diisoheptyl phthalate (DIHP)
68515-50-4	271-093-5	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear (DIHP)
115-96-8	204-118-5	Tris(2-chloroethyl)phosphate (TCEP)
13674-87-8	237-159-2	Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)
13674-84-5	237-158-7	Tris(2-chloro-1-methylethyl) phosphate (TCCP)
10043-35-3	233-139-2	Boric acid
375-95-1	206-801-3	Perfluorononan-1-oic-acid (PFNA)
50-00-0	200-001-8	Formaldehyde

Cluster I c)

Cluster I c) comprises substances of the highest hazard group, for which the presence in EEE is uncertain (incl. information from IEC 62474, stakeholder contributions from industry associations, or from individual stakeholders, as noted in the RoHS Working List).

CAS No	EC No	Name
1303-96-4	603-411-9	Disodium tetraborate, anhydrous
1303-86-2	215-125-8	Diboron trioxide
335-76-2	206-400-3	Perfluorodecanoic acid (PFDA)
117-82-8	204-212-6	Bis(2-methoxyethyl) phthalate (DMEP)
85-42-7	201-604-9	Cyclohexane-1,2-dicarboxylic anhydride
548-62-9	208-953-6	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (Crystal Violet)
123-77-3	204-650-8	C,C'-azodi(formamide) = Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)
106-94-5	203-445-0	1-bromopropane (n-propyl bromide)

111-96-6	203-924-4	Bis(2-methoxyethyl) ether (Diglyme)
68-12-2	200-679-5	N,N-dimethylformamide (DMF)
872-50-4	212-828-1	1-methyl-2-pyrrolidinone (NMP)
25550-51-0	247-094-1	Hexahydromethylphthalic anhydride (MHHPA)
19438-60-9	243-072-0	Hexahydro-4-methylphthalic anhydride
48122-14-1	256-356-4	Hexahydro-1-methylphthalic anhydride
57110-29-9	260-566-1	Hexahydro-3-methylphthalic anhydride
127-19-5	204-826-4	N,N-dimethylacetamide (DMAC)
1303-28-2	215-116-9	Diarsenic pentaoxide; Arsenic pentoxide; Arsenic oxide
1327-53-3	215-481-4	Diarsenic trioxide; Arsenic trioxide

Cluster I d)

Cluster I d) comprises substances of lower hazard groups.

CAS No	EC No	Name
25973-55-1	247-384-8	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)
68515-51-5	271-094-0	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters

Cluster I e)

Cluster I e) comprises substances of lower hazard groups, for which the presence in EEE is uncertain (incl. information from IEC 62474, stakeholder contributions from industry associations, or from individual stakeholders, as noted in the RoHS Working List).

CAS No	EC No	Name
2058-94-8	218-165-4	Henicosfluoroundecanoic acid (PFUnDA)
376-06-7	206-803-4	Heptacosfluorotetradecanoic acid (PFTDA)
307-55-1	206-203-2	Tricosfluorododecanoic acid (PFDODA)

72629-94-8	276-745-2	Perfluorotridecanoic acid
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