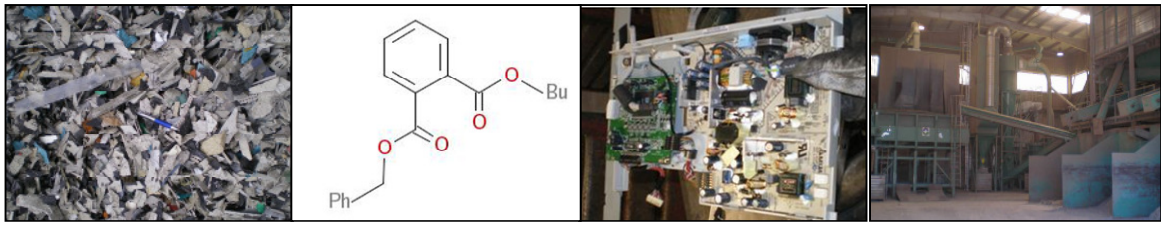
ENVIRONMENT AGENCY AUSTRIA umweltbundesamt

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

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

2nd Interim Report



Vienna, September 2013

Prepared by

Umweltbundesamt

The study was commissioned by the European Commission, Directorate General Environment, DG ENV/CLIMA.SRD.2, Brussels

1 INTRODUCTION TO THE 2ND INTERIM REPORT

WP1 of the project was to develop a methodology for the identification and assessment of substances for inclusion in the list of restricted substances (Annex II) under the RoHS2 Directive.

WP2 of the project deals with applying this methodology to selected substances.

This report describes:

- the process of developing the methodology and establishing a manual which gives guidance on how to apply it (including stakeholder involvement).

  The 2nd draft of the manual is attached as an Annex to this report.
- the results of applying Part I (Identification) and Part II (Pre-assessment) of the methodology

The table below displays the project schedule and the current status of the individual tasks of the four work packages.

Table 1: Project schedule and current status of tasks

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												
Colour code		finished				ongoing				Not yet started			

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

2 INTERIM RESULTS

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

Methodology approach

The general methodology approach was published on the project website on 20 February 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).

Manual, first draft

Considering the received comments a first draft of the manual was published on the project website on 7 May 2013 and put up for discussion during the 3rd internet consultation (7 May – 10 June 2013) and during the second stakeholder meeting held on 14 May 2013 in Brussels. The aspects discussed during the 2nd stakeholder meeting are summarized in the minutes of the meeting (see Chapter 4.1, Annex).

Manual, second draft

The second draft of the manual, which is provided as an Annex to the present report, includes comments received during the 2nd stakeholder meeting and during the 3rd internet consultation.

2.2 Identification of substances

The identification of substances used 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 (1) a, b, c was performed as described in the methodology manual.

2.2.1 Step I 1) Creation of an inventory of substances used in EEE

The sources of information used for the inventory of substances in EEE" (PART I, Step 1), i.e. databases and studies on EEE and WEEE, are provided as an Annex to the manual (Chapter 6.1).

Some of the substance lists which were used to build up the EEE inventory also contain substances which are not present in EEE but are used during the production process. Examples are the SPIN-database or the IEC 62474 Database „Declarable Substances". Therefore, a manual screening of those substances was performed.

2.2.2 Step I 2a) Selection of substances used in EEE, which are hazardous

The selection of the substances was based on their fulfilment of the following criteria as specified in the manual.

Table 2: Criteria for the identification of candidates from a master list

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
Radioactive

2.2.3 Step I 2b) Select substances used in EEE which are of concern during WEEE management (Article 6 (1) a, b, c)

The following sources have been evaluated for identification of substances and substance groups that are of concern during waste management – even if they do not fulfill the criteria specified in the table above:

- DANISH EPA 2012;
- KEMI 2011;
- ÖKOINSTITUT 2008;
- Berkley Center for Green Chemistry 2012;
- Umweltbundesamt 2008.

2.2.4 Inventory of substances used in EEE

The inventory of substances used in EEE established as described above resulted in a list of 705 entries.

After manually deleting substances which are most likely not present in EEE (i.e. only used in production) **579 entries** remained. 556 entries thereof were specified by a single identifier (CAS and/or EC-No). In addition 23 entries, either substance groups or substances, where no single identifier is available, are contained in the list.

The EEE-substance-inventory is provided as an Annex (Chapter 4.1) to this report.

As due to the requirements of ROHS2 special attention shall be given to the use of nano-materials in EEE the recent review of nano-materials by the European Commission[1] was analyzed. More than 30 substances used as nano-materials were reported (Commission staff working paper, 2012)

2.2.5 Hazardous substances used in EEE

A selection of substances fulfilling the criteria described in Table 1 led to 277 substances (Outcome of Step I 2a).

2.2.6 Substances used in EEE which fulfil the criteria listed in Article 6 (1) a) to c) of RoHS2

Existing evidence that one of the criteria specified by Article 6 (1) a, b, or c is fulfilled led to the selection of 22 elements and inorganic compounds and 36 organic substances and substance groups (Outcome of Step I 2b).

[1] **http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_staff_working_paper_accompanying_com(2012)_572.pdf**

2.3 Pre-assessment of selected substances

2.3.1 Prioritization of substances

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

1) In general, the allocation to human health and environmental hazard groups was based on the CLP classification system on the one hand and on criteria defined within REACH on the other.
2) Substances fulfilling the SVHC criteria as defined within REACH receive highest priority. These are CMR (carcinogenic, mutagenic, toxic to reproduction) substances of category 1 and substances acutely toxic category 1 and PBT and vPvB substances respectively (persistent, bioaccumulative and toxic and very persistent and very bio-accumulative, respectively). Substances which have already undergone the REACH evaluation process for other reasons are also regarded as high priority substances.
3) Those substances from the list which were categorized as Human Health Hazard Group I and either as Environmental Hazard Group I or II were selected. Due to the limited number of fully assessed PBT (persistent, bioaccumulative and toxic) substances which fulfil the criterion for Environmental Hazard group I, Environmental Hazard Group II was selected, too.
4) Based on the information already collected for identifying substances being of concern during waste management substances/substance groups fulfilling any of the criteria specified by Article 6 (1) a, b or c of RoHS2 (red category) were selected.
5) For those substances which were selected due to their hazardous properties (human health and environmental hazards) the waste relevance was assessed.
6) For those substances, which were selected due to their waste relevance human, health and environmental hazard properties were evaluated. For substances, which have no harmonised classification, the self-classifications by notifiers were analysed.

2.3.2 Evaluation of the legal restriction status

The following information on the legal restriction status was added in the prioritization-list.

- The list of substances was evaluated for the substances' presence in the lists of prohibited/restricted substances in accordance with the POPs Regulation, (EC) No 850/2004 amended by (EU) No 756/2010 and (EU No 757/2010)
- To obtain information on the REACH status of the compounds the ECHA website (section: Information on chemicals; **http://echa.europa.eu/information-on-chemicals**) has been screened (date 28.06.2013):The CAS numbers of the individual compounds were entered in the search mask. The retrieved results - whether the substance is registered in the SVHC candidate and/or in the authorisation list – have been recorded.

2.3.3 Results of the prioritization of substances

The main results of the prioritization can be summarized as follows:

In total, 11 substances were found which fulfil all 3 waste criteria and the hazard properties (human health & environment) of which are in priority group I. These are: ***Priority I***

Phtalates:

- DEHP
- BBP
- DBP
- Diisobutylphtalate

Halogenated flame retardants

- Hexabromocyclododecane
- Dibromo-neopentyl-glycol
- Dibromo-propanol
- SCCP (short chained chlorinated paraffins), C10-13

Other halogenated compounds

- 1,2-dibromoethane
- tris(2-chloroethyl)phosphate
- Hexachlorobenzene (→ already listed in the Stockholm Convention!)

In total, 4 substances were found which fulfil all 3 waste criteria and the hazard properties (human health & environment) of which are in priority group II. These are: ***Priority II***

- Diethyl phthalate (DEP)
- MCCP (medium chained chlorinated paraffins), C14 – C17
- Antimontrioxid
- Tetrabromobisphenol A"

One substance could be identified in the overall priority category III: ***Priority III***

- Polyvinylchloride

Five substances could be identified in the overall priority category IV: ***Priority IV***

Nickel

- Nickel sulfate
- Nickel bis(sulfamidate); Nickel sulfamate

Beryllium

- Beryllium metal
- Beryllium oxide (BeO)

and

- Indium phosphide

The prioritization results in detail are provided as a separate document („Prioritization Results.xls.“)

3 ABBREVIATIONS

BCF ..... Bioconcentration factor

BREF ..... Best available technology references document

BBP ..... Butyl benzyl phthalate

CLP ..... Classification and Labelling regime

CMR ..... Carcinogenic category 1 or 2; mutagenic category 1 or 2, toxic for reproduction category 1 or 2 according to CLP classifications

CSR ..... Chemical safety report

DBP ..... Dibutyl phthalate

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

DNEL ..... Derived no effect level

ECHA ..... European Chemicals Agency

EEE ..... Electrical and electronic equipment

HBCDD ..... Hexabromocyclododecane

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

NOAEC ..... No observable adverse effect concentration

NOAEL ..... No observable adverse effect level

PBT ..... Persistent, bioaccumulative and toxic

PNEC ..... Predicted no effect concentration

RAC ..... Risk assessment committee

RAR ..... Risk assessment report

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

RoHS ..... Restriction of Hazardous Substances

RCR ..... Risk characterisation ratio

SEAC ..... Socio-economic committee

STOT SE ..... specific target organ toxicity: single exposure

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

SVHC ..... Substance of very high concern

vPvB ..... very Persistent and very Bioaccumulative

WEEE ..... Waste electrical and electronic equipment

4 ANNEX

4.1 2013-Inventory of substances used in EEE

See separate document (EEE-Substance-Inventory-2013.xls)

4.2 Prioritization results

See separate document (Prioritization.xls)

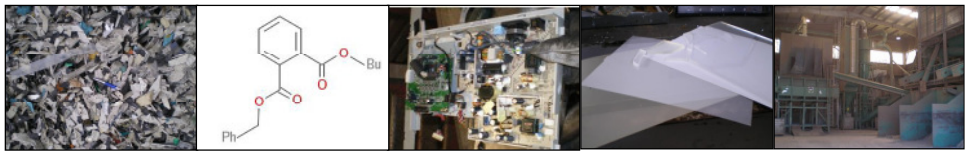
4.3 Minutes of the1st stakeholder meeting held on 13 March 2013

Minutes

First stakeholder meeting

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

Prepared by Umweltbundesamt



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 in-

volved. 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.

List of participants:

No	Name/Category	Mail
	Commission Services	
1	**EU** - Artemis Hatzi (project team contractor)	artemis.hatzi@ec.europa.eu
2	**EU** - Hans-Christian Eberl (project leader contractor)	hans-christian.eberl@ec.europa.eu
3	**EU** - Giuseppina Luvara	giuseppina.luvara@ec.europa.eu
4	**EU** - Julien De-Cruz	julien.de-cruz@ec.europa.eu
5	**EU** - Mihaela Stefanescu	mihaela.stefanescu@ec.europa.eu
6	**EU** - Iain Forsyth	iain.forsyth@ec.europa.eu
	Member States Representatives	
7	**Denmark** - Dorte Bjerregaard Lerche	doble@mst.dk
8	**Finland** - Else Peuranen	tuottajavastuu@ely-keskus.fi
9	**Germany** - Heike Schröder	heike.schroeder@bmu.bund.de
10	**Germany** - Jana Dörschel	jana.doerschel@bmwi.bund.de
11	**Netherlands** - Renee Sondervan	renee.sondervan@minienm.nl
12	**Norway** - Ulla Hegg	ulla.hegg@mfa.no
13	**Poland** - Renata Znamirowska-Orzechowska	renata.znamirowska-orzechowska@mg.gov.pl
14	**UK** - Iain Nicol	iain.nicol@bis.gsi.gov.uk
	Industry Associations	
15	**American Chamber of Commerce to the EU** - Julie Linde Kjeldsen	jlk@amchameu.eu
16	**Austrian Economic Chamber** - Thomas Fischer	thomas.fischer@wko.at
17	**CECED** - European Committee of Domestic Equipment Manufacturers - Malte Becker (Electrolux)	malte.becker@electrolux.be
18	**CEFIC** - European Chemical Industry Council - Cristiana Gaburri	cga@cefic.be
19	**COCIR** - European Association of the radiological, electromedical and healthcare - Riccardo Corridori	corridori@cocir.org
20	**DigitalEurope** - Julian Lageard	julian.lageard@intel.com
21	**DigitalEurope** - Lars Brückner	lars.bruckner@emea.nec.com
22	**EDMA** - European Diagnostic Manufacturers Association - Petra Zoellner	p.zoellner@edma-ivd.eu
23	**EFRA** - European Flame Retardants Association - Florian Kohl	florian.kohl@albemarle.com
24	**EGMF** - European Garden Machinery industry Federation - Marcel Dutrieux	marcel.dutrieux@honda-eu.com
25	**EPPA** - European Promotional Products Association - Meglena Mihova	meglena.mihova@eppa.com

No	Name/Category	Mail
26	**ESIA** - European Semiconductor Industry Association - Shane Harte	sharte@eeca.be
27	**Eurometaux** - European Association of Metals - Inneke Claes	claes@eurometaux.be
28	**IPC** - Association Connecting Electronics Industries - Fern Abrams	fernabrams@ipc.org
29	**JBCE** - Japanese Business Council in Europe - Nakai Akihito	nakai@jbce.org
30	**JBCE** - Japanese Business Council in Europe - Danny Van Roijen	danny.van.roijen@pioneer.eu
31	**ORGALIME** - European Engineering Industries Association - Picard Anne-Louise	anne-louise.picard@orgalime.org
32	**pinfa** - Phosphorus, Inorganic and Nitrogen Flame Retardants Association - Adrian Beard	adrian.beard@clariant.com
33	**SEMI** - Global industry association serving the manufacturing supply chain - Ourania Georgoutsakou	gourania@semi.org
34	**TechAmerica Europe** - Chiara Venturini	chiara.venturini@techamerica.org
35	**TechAmerica Europe** - Kurt van der Herten	kurt.vanderherten@be.ibm.com
	Industry Companies / Consultants	
36	**Apple** - Thomas Ebert	ebert.t@apple.com
37	**Daikin Europe** - Veerle Beelaerts	beelaerts.v@daikineurope.com
38	**DELL** - Markus Stutz	markus_stutz@dell.com
39	**DENSO** International Europe - Peter Flanker	p.flanker@denso.nl
40	**ERA Technology** - Chris Robertson	chris.robertson@era.co.uk
41	**Hewlett-Packard Company** - Pieter Paul Laenen	pieter-paul.laenen@hp.com
42	**Hewlett-Packard Company** - Ray Moskaluk	ray.moskaluk@hp.com
43	**Kreab Gavin Anderson** - Marie Görkem	mgorkem@kreabgavinanderson.com
44	**Panasonic** - Satoshi Kayano	satoshi.kayano@eu.panasonic.com
45	**Ridens Consulting** - Caroline Calvez	ccalvez@me.com
	NGOs	
46	**ChemSec** - International Chemical Secretariat - Frida Hök	frida@chemsec.org
	Umwetlbundesamt GmbH	
47	**Umweltbundesamt GmbH** - Brigitte Karigl (project leader consultant)	brigitte.karigl@umweltbundesamt.at
48	**Umweltbundesamt GmbH** - Maria Tesar (project team consultant)	maria.tesar@umweltbundesamt.at
49	**Umweltbundesamt GmbH** - Maria Uhl (project team consultant)	maria.uhl@umweltbundesamt.at
50	**Umweltbundesamt GmbH** - Sabine Cladrowa (project team consultant)	sabine.cladrowa@umweltbundesamt.at

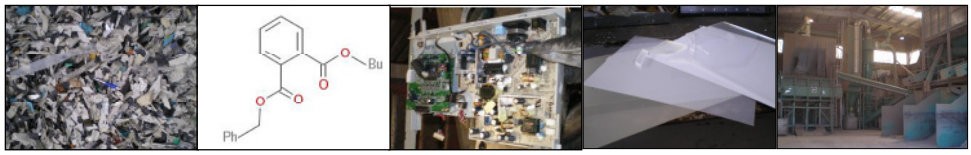
4.4 Minutes of the 2nd stakeholder meeting held on 14 May 2013

Minutes

Second stakeholder meeting

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

Prepared by Umweltbundesamt, amended 28 May 2013



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 substances 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, pre-assessment 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
American Chamber of Commerce to the EU - Leah Charpentier
Austrian Economic Chamber - Thomas Fischer
BeST - Beryllium Science & Technology Association - Caroline Calvez
BeST - Beryllium Science & Technology Association - Heleen Vollers
CECED - European Committee of Domestic Equipment Manufacturers - Malte Becker (Electrolux)
CEFIC - European Chemical Industry Council - Maggie Saykali
ChemSec - International Chemical Secretariat - Frida Hök
COCIR - European Association of the radiological, electromedical and healthcare - Riccardo Corridori
Daikin Europe - Veerle Beelaerts
DELL - Markus Stutz
DigitalEurope - Julian Lageard
JBCE - Lars Brückner
EDMA - European Diagnostic Manufacturers Association - Petra Zoellner
EFRA - European Flame Retardants Association - Florian Kohl
ESIA - European Semiconductor Industry Association - Shane Harte
Eurometaux - European Association of Metals - Inneke Claes
Hewlett-Packard Company - Pieter Paul Laenen
Hewlett-Packard Company - Ray Moskaluk
ICL Industrial Products (IP) - Willem Hofland
JBCE - Japanese Business Council in Europe - Danny Van Roijen
JBCE - Japanese Business Council in Europe - Nakai Akihito
NIA - Nanotechnology Industries Association - Guillaume Flament
ORGALIME - European Engineering Industries Association - Picard Anne-Louise
ORGALIME - European Engineering Industries Association - Sigrid Linher
SEMI - Global industry association - Ourania Georgoutsakou
Siemens AG - Axel Brenner
TechAmerica Europe - Chiara Venturini
TechAmerica Europe - Kurt van der Herten
U.S. Mission to the European Union - Matthew Kopetski
ZVEI - Zentralverband Elektrotechnik- und Elektronikindustrie e.V. - Andre Koring
Lighting Europe – Attila Mórotz
Amcham Meglena - Mihova,
Denmark - Dorte Bjerregaard Lerche
Estonia - Malle Piirsoo
Finland - Marika Keskinen
Sweden - Annika Varnas
UK - Peter Askew
European Commission - Giuseppina Luvarà
European Commission - Hans-Christian Eberl (project leader contractor)
European Commission - Iain Forsyth
European Commission - Mihaela Stefanescu
Umweltbundesamt GmbH - Brigitte Karigl (project leader consultant)
Umweltbundesamt GmbH - Maria Tesar (project team consultant)
Umweltbundesamt GmbH - Maria Uhl (project team consultant)