EEE Substance Inventory

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

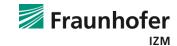
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Outline

- Goal and method
- Stakeholder process
- Actions taken since the last stakeholder consultation
- Results and discussion
- Discussion (15 mins)

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Goal and method

- Goal: Identification and prioritisation of substances for a detailed assessment for the inclusion in Annex II under the RoHS Directive (list of restricted substances)
 - Inventory of substances with hazardous properties in EEE that are prioritized for a detailed assessment for a restriction under RoHS Annex II
- Method: Following Part I and II of the methodology manual to:
 - Create/update an inventory of substances in EEE from a range of sources (incl. REACH registered substances; IEC 62474 declarable substances DB; studies and reports) (Part I)
 - Research and list relevant attributes of each substance (status under RoHS, REACH, and other EU legislation; hazardous properties; volumes of use in EEE; etc.) (Part I)
 - Prioritise substances according to defined criteria (Part II)

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Goal and method

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

Criteria		Colour coded priority								
Human Health & Environment (REACH Annexes)										
High volume of use (nano)										
Resulting overall priority of substances / substance groups	I	11	111	IV	V	VI	VII	VIII	іх	x

Source: Adapted with revisions from AUBA (2013)

Additional criterion: Substances that are listed on Annex XIV or XVII of REACH, or are proposed for inclusion, are also prioritised

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Stakeholder process

- **3 stakeholder consultations** were held with relevance to the substance inventory*
 - 2018 Consultation 2: EEE substance inventory
 - 2019 Consultation 3: Pre-prioritised substance inventory
 - 2019 Consultation 4: Prioritised shortlist

Information was requested on

- Additional substances that are used in EEE but were not yet included in the inventory
- Information on the usage of substances in the EU (presence in EEE, applications, volumes of use, use as nanomaterial) in general and in EEE; additive or reactive use, substitution
- Evidence that would change the priority group for listed substances
- Evidence that a substance has known impacts according to RoHS Article 6(1)(a-c)
- Contributions were received from 18 stakeholders in total (mostly associations, a few individual companies)*

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Actions taken since the last stakeholder consultation

Addition of 3 substances that were falsely eliminated from the list in a previous step:

- 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)
- Removal of 1 substance that was previously falsely indicated for use as nanomaterial in EEE:
- 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)
- Sorting of the 44 substances with the highest priority into 5 clusters

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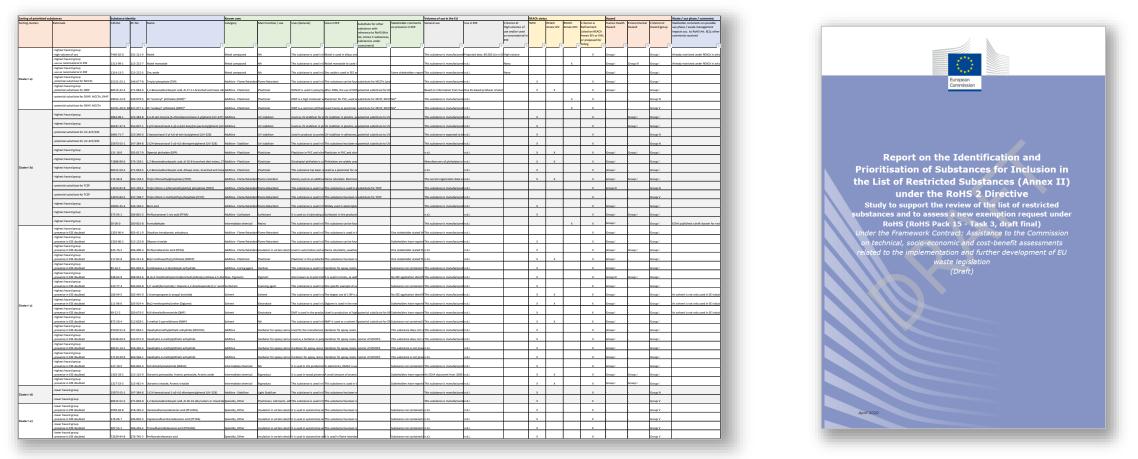
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Results

Prioritised substance inventory (spreadsheet, 2 tabs)

Report (draft version*)



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*Available at: https://rohs.exemptions.oeko.info/index.php?id=341

Results: Prioritised substance inventory (spreadsheet)

Tab 1: Prioritised substances

- 44 substances/substance groups of the highest priority (group I)
- Including detailed information on each substance
- Sorted into 5 clusters

Tab 2: Non-prioritised substances

- 799 substances/substance groups of lower priority (groups II – X)
- Including basic information on each substance
- Only sorted according to group#



Results: Prioritised substances – Included information on each substance

Known uses												
Category	Main	function / use	Uses (Ge	neral)	Uses	in EEE		subst releva list, A subst	itute for othe ance with ance to RoHS nnex II substa ances under sment)	i (this	Stakeholder o on presence i	
Volumes of use	in the EU					REACh st	atus					
General use		Use in EEE		Criterion B: High volumes of use and/or usec as nanomateria EEE	1	SVHC		ACh nex XIV	REACh Annex XVII	Refir Liste Anne	rion A nement: d on REACh ex XIV or XVII, roposed for g	
Hazard			Waste	/ use phase / co	mm	ents						
Human Health Hazard	Environmenta Hazard	l Criterion A: Hazard group	Stakho use ph impact	Ider comments c ase / waste mana s acc. to RoHS A ents received	on po agem	ossible nent					9	
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Results: Prioritised substances – Criteria for sorting into 5 clusters

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 EEE
 - E.g. IEC 62474 Declarable Substances DB; stakeholder comments
 - Information was noted in the list but not considered sufficient to remove substances from the list as it could not be ensured that statements were representative for all EEE sectors / manufacturers

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Results: Prioritised substances – Cluster I a)

Substance identity			Sorting of prioritised substances	Known uses	
CAS No	EC No	Name	Sorting rationale		
7440-02-0	231-111-4	Nickel	 highest hazard group high volume of use 	Volumes of use	
1313-99-1	215-215-7	Nickel monoxide	 highest hazard group use as nanomaterial in EEE 	Hazard	
1314-13-2	215-222-5	Zinc oxide	 highest hazard group use as nanomaterial in EEE 	Waste / use phase / comments	
25155-23-1	246-677-8	Trixylyl phosphate (TXP)	 highest hazard group potential substitute for MCCPs 		
68515-42-4	271-084-6	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	 highest hazard group potential substitute for DIDP 		
28553-12-0	249-079-5	Di-"isononyl" phthalate (DINP)*	- potential substitute for DEHP, MCCPs, DIHP		
26761-40-0; 68515-49-1	247-977-1; 271-091-4	Di-"isodecyl" phthalate (DIDP)*	- potential substitute for DEHP, MCCPs		

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Results: Prioritised substances – Cluster I b)

Substance identity			Sorting of prioritised substances	Known uses
CAS No	EC No	Name	Sorting rationale	
3864-99-1	223-383-8	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	- highest hazard group	Volumes of use
36437-37-3	253-037-1	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-	- highest hazard group	REACh status
3846-71-7	223-346-6	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	- potential substitute for UV-327/350	Hazard
25973-55-1	247-384-8	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	- potential substitute for UV-327/350	
131-18-0	205-017-9	Dipentyl phthalate (DPP)	- highest hazard group	Waste / use phase comments
71888-89-6	276-158-1	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7	- highest hazard group	comments
68515-50-4	271-093-5	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linea	- highest hazard group	
115-96-8	204-118-5	Tris(2-chloroethyl)phosphate (TCEP)	- highest hazard group	
13674-87-8	237-159-2	Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)	- potential substitute for TCEP	
13674-84-5	237-158-7	Tris(2-chloro-1-methylethyl) phosphate (TCCP)	- potential substitute for TCEP	
10043-35-3	233-139-2	Boric acid	- highest hazard group	
375-95-1	206-801-3	Perfluorononan-1-oic-acid (PFNA)	- highest hazard group	
50-00-0	200-001-8	Formaldehyde	- highest hazard group	8

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Results: Prioritised substances – Cluster I c) (1/2)

Substance id	lentity		Sorting of prioritised substances	Known use
CAS No	EC No	Name	Sorting rationale	KIIOWII USE
1303-96-4	603-411-9	Disodium tetraborate, anhydrous	 highest hazard group presence in EEE uncertain 	Volumes of u
1303-86-2	215-125-8	Diboron trioxide	 highest hazard group presence in EEE uncertain 	REACh status
335-76-2	206-400-3	Perfluorodecanoic acid (PFDA)	 highest hazard group presence in EEE uncertain 	Hazard
117-82-8	204-212-6	Bis(2-methoxyethyl) phthalate (DMEP)	 highest hazard group presence in EEE uncertain 	Waste / use comments
85-42-7	201-604-9	Cyclohexane-1,2-dicarboxylic anhydride	 highest hazard group presence in EEE uncertain 	
548-62-9	208-953-6	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-die	- highest hazard group - presence in EEE uncertain	
123-77-3	204-650-8	C,C'-azodi(formamide) = Diazene-1,2-dicarboxamide (C,C'-azod	- highest hazard group i- presence in EEE uncertain	
106-94-5	203-445-0	1-bromopropane (n-propyl bromide)	 highest hazard group presence in EEE uncertain 	
111-96-6	203-924-4	Bis(2-methoxyethyl) ether (Diglyme)	 highest hazard group presence in EEE uncertain 	

use

phase /

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Results: Prioritised substances – Cluster I c) (2/2)

Substance id	lentity		Sorting of prioritised substances	Known usos
CAS No	EC No	Name	Sorting rationale	Known uses
68-12-2	200-679-5	N,N-dimethylformamide (DMF)	 highest hazard group presence in EEE uncertain 	Volumes of use
872-50-4	212-828-1	1-methyl-2-pyrrolidinone (NMP)	 highest hazard group presence in EEE uncertain 	REACh status
25550-51-0	247-094-1	Hexahydromethylphthalic anhydride (MHHPA)	 highest hazard group presence in EEE uncertain 	Hazard
19438-60-9	243-072-0	Hexahydro-4-methylphthalic anhydride	 highest hazard group presence in EEE uncertain 	Waste / use pha comments
48122-14-1	256-356-4	Hexahydro-1-methylphthalic anhydride	 highest hazard group presence in EEE uncertain 	
57110-29-9	260-566-1	Hexahydro-3-methylphthalic anhydride	 highest hazard group presence in EEE uncertain 	
127-19-5	204-826-4	N,N-dimethylacetamide (DMAC)	 highest hazard group presence in EEE uncertain 	
1303-28-2	215-116-9	Diarsenic pentaoxide; Arsenic pentoxide; Arsenic oxide	 highest hazard group presence in EEE uncertain 	
1327-53-3	215-481-4	Diarsenic trioxide; Arsenic trioxide	 highest hazard group presence in EEE uncertain 	

phase /

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Results: Prioritised substances – Cluster I d) and e)

Cluster d)

Substance ide	entity		Sorting of prioritised substances	Known uses
CAS No	EC No	Name	Sorting rationale	
				Volumes of u
25973-55-1	247-384-8	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	- lower hazard group	
				REACh status
68515-51-5	271-094-0	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed de	- lower hazard group	Llesevel

Cluster e)

Substance identity			Sorting of prioritised substances
CAS No	CAS No EC No Name		Sorting rationale
2058-94-8	218-165-4	Henicosafluoroundecanoic acid (PFUnDA)	 lower hazard group presence in EEE uncertain
376-06-7	206-803-4	Heptacosafluorotetradecanoic acid (PFTDA)	 lower hazard group presence in EEE uncertain
307-55-1	206-203-2	Tricosafluorododecanoic acid (PFDoDA)	 lower hazard group presence in EEE uncertain
72629-94-8	276-745-2	Perfluorotridecanoic acid	 lower hazard group presence in EEE uncertain

es

use

Hazard

Waste / use phase / comments

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Interpretation of results

- Substances of the highest priority are not automatically included in Annex II of the RoHS Directive
- Substances of the highest priority are prioritised for a detailed assessment according to Part III of the methodology, which takes into account additional information (including exposure assessment, alternative substances/technologies, socio-economic impacts of inclusion in Annex II under RoHS, etc.), resulting in a recommendation for or against inclusion of assessed substances in Annex II under RoHS
- The European Commission may decide to include substances of highest priority in a detailed assessment in the future



Discussion points (1/3)

- Data availability: Data on volumes of use (quantity) of substances present in EEE in the EU are practically not available
 - Registration dossiers under REACH account for substance volumes manufactured or imported into the EU as such, but not in articles – EEE are largely imported into the EU
 - Industry and associations commonly have quantitative data for their own production/ sector, but not on quantities in EEE in the EU in total
 - Some stakeholder statements regarding the presence of substances in EEE were contradictory (used in EEE / not used in EEE)
- Therefore, quantity data was not sufficiently available to generate a magnitude ranking → data gap





• **Question**: Why is nickel in the highest priority group?

• **Answer**: Nickel fulfils several of the criteria that indicate the highest priority:

- Highest hazard group due to harmonized classification (acc. CLP Annex VI) as:
 - Carcinogen category 2 (Carc 2)
 - Specific target organ toxicity after repeated exosure category 1 (STOT RE 1)
 - Skin sensitisation category 1 (Skin Sens. 1)
- High volume of use: 80.000 t/a in EU-28 in 2020 [1] for nickel and its compounds
- Listed on REACH Annex XVII

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Question: Why is specific substance XY ranked as it is?

Answer: The priority of substances included in the process were determined following the methodology manual (please see for details of the methodology). Final results (spreadsheet) will include all properties of prioritised substances that determined their priority and cluster (clusters I a – e).

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Additional discussion points?

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Human Health Hazard Groups

Table 1-2:

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

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Table 1-3: **Environmental Hazard Groups**

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

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