European Commission DG ENV

A project under the Framework contract
G.4/FRA/2007/0067

STUDY TO SUPPORT THE IMPACT ASSESSMENT OF THE RoHS REVIEW

Final report

September 16, 2008

In association with

Institute for European Environmental Policy

VITO

Bio Intelligence Service - Scaling sustainable development
Industrial Ecology - Nutritional Health

Bio Intelligence Service S.A.S - bio@biois.com
1 rue Berthelot - 94200 Ivry-sur-Seine - France
Tél. +33 (0)1 56 20 23 98 - Fax. +33 (0)1 58 46 09 95

Contact Bio Intelligence Service S.A.S.
Cécile des Abbayes – Lea Turunen
☏ + 33 (0) 1 56 20 28 98
cecile.desabbayes@biois.com
lea.turunen@biois.com

Citation:

This project should be quoted as follows:

BIO, IEEP and VITO (2008) *Study to support the impact assessment of the RoHS Directive review, Final report.*

Project team:

Bio Intelligence Service

Ms. Cécile des Abbayes

Ms. Lea Turunen

Ms. Marta Liput

IEEP

Ms. Catherine Bowyer

Mr. Peter Hjerp

VITO

Mr. Ive Vanderreydt

Content

1. INTRODUCTION

The RoHS Directive 2002/95/EC[1] (Box 1) aims to approximate the laws of the Member States as regards to the restriction of the use of hazardous substances in electrical and electronic equipment and to contribute to the protection of human health as well as environmentally sound recovery and the disposal of waste electrical and electronic equipment.

Box 1: The RoHS Directive

The Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment 2002/95/EC (RoHS) was adopted in February 2003 by the European Union, and took effect on 1 July 2006. The RoHS Directive applies to 8 categories of the Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/EC: large and small household appliances, IT and telecommunications equipment, consumer equipment, lighting equipment, electronic and electrical tools, toys, leisure and sports equipment, automatic dispensers.

This Directive restricts the use of six hazardous substances in the electronic and electrical equipment:

1. Lead
2. Mercury
3. Cadmium
4. Hexavalent chromium
5. Polybrominated biphenyls (PBB)
6. Polybrominated diphenyl ether (PBDE)

Some specific applications listed in Annex 1 of the Directive are exempted. Exemptions are periodically rewieved. Moreover, Decision 2005/618/EC, added as in Annex to RoHS Directive, specifies that the maximum permitted concentrations are 0.1% (except for cadmium, which is limited to 0.01%) by weight in homogeneous materials.

Article 6 of the RoHS Directive gives a mandate to the Commission to review the measures given in the Directive. The review should assess the environmental, social and economic impacts of potential amendments.

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:037:0019:0023:EN:PDF

The 'Study to support the impact assessment of the RoHS review' has been conducted by Bio Intelligence Service, in association with IEEP and VITO. The objective of this work is to assess available data and information, synthesise this information, identify and address the information gaps in order to support the Commission services in drafting their impact assessment for the proposal of the RoHS review. Moreover it aims to develop an analysis of some policy options presented in the second consultation document[2], including where appropriate the amendment of existing options and the development of alternatives. The study includes the collection of specific data and insights on the current practices, the identification of different options as well as the presentation of their pros and cons.

The team would like to thank all the stakeholders from industry and the previous studies authors who kindly provided information to support our work.

This report contains a general overview of the content and conclusion of the individual fact sheets for the different potential amendments. The fact sheets in Annex show the results of the data gathering, the working insights, arguments and conclusions for every issue. Furthermore one additional fact sheet dealing with administrative costs of the amendments of the RoHS review is presented.

1.1 OVERVIEW OF THE WORK

Several studies and other activities have been launched and carried out in the last years in preparation to the review of the RoHS Directive, notably:

- Study on the inclusion of medical devices and control and monitoring instruments in the scope of RoHS (by ERA for DG ENV)[3]
- Study on RoHS's impact on innovation and competitiveness (by ARCADIS & RPA for DG ENTR)[4]
- Study on possible inclusion of additional hazardous substances (by Öko-Institut for DG ENV)[5]
- Studies carried out during 2007 in the context of the WEEE review[6]

Moreover, DG ENV has launched two stakeholder consultations, one in 2007 and the second in the beginning of 2008[7]. First one covered the topics of the review, while the second particularly focussed on policy options within each topic. This project evaluates

2 http://ec.europa.eu/environment/waste/weee/pdf/2nd_consultation.pdf
3 http://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf
4 http://ec.europa.eu/enterprise/environment/reports_studies/index.htm
5 http://hse-rohs.oeko.info
6 http://ec.europa.eu/environment/waste/weee/studies_en.htm
7 http://ec.europa.eu/environment/waste/weee/events_en.htm

four types of possible amendments to the RoHS Directive, which were presented in the 2nd stakeholder consultation document.

The first type deals with possible inclusion into the scope of the Directive of two additional categories of equipment: Categories 8 and 9 products, which are respectively medical devices and monitoring and control instruments.

The second type is taking under consideration potential technical changes to the scope of the Directive in order to clarify some areas of possible misinterpretation.

Next concern is about the inclusion of an appropriate definition for 'homogeneous material' in the RoHS Directive.

The last issues are about facilitating implementation of the Directive. In view of this part are the market surveillance mechanisms, conformity assessment and exemptions procedures, possible insertion of review clause etc.

1.2 COVERAGE OF THE WORK

The potential amendments to the RoHS Directive considered in this study are presented in Table 1. These amendments were chosen by the European Commission at the launch of the study amongst the different options presented in the 2nd Consultation Document.

Table 1 – Potential amendments with options considered in the study

I. Inclusion of Categories 8&9 products in the scope of RoHS Directive	
option 1	Business-as-usual - continue excluding Categories 8 & 9 altogether
option 2	Include Categories 8 & 9 with deferred deadline (indicatively 2014)
option 3	Include Categories 8 & 9 from the beginning (indicatively around 2012) with the exemptions proposed by ERA
option 4	Include Categories 8 & 9 with deferred deadlines (indicatively 2014) and with exemptions proposed by ERA1 as well as general exemption for lead in solders
option 5	For Category 9, differentiate between consumer/industrial equipment for (deadline for industrial equipment indicatively 2018)
option 6	For Category 8, differentiate for In Vitro Diagnostics (IVD) (deadline 2016) and Active Implanted Medical Devices (AIMD) (permanent exclusion or exemption until 2020)

II. Technical changes to the scope of the Directive	
option 1	Business-as-usual
option 2	Include explicitly spare parts & components
option 3	"Repair as produced" principle: exclude parts for repairing and for the reuse of products lawfully placed on the market
option 4	Explicit inclusion of 'finished products ending up in fixed installations' in the scope of the RoHS Directive
option 5	Explicit inclusion of 'finished products ending up in fixed installations' in the scope of the RoHS Directive
option 6	Abandon the general exemption for LSIT
option 7	Explicit inclusion of electricity producing equipment in the scope of the RoHS Directive
III. Definitions - Inclusion of definition for 'homogeneous material'	
option 1	Inclusion of definition: - Business-as-usual (definition in FAQ document) - Inclusion of the definition in RoHS Directive - Inclusion of the definition in an international standard
option 2	Small components: - Business-as-usual - Maximum size limit of 4 mm^3 - Maximum size limit of 40 mm^3
option 3	Metallic coatings: - Business-as-usual - Ban all intentionally added HS
IV. Facilitating implementation	
Introduce market surveillance mechanisms	
option 1	Business-as-usual
option 2	Introduce market surveillance requirements under RoHS
Inclusion of conformity assessment procedures	
option 1	Business-as-usual – No formal approach simply informal guidance
option 2	Self Declaration
option 3	Third Party verification

Insert a review clause with or without progress criteria/indicators	
option 1	Business-as-usual
option 2	Review based on the use of indicators and criteria
option 3	Develop a review clause that contains specific actions and elements of the Directive to be reviewed by a specified date
option 4	Totally unspecified review clause as per the waste framework Directive proposal
Industry and not public authorities to assume the burden of proof and cost	
option 1	Business-as-usual – exemption processes remain as they are
option 2	Shifting the burden of proof to industry
option 3	Establishment of a Notified Body
Manufacturers to provide substitution plan when requesting exemptions	
option 1	Business-as-usual – exemption processes remain as they are
option 2	A basic "light" substitution plan based on the requirements of REACH but adapted to RoHS.
option 3	A comprehensive "full" substitution plan based on the requirements of REACH but adapted to RoHS
Introduce cost/broader sustainability criteria for granting exemptions	

Administrative costs of the amendment of the RoHS review

1.3 PROJECT DEVELOPMENT STAGES

The project started on March, 13th 2008 and lasts until July, 13th (4 months). The aims and objectives of the work were presented at the inception meeting held on March, 10th 2008. Based on the 2nd Consultation Document final options were identified (see above).

Project development stages consisted of four tasks:

TASK 1 – Information review

Review information available from the studies mentioned above.

TASK 2 – Analysis of options

Examine the policy options – adding of reformulating options, rank options etc.

TASK 3 – Collection of additional information

Complete the information and data gaps identified during information review in accordance to relevant options.

TASK 4 – Final options and impact assessment

Present the final options and their impact assessment (according to Commission guidelines).

Figure 1 presents the planning of the study.

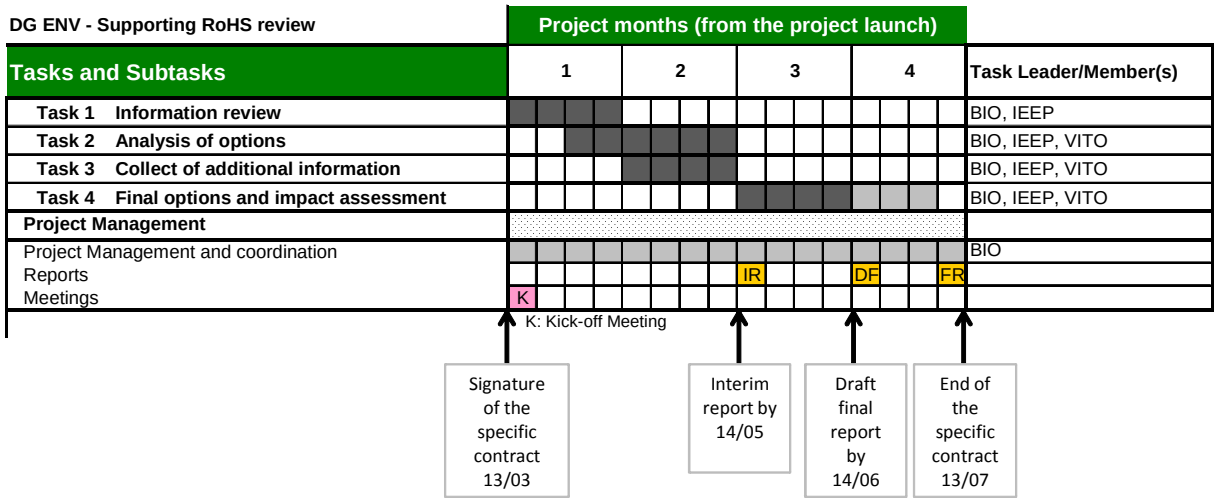

Figure 1 – Study planning

1.4 OVERVIEW OF METHODOLOGY

This study follows the methodology described in the European Commission Impact Assessment guidelines[8]. Impact Assessment (IA) is a process of identifying, predicting, evaluating and mitigating the environmental, economic and social effects of policy options prior to major decisions being taken and commitments made. It consists of five logical steps which structure the preparation of policy proposals:

Step 1 - Problem definition and objectives

Step 2 - Identification of options

Step 3 - Analysis of impact

Step 4 - Comparison of policy options

Step 5 - Conclusion

The aim of an IA is to support the legislators' decision-making process, with an in-depth analysis of all legislative options available and possible impacts that may derive from them. This procedure aims to improve the quality of the policy proposals in terms of

[8] available on http://ec.europa.eu/governance/impact/docs_en.htm

their efficiency, effectiveness and coherency. It identifies alternative policy options and their likely positive and negative impacts, with a particular focus on economic, environmental and social effects, in line with the EU Sustainable Development Strategy.

Figure 2 presents the different tasks of the study linked with the five steps of the IA methodology.

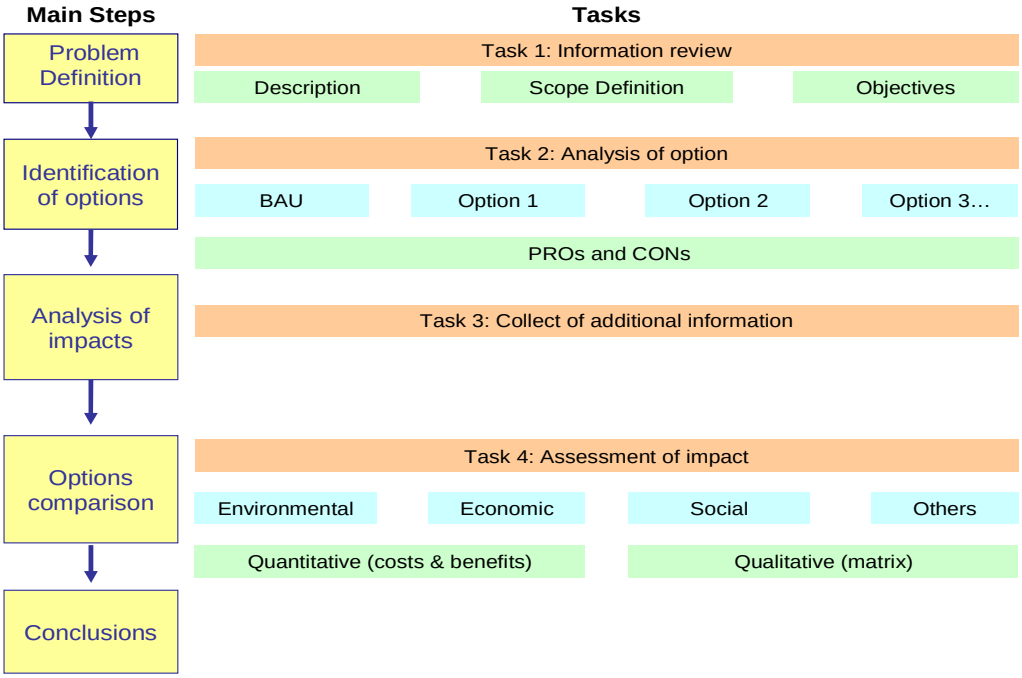

Figure 2 – Methodology

For every policy option assessed in the different fact sheets, the comparison of the different sub-options is presented in the form of a matrix (Table 2). The environmental, economic, social and other issues are explored. In each cell of the matrix a qualitative score is given:

+++	Very beneficial effect
++	Substantial beneficial effect
+	Slight beneficial effect
0	No effect
-	Negative effect
--	Substantial negative effect
---	Very negative effect
N/A	Not applicable

If there are external influencing factors, a range may be used, for example "0 to –" or even "- to +". Such scores will be clarified by an additional note to the matrix.

The detail level of the analysis depends of the amount of information gathered as well as their quality.

Table 2 – Impact Assessment matrix

	Option 1: no action (BAU)	Option 2:	Option 3:
Environmental impacts			
Level of use of hazardous substances			
Level of environmental protection/improvement			
Economic impacts			
Firms: costs			
Firms: competitiveness (internal & external market)			
Innovation and research			
Public authorities (budget; resources)			
Social Issues			
Impact on consumers (availability / price)			
Public health and safety			
Other Impacts			
Clarity and consistency (e.g. with other legislation)			
Practical workability and enforceability			

2. OVERVIEW OF THE CONTENT AND CONCLUSION OF THE INDIVIDUAL FACT SHEETS

2.1 INCLUSION OF CATEGORIES 8&9 PRODUCTS IN THE SCOPE OF ROHS DIRECTIVE

Aim of the task:

This task intends to evaluate the impacts of the possible inclusion of two additional categories of equipment in the scope of RoHS Directive: medical devices (so called "category 8" equipment) and monitoring and control instruments ("category 9" equipment), which are currently out of the scope of the Directive.

The work is based on a background literature survey and contacts with the contractors of the relevant studies carried out for DG ENV and DG ENTR on RoHS and WEEE revision. In addition, the responses to the 2nd Consultation on the RoHS review have been considered, and further contacts with some industry stakeholders were taken.

Background:

RoHS Directive 2002/95/EC covers equipment falling under the categories set out in Annex IA to WEEE Directive (2002/96/EC), except categories 8 and 9. However, the Article 6 of the RoHS Directive gives a clear mandate to the Commission to reconsider these categories in the context of the review of the Directive.

"The Commission shall review the measures provided for in the Directive to take into account; as necessary, new scientific evidence.

In particular the Commission shall present proposals for including in the scope of this Directive equipment which falls under categories 8 and 9."

Issue summary:

Based on the preliminary policy options presented in the 2nd Consultation Document, the following options regarding the inclusion of Category 8&9 equipment were considered:

OPTION 1: **Business-as-usual - continue excluding Categories 8 & 9 altogether**

OPTION 2: **Include Categories 8 & 9 with deferred deadline (indicatively 2014)**

OPTION 3: **Include Categories 8 & 9 from the beginning (indicatively around 2012) with the exemptions proposed by ERA**

OPTION 4: **Include Categories 8 & 9 with deferred deadlines (indicatively 2014) and with exemptions proposed by ERA as well as general exemption for lead in solders**

In addition, two options are being considered, which would be accumulative to options 2 – 4 above:

OPTION 5: **For Category 9, differentiate between consumer/industrial equipment for (deferred deadline for industrial equipment, latest 2018)**

OPTION 6: **For Category 8, differentiate for In Vitro Diagnostics (IVD) (deadline 2016) and Active Implanted Medical Devices (AIMD) (permanent exclusion or exemption until 2020)**

Analysis:

- Environmental impacts

The total quantity of equipment within Categories 8 and 9 sold annually has been estimated at no more than 60,000 tonnes, which is approximately 1% of all electrical equipment sold annually in the EU. Of the six RoHS substances, lead is used in Category 8 and 9 equipment in the largest quantities; it is estimated at 1,414 tonnes annually, while the quantities of other substances are estimated at 2.2 tonnes of cadmium, 30 kg mercury, 800 kg of hexavalent chromium and <10 tonnes in total for the two flame-retardants PBB and PBDE.

In order to assess the relative environmental benefits of the different options, a comparison of the reduction of hazardous substances used in EEE induced by every option over the ten year period 2010 – 2020 is presented (Figure 3).

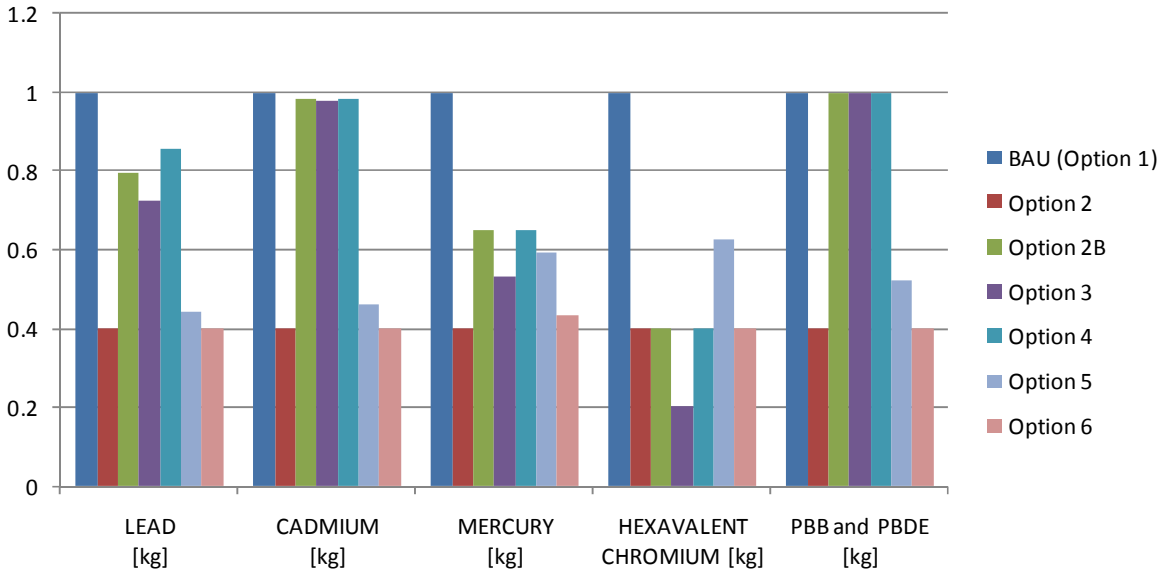

Figure 3 – Comparison of hazardous substances put on the market in Cat. 8 & 9 equipment in the period of 2010-2020 (Business as usual set equal to 1)

Furthermore, an evaluation of the human toxicity and ecotoxicity potential impacts generated by the end-of-life treatment of the hazardous substances in Cat. 8 and 9 is carried out. The complex issue of the effects of lead substitution in solders of EEE are

discussed extensively; generally it appears that this option enables to reduce the potential toxicity impacts. Information on the total energy consumption of the different solders remains rather contradictory.

- Economic impacts

Economic impact of possible inclusion of Cat 8&9 equipment covers compliance costs, impact on competition as well as on innovation and research. Based on available market data and assumptions, a very rough estimate of the overall compliance costs for Cat. 8 and 9 was assessed to be in the range of €400 to €1600 million. However quantified cost estimates should not hinder other very important issues linked to inclusion in RoHS scope for Cat 8&9 firms, which are the potential lack of reliability of lead substitutes, the limited resource requirements involved for the conversion of products, and the exemptions for hazardous substances for specific uses. Anyway, according to the industry, the cost of compliance and consequent availability and diversity of products are affected to a significant extent by the compliance schedule as well as possibility for exemptions.

RoHS should not affect the competitivity of industry within Europe, but could have significant impact on worldwide markets. Innovation and research could be narrowed down as R&D efforts are diverted to product redesign. On the other hand, continued exclusion of Category 8 and 9 products would miss the opportunity to encourage innovation of products in context of reduction of toxicity..

- Social impacts

Impacts on availability of products, public health and safety were examined. If prices were to rise on average by 5% due to RoHS, this would cost EU healthcare providers €2.7 billion per annum. However, as all healthcare providers have limited budgets, this would result in buying fewer or less advanced items of new equipment. This in turn would affect healthcare in EU as well as patient health and quality of life. Impacts on employment are considered rather negligible.

Conclusion:

Environmental impact potentials of the hazardous substances in Cat. 8 and 9 products were assessed using LCA impact characterisation factors. However, this assessment contains many uncertainties, as for example the end-of-life step of Cat.8 and 9 cannot be appropriately modelled with available data. Hence quantities of hazardous substances used in equipment seem to be a better, surrogate measure to estimate the potential environmental and public health impacts of the different options.

Of course, considering only the quantities does not take into account that if the products are effectively collected and treated in the end-of-life, as industry claims, most of the hazardous substances would not be released to the environment. On the other hand, restriction of these substances will not only avoid their emission to the environment at the end-of-life, but also potential emissions at the production phase.

There are many anecdotal or case study-like data on the costs related to the RoHS compliance of Cat. 8 and 9 products. But, even the overall cost to the relevant sectors has turned out to be difficult to estimate. Industry associations have been unable to provide detailed information on the economic impacts.

Based on available market data and assumptions, indicative overall compliance costs for Cat. 8 and 9 were estimated but these figures should be treated with great caution. A survey covering extensively the producers in Cat. 8 and 9 would seem necessary to estimate the compliance costs in more detail for these categories. But that has unfortunately been out of the scope of this study.

Considering the difficulties in deriving an overall estimation of compliance costs, it has been rather impossible to compare the impacts of the different options in monetary terms. And, as pointed out by industry, the costs in Euros to industry do not provide a full picture of the impacts. Availability and reliability of products have important implication to public health and other important domains.

The comparison of options in terms of quantities of hazardous substances put on the market in Cat. 8 and 9 products in a ten year period (2010 – 2020) reveals that there is only marginal difference between the compliance date in 2012 and 2014. The later date would, however, ease the compliance costs for industry and avoid market disruptions, which industry considers significant if compliance date is set at 2012.

Existing exemptions are being assessed by Öko-Institut in a separate project, which will also consider the eventual requirements of Category 8 and 9 regarding these exemptions. Thus, they have not been looked at within this project. Regarding exemptions requested specifically for Category 8 and 9, ERA exemptions have been re-assessed. “Table 71” are still considered justified and hence their inclusion in the provisions of the revised Directive would avoid significant administrative burden related to exemption process. For “Table 72” no convincing evidence was found that they would still be justified after 2012.

General exemption for lead in solders seems poorly justified if compliance date is 2014. It could avoid the need for deferred dates for industrial Cat.9 equipment, IVD and AIMD, but it seems more appropriate to create specific provisions to these product groups rather than provide a general exemption for all products in these categories. Lead in solders being the biggest issue to achieve RoHS compliance, a general exemption for it would seem to compromise the environmental objectives.

General exemption for lead could be combined with compliance date of 2012, but it could then halt the redesign of lead-free products and thus also compromise the environmental objectives.

Based on the comparison of options in terms of hazardous substances over ten year period reveals that the later dates for Cat. 9 industrial, IVD and AIMD product groups would not greatly compromise the environmental goal. But, these options could avoid

significant compliance costs to industry and ensure availability and reliability of these safety critical appliances.

2.2 CLARIFICATION OF THE SCOPE: SPARE PARTS AND COMPONENTS & "REPAIR AS PRODUCED PRINCIPLE" & CONSUMABLES

Aim of the task:

The task intends to evaluate the impact of possible technical changes to the scope of the RoHS Directive in order to clarify it. The overall objective is to have a clearer outline of products being covered by the RoHS Directive specifically spare parts and components as well as consumables.

Background:

During implementation of the RoHS Directive 2002/95/EC, differences and uncertainties concerning the interpretation of the scope have been identified. It may be possible to clarify these issues as part of the review of the Directive. The Article 2 of the RoHS Directive defines the scope of the Directive as follows:

*1. Without prejudice to Article 6, this Directive shall **apply to** electrical and electronic **equipment** falling under the categories 1, 2, 3, 4, 5, 6, 7 and 10 set out in Annex IA to Directive No 2002/96/EC (WEEE) and to electric light bulbs, and luminaires in households.*

2. ...

*3. This Directive **does not apply to spare parts** for the repair, or to the reuse, of electrical and electronic equipment **put on the market before 1 July 2006**.*

Issue summary:

Based on the preliminary policy options presented in the 2nd Consultation Document the task considered the following options regarding the technical changes to the scope of the Directive, compared to the common "no change in the Directive" (i.e. business as usual) option:

- Include explicitly spare parts and components
- "Repair as produced" principle: exclude parts for repairing and the reuse of products lawfully placed on the market
- Clarify status of consumables

Analysis:

The analysis is mostly qualitative due to the lack of qualitative data on the relevant issues.

- Option 1: Include explicitly spare parts & components (placed on the market as individual parts for end-users)

The 'spare parts' are understood to be linked to a given equipment and meant for its repair ; 'component' is understood to be a part/element to be used in EEE, but which is not specific to one given equipment and which cannot be used individually. Thus, 'spare parts' are relevant for all equipment categories, whereas 'component' rather refers to electronic (IT) parts such as processors, fans, CD/DVD drives, internal hard disks, mother boards, etc. (sold individually to end-user).

Currently spare parts and components placed on the market individually are not explicitly under the scope of RoHS Directive. However, spare parts for the equipment placed on the market after July 2006 can be considered implicitly in the scope, while components are rather considered out of the scope of the Directive in the current situation.

An amendment to the Directive specifying that spare parts & components are within the scope could marginally enforce environmental benefits. As soon as RoHS Directive applies to finished products, all parts and components intended to be included in finished products should already be compliant. The status of B2C components only seems to be unclear, but industry stakeholders contacted confirmed that in general they do not make any difference in terms of RoHS-compliance between components B2B and B2C.

For the abovementioned reasons, the economic impacts of the redesign of components/parts due to this option are also considered minimal. However this option could entail additional cost and limited administrative burden for some component manufacturers, who would have to provide conformity certificates.

The social impacts of this option are also considered negligible.

- Option 2: "Repair as produced" principle: exclude parts for repairing and for the reuse of products lawfully placed on the market

At present if an exemption is removed, any product put on the market after 1 July 2006 cannot be repaired using a spare part which made use of this exemption. This will result in equipment reaching end of life prematurely. The environmental benefits of this option thus contribute to extending life time and avoiding untimely disposal of equipment.

It is considered that replacing the single date in Article 2.3 by a principle "exclude parts for the repair, or to reuse, of equipment lawfully place on the market" would enhance legal clarity and security. In practise, it seems to be extremely difficult to make sure that spare parts are only used for appliances 'legally placed on the market'. But as has been pointed out by industry, this is already the case with the current provision that exempts spare parts for appliances put on the market before July 2006 from the scope of the Directive. The industry considers that there is no practical means to verify or

enforce this. Thus, the enforceability of this option is rather poor but not necessarily worse than the enforceability of current situation.

- Option 3: Clarify status of consumables

In this part specifically printer cartridges are investigated. Based on the fact that according to the industry stakeholders contacted, the cartridges themselves, and also the ink/toner seem to be already RoHS compliant, the inclusion of the cartridges into the scope would not bring any additional environmental benefits, neither costs related to R&D or product re-design. However, the compliance verification process would place an additional burden on manufacturers; testing, gathering data etc. would be the most important cost driver. This burden is nevertheless disproportionate with the health and environmental gains mentioned above.

Conclusion:

It has not been possible to clarify the issue to the extent that would allow quantitative assessment of the impacts. All the proposed option would seem to clarify the scope of the Directive, while having limited or negligible environmental, economic and social impacts. Moreover, to avoid confusion, 'component', 'spare part' as well as 'consumables' need to be properly defined.

2.3 CLARIFICATION OF THE SCOPE: FINISHED PRODUCTS ENDING UP IN FIXED INSTALLATIONS, LSIT AND ELECTRICITY PRODUCING EQUIPMENT

Aim of the task:

This task deals with possible options to improve the delineation of products falling under the RoHS Directive, by explicitly including or excluding specific products or categories.

Background:

Difficulties and differences in the interpretation of the scope of the RoHS Directive have lead to confusion to both industry and authorities.

The confusion is caused by both referring to the WEEE Directive in the scope of the RoHS Directive and the (non-)limitative character of the Annexes of the WEEE Directive. Moreover, the obligation for periodically reviewing the exemption for LSIT is not clear.

The overall objective is to have a clearer outline of products being covered by the RoHS Directive. The assessment of explicitly including or excluding products from the scope of the RoHS Directive forms a substantial contribution to reaching this objective.

The product groups concerned in the factsheet for clarification of the scope of the RoHS Directive are:

- 'finished products in fixed installations' (option 2)
- LSIT (option 3)
- Electricity producing equipment (option 4).

For each product category a specific, but different, reason exists to include it in the scope of the RoHS Directive.

Analysis and conclusion:

To support the inclusion (or exclusion) of the product categories, the social, economic and environmental impacts are assessed per option.

Although for option 2 (finished product in fixed installation) the impacts of a possible inclusion could not be quantified, including this equipment seems reasonable as only (finished) products that belong to one of the product categories that are already in the scope of the RoHS Directive would be affected.

Also for the inclusion of LSIT in the scope of RoHS Directive (option 3), the possible impacts could not be quantified because of a lack of specific data on this product group. Because of their affinity with electric and electronic tools (product group currently covered by the RoHS Directive) however, an inclusion in the scope of the RoHS Directive seems not insurmountable.

For option 4 (electricity producing equipment) the focus is set on portable generators and EEE supplied with power by solar cells, as this product group complies with the definition of EEE and falls under the categories of Annex IA of the WEEE Directive (= the scope of RoHS Directive). For portable generators, quantification of the impacts shows that the total amounts of hazardous substances being involved are potentially significant, and that an inclusion in the scope of the RoHS Directive seems appropriate in terms of environmental protection. For EEE powered by solar cells, CdTe and CIS thin film PV modules are not compliant with the RoHS Directive, but they are currently not used in PV cells powering consumer applications. Also in the future, CdTe and CIS PV modules cannot be used in consumer applications.

When explicitly including fixed installations, LSIT or electricity producing equipment in the scope of the RoHS Directive, equivalent alternatives should exist in order not to increase potential catastrophic consequences of a failure of this type of equipment. It has not been in the scope of this study to carry out a detailed technical assessment on the reliability of alternatives in these applications.

2.4 INCLUSION OF DEFINITION FOR 'HOMOGENEOUS MATERIAL'

Aim of the task:

This task deals with the inclusion of an appropriate definition for 'homogeneous material' in the RoHS Directive.

Background:

The maximum concentration values for hazardous substances, as in Annex of the RoHS Directive, are expressed as weight percentage in homogeneous materials, but the definition of homogeneous material is not included in the Directive. Furthermore, the definition in the FAQ document, that is generally used, is rejected by some stakeholders, specifically with regard to small components and the presence of chromium VI in metallic coatings.

The overall objective of the factsheet is to have an appropriate and enforceable definition for 'homogeneous material' in relation with RoHS Directive. The assessment of the inclusion of an appropriate definition in the Directive forms a substantial contribution to reach this objective.

For the elaboration of policy options, a distinction is made between 3 topics related to the inclusion of the definition of 'homogeneous material' in RoHS Directive:

1. Inclusion of the definition in RoHS Directive
2. Dealing with small components
3. Dealing with metal concentrations in metallic coatings

For every topic several options are defined and analysed:

Option 1: Inclusion of definition
   a. Business-as-usual (= definition in FAQ document)
   b. Inclusion of the definition in RoHS Directive
   c. Inclusion of the definition in an international standard

Option 2: Small components
   a. Business-as-usual
   b. Maximum size limit of 4 mm^3
   c. Maximum size limit of 40 mm^3

Option 3: Metallic coatings
   a. Business-as-usual
   b. Ban all intentionally added HS

Analysis and conclusion:

The possible manners to deal with the inclusion of the definition of 'homogeneous material' focus on the difference in enforceability and flexibility between the considered options. The inclusion of the definition in the RoHS Directive (option 1b) is from a legislative point of view the most enforceable option, but at the same time from a technical point of view the least flexible option, whereas for option 1c (definition in international standard) it is the opposite way, and option 1a (current situation, definition in FAQ document) being in between.

As for small components the costs/time for taking a representative sample in the verification test procedure, according to the current definition of homogeneous material (option 2a), can be disproportionate to the environmental gain, setting a maximum size

limit of 4mm³ in the case where (further) disjointment is reasonably not possible can be an appropriate way to meet both the needs for environmental protection and for a more practical sampling requirement for compliance testing (as to control sampling and analysis costs). Additionally, as the Chinese RoHS legislation uses already a maximum size limit of 4 mm³, introducing this size limit in the European RoHS Directive enhances clarity and consistency.

Nevertheless it has to be stressed that introducing a maximum size limit of 4 mm³ will decrease, although probably to a limited extent, the environmental protection as compared to the current situation.

By using full material declarations even allowing a maximum size limit of 40 mm³ (option 2c) can be considered, provided that there is no change of the current compliance criteria. Material data used to set the size limit on 40 mm³, was collected before the RoHS Directive was in force. At the moment it is not possible to acquire the components used in this study because they are RoHS non-compliant and no longer available from the manufacturers. Therefore it is not possible to verify these results experimentally.

The decrease of the environmental protection (as discussed for a 4 mm³ maximum size limit) is estimated to apply even more to the higher maximum size limit of 40 mm³. But again, the effect on the environmental protection in absolute terms is estimated limited.

Furthermore, the introduction of a maximum size limit is not compatible with the current exemptions in the RoHS Directive as the homogenisation of components for compliance testing will make it impossible to apply some of these exemptions.

Currently (option 3a) for metallic coatings on EEE, representative sampling according to the definition of homogeneous material is hard to apply because of representative sampling of a metallic coating (due to the nature of the plating) and because of performing a quantitative analysis of Cr(VI) in a coating (due to the nature of Cr(VI)).

To cope with these problems an option is to ban all intentionally added Cr(VI) in metallic coatings, as for most (or all) purposes a Cr(VI)-free chromate coating (so only containing Cr(III)) exists as alternative. In this way the existing method to analyse Cr(VI) qualitatively can be used for compliance purposes.

In a similar way all intentionally added lead, mercury and cadmium can be banned in metallic coatings.

2.5 BURDEN OF PROOF AND THE PROVISION OF A SUBSTITUTION PLAN WHEN REQUESTING EXEMPTIONS

Background:

Currently the approval process for exemptions is complicated, involving an initial screening by a subcontracted consultant, followed by the comitology procedure. The process has led to an expanding list of exemption requests. Furthermore, there have

been a number of repeated requests for exemptions which have already been denied, as well as requests for more specialised applications which cover limited numbers of products. Some of the exemption requests are still unresolved even if they have been processed for over two years.

Whereas the RoHS Directive bans or limits the use of hazardous substances in EEE products, the Directive allows for exemptions from its provisions where the benefits of retaining certain hazardous substances until an effective substitute can be identified outweigh the perceived drop in performance of certain products or the environmental benefits for phasing out the hazardous substance.

Issue/problem addressed:

There is a need to streamline and improve the quality of the exemptions approval process. The industry is already required to provide information to those reviewing the exemptions on the availability of alternatives. It is also common practice for the reviewer to contact the company and ask them of a roadmap of how and when they are able to substitute the harmful substance for which an exemption is sought. So even if substitution plans are not currently a legal requirement the industry is already required to provide the reviewer with this information if they want their exemption application to be successful. Hence any legal requirements of a substitution plan do not move the burden of proof to the industry, because this is already the case. However, a legal requirement for a substitution plan as part of the exemption application would clarify the necessity of considering this aspect as well as bringing to the forefront the role of exemptions being a temporary solution. As the exemption process and any requirements of a substitution plan are interlinked, both issues were assessed.

Analysis:

Under a REACH Technical Assistance contract with DG Enterprise and Industry, RPA consultants were commissioned to provide technical support and targeted advice to the appraisals of various REACH provisions. The report9 looks at the relationship between the identification of alternatives (as part of the authorisation procedure) and the substitution plan. Substitution is defined in the report as replacement of one chemical with another, where this replacement can be undertaken with little reformulation required in order to deliver the desired functionality. The report gives also a broader definition for substitution, which also covers the adoption of an alternative technology or product which involves no reliance on the chemical of concern.

The report identifies two potential starting points for developing a substitution plan. The first is when the analysis of alternatives is unable to clearly identify a technically feasible alternative. In this case, the substitution plan is likely to focus on the R&D required to identify potential alternatives amongst those substances not yet analysed or to develop a new substance, processing method or product. When a technically feasible alternative

9 RPA (2006), *Technical Assistance for REACH Impact Assessment Updates,* Summary Report, ENTR/05/100, December 2006.

is identified, then there would need to be a further round of time planning with regard to its adoption. The second starting point is when suitable alternatives have been identified. In this case, the substitution plan would be aimed at undertaking any further R&D required and setting out the time frame for adoption of the alternative(s). Thus, in identifying the costs associated with a mandatory requirement for substitution plans in all cases, it is important to separate out what would be undertaken for the analysis of alternatives as opposed to the substitution plan.

The analysis of alternatives is not described as part of the substitution plan under REACH. Instead the analysis of alternatives is the stage that triggers the requirement for a substitution plan (in case alternatives do exist). Consequently the "second starting point" in the RPA report is normally the stage that follows the identification of alternatives under REACH, and hence not always a starting point but the next step. However, even if the "analysis of alternatives" is not part of the substitution plan under REACH, it is clear that they are very closely linked and overlap. Because of this relationship between "analysis of alternatives" and the "adaptation of a substitution plan", it is important to decide to what level and detail applicants are required to focus on analysis and/or adaptation. It is suggested that the "light" version of a substitution plan would cover a basic analysis of alternatives and the "full" version of a substitution plan would cover a comprehensive analysis of alternatives with both versions covering the same adaptation requirements.

We have also added to the "light" ad "full" options the requirement of a maximum validity period of granted exemptions of four years, as options 3 and 5.

Option 1: Business-as-usual – exemption processes remain as they are

Option 2: Introduction of a basic "light" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS.

Option 3: Introduction of a basic "light" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS with a maximum validity period of 4 years for granted exemptions.

Option 4: Introduction of a comprehensive "full" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS.

Option 5: Introduction of a comprehensive "full" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS with a maximum validity period of 4 years for granted exemptions.

Conclusions:

Based on the analysis the options 3-5 seem most promising. However, any costs or benefits linked to a substitution plan are only indicative as they are highly dependent on what substance/process is being substituted and the specific requirements of the substitution plan. It has also become clear that the relationship between "analysis of alternatives" and the "adaptation of a substitution plan" are closely linked and it is

important to decide to what level and detail applicants are required to focus on analysis and/or adaptation before more detailed estimations of impacts can be made.

2.6 INCLUSION OF CONFORMITY ASSESSMENT PROCEDURES

Issue/problem addressed:

A lack of a formal compliance assessment approach under the RoHS Directive has led to different interpretations of some aspects of the Directive across Member States. This in turn has resulted in difficulties related to the free movement of goods, uncertainty for manufacturers and additional costs due to differing requirements for demonstrating compliance. Importantly and fundamentally, without formal compliance assessment procedures it is impossible to ensure that product on the EU market place comply with the requirements of ROHS hence, that the environment and human health are protected. The latter is essential as good law making is more than simply setting out rules to be followed it requires their effective implementation to deliver the desired change.

Background:

The Directive does not set any requirements for compliance documentation or the compliance and enforcement process. This is partly a consequence of the Directive having originally been conceived as an element of the WEEE Directive. Consequently there is a lack of standardised approaches across Europe to the monitoring of ROHS implementation making it impossible to identify compliance with the law and ensure that the environment and human health are protected effectively.

Options and summary of analysis:

There is clearly a need to alter the approach to ensuring compliance under the Directive as this is leading to significant barriers, costs and problems. The assessment of the Business as Usual option identifies potentially negative impacts environmentally, in terms of costs and competitiveness of industry and socially associated with health and safety and consumer confidence. There are two alternatives options to the BAU outlined these are:

- Option 2 - Self Declaration by producers – based on the presumption of compliance and supported by effective reporting by producers, systems for checking of suppliers and a robust approach to market surveillance
- Option 3 – Third Party Verification – essentially requiring upfront assessment before a product can be allowed access to the market place with producers paying for the services

The conclusions of this research are that both could potentially lead to an improved system of conformity assessment. However, their effectiveness would fundamentally depend upon a robust and transparent approach to implementation, adequate checks to

ensure the systems in place are effective and resources. Importantly the difference in terms of impact from the BAU will vary across the EU given that different approaches adopted in Member States.

Self declaration is the option preferred by industry and most closely reflects the approaches adopted in many of the leading Member States. This would require limited burden to be placed on businesses but potentially would require significant public resources to review efforts and also ensure in parallel a rigorous market surveillance system. Importantly, in order for market surveillance to be delivered effectively the requirements for industry must be consistent across all Member States and the approaches to checking of supplier information and good practice clearly defined.

2.7 INTRODUCTION OF COST / BROADER SUSTAINABILITY CRITERIA FOR GRANTING EXEMPTIONS

Background and Issue/problem assessed:

Currently only environmental and health impacts are taking into consideration as criteria in the exemption process. It has been argued that sustainability is not just about the environmental and health impacts but ought to take into consideration economic and social costs as well.

Analysis:

Exemptions should be tailored to specific circumstances and justified on a case by case basis. There is a president for the inclusion of economic considerations into decisions aimed to meet an environmental end. Examples of such criteria are for example under the EU ETS Directive the provision of unreasonable cost is applied to monitoring requirements and the level at ambition that monitoring of a particular installation must achieve. Meanwhile provisions such as BATNEEC also take into consideration the practicability of achieving an environmental end based on economic costs. However, the appropriateness of the use of additional clauses will vary depending on the substances, their use and the nature of the product in question.

According to REACH an authorisation can still be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies.

This clause introduces an element whereby economics and practicability can be taken into account. However, it should be noted that this may weaken the environmental credentials of the exemption process. In addition concepts such as what costs are practicable or unreasonable are notoriously difficult to apply and leading to inconsistent application.

We do not feel that it is possible to assess the impacts of such an inclusion given the huge variety of circumstances that might be experienced and variability of substances being dealt with. It was therefore proposed that the approach to introducing costs/broader sustainability consideration in other measures would be examined in more detail along with the responses to the consultation document and how the issue has been dealt under REACH.

Conclusions:

REACH allows authorisations to be granted where the socio-economic benefits of a particular use of a substance outweigh the costs, even where safe use cannot be demonstrated. There is no such provision in RoHS; instead exemptions apply only where substitution is not possible from a scientific or technical viewpoint. It is thus possible that REACH could allow a use prohibited under RoHS.

Under RoHS any application of socio-economic analysis would be part of the review of exemptions. In this case it is assumed that, as in the case of the current procedure, the industry would be responsible to justify the use of a hazardous substance under RoHS based on socio-economic benefits outweighing those inflicted on the environment and human health.

A proper socio-economic analysis is a highly complicated task. A report10 by IMV reviewed 22 EU Risk Reduction and socio-economic analysis under existing Chemical Substance Regulation 793/93 and under six US economic assessments under the US Toxic Substance Act.

Based on the findings the report concludes, in relation to REACH, that that even with more resources devoted to analysis, ensuring a balanced, and truly well-informed socio-economic analysis is bound to remain a complicated task.

In providing recommendations for the European Chemicals Agency the report points out future socio-economic analysis need to have a sound logic and well applied methodology that makes important assumptions and limitations visible for the Agency. However, even with this in place, stakeholders would still be expected to have a wide discretion for how to carry out socio-economic analysis in practice. The report therefore recommends that all analysis would have to be subjected to an obligatory quality assessment.

Based on the above, any inclusion of socio-economic analysis into the exemption procedure would require a considerable increase in staff reviewing the quality of the exemption applications as well as a considerable burden of proof and administrative costs for the industry in order to submit an exemption application based on socio-economic analysis.

[10] IVM (2007), *Challenges for Economic Analysis under REACH, What can we learn from previous experience?* May 2007.

2.8 INSERTION OF A REVIEW CLAUSE

Issue/problem addressed:

What approach to follow in terms of including a review clause within RoHS in terms of achieving good regulation and an effective outcome for the Directive?

Background:

Currently a review clause exists within the RoHS Directive stating that the Commission shall review the Directive to take into account new scientific evidence. Since the publication of the original proposal for the RoHS Directive the Commission adopted a Communication on 'Simplifying and improving the regulatory environment' (COM(2002) 278) that sets out the importance of review clauses. Additionally, different models of review clause exist in measures linked to the RoHS Directive from simple references to the need to monitor impacts, report and revise a Directive if needed to very specific review periods for the review of important and controversial elements of legislative measure. Therefore, a decision must be made as to what is the most appropriate approach to pursue within a revised RoHS Directive in terms of review, what might or is realistic to cover. Within the 2nd consultation it was proposed that review clauses might be linked in some way to the substances covered by the Directive or to technical changes in the scope of RoHS. Additionally it was discussed as to whether reviews might be linked to the inclusion of a substance into RoHS by a given deadline.

Summary of analysis:

It does not appear appropriate to impact assess the inclusion of a review clause. The inclusion of a review clause is essentially a political decision by the Commission based on the needs and requirements to amend a Directive along with future knowledge and understanding. The benefits of a review clause setting out specific items for consideration by a specific date would be to increase certainty; however, this would also commit the Commission to a set cycle of review. A review clause could be included setting out a specific timetable. Alternatively, however, the Directive can simply require that impacts and approaches to implementation be monitored and reported and based on the findings of this research the Directive will be reviewed as and when considered appropriate to meet the needs of the market.

The review process is essentially a legislative tool and it is good practice to include such a clause in a Directive. Decisions to undertake a review should be based on robust monitoring and reporting. Any indicators or criteria used to establish when a review should take place must reflect the aims of the Directive and its potential impacts both positive and negative.

Details are provided on possible indicators and criteria for triggering a review. The most commonly used is time elapsed since the adoption of the legislation based deadlines for the completion of specified tasks. Alternatively, if monitoring provisions are sufficient, a review might be triggered if it is found that levels of non compliance are rising rapidly or

that new potentially hazardous material is appearing on the EU market within EEE that need controlling. The linkage with the importance of information provision for enabling effective review is highlighted.

2.9 INTRODUCTION OF MARKET SURVEILLANCE MECHANISMS

Issue/problem addressed:

There are currently no specific market surveillance requirements in relation to the RoHS Directive, although there are systems for this set up under the WEEE Directive. The current Directive contains relatively vague requirements in relation to what Member States must achieve in order to ensure the prevention of products non compliant with RoHS entering the market place. This has lead to difficulties in terms of inconsistency in approach across Europe, uneven cost distribution for industry, potential for non compliant product to remain on the market place and not face enforcement action, and importantly potentially undermines efforts to protect the environment and human health using the ROHS Directive.

To complement existing requirements within ROHS and other product focused policy, in 2007 the Commission proposed a Decision on the marketing of products (COM(2007)53) and a Regulation on accreditation and market surveillance for the marketing of products (COM(2007)37). These proposed measures would put in place systems for the monitoring and assessment of the qualities of products on the European market place more generally. However, the proposed Regulation would still contain relatively vague requirements for the actions to be conducted by Member States in relation to market surveillance.

Background:

According to the second consultation document 'effective market surveillance mechanisms at national level would greatly enhance the environmental benefit of RoHS by minimising the number of non-compliant products; a major disincentive for free riding, it would contribute to a level playing field for producers'. An Informal Enforcement Bodies Network already exists however, while efforts have been of use Member State uptake of the outputs is widely varied. Within the second consultation responses there was overwhelming support for the introduction of measures to deliver better market surveillance and consequently better monitor the compliance of products on the market place.

Options and summary of analysis:

There is clearly a need to have clarity over the approach to market surveillance. This is the foundation of assessing the conformity of products on the market place, enforcing against non compliance and fundamentally delivering the aims of the ROHS Directive.

There are different approaches possible. One option would be to simply abide by the rules under the proposed Decision and Regulation on marketing of products – what will

become the BAU upon their adoption. However, while focusing on the surveillance of products on the market place these measures do not specifically consider EEE nor the requirements of ROHS. The forthcoming requirements may, therefore, lack specificity in terms of implementing the complex requirements of RoHS.

An alternative, and option 2 considered within this assessment, is for requirements to be included in ROHS. These would build upon those new provisions set out in the forthcoming Decision and Regulation, but take them a step further as is appropriate for a specific and important legislative measure such as ROHS. This approach could involve simply a brief reference within the Directive accompanied by binding guidelines agreed at a later date - based broadly on the provisions Article 14 of the 'Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products'. Or alternatively full details could be included in an annex to the ROHS Directive itself.

The impacts of adopting new provisions on market surveillance under ROHS are considered to be broadly positive in terms of environmental benefit, social impact, the costs and competitiveness of industry, innovation and the workability and clarity of legislation. The only negative impact, primarily in terms of cost, is considered to be for the regulatory authorities who would have to implement a more rigorous assessment system. Importantly, given the current variability in approach by Member States to market surveillance, the impacts will vary in strength depending upon the existing situation.

3. FACT SHEET ON THE INCLUSION OF CATEGORY 8&9 PRODUCTS IN THE SCOPE OF ROHS DIRECTIVE

3.1 ISSUE

Issue/problem addressed:

The present work intends to evaluate the impacts of the possible inclusion of two additional categories of equipment in the scope of RoHS Directive: medical devices (so called "category 8" equipment) and monitoring and control instruments ("category 9" equipment), which are currently out of the scope of the Directive.

This factsheet presents the information concerning the impacts based on a background literature survey and preliminary contacts with the contractors of the relevant studies carried out for DG ENV and DG ENTR on RoHS and WEEE revision. In addition, the responses to the 2nd Consultation on the RoHS review have been considered.

Background:

RoHS Directive 2002/95/EC aims to approximate the laws of the Member States as regards the restriction of the use of hazardous substances in electrical and electronic equipment and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment.

The Directive applies to the equipment falling under the categories set out in Annex IA to WEEE Directive (2002/96/EC), except categories 8 and 9. However, the Article 6 of the RoHS Directive gives a clear mandate to the Commission to reconsider these categories in the context of the review of the Directive.

"The Commission shall review the measures provided for in the Directive to take into account; as necessary, new scientific evidence.

In particular the Commission shall, present proposals for including in the scope of this Directive equipment which falls under categories 8 and 9."

Options:

Based on the preliminary policy options presented in the 2nd Consultation Document [EC 2008], the present work considers the following options regarding the inclusion of Category 8&9 equipment:

OPTION 1: **Business-as-usual - continue excluding Categories 8 & 9 altogether**

OPTION 2: **Include Categories 8 & 9 with deferred deadline (indicatively 2014)**

OPTION 3: **Include Categories 8 & 9 from the beginning (indicatively around 2012) with the exemptions proposed by ERA[11]**

OPTION 4: **Include Categories 8 & 9 with deferred deadlines (indicatively 2014) and with exemptions proposed by ERA[11] as well as general exemption for lead in solders**

In addition, two options are being considered, which would be accumulative to options 2 – 4 above:

OPTION 5: **For Category 9, differentiate between consumer/industrial equipment for (deferred deadline for industrial equipment, latest 2018)**

OPTION 6: **For Category 8, differentiate for In Vitro Diagnostics (IVD) (deadline 2016) and Active Implanted Medical Devices (AIMD) (permanent exclusion or exemption until 2020)**

3.1.1. CURRENT PRACTICE/SITUATION

Category 8 and 9 equipment

Categories 8 and 9 consist of medical devices and monitoring and control instruments, respectively. Medical Devices (Directive 93/42/EEC) include a very wide range of products mainly aimed at hospitals. Some are relatively simple products but others are highly complex and safety-critical electronic products like computed tomography scanners (CT), positron emission tomography (PET) and magnetic resonance imaging (MRI).

Category 9 sector may be divided into three sub-sectors:

- Office and Domestic Monitoring and Control – metering and control of temperature, electric power, gas, smoke detectors etc.
- Test & Measurement Equipment – applications of measurement products are for accurate measurement and analysis (testing), accurate signal sources or continuous monitoring. A few products have control functions. This sector provides equipment for many industrial applications including electrical and electronic product for testing electronic assemblies, industrial plant maintenance, and chemical analysis.
- Industrial Automation – equipment for monitoring and control of manufacturing processes based on measurement and feedback on physical parameters.

While some of Category 9 products, especially in the office and domestic sector are relatively simple, (e.g. battery testers, breath alcohol analysers, distance metering products, consumer electricity meters, light and sound sensors and level controllers, metal detectors, temperature indicators, heating regulators, timers) products for laboratory and industrial applications tend to be technically complex.

Failure of products in these categories can potentially have severe consequences including losses of life and serious environmental damage.

[11] [Goodman 2006]

Legal situation

Currently, medical devices ("category 8", referring to Annex IA to WEEE Directive) and monitoring and control instruments ("category 9") are out of the scope of the RoHS Directive.

Especially Category 8 equipment needs to comply with specific medical device directives and often approval by Notified Bodies is required:

Before medical devices can be placed on the EU market they must comply with the 'essential requirements' of the relevant Directive. Currently there are three Medical Device Directives: the Medical Device Directive (93/42/EEC), the Active Implantable Medical Device Directive (90/385/EEC) and the In Vitro Diagnostic Medical Device Directive (98/79/EC). They aim at ensuring that medical devices meet safety and performance levels, and that any risks associated with using the device are acceptable when weighed against the healthcare benefits to the patient. Also, some Category 9 products need to gain approval from notified bodies.

Products in both categories may need to comply with directives such as Low Voltage Directive (LVD), Electromagnetic Compatibility Directive (EMC), Equipment intended for use in Potentially Explosive Atmospheres Directive (ATEX) and Machinery Directive.

In other parts of the world, there is currently no legislative pressure on medical devices to comply with RoHS type restrictions. The Japanese RoHS labelling requirements (J-MOSS) apply to household and IT equipment, and there are no plans to extend this to cover medical devices. The California RoHS restrictions have a narrower scope than EU regulation and do not apply to medical devices. Two recent attempts to extend the California RoHS restrictions to cover the same scope as the EU RoHS Directive were rejected. The China RoHS requirements do apply to medical devices in principle, but this is yet to be implemented in practise. The Korea RoHS major requirements apply to ten specific product categories – medical devices are not included among them. Australia, Taiwan and other parts of the world have not yet introduced RoHS-type restrictions for electrical and electronic equipment. [COCIR 2008]

Category 8 and 9 equipment quantities and hazardous substances

The total quantity of equipment within Categories 8 and 9 sold annually has been estimated at no more than 60000 tonnes, which is approximately 1% of all electrical equipment sold annually in the EU. Of the six RoHS substances, lead is used in Category 8 and 9 equipment in the largest quantities; it is estimated at 1414 tonnes, while the quantities of other substances are estimated at 2.2 tonnes of cadmium, 30 kg mercury, 800 kg of hexavalent chromium and <10 tonnes in total for the two flame-retardants PBB and PBDE. [Goodman 2006]

3.1.2. ISSUES/PROBLEMS TO EXPLORE

In accordance with the Article 6 of the RoHS Directive, the present work intends to assess whether the Category 8 and 9 equipments could be brought within the scope of this Directive and at what schedule. Furthermore, the need for exemptions in general will be assessed.

These Categories were originally excluded from the scope of the RoHS Directive due to the concern over the reliability of substitute materials, especially lead-free solders. Reliability is especially important for this equipment as they:

- contribute to the human health, safety, environmental protection, and the progress of science and technologies;
- have high requirements for reliability, accuracy, and safety;
- have long product life (10-20 years).

Furthermore, the specific characteristics of these product categories include low production volumes and wide range of applications, as well as need for various specific components by custom design. Due to these reasons, the re-design of these products to comply with RoHS requirements is estimated to involve higher costs than re-design of products in other categories.

In February 2008, the Commission published a list of preliminary policy options for the review of the RoHS Directive and invited comments and relevant information from stakeholders. Based on the responses to this consultation some of the preliminary options could already be discarded with the agreement of the Commission. The following options are considered in the current work:

- **Option 1: Business-as-usual - Continue excluding both categories altogether**

Category 8 and 9 equipments were originally excluded from the scope of the Directive, because there was a concern about reliability of substitute materials, especially lead-free solders.

- **Option 2: Include Categories 8 & 9 with deferred deadline (indicatively 2014)**

This option would allow, in comparison to Option 3, more time for research, additional testing and approval by Notified Bodies for equipment in these two Categories. In this option, the amended Directive would not provide a list of exemptions relevant for Categories 8 & 9, but this does not of course mean that no such exemptions would be granted. This would however require the submission of the exemption request and a decision on each request separately.

- **Option 3: Include Categories 8 & 9 from the beginning (indicatively around 2012) with the exemptions proposed by ERA**

This option would require a fast conversion of most of the products. Providing for exemptions proposed by ERA would avoid the need to submit requests for these exemptions one by one.

- **Option 4: Include Categories 8 & 9 with deferred deadlines (indicatively 2014) and with exemptions proposed by ERA as well as general exemption for lead in solders**

This option would again allow, in comparison to Option 3, more time to achieve compliance. In addition, it would provide for ERA exemptions and a general exemption for lead in solders for Cat. 8 and 9 products.

- **Option 5: For Category 9, differentiate between consumer/industrial equipment for (deferred deadline for industrial equipment, latest 2018)**

This option would more time for the more complex and critical industrial equipment to achieve compliance.

- **Option 6: For Category 8, differentiate for In Vitro Diagnostics (IVD) (deadline 2016) and Active Implanted Medical Devices (AIMD) (permanent exclusion or exemption until 2020)**

IVD devices are very complex instruments which carry out many different tests. When the equipment is modified, all of these tests have to be laboriously validated to ensure that precision is not compromised. Active implanted medical devices (AIMD) are the most safety critical of all medical devices. They include heart pacemakers, defibrillators and insulin pumps. Early unexpected failure could be fatal.

The time required for manufactures to modify these equipments, validate and gain the approval for all of their products is longer than for other medical devices. The implementation in 2016 and 2020, respectively, would allow time for this.

3.2 PROS & CONS

Option 1: Continue excluding one or both categories altogether

Pros:

- avoidance of possible additional costs and burdens for Cat 8&9 manufacturers as well as administrators
- more flexibility for Cat8&9 manufactures to implement eco-design on their own pace
- no product will be withdrawn from EU market due to RoHS compliance requirements

Cons:

- inclusion will have very small impact on the environment
- unfair to those who have already taken steps to comply with the Directive, companies that have been investing a lot in research of RoHS compliant alternatives would now be punished for actually having worked towards that goal

- there would be no true encouragement for innovation of products in context of reduction of toxicity

Option 2: Include both categories but with deferred deadline (e.g. 2014)

Pros:

- would bring Cat.8&9 into the scope thus promoting the environmental objectives of the Directive
- allows more time (compared to implementation e.g. 2012) for manufactures, thus limiting the compliance costs

Cons:

- significant administrative burden due to exemptions requests
- until the decision on exemptions, the compliance requirements remain unclear

Option 3: Include both from the beginning (2012) with the exemptions proposed by ERA

Pros:

- enhance environmental objective of the Directive with no delay

Cons:

- the implementation date does not take into account the time needed for product approval, as the long-term reliability data is available in 2012
- time to achieve compliance is deemed not be sufficient especially for SME which are manufacturing wide range of equipment
- many products might be discontinued, thus disadvantaging European end users

Option 4: Include both with exemptions and deferred deadlines and general exemption for lead in solders

Pros:

- cat.8&9 would be included in RoHS at low cost without limited impact on reliability or availability of products or services
- very few products will be withdrawn from the EU market
- the ability to maintain innovation would be maintained as R&D staff can concentrate on development of new RoHS-comply products.

Cons:

- general exemption for lead in solders would compromise the environmental objective and is not justified by technical reasons

Option 5: Differentiate between consumer/industrial equipment for cat.9 (max. deadline for industrial equipment: 2018)

Pros:

- the deferred date would allow most products to be modified despite the limitations on availability of engineers (the extent depends on the implementation date)
- would avoid withdrawal of many products from the EU market and consequent negative impact on users.
- only a small rise in the scale price of products would occur (and possibly no increase in some cases) as the additional cost of producing new RoHS compliant designs is much smaller than that of modify existing models

Cons:

- unless 'industrial Cat. 9 equipment' is properly defined, would add grey areas and leave room for different interpretations

Option 6: Differentiate for In Vitro Diagnostics (IVD) and Active Implanted Medical Devices (AIMD)

Pros:

- would take into account the specificities of IVD and AIMD and thus avoid the disruption within the market
- innovation in the IVD field would be not severely hampered as all research resources would not have to be reallocation to speedy product conversion
- would not impact the cost of devices and thus would have a significant effect on healthcare

Cons:

- permanent exemption for AIMD would give wrong signal to industry (eliminate any incentive for innovation in use of safer material) and bar innovation

3.3 ANALYSIS OF OPTIONS

Table 3 below presents the comparison of the different options to the Business-as-usual scenario (Option 1), which by definition would have no, i.e. zero effect on the different impact assessment criteria. The results, both for inclusion of Cat.8&9 in general and for the different options, and the thought process behind the ratings will be explained in the subsections following the matrix. The analysis is mostly qualitative due to the lack of qualitative data on the relevant issues.

It is important to note that Option 5 and 6 are add-on options to the more general policy Options 2 – 4. The impact assessment for these two options compares an option to a

situation where this option is not implemented. In the impact assessment of Option 2 – 4, the specific cases covered under Option 5 and 6 have not been explicitly discussed.

Table 3 – Summary of assessed impacts

	1	2	3	4	5	6
					in addition to Options 2 - 4	
Level of environmental protection/improvement[12]	0	+	++	+ to -	(-)	(-)
Economic impacts						
Firms: costs & competitiveness	0	--	---	-	++(+)	+
Innovation and research	0	--	---	-	++	+
Consumers and households	0	N/A	N/A	N/A	N/A	N/A
Public authorities	0	0 to -	--	0 to -	+	+
Social Issues						
Employment and labour market	0	0	0	0	0	0
Public health and safety	0	--	---	-	+	++
Other Impacts						
Clarity and consistency	0	+ to -	+	+	-	0 to -
Severity of barriers to be expected	0	-	-	0 to +	+	+
Administrative effort	0	---	--	-	+	+
Practical workability and enforceability	0	-	-	+	+	+

3.3.1. ENVIRONMENTAL IMPACTS

- **Quantities of the RoHS substances used in Category 8 and 9 equipment**

[Goodman 2006] estimates that around 30000 tonnes (0.03 million tonnes) of Cat. 8 products and around 30000 tonnes (0.03 million tonnes) of Cat. 9 products are annually placed onto the EU market. Based on these product quantities, the quantities of the six RoHS substances put on the market in Cat. 8 and 9 per year were estimated (Table 4). The quantities of restricted substances in **Category 8 equipment** are based on the information from manufacturers and these quantities are considered to be rather an

[12] In this context related to level of use of hazardous substances

accurate estimation. For **Category 9 equipment**, it has been noted that most manufacturers of these appliances (except for the Test & Measurement Coalition[13]) were not able to provide relevant data and it had to be estimated from a variety of other sources. Table 4 presents the estimations provided by [Goodman 2006].

Table 4 – Quantities of the six RoHS substances put on to the market annually in Category 8 and 9 equipment and sub-categories relevant for the policy options. [Goodman 2006]

	LEAD [kg]	CADMIUM [kg]	MERCURY [kg]	HEXAVALENT CHROMIUM [kg]	PBB and PBDE [tonnes]
Category 8 and 9 equipment in total	1413500	2225	30	800	8000
of which*					
in equipment covered by "ERA exemptions"	926500	2165	12.5	-	8000
in solders	150000	-	-	-	-
IVD	9070	-	5	-	-
AIMD	800	-	-	-	-
Category 9 alone	192555	462	20	599	4000
* It should be noted that these sub-categories are overlapping, for example the amount of lead in solders is covered by "ERA exemptions".					

The quantities used are constantly changing: the current RoHS Directive is leading to current changes in the products as many suppliers are already redesigning many components without RoHS substances where it is feasible, especially if the components are also used in the product categories already covered by the Directive [COCIR et al. 2007]. Many manufacturers are also using lead-free solders in new models already. This will result in the decrease in the quantity of lead used in Category 8 and 9 products in future years. Furthermore, restrictions in the USA have resulted in very significant reductions in the quantity of mercury used in electrical products in the EU during 2004 and 2005 and this is on-going. [Goodman 2006]

For example, in IVD instruments the current estimated usage of lead is 9 tonnes per year (which is in accordance with the quantity presented in [Goodman 2006]): 6 tonnes in leaded solder, the rest in alloys [COCIR et al. 2007]. COCIR et al. estimate that the change of leaded to non leaded solder by component manufacturers, which is currently taking place, will reduce by 90% the amount of lead used by the IVD industry.

[13] The Test & Measurement Coalition represents an ad-hoc grouping of companies active in the category 9 type products. The Coalition includes 6 leading companies in the sector: Agilent Technologies, Fluke, Keithley Instruments, National Instruments, Tektronix, Anritsu. The coalition membership represents roughly 60% of global production of professional/industrial Test&Measurement equipment.

Consequently, the usage of lead in leaded solder in IVD within ten years is estimated to decrease to 600kg/year even if Category 8 is not included in the scope of RoHS.

- **Consolidation of the data on quantities of RoHS restricted substances in Category 9**

As mentioned above, the estimation of quantities of restricted substances in Category 9 equipment was not highly accurate [Goodman 2006]. This is due, on the one hand, to the fact that manufacturers are unclear of the scope of control and measurement instruments. Furthermore, apart from Test & Measurement (T&M) Coalition, which represents 6 major Category 9 manufacturers, there is no trade association focusing on these equipments.

We were in contact with T&M Coalition, who represents 60% of the professional /industrial test and measurement equipment within the category 9 market sector. However, they already provided accurate estimates concerning their appliances to the ERA study. They could not provide further information on the rest of the Cat.9 professional market sector, which consists of:

- One big player – Rohde&Schwarz, representing 10% of the market. According to T&M Coalition this is a family-owned company and their policy is not to join any association.
- The rest of the professional market sector is made up of small companies, which, according to T&M, do not have the capacity and resources to be actively involved in the consultation process.

Despite our efforts, we could not get further information from Rohde&Schwarz and it was not feasible to carry out a survey among the small companies.

Neither was it possible to obtain additional data on quantities of Category 9 consumer appliances, which according to the estimates of [Goodman 2006] could represent almost half of the weight placed on the market[14].

The final report on the review of the WEEE Directive [UNU 2007] estimated the quantities of appliance put on the market for the different WEEE categories. The scale-up of the values from the different national registries to EU27 reveals wide variations for both Cat. 8 and 9, and thus are not considered very reliable. Data from only two countries (Hungary and Spain) indicates that commercial sector accounted about 75% of the total weight of material in Cat. 9 put onto the market (for Cat. 8, the share of commercial sector was about 90%, based on this limited data). The report further concludes that currently, the data available from the WEEE compliance schemes is insufficient to determine average composition for Cat. 9 products.

[14] if building thermostats and smoke detectors are counted as consumer appliances

Hence, the amounts of substances in Cat. 9 (and Cat. 8) presented in [Goodman 2006] are considered the best estimates, noting that there has been a general agreement on these values.

In general, estimating the quantities used is challenging as they are constantly changing due to new worldwide restrictions. A lot of manufacturers are continuously modifying their products in order to comply with the RoHS Directive and are increasingly using lead-free solders.

Environmental impacts of the options

The objective of the RoHS Directive is to reduce the environmental impact of new electrical and electronic equipment in Europe during the manufacture of appliances and at the end-of-life phase. The options for including Cat. 8 and 9 appliances within the scope of the Directive would all further reduce the quantities of hazardous substances in these appliances and can thus be considered to have a beneficial impact on the environment and human health.

Based on the data presented in Table 4, it is possible to estimate the amount of hazardous substances put on the market that would be avoided by each policy option, assuming that there are no independent developments in the quantities. However, due to de facto on-going developments, for example due to changes in component availability, these quantities are likely to overestimate the benefits of including the Cat 8 and 9 within the scope of RoHS. On the other hand, it can also be argued that this development is, to an extent, taking place due to the effect of anticipating the restrictions becoming obligatory for Cat. 8&9 equipment as the RoHS Directive is revised.

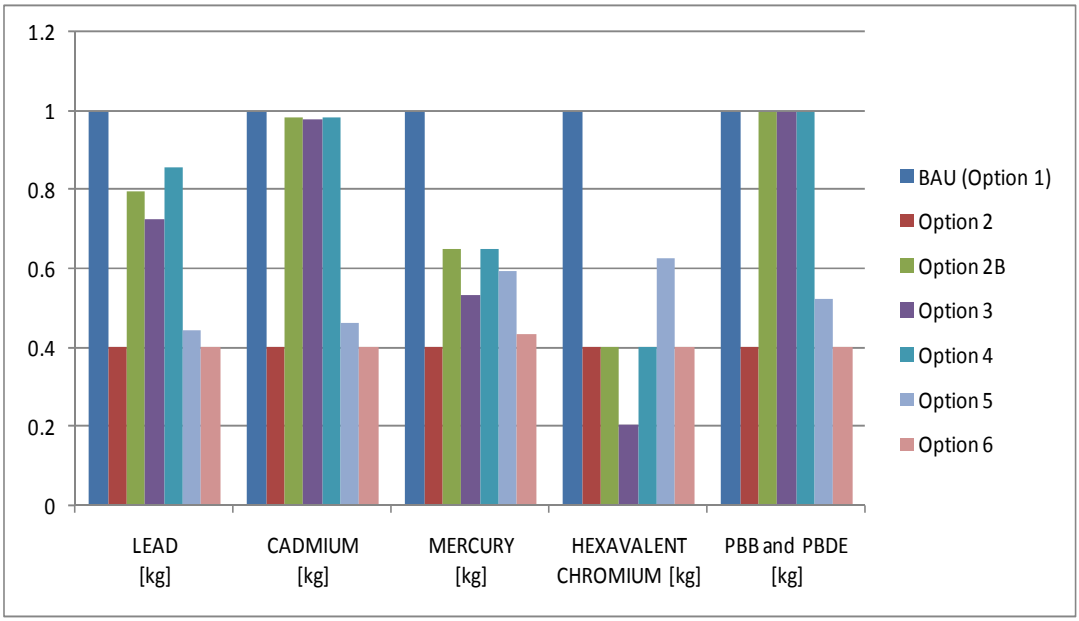

Figure 4 – Comparison of hazardous substances put on the market in Cat. 8 & 9 equipment in the period of 2010-2020 (Business as usual set equal to 1)

It can be seen from Figure 4 that the Option 2, i.e. bringing Cat. 8 and 9 in the scope without exemptions could theoretically reduce the quantities by 60% over a ten year period. However, the fact that exemptions are not allowed in the amended Directive does not mean that companies cannot and will not apply exemptions one by one. Given that the "ERA exemptions" are justified and that they would eventually be granted, the realistic impact of Option 2 is more modest (depicted as Option 2B in Figure 4).

Due to the fact that the justified exemptions, which are allowed in Options 2B, 3 and 4 cover most of the lead, cadmium and PBB/PBDE[15] use in Cat. 8 and 9, the reduction in the quantities are modest compared to the business-as-usual scenario and vary little between the options.

Options 5[16] and 6 are not complete options in themselves but rather optional variations to the more general options covering all Cat.8 and 9. Thus, in order to compare them to the other options over the 10-year period, an assumption had to be made regarding the general scenario. Options 5 and 6 were thus built upon Option 2, so the effect of allowing later implementation date for industrial Cat. 9 equipment and IVD and AIMD, respectively is illustrated by the difference between Option 2 and option 5 and 6, respectively. The effect of exemptions is not taken into account.

[Goodman 2006] did not provide estimation of the quantities of hazardous substances in consumer and industrial Cat.9 equipment. According to [UNU 2007], professional equipment presents 75% of the total weight of Cat.9 equipment. Same assumption is adopted to the hazardous substances, but it is admitted that this may underestimate the quantity of hazardous substances in industrial products, which in reality are more likely to contain restricted substances. Much of the consumer appliances are, or will shortly be, RoHS compliant due to the general EEE market development towards RoHS compliance.

Option 6 has been depicted in Figure 4, but as it is not a complete option in itself but rather an additional option, an assumption had to be made regarding the general scenario. Option 6 was thus built upon Option 2, so the effect of allowing later implementation date for IVD and AIMD is illustrated by the difference between Option 2 and 6 (the effect of exemptions in not taken into account). It can be seen that later implementation date for these specific equipment groups would have hardly any environmental consequences, due to their relatively small share in the Cat. 8 and 9 equipments.

It should be noted, for all options, that a later compliance date, e.g. 2018 for industrial Cat. 9 products, does not mean that the quantities of hazardous substances in the products will stay at their current levels until 2018 (as implicitly assumed in Figure 4). The compliance date marks the time when all the appliances (except the uses that are

[15] Exemption for Deca-BDE

[16] Compliance by 2018 is assumed here.

exempted) will be RoHS compliant. The redesign and the changes in hazardous substance content will go down gradually over time. Thus, if we considered a constant redesign effort, most of the appliances would be RoHS compliant already some years before the compliance date. This of course calls for a firm deadline date with no possibility of exemption; otherwise the industry may delay the change.

The environmental impacts of the RoHS Directive are often discussed in terms of quantities of hazardous substances used in the equipment. However, this provides only a surrogate measure of the "real" environmental impacts of the options. Firstly, the quantity of substances ending up in the environment impacts depend on the way a product is handled at the end-of-life. Secondly, the impact of the substances released to the environment is determined by case-specific and complex dose-response relationships.

Hence, it is not straightforward to estimate what the true impacts of the substances in Cat. 8&9 products would be.

Recycling is already the common practise to treat the professional Cat.8&9 products at the end of life, according to the industry. The European healthcare industry states that over 90% of the Category 8 equipment is to be recycled and thus do not end up in the environment [COCIR et al. 2007]. [UNU 2007] also states that most of the B2B appliances (which make up approx. 90% of the total) are already collected and treated outside the consumer oriented compliance schemes. T&M Coalition has confirmed that "next to none" of its products (professional/industrial test and measurement within category 9) are land filled, incinerated or otherwise end up in the environment due to re-use, refurbishment, recycling and take back. Many professional/industrial appliances contain valuable parts and materials and thus companies favour direct take-back of their old appliances.

[UNU 2007] shows the estimated amount of WEEE currently collected and treated as a percentage of the amounts of WEEE arising for the EU27 in 2005. For Cat.8 this is 49.7% and Cat.9 65.2%, but these figures do not capture all the industry take-back schemes (non consumer oriented). Furthermore, as pointed out by industry, due to the long lifetime of these products there is a big lag between the time product is placed onto the market and the time of their disposal. This is strengthened by the tendency of many users to stock old products for eventual back-up. The sales of these appliances have gone up due to technical evolution and furthermore, new appliances tend to be more sophisticated than products sold 10-15 years ago. According to medical industry new appliances are often larger (heavier) due to added functionalities[17]. Thus there is a large difference between the weight of the products placed on the market and those collected today. Thus the above figures of around 50% do not reflect the true recycled percentage of the end-of-life products in Cat. 8 and 9.

[17] The T&M Coalition considers that this statement is incorrect, so there may be a difference between appliance groups.

[UNU 2007] report highlights that the data availability and quality concerning the recycling for these product categories is weak or none. Due to lack of data also on appliance quantities and composition, environmental or economic analysis on these categories was not possible within the study.

Recycling and special treatment of EEE is carried out to limit the environmental impacts of these products at the end-of-life, but even these operations usually have a certain impact on the environment. Assuming that most of Category 8 and 9 equipment are already recycled via specific industry take-back systems, the environmental impact of the hazardous substances contained in them depend on the quality of the recycling operation.

Considering this, two extreme scenarios, corresponding to a high and a low level of recycling, are elaborated to calculate the potential environmental impacts of the end-of-life treatment of categories 8 & 9 products. The first scenario, which is extrapolated from statements by the European Healthcare Industry and the T&M Coalition, assumes that 90% of category 8 and 9 products are recycled. Second scenario adopts percentages from [UNU 2007] study where the figure for recycling is 57%. The remaining quantity is considered to be either landfilled or incinerated (according to a MSW scenario based on the data from Eurostat, where 63% of the products would be landfilled and 38% incinerated). The content of each scenario is presented in Table 5.

Table 5 - Scenarios used for environmental impact analysis

	Recycling	Landfill	Incineration
1. Scenario 1: high level of recycling	**90%**	**6%**	**4%**
2. Scenario 2: low level of recycling	**57%**	**27%**	**16%**

Landfill or incineration is seen as a route for the hazardous substances to be released to the environment, although there are very limited data on their fate. Process control of landfills and incinerators, alongside mineralization mechanisms in landfills, limit the quantity of hazardous substances that are actually released to the environment.

No specific data is available describing the leaching potential of the hazardous substances in EEE. Potentially and over very long time, all hazardous substances could leach to the environment, but in reasonable timeframe the amounts are much lower. A study on the end of life of battery waste [ERM 2006] assumes that 5% of heavy metals in landfilled batteries are leached to the environment (groundwater), the remaining locked in landfills either as non-compromised equipment or as mineralised compounds resistant to leaching. This assumption was adopted for the scenarios above.

Neither is there data on the emissions to air that arise from the incineration of EEE. The [ERM 2006] assumed that 0.5% of the heavy metals in batteries are emitted to air from the municipal incineration plant and the remaining 99.5% are removed through flue gas treatment and bottom ash. These residues are assumed to be disposed to landfill and

the ERM study further assumes that 2.5% of the heavy metals content landfilled is leached to water. Again, these assumptions were used for the two scenarios.

According to [COWI 2002] it is estimated that the total losses of lead to air and water by the recycling activity are about 0.06% of the amount disposed of the recovery, including 0.001% is emitted to the air. This assumption was used for the calculations for the two scenarios, extrapolating this data for all kinds of hazardous substances, in the absence of more specific data.

The agreed CML life-cycle assessment characterisation factors[18] for Pb, Cd, Hg and Cr(VI) were used to derive the human and eco-toxicity potential related to these substances[19]. These factors are specific for the different environmental compartments (groundwater, air, etc.), and for this reason the substances need to be allocated to the different compartments. The specific end-of-life scenario described above is needed for this.

Table 6 presents the toxicity potentials under a BAU situation respectively for the two EOL scenarios (human toxicity, freshwater aquatic, freshwater sedimental and terrestrial ecotoxicity) corresponding to the RoHS restricted substances contained in Cat.8&9 products that are put on the European market during the period 2010 - 2020 (corresponding to quantities presented in Figure 4). These potential impacts could eventually be (partly) avoided by including the equipment in the scope of the RoHS Directive.

Table 6 – Toxicity potential of the RoHS restricted substances contained in the Cat.8 & 9 products that would be put on the market according a BAU scenario during the period 2010 – 2020, calculated considering two hypothetical end-of-life scenarios

Indicator	Unit	Scenario 1	Scenario 2
Human toxicity	kg 1,4-DB eq	8.58E+06	3.31E+07
Freshwater aquatic ecotox.	kg 1,4-DB eq	7.80E+05	3.07E+06
Freshwater sedimental ecotox.	kg 1,4-DB eq	2.00E+06	7.88E+06
Terrestrial ecotoxicity	kg 1,4-DB eq	5.49E+04	2.12E+05

Below four graphs are presented for every toxicity indicator with the differentiation between policy options, end-of-life scenarios and substances.

[18] These factors are commonly employed by LCA professionals, and also used in [UNU 2007] and [Bogaeart 2008].

[19] PBB and PBDE were not taken into account as there are no characterization factors for these substances

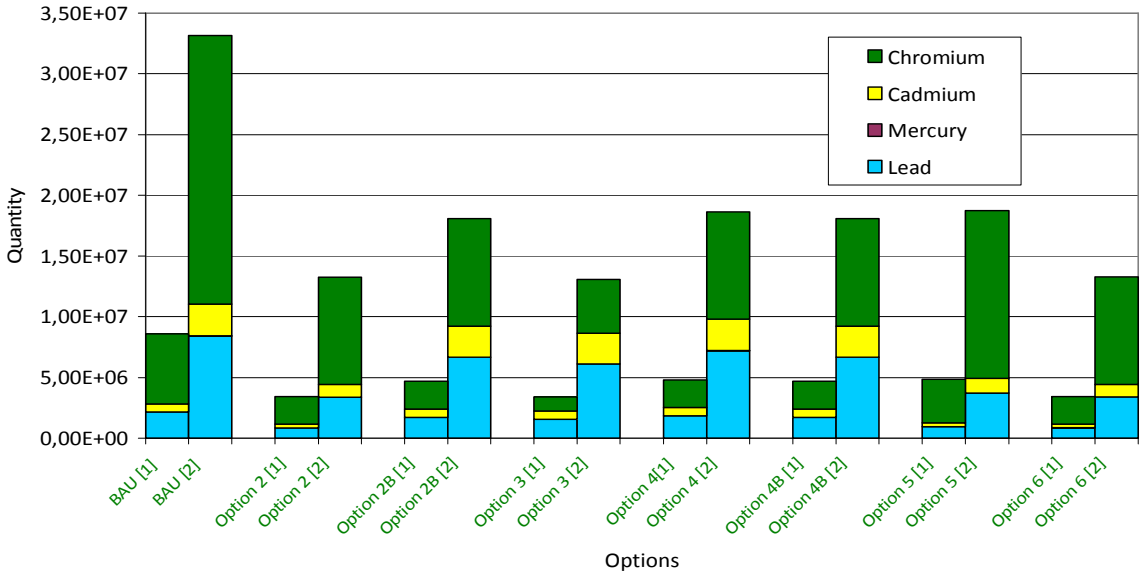

Figure 5 – Human toxicity potential [kg 1,4-DB eq] of the RoHS restricted substances in the Cat.8 & 9 products contained in EEE during the 2010 – 2020 period, according to the different policy options under study, and two extreme end-of-life scenarios (1: high level of recycling ; 2: low level of recycling).

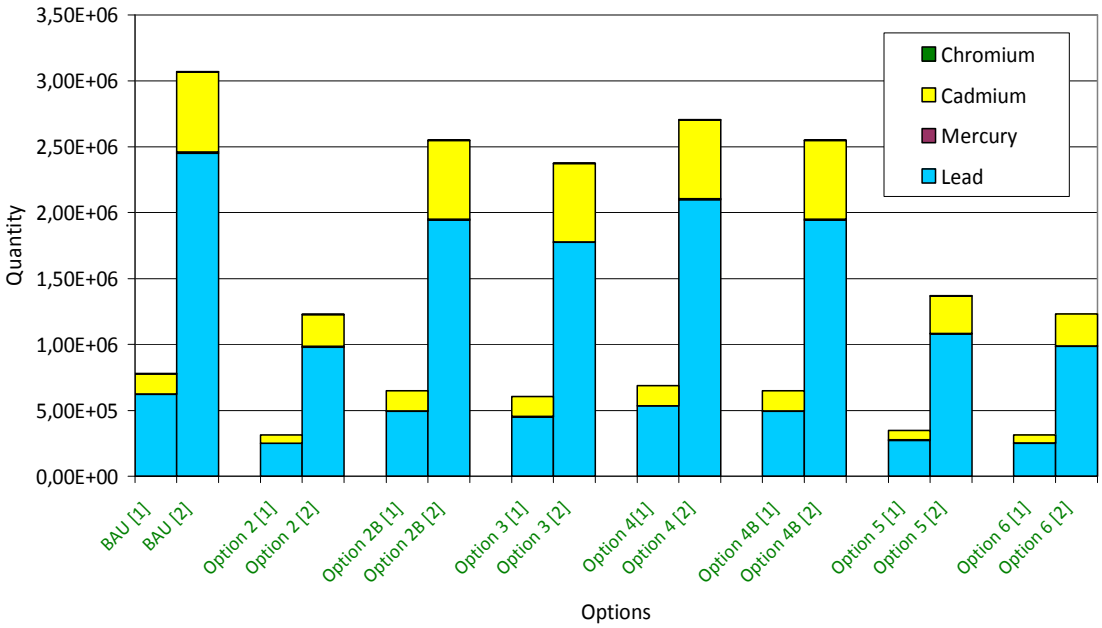

Figure 6 – Freshwater aquatic ecotoxicity potential [kg 1,4-DB eq] of the RoHS restricted substances in the Cat.8 & 9 products contained in EEE during the 2010 – 2020 period, according to the different policy options under study, and two extreme end-of-life scenarios (1: high level of recycling ; 2: low level of recycling).

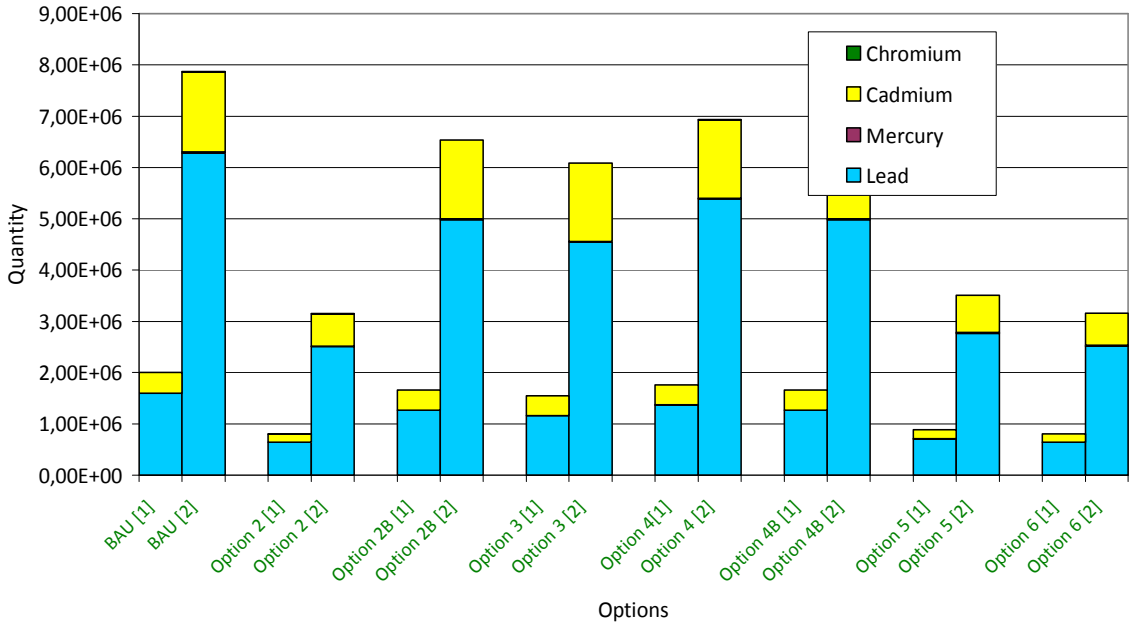

Figure 7 – Freshwater sedimental ecotoxicity potential [kg 1,4-DB eq] of the RoHS restricted substances in the Cat.8 & 9 products contained in EEE during the 2010 – 2020 period, according to the different policy options under study, and two extreme end-of-life scenarios (1: high level of recycling ; 2: low level of recycling).

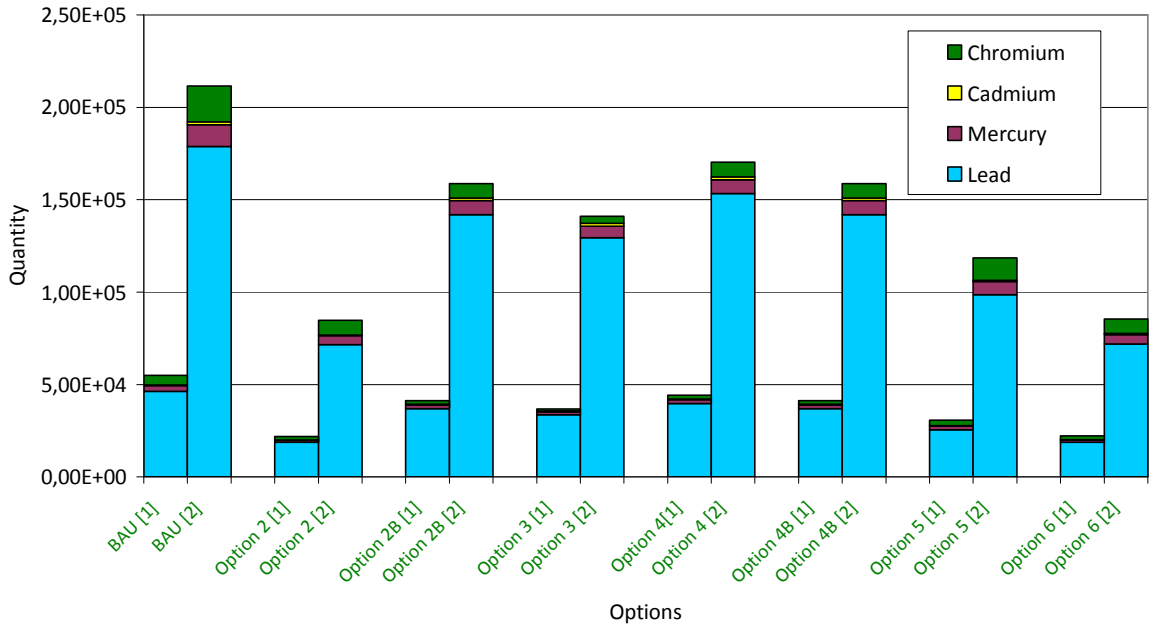

Figure 8 – Terrestrial ecotoxicity potential [kg 1,4-DB eq] of the RoHS restricted substances in the Cat.8 & 9 products contained in EEE during the 2010 – 2020 period, according to the different policy options under study, and two extreme end-of-life scenarios (1: high level of recycling ; 2: low level of recycling).

Though the results shown above in Figure 5 to Figure 8 must be taken with care, as they are based on rather rough assumptions, the following general trends can be observed:

- Recycling enables to significantly decrease the potential toxicity impacts of the end-of-life treatment of EEE containing hazardous substances;
- For the 4 toxicity indicators, lead appears as the major contributor to potential impacts, which is coherent with the fact that lead amounts contained in EEE are much higher than the quantities of other substances;
- As regards human toxicity, potential impacts linked to the presence of chromium are significant. This is due to the fact that even if the quantities of chromium VI are relatively low as compared to e.g. lead, the potential human toxicity impact of this substance is high.

The impacts represented by these toxicity potentials may be difficult to understand without any point of comparison. 'Normalisation' is a common step in life cycle analysis, which compares the results to normalisation values and gives indication on the order of magnitude of the potential impact. Table 7 presents a set of normalisation values: Impacts generated by EU27 inhabitants per year (based on the CML normalisation values per person and Eurostat population statistics).

Table 7 – The set of normalisation values for toxicity results

Indicator	**Unit**	**Normalisation values: Impact generated by EU27 inhabitants per year**
Human toxicity	kg 1,4-DB eq	1.01E+13
Freshwater aquatic ecotox.	kg 1,4-DB eq	6.70E+11
Freshwater sedimental ecotox.	kg 1,4-DB eq	6.85E+11
Terrestrial ecotoxicity	kg 1,4-DB eq	6.26E+10

Table 8 presents the toxicity potentials that were presented in Table 6, normalised to EU27 habitants' total impacts using the normalisation values of Table 7. The normalisation is based on the best available data, but is associated with high inherent uncertainty. So the results should be considered indicative; yet this should not change the conclusions. The normalised values are interpreted as follows: for example, the human toxicity potential of hazardous substances in Cat.8&9 put onto the market in the 2010 – 2020 period, correspond to 0.000009% [scenario 1] or 0.00033% [scenario 2] of the human toxicity potential generated by the total population of EU27 in one year.

Table 8 – Toxicity potential of the RoHS restricted substances contained in the Cat.8 & 9 products during the period 2010 – 2020 normalised to EU27 impacts

Indicator	**Scenario 1** results normalised to EU27 impacts	**Scenario 2** results normalised to EU27 impacts
Human toxicity	0.000009%	0.00033%
Freshwater aquatic ecotox.	0.00012%	0.00046%
Freshwater sedimental ecotox.	0.00029%	0.00115%
Terrestrial ecotoxicity	0.0009%	0.00034%

As the comparison to the total impacts generated by the European population shows, the impacts of RoHS substances in Cat.8 and 9 equipments are extremely small.

It should not be forgotten that restriction of hazardous substances also avoids their production which also has environmental impacts. The net effect of substitution to the impacts of production depends on the substitutions materials and has not been quantified in the context of this work.

Mr. Goodman (pers. comm.) mentioned the lack of information on the environmental impacts of substitutes as a major data gap in estimating the environmental impacts of the different options. However, this applies to all product categories and thus it does not seem necessary, neither would it be possible, to include this dimension in the impact assessment.

Environmental effects of lead substitution in solders in general

[ARCADIS & RPA 2008] discusses extensively the effects of lead substitution in solders of EEE in general:

According to [Deubzer 2007, in ARCADIS & RPA 2008], lead-free soldering substantially reduces the worldwide potential toxicity and the risk of toxic impacts of metal emissions into the environment from soldering wastes and from printed wiring boards at the end-of-life stage. The RoHS Directive therefore would achieve its intention to reduce the toxicity of the WEEE. Collection and recovery of WEEE further on reduce the toxicity. Silver as the main toxicity driver in lead-free soldering material use can be recycled to more than 95 % in the copper smelters. As lead-toxicity as well benefits from higher recovery rates, the SnPb-normalized toxicity of the emissions decreases with increasing recycling rates, but moderately only, from around 23 % down to around 20 % for 60 % WEEE recovery.

Further the study by Deubzer found that lead-free soldering increases energy consumption with around 40 %, although higher WEEE recovery rates moderately improve the situation, from around 43 % down to 36 % for 60 % WEEE recovery. The energy consumption for both tin-lead and lead-free soldering is mainly related to the

soldering processes. Higher energy consumption of the lead-free solders is explained by their higher melting point. [Deubzer 2007, in ARCADIS & RPA 2008]. The increase depends on the soldering technology. According to Mr. Willems[20], in the case of wave soldering there is a temperature increase of the solder bath of typical 245-250 °C to 260-265 °C resulting in a moderate increase of heat loss to be compensated. The reflow oven has an increase in set point of 20 to 40 °C.

[Goodman 2006] also quotes an estimate according to which changing to lead-free soldering causes an increase in energy consumption in surface mount processes by approximately 12% because of the higher melting temperature. According to Mr. Willems[20], the 12% figure of [Goodman 2006] is likely underestimating the energy consumption increase.

According to Goodman [2006] there would be an increase in energy demand also because of the need for additional washing and drying of printed wired boards (PWB). Mr. Willems has contested this as according to him, washing and drying is not standard practice in the European industry which is widely using no-clean soldering technology. Yet, he adds that high reliability electronics may use cleaning (automotive, aerospace, military, etc.). Hence cleaning may be relevant in the manufacture of Category 8 and 9 products with high reliability requirements.

According to Deubzer, metal mining and smelting, in particular of silver and of tin, add to the energy consumption of lead-free solders. [Deubzer 2007, in ARCADIS & RPA 2008]. However, this has been contested by a stakeholder[21] as "not proven and unlikely". According to the comment, recent information suggests that the gross energy requirement for the production of Pb and Sn are almost identical.

[ARCADIS & RPA 2008] briefly note that there is also an alternative point of view with regard to the energy consumption of some types of Pb-free soldering. Indeed, according to a project carried out under a grant from US EPA [Geibig and Socolof 2005], the energy consumption for some types of Pb-free solders is lower than Pb solders. The energy consumption can also vary widely depending on the solder type[22] and the equipment specifications and process operating parameters employed by the facility. Table 9 presents the energy consumption data collected during reflow solder testing conducted at two separate facilities, using an identical protocol and under controlled conditions to facilitate the comparison. The results show that the power consumption for this process varied significantly across facilities, despite the use of similar test protocols.

[20] Willems, G., IMEC & SIRRIS (comment provided 14/07/2008)

[21] A confidential stakeholder comment received 09/07/2008

[22] Willems, G., IMEC & SIRRIS (comment provided 14/07/2008) has pointed out that lower melting point alloys such as SnBi obviously require less energy to solder. They also have completely different properties than SnPb or SAC solders and, therefore, are simply not a viable alternative in all applications.

Table 9 – Power consumption in solder application during reflow testing at two facilities [Geibig and Socolof 2005]

Solder type	Facility 1 [kW]	Facility 2 [kW]	Power reduction
SnPb (Tin/Lead, BAU)	23.3	8.3	-65%
SAC (Tin/Silver/Copper)	25.2	9.1	-64%
BSA (Bismuth/Tin/Silver)	15.7	6.8	-57%
SABC (Tin/Silver/Bismuth/Copper)	25.2	9.1	-64%

Equipment designed for the high temperatures associated with lead-free, such as the oven at Facility 2, are developed using the latest technologies and are optimised to achieve greater temperature stability through increased thermal efficiency. Given the importance of the use/application stage and the relative thermal inefficiency of assembly equipment optimized for SnPb (Facility 1), an opportunity exists to reduce the amount of energy consumed during lead-free assembly through equipment changes and process optimisation[23].

Furthermore, this LCA study highlights that the ranking of the different solders varies according to the impact category. Thus there may be no clear environmental or health benefit of replacing lead in solders with the currently available alternatives. A stakeholder also suggests, based on the experience of technical and eco-design expert in businesses), that restricting lead used in solder on printed-circuit boards has been questionable (or worse) for environmental implications.[24]

According to Geibig and Socolof [2005], given the importance of the upstream processes in many of the life-cycle impact categories, and the high percentage of virgin material used to manufacture the solders, an opportunity exists to reduce these impacts through the use of recycled metal. Reclaimed metal derived from either post-industrial or post-consumer recycling produces less environmental impact per volume than does the mining and extraction of virgin metal. Substituting recycled metals for virgin content will reduce the overall environmental footprint of the solder life cycle in several categories.

[ARCADIS & RPA 2008] concludes that "as the discussion on the environmental impact of Pb-free soldering is very complex, ambiguous and still on-going, no definitive conclusion can be drawn on this topic in the scope of this report." The extensive comments received on this issue in the context of this study also lead to such conclusion.

[23] According to Willems, G., IMEC & SIRRIS (comment provided 14/07/2008) this is jumping to conclusions based on very limited data: "Obviously, modern ovens are somewhat more energy efficient than older ones, but the improvement is to be counted in the 1-10% range, not the 60% range as Table 9 tends to suggest. There is no miracle solution. High energy prices will drive energy efficiency. By any count the energy efficiency gained with new equipment will pale when compared to the energy consumption increase related to the higher soldering temperature set points."

[24] Pamela Gordon, Technology Forecasters Inc. (comment received 15/07/2008).

3.3.2. ECONOMIC IMPACTS

Firms: costs and competitiveness

Re-design of products in order to comply with RoHS always calls for some resources. Compared to EEE in general, there are two main challenges regarding the RoHS compliance of Cat. 8 and 9 equipment:

- The re-design of existing products. In this context the big issue is lead in solders, including two specific considerations:
  - Reliability of substitutes
  - Resource requirements of conversion
- Exemptions for hazardous substances in specific uses

The re-design of existing products (lead in solders): Resource requirements

Lead solders have been extensively used in Category 8 and 9 products and bringing these categories into scope will require significant substitution and redesign of a large number of products.

The RoHS Directive is already indirectly affecting manufacturers of Category 8 and 9 products and more and more products are approaching RoHS compliance as:

- the majority of mass produced electronic components are being changed to comply with RoHS and have already been replaced by versions that do not contain RoHS restricted substances [Goodman 2006];

  For example, approximately 25% - 50% of components on PCBAs (printed circuit board assemblies) in Category 8 products are lead-free already now [COCIR et al. 2007].

- manufacturers are increasingly being forced to use lead-free solders wherever technically possible to meet customer requirements in the Japanese markets[25]. Consequently, several Cat. 9 equipment manufacturers have decided to replace RoHS-restricted substances to the extent possible. [Goodman 2006].

On the other hand, Cat. 8 and 9 products can contain up to 25% of custom or specialist parts that are not used in equipment in the other eight WEEE categories and hence not necessarily RoHS compliant [Goodman 2006]. According to the health care industry, to-date, almost no equipment in this category is fully RoHS compliant while many products are already close to compliance. Only some medical monitors and computer hardware are ROHS compliant. [COCIR et al. 2007]

[25] There are currently no legal restrictions on the use of lead in Japan, but the market prefers lead-free products due to significant cost implications for lead containing equipment at the end of life.

In general, economic impacts incurring due to RoHS are estimated to be higher for Category 8 & 9 products than for many other EEE due to the characteristics of these products. [Goodman 2006] provides the following table to illustrate the differences between specialist industrial Category 9 equipment in and mass-produced consumer products. On the other hand, especially Cat.9 also includes consumer type appliances for which the economic impact incurring due to RoHS are likely to be modest.

Characteristic	**Specialist industrial Category 9 equipment**	**Mobile phone**
Typical numbers sold	350	5.5 million
% of pre-2003 products on the market in 2006	>80%	<1%
Number of current distinct models per manufacturer	1600	300
Number of engineers available for each product	1.9	61.6
Time between launch of one product and its replacement	7 years on average	~6 months
Custom made parts	~25%	<5%
Time required for reliability testing (average per model)	4.3	0.7
Authorisation	Up to 2 years	<6 months
Data from the Test and Measurement Coalition		

The compliance is considered to be more costly for many of these equipments also since they have to comply with a wide range of other regulations and, especially regards to Cat. 8 products such as IVD, even small changes made in order to comply with RoHS will require lengthy retesting, reauthorisation and resubmission to notified bodies for licensing before the products can be sold.

RoHS compliance does introduce some added costs and additional work for any electrical product because in general, production costs are a few percent higher [Goodman 2006]. According to Eucomed, tin/silver/copper metal price (for lead-free soldering) is about 4 times that of tin/lead but 90% of RoHS-compliant components are the same price as older non-compliant versions. However, a small percentage is 10% more expensive and most custom parts will incur a price increase.

Medical sector is characterised as having large number of small to medium sized enterprises (around 80%) and the share of SMEs in the monitoring and control sector is probably similar or larger. SMEs, particularly those with a large variety of products, would have much greater difficulty complying with the RoHS Directive's requirement because they do not have the necessary available resources or manpower. The direct impact of additional costs of product's manufacturing is increased price. It is estimated that cost per product to modify it to comply with RoHS could be as high as 20% although most will be less than this and in the range from 1 to 10%. Additionally, modifying

products from non-RoHS compliant to RoHS compliant and changing to lead-free soldering causes an increase in energy consumption. Energy costs would be 12% more due to higher melting temperature. One manufacturer has estimated that the cost of additional testing and re-certification for one product modified to comply with RoHS could be as much as €1 million taking 2 or more years. If 1 million items are going to be sold, the cost per item would be €1. However products from categories 8&9 are sold in smaller numbers and when only 200 were to be sold per year, the cost increase will be €5000. The average price of industrial equipment is €5160.

Quantification of the compliance costs

Despite the direct contacts with the Test & Measurement Coalition, COCIR, Eucomed and EDMA, it has not been possible to obtain estimates on the total economic impacts of the different policy options quantified in Euros, neither a total estimate regarding the RoHS compliance costs of these product groups.

It is noteworthy that the industry of both Category 8 and 9 considers that the inclusion of these products in the scope of RoHS Directive is economically feasible, especially if the schedule takes into account the characteristics of these sectors and their appliances in general, and of the specific sub-categories in particular; and if justified exemptions are granted. Thus, it seems that the enlargement of the scope to these products, with a suitable schedule, would not have a detrimental effect to the competitiveness of the sector.

Especially the medical device industry has underlined that the economic or the environmental impacts are not the real issue and presenting a single figure to express the cost of compliance to industry for each option would divert the attention away of the critical issue of reliability. According to EDMA, 0.1% reduction in the reliability of heart pacemakers could lead to 5-7 deaths per year. Thus a hurried product conversion without adequate testing could quickly result in the loss of life, and lower reliability would also lead to a removal of the product from the market.

The conformity testing prescribed in the medical device directives aims at ensuring the quality of these appliances, which can also mean that without sufficient proof a product (for example the heart pacemaker) cannot be placed onto the market. This could lead to non-availability of many products, with consequent impacts on the public health, if sufficient time has not been allowed for product re-design, testing and approval procedures.

Category 9 may seem to be less critical at first sight, but as a matter of fact it may be the most critical product group. Notably, other product groups, including medical devices are only as good as the testers (Category 9 products) verifying their performance.

In general, the European health care industry associations estimate the overall additional costs as a consequence to RoHS Directive implementation to be "**1 - 4%** of total worldwide medical device market of greater than 100 billion dollars" [COCIR et al.

2007]. The lower estimate is in line with the results of the CEA[26] study, which estimates the total RoHS compliance cost for the electronics industry to total 1.1% of industry revenue on average [CEA 2008].

Anecdotally, based on the experience of Ms. Gordon (pers.comm.) with Category 8 and 9 clients who are heading now to compliance, the costs are a bit lower to achieve compliance today compared to the costs estimated in [CEA 2008] – given that components and materials with the six restricted substances are far more accessible today and that they are using best compliance practices from companies that have achieved compliance a couple of years ago. Many out-of-scope companies have the advantage of being able to be proactive vs. reactive, and achieve RoHS compliance at their own pace. On the other hand, once categories 8 and 9 are brought in to scope, voluntary costs levels may no longer be sufficient. While compliance costs still will not be as high for secondarily-included products as it was for the first wave of in-scope products, the costs may be close. The originally exempted products were excluded from the initial list owing to costs to convert products with very long lifecycles, which defines many category 8 and 9 product classes, and other reasons. Furthermore, many medical products will have the added costs associated with other regulatory hurdles such as the US Food and Drug Administration (FDA) approval or the Medical Device Directive in the EU.

The contractors sought more information on the turnover of the Cat. 8 and 9 sectors and the available information is provided in Section 3.6. For Cat. 8 the market data include a wide variety of non-EEE medical devices and an assumption needed to be made to estimate the turnover of the medical industry corresponding to medical EEE. For Category 9, the data was only available regarding the market of industrial equipment test and measurement equipment. Based on the incomplete data and the assumptions and calculations presented in Annex to this factsheet (Section 3.6), a very rough, and probably too low an estimate of the compliance costs to Cat.8 & 9 groups is derived, ranging from €400 to €1600 million (corresponding to 1 and 4% quoted above). This estimate should be treated with caution and it should be considered a very indicative estimate only.

We have sought comments to the assumptions made and the estimation from the relevant industry associations (COCIR, EDMA and Eucomed), but they have been unable to further comment on them.

It is important to note that the above estimate does not include the costs incurring due to the loss of sales, which may occur if these products are required to comply with RoHS in too tight a schedule or if necessary exemptions are not granted in timely manner.

According to the industry, the cost of compliance and consequent availability and diversity of products are affected to a significant extent by the compliance schedule as

[26] Consumer Electronics Association, USA

well as possibility for exemptions as presented in Table 8 for Category 9 products.[27] Where new products are developed and designed to comply with RoHS, the only additional costs are for research and for any increased component and material price increase. This would call for an implementation data that allows the majority of existing models to be phased out at the original schedule. Additional costs are incurred if existing products need to be changed (due to a tight deadline) due to redesign, retesting and re-licensing. These costs can be significant and would inevitably be passed on to users (e.g. hospitals). [Goodman 2006].

Table 10 – Estimates from industry of proportion of products that would be withdrawn from the EU market based on the date that Category 9 is included within the scope of RoHS [Goodman 2006]

Options regarding exemptions	Proportion of products that would be withdrawn from the EU market based on the compliance from	
	2012	2018
No new exemptions	40 – 50%	5 – 10%
With "ERA exemptions" excluding Cr(IV) passivation and Pb in solders	35 – 40%	5%
With "ERA exemptions" including Cr(IV) passivation and Pb in solders	2 – 10%	0%

Competition

RoHS should affect all manufacturers in EU equally and so no competitive pressures within Europe are expected.

Eucomed has pointed out that the EU has 30% of the world's medical market with exports of 50 billion Euros against imports of 30 billion Euros. Therefore, inclusion of categories 8&9 within the scope of the RoHS Directive could have a significant impact on EU industry due to competition with US or Asia manufacturers on worldwide markets.

Innovation and research

According to [Goodman 2006], substance restrictions could impose limitations on the development of innovative new products. While this may be a valid argument for all product categories, in the context of Category 8 and 9 products, such limitations could mean that potentially life-saving and environmentally beneficial inventions would not be developed. Under the present system, where a product is within the scope of RoHS, a new innovation requiring the use of a restricted substance could be used only if an exemption were to be granted. Currently, this process is taking at least one year which fits poorly with the financing mechanisms of the leading edge technology, which are

[27] T&M Coalition has provided a more detailed table to the Commission and to the contractors, but has indicated such data confidential.

often carried out as short term contracts (1-3 years). Furthermore, diverting R&D effort to product redesign to comply with RoHS can result in loss of leading edge technology by European producers.

[COCIR et al. 2007] mentions the hidden costs related to the loss of innovation and technology due to lead-free transition utilising valuable engineering resources as well as lost opportunity for society in advances in healthcare. However these costs cannot be quantified.

On the other hand, continued exclusion of Category 8 and 9 products would miss the opportunity to encourage innovation of products in context of reduction of toxicity.

3.3.3. SOCIAL IMPACTS

- **Impact on availability**

The cost of implementation of the RoHS Directive, borne by the producer, was discussed in the previous section. The producer will of course pass this cost on to the customers if possible. This will mean an immediate price rise for products where the costs are large in proportion to the product price – this is most likely for products manufactured in small numbers. A significant price increase especially in Category 8 but also in 9 products could potentially have an indirect impact on healthcare provisions, the environment and on safety.

The cost impact of RoHS on the businesses of Categories 1-7 and 10 vary from under 1% to up to 4% of turnover. Most Category 8 and 9 products are different to products in the other categories and it is reasonable to accept that the cost of compliance for Cat. 8 and 9 products will be at least as for the other categories. In many cases it could be significantly higher, for example around 10% for IVD products and possibly more for specialised test instruments. [Goodman 2006].

If prices were to rise on average by 5%, this would cost EU healthcare providers €2.7 billion per annum[28]. However, as all healthcare providers have limited budgets, this would result instead in them being able to buy fewer, or less advanced items of new equipment and this in turn would affect healthcare in EU as well as patient health and quality of life. According to additional costs for manufacturing RoHS compliant products (when the deadline of compliance is too short) price increases will be necessary and, if these were excessive, the products would have to be withdrawn from the market. The loss of product diversity would have a negative impact on users within the EU.

[28] [Goodman 2006] considers that if the date of inclusion is "too early", average prices could go up by 5% with consequent impact on healthcare expenditure. This estimate has been considered high by a stakeholder comment, but for example according to [CEA 2008], the average cost increase experienced by original equipment manufacturers or added by contract manufacturers due to RoHS (component, module and manufacturing costs) was 11.6%. This cost increase may be transferred to the customer.

[Goodman 2006] considers that this is a significant concern only if Category 8 and 9 equipments are included in the scope of RoHS too early as discussed in the previous section.

- **Impact on public health and safety**

The price and availability concerns can indirectly affect public health and safety if appropriate medical and/or devices cannot be purchased due to budget constraints.

Inclusion of Category 8 and 9 equipments into the scope of RoHS without exemptions could have a direct negative effect on public health and safety. For example, hazardous substances such as lead are used for personal protection, especially in Cat. 8 equipment, shielding patients and personnel from unwanted ionizing radiation. Total lead ban in these equipments without exemptions would either expose patients and personnel to harmful radiation during treatment and analysis.

AEA Europe[29] has further highlighted that many Category 9 products are increasingly being used in applications that are specifically excluded from the scope of the RoHS Directive – these include safety applications in military systems, ships, large amusement rides, power generation facilities, chemical and petro-chemical plants etc. As the exemption in the Directive only applies to equipment that is solely intended for military purposes, too early inclusion of Category 9 in RoHS could therefore impact safety applications that are outside the scope of RoHS.

- **Employment**

Due to the scarcity of data, it is very difficult to assess the impact on employment of the inclusion of Category 8 and 9. Some believe that additional employment could be created by Research & Development to achieve RoHS, while others fear that to recoup compliance costs, companies may even reduce workforce. However, based on the results of the CEA survey the impacts in terms of employment would seem to be small. According to [CEA 2008] the vast majority of companies relied on existing, internal resources and hired zero or one employee for RoHS compliance. At the same time, to compensate compliance costs, companies were less likely to reduce headcount than to choose other options (raise prices, introduce new products to increase revenue, or do nothing).

3.3.4. OPTION 1 VS. OPTIONS 2 - 4

The environmental comparison of the options has been presented in Section 3.3.1.

Option 1, would not incur specific additional costs. But excluding Cat. 8&9 equipments from the scope of RoHS may not be a sustainable long term option from a business

[29] Comment provided 11/07/2008

standpoint, as stated by Test & Measurement Coalition[30]: "In practice many companies in our sector are underway making transition efforts. Companies that have been investing a lot in research of RoHS compliant alternatives would now be punished for actually having worked towards that goal." [T&M Coalition 2008]

3.3.5. OPTION 3 VS. OPTIONS 2 AND 4: COMPLIANCE DATE

The compliance date (2012 or 2014) has limited environmental impacts, as illustrated previously in Figure 4. The options regarding the compliance date differ rather in their economic impacts, which indirectly may have also social impacts (e.g. the costs to industry may affect the availability and/or cost of Cat. 8 appliances and thus public health care).

The compliance date is above all related to the issue of lead solders (issue of specific exemptions will be discussed in the following section). As noted in [Goodman 2006], although there is no doubt that lead-free solders are suitable for equipment where temperature changes are small and the expected life is less than 10 years, there is up to now no field data available to confirm the reliability of equipment which is expected to operate for 10 or more years in hostile conditions (extremes of temperature, severe vibration, corrosive atmospheres, etc.) which Category 8 and 9 products often experience.

The ERA report further notes that industry experience regarding lead-free solders is improving through accelerated testing of lead-free solders. But this laboratory data should be validated against real-life field data. [Goodman 2006] further explains that "it is likely that by 2012, accurate models will be available and that these will have been validated against field data from the very large number of RoHS compliant electrical equipment that will be placed on the market from the end of 2005 onwards. Knowledge of the relationship between strain and number of thermal cycles to failure for lead-free solders will be required in order to accurately predict field life of products." [Goodman 2006]

[Goodman 2006] estimated 2012 to be a realistic compliance date, whereas in their contributions relevant industry associations have considered this to be too early a date.

Based on an up-date from Mr. Goodman [pers. comm.], if a manufacturer starts research today – 2008 – on lead-free soldering of their products, they will be able to make RoHS compliant products by 2012. He considers that four years are more than sufficient time to set up new processes, carry out trials and test products. But, as he points out, this work will not give information on the long term reliability; this data should be available by 2012 as also described in [Goodman 2006]. However, even if the product is redesigned by 2012 and data confirm the reliability of lead-free solders, Cat. 8 and some Cat.9 products are not likely to be ready to be placed on the market

[30] Represents around 60% of the professional/industrial test and measurement equipment within the category 9 market sector.

immediately in 2010. The manufacturers need to gain approval for products if they change anything significant[31]. Reliability data is needed to gain regulatory approval from Notified Bodies, which is required before RoHS compliant versions can be sold in the EU. Furthermore, obtaining authorisation is expensive and so manufacturers do not want to do this "just in case" i.e. they will only seek authorisation once the reliability issues are clear. If by 2012 it is clear that long term reliability is ok and that lead solders will not be exempt, then the manufacturers will apply for approval which could take up to 1 year, which explains the proposal from industry to set the compliance data at 2014.

The industry has estimated that if adequate field data is available by 2012, it can then take a further 18 months to test and validate complex products in order to prepare the technical file for review by the Notified Body. Once the technical file is ready, it can then take up to a year to gain approval from a Notified Body. In the mean time, the RoHS compliant version cannot be sold in the EU.

Industry has also mentioned the lack of skilled engineers as a barrier to a tight compliance date. Many Cat. 8 and 9 equipment are highly specialised equipment and according to industry it is in practise impossible to find many experienced engineers on the spot to speedily re-design all the products.

Options 2 and 4 would allow time for this and should thus not have significant impacts on the manufacturers or the availability of products, except for industrial Cat.9 equipment IVD and AIMD for which compliance by 2014 is deemed difficult (this will be discussed later).

It should be noted that the lead-solders are the main problematic issue with the 2012 compliance date. Option 4 includes a general exemption for lead in solders. It would clearly reduce the compliance costs to the industry, but seems an unnecessary allowance in 2014. It may be more sensible to combine this general exemption with the implementation date of 2012 (Option 3), as the solders are the biggest obstacle to early compliance. However, the industry is working towards eliminating lead-solders and, except the three specific cases (IVD, AIMD and industrial Cat.9), should be able to meet the deadline of 2014. Providing an exemption in 2012 would be a disincentive for lead-free product development and could thus compromise the environmental objective. A clearly temporary exemption of 2 or 4 years from 2012 onwards could be more reasonable.

According to the discussion carried out in the course of the project, for Cat.8 & 9 equipment in general the economic impacts of inclusion in 2012 with a general (temporary) exemption for lead in solders would not seem to be unreasonable (specific exemptions and product categories: industrial Cat.9, IVD and AIMD are discussed later). Option 3 without lead exemption is considered to lead to withdrawal of many products from the market and (temporary) unavailability of products.

[31] change of solder type is generally considered to be a significant change, although at least some notified bodies do not consider it to be so [pers.comm. Mr. Goodman]

Industry has been unable to provide estimates on the compliance costs and other economic impacts related to the different compliance dates.

3.3.6. OPTION 2 VS. OPTIONS 3 AND 4: EXEMPTIONS

The environmental comparison of the options has been presented in Section 2.4.1. It shows that including Cat. 8 and 9 in the scope of RoHS without any exemptions would lead to significant quantities of hazardous substances, especially lead. But as already described in that section, such a scenario is likely relevant: Imposing RoHS compliance on Category 8 and 9 products without additional exemptions would have significant impact on withdrawing products from EU market. Without any exemptions, many products, where substitutes are not available, would be restricted. More than half of the lead is used as shielding for ionising for which there is no suitable substitute. The similar case is with cadmium used in radiation detectors. Industry has estimated that up to half of the products would have to be withdrawn from the EU market if the necessary exemptions are not granted. This would affect the competitiveness of EU market due to loss of diversity of the products and also have impacts on the public health.

T&M Coalition has estimated that without the necessary exemptions (see below), the costs for the industry due to loss of sales are up to 11 times the costs of implementing RoHS with exemptions. Medical device industry has also estimated the potential sales revenue loss from not being able to sell units in the EU due to lack of necessary exemptions; however, these estimations cannot be provided in this report for confidentiality reasons.

Even if the exemptions are not granted as part of the revised Directive, this of course does not mean that none of them will be granted through to a separate exemption procedure. In reality, the industry would of course apply for specific exemptions. Considering that even in Option 2 necessary options will be granted, the environmental impacts of these three options are very similar.

The biggest difference is that as Option 2 does not include exemptions as part of the amended Directive, it would introduce legal uncertainty until the decision on the exemption is given. Until the decision on the exemption requests is made, products may have to be temporarily withdrawn from the market with consequent costs in loss of sales. Furthermore, dealing with all the requests on a case-by-case basis would incur high administrative costs both for industry and public authorities.[32]

Provision in the Directive for justified "ERA exemptions" (Options 3 and 4), and possibly additional exemptions that have been requested to date, would avoid significant costs both to industry and Commission and Member States.

[32] Costs associated with the exemption process are the focus of a separate impact assessment issue.

Exemptions proposed by ERA

The exemptions for Cat. 8 and 9 proposed by ERA [Goodman 2006] were reviewed with the kind help of Dr. Goodman. The up-dated "**Table 71**" is presented in Table 11 below.

Table 11 – Update of the exemptions for Categories 8 and 9 that were considered justified in Table 71 of [Goodman 2006][33]

	Definition of new exemption request	May 2008 update comment
	Equipment utilising or detecting ionising radiation	
1	Lead, cadmium and mercury in detectors for ionising radiation	Still required.
2	Lead bearings in X-ray tubes	Will be required beyond 2012
3	Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate	Exemption will continue to be required. However, this may not be needed for the MCP and CP devices if they are regarded as "electronic components" covered by exemption 5 as the lead is in glass. However, there is no definition of "electronic components" and these devices are not clearly electronic components. They are significantly different in function to transistors, resistors, etc. so separate exemption is recommended to cover these.
4	Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons	It is unclear whether these devices would be defined as "electronic components"; lead is used in glass and so would be covered by exemption 5 if these are defined as electronic components. This however is not clear (see item 3 above).
5	Lead in shielding for ionising radiation	Substitutes exist for some applications but not for all. Use of the main substitute tungsten has significant negative environmental impact for manufacture and recycling, environmentally, lead may overall be preferable[34]. A life cycle assessment would be needed to confirm this.
6	Lead in X-ray test objects	Still required.
7	Lead stearate X-ray diffraction crystals	Still required.

[33] Personal communications with P. Goodman, April-May 2008

[34] According to comment from AEA Europe, lead in this application is still "required" and not only "preferable" (comment provided 11/07/2008)

8	Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers	Required while legal requirement to analyse lead in paint exists.
	Sensors, detectors and electrodes (plus item 1)	
1a	Lead and cadmium in ion selective electrodes including glass of pH electrodes	Lead and cadmium still required in ion selective electrodes. Lead in glass of pH electrodes may be with exemption 5 if these are regarded as electronic components. A manufacturer has announced a lead-free glass pH electrode but these are not widely available yet in EU. (See further assessment below)
1b	Lead anodes in electrochemical oxygen sensors	Still required.
1c	Lead, cadmium and mercury in infra-red light detectors	Still required.
1d	Mercury in reference electrodes: Low chloride mercury chloride, mercury sulphate and mercury oxide	Required for low chloride, oxide and sulphate electrodes.
	Others	
9	Cadmium in helium-cadmium lasers	Still required.
10	Lead and cadmium in atomic adsorption spectroscopy lamps	Still required.
11	Lead in alloys as superconductor and thermal conductor in MRI	Still required.
12	Lead and cadmium in metallic bonds to superconducting materials in MRI and SQUID detectors	Still required.
13	Lead in counterweights	Many manufacturers are changing to alternative materials in new product designs but are unable to change existing models some of which are expected to be on the EU market after 2012. Exemption for surgical microscopes likely to be required. (See further assessment below)
14	Lead in single crystal piezoelectric materials for ultrasonic transducers	Still required unless this can be regarded as lead in ceramic. There is no “official” definition of ceramic but most published definitions would exclude this application.

15	Lead in solders for bonding to ultrasonic transducers	Still required but probably not beyond 2016
16	Mercury in very high accuracy capacitance and loss measurement bridges and in high frequency RF switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay	This is very specific exemption for limited applications where it appears to be still required.
17	Lead in solders in portable emergency defibrillators	Likely to be required.
	Temporary exemptions required for reasons other than the criteria specified in Article 5.1 (b) of the RoHS Directive	
18	Lead in solders of high performance infrared imaging modules to detect in the range 8 – 14 µm	Probably still required. (See further assessment below)
19	Lead in Liquid crystal on silicon (LCoS) displays	Probably still required. (See further assessment below)
20	Cadmium in X-rays measurements filters	Exemption justified based on socio-economic criteria but not on Article 5.1b as substitute exists. However note that removal of product from EU market could have a negative impact on human health which is within Article 5.1b criteria.

On the exemptions no. 1a, 13, 18 and 19 in the above table, original applicants were contacted, following the recommendation of Dr. Goodman, to determine the current status:

Exemption 1a: This exemption covers actually two separate but interlinked issues "Cadmium and lead in ion selective electrodes (ISE) (for the measurement of Cd and Pb)" and “lead in glass electrodes (e.g. for the measurement of pH, but also for other ions)”.

- Cadmium and lead in ion selective electrodes (ISE): As indicated in the table above, this exemption is still required and justified. These electrodes use the very low solubility metal sulphides - cadmium sulphide to measure cadmium concentrations and lead sulphide to measure lead concentrations[35]. There are no alternatives to these materials in electrodes to sense cadmium and lead.
- Lead in glass of pH electrodes (e.g. for IES for the measurement of pH): Two manufacturers were contacted on this issue: One of them considers that the

[35] An ISE measures the ions based on the principle of "lattice-defect-conduction-system" which means ion contact to the lattice-defect. To be able to detect lead- and cadmium ions, these substances are needed in the lattice of the electrode.

exemption is still required. According to the manufacturer, work is currently carried out to develop some pH electrodes without leaded glass, but this will not be applicable to all glass ISE & pH sensors. According to this manufacturer, lead glass is used in electrodes as it has good transparent clarity, and is chemically inert. Thus it can be used for years in extremely caustic and highly acidic solutions without deteriorating. Glassblowers who make pH electrodes use it also because of the "workability" of the glass, and the fact that it matches the expansion coefficients of commonly used pH glasses. These require very high impedance which is not possible with soda glass and the lead addition provides this.

The other manufacturer told that they have never expected an exemption for “lead in glass of pH electrodes” in their activities towards RoHS compliance. They are currently trying strongly to develop the lead-free pH electrodes, and already provide some types of lead-free pH electrodes.

It should be noted that both companies manufacture around 100 types of pH glass electrodes, so the different views are not grounded in differences in product variety.

Exemption no. 13: According to the manufacturer, this exemption is still needed for the following reasons, which were already communicated to Dr. Goodman during the project carried out in 2006:

Lead is needed as counterbalance for equipment which requires little floor space in operating rooms. The high density and thus low volume of Pb are crucial especially for space-limited applications. Counterbalances are needed for the precise movement of equipment components, without negatively influencing the patient or operator. There are no appropriate substitute materials: Tungsten is no option, as can be seen from [Goodman 2006]; steel is no option, since the volume would increase (four times more installation space and a double footprint required). Lead weights in devices can be completely recycled.

Exemption no. 18: The original applicant of this exemption has been contacted, but the respondent could not comment on the technical requirement for lead in the construction of the infra red detector arrays. However, he told that there is a further lead issue associated with integration of the devices into modules (‘engines’) and he thought that this exemption primarily relates to this:

The infrared arrays and engines (typically purchased as a complete appliance rather than separate components) originated in the USA as military devices. Their suppliers are still predominantly military and aerospace biased companies in e.g. the USA and Israel. Lead solder continues to be specified for military and aerospace purposes. These manufacturers may have little incentive to offer lead-free variants, at least in a short schedule. European developers of equipment requiring advanced infra red arrays are thus disadvantaged if they are constrained to work with only lead-free products.

Further, according to the manufacturer, the '8-14µm' qualifier is not well considered. It covers a large number of modules manufactured. But modules are also made to operate in the near infrared, roughly (1-3 µm) and the mid infrared, roughly (3-5 µm). In fact these are more specialised and have a stronger case for exemption. According to the

manufacturer, applying the exemption to wavelengths longer than 1.2 microns would be appropriate, so as to omit the silicon-based visible-light and near-visible-light camera modules that are manufactured in large volumes.

Exemption no. 19: Since the LCoS device is rather temperature sensitive, the lead-free solder cannot be used to fix the LCoS to the PCB. Furthermore, these devices, in the quality requested, seem only to be available from producers that manufacture mainly for the military sector and whose products in general do not need to be RoHS-compliant.

Based on up-dated on the assessment in [Goodman 2006], the "**Table 71**" are still considered justified and do not overlap with existing exemptions (personal communication with Mr. Goodman and Ms Zangl). The only possible exception could be the part of 1a on "lead in glass of pH electrodes" which may no longer be justified on the basis of technical feasibility criteria.

According to Dr. Goodman, "**Table 72**" is still correct i.e. these exemptions would not be needed after 2012.

AeA Europe considers that it is still too early to state that these exemptions will not be needed in 2012: "Table 72 states that some exemptions 'should not be necessary' and that replacement technology 'should be available'. However the ERA report was completed two years ago and tried to predict technology advancements. Nearer to the date it will need to be confirmed that substitutions will in fact be available." However, AeA Europe has not provided a substitution analysis to back up this statement.

The medical device industry considers most Table 72 exemptions still "absolutely essential" (Table 12), but they have not explained why the substitution of hazardous substances in these applications would not be feasible. Test&Measurement Coalition consider that in addition to Table 71 exemptions, only the exemption for 'lead in solders' is necessary (i.e. a general exemption for lead in solders).

Table 12 – Exemptions identified in "Table 72" that are still considered necessary by the medical device industry [COCIR et al. 2008b]

	Description of the exemption	Medical device product families that require this option
2	Lead as PVC stabiliser in medical tubing	ECG leadsets, cables and patient monitoring cables; Anaesthesia equipment
3	Cadmium pigments in ECG patient cables	ECG leadsets, cables and patient monitoring cables
4	Flexible copper cadmium wire	Ultrasound equipment

5	Cr(VI) in alkali dispensers for in-situ production of photocathodes	All image intensifier tubes and assemblies; All diagnostic X-ray systems (fluoroscopy, radiography, surgery, mammography, simulators, etc.)
6	Cadmium in output phosphors of image intensifiers	All X-ray systems (fluoroscopy, radiography, surgery), e.g. mammography and mobile systems; CT systems and related PET/CT and SPECT/CT systems
7	Specific opto-coupler for IVD instruments	IVD instruments
8	Lead in solders	All X-ray, ultrasound, MRI, CT, nuclear medicine and IVD clinical analysers (e.g. urine analysers, life science analysers); Linear accelerators, radiotherapy simulators, kV and MV electronic imaging, Gamma-ray beam therapy equipment and MEG systems; Immunology based diagnostic test equipment, complete blood cell count equipment, hearing aid products and several surgical devices.
9	Lead in solders for array interconnections to photodiode CT detectors	CT systems and related PET/CT and SPECT/CT systems
10	Lead in solders for connections to micro-BGA area arrays	Hearing aid products; CT systems, PET and SPECT systems, including PET/CT , SPECT/CT and PET/MR; All portable cardiac care and patient monitoring devices; all portable ultrasound devices (patient worn devices, AEDs); Urine based automated screening tests

Medical industry has also identified new additional exemptions (Table 13), but again no justification has been given as to why substitution would not be feasible.

Table 13 – New additional exemptions identified by the medical device industry [COCIR et al. 2008b]

	Description of the exemption	**Medical device product families that require this option**
1	Lead in plating finishes on leadless devices, e.g. BGAs, CSP, WLCSP, QFN	All X-ray, ultrasound, MRI, CT, nuclear medicine equipment and MEG systems
2	Lead as an alloying element in aluminium up to 5% by weight for machinability	MV and kV imaging devices for radiotherapy and radiosurgery; Patient support systems
3a	Lead for X-ray grids	All image intensifier tubes and assemblies;

3b	Lead in anti-scatter in CT X-ray detectors	All diagnostic X-ray systems (fluoroscopy, radiography, surgery, mammography, simulators, etc.)
4a	Lead for thermal management in cryocooler cold heads in MRI magnets	All MRI devices and PET/MRI systems
4b	Lead in solders in MRI radio frequency send and receive coils	
5	Lead in solders for cryogenic MRI applications	All MRI devices and PET/MRI systems
6	Lead in solders for array connections and interconnections of CT X-ray detectors (This builds upon one of the "Table 72" exemptions i.e. lead in solders for array interconnections to photodiode detectors)	CT systems and related PET/CT and SPECT/CT systems
7	Lead as a PVC stabiliser in wire insulation and for PVC material used in sensing hardware	PET/CE, SPECT/CT, PET/MR and SPECT systems
8	Lead to enable thermal compression process to make a vacuum tight connection between aluminium and steel for X-ray image intensifiers	23cm and 31cm image intensifier tubes and assemblies for X-ray imaging applications
9	Lead in solder for implantable pacemakers and defibrillators	Implantable pacemakers and defibrillators
10	Lead used in pin connector systems requiring non-magnetic connectors	MEG systems
11	Lead for thermal management in cryocooler cold heads in MEG systems	MEG systems
12	Cr(VI) in passivation coatings where good electrical conductivity is required for EMC shielding	MEG systems
13	Lead acetate marker for use in stereotactic body frame for use with CT and MRI	Stereotactic body frame
14	Lead and lead alloys for collimation of ionising radiation	Radiotherapy equipment including linear accelators, radiotherapy simulators, gamma-ray beam therapy and kV and MV electronic imaging
15	Lead in positioning system for gamma beam therapy equipment	Gamma-beam therapy equipment

Within the current study, it has not been feasible to further assess these new additional exemptions (Table 13). But stakeholders have commented on some of them

'New exemption no. 1' (Table 13): "BGAs, CSP, WLCSP are not leadless devices, while QFN is. Furthermore, micro BGA area array (Table 12, exemption 10) is the same as a CSP. All this is about having the same 'lead in solder' - exemption as the telecom industry (existing exemption no. 23) and having a plating/ball/terminal that is compatible with SnPb and which is whisker-free".

'New exemption no. 2' (Table 13): "Seems unlikely that this requirement differs significantly from the existing exemption no. 6."

'New exemption no. 7' (Table 13): "Seems unlikely that this would be needed as there are other stabilisers with higher performance available."

3.3.7. OPTION 5 VS. "NO OPTION 5"

[Goodman 2006] estimated that 2012 - or 2014 - as a date of compliance should be sufficient for most producers of Category 8 and 9 products, but with three notable exceptions, one being industrial test and measurement equipment.

The RoHS compliance for Category 9 industrial equipment is considered much more challenging than for consumer products. Many industrial category 9 products operate 24 hours a day, 365 days a year, and are expected to operate for very long periods between failures. The average product life of industrial test and analysis equipment is about 10 years and can be as long as 30 years, while consumer type monitoring equipment has shorter lives and product designs are changed more frequently than industrial equipment.

Per product model, the industrial equipment is sold in the numbers ranging from 2 (or fewer) products per year to 10000 per year at most. The total number of different products is very large and the products are typically very complex due to the specialised needs of the industry. Products are redesigned on average every seven years although there is considerable variation. Early inclusion of all Category 9 equipment would thus impact especially the industrial equipment.

Unlike consumer products, such equipment often operates in extreme harsh environments (temperature, humidity, dust, vibration, shock, potentially explosive atmospheres, etc.), where access for replacement is limited and can only be performed by specialists. Failures of such products will have a negative effect on users (particularly medical and industrial users) leading to commercial losses at best, and frequently to safety and environmental losses. [AMCHAM 2008]

In relation to the susceptibility of lead-free assemblies to corrosion, [Goodman 2006] concludes that while it should be possible to prevent serious problems in most environment, highly polluted atmospheres for example in chemical plants may require costly additional protection measures to protect the equipment.

In order to estimate the environmental impacts of this option, i.e. allowing a later implementation date for industrial Cat. 9 equipment, it is necessary to know the amount

of equipment and the amount of RoHS restricted substances in consumer and industrial products, respectively.

Table 3 of [Goodman 2006] provides estimates for the different types of Category 9 equipment, but does not specify clearly whether they are consumer or industrial equipment. Assuming that 'smoke detectors', 'heating regulators' and 'thermostats' are consumer or "consumer-like" equipment, while 'measuring, weighing or adjusting appliances as laboratory equipment' and 'other monitoring and control instruments used in industrial installations' are industrial equipment, approximately 40% by weight of the Cat. 9 equipment placed on the EU market would be consumer equipment and 60% industrial equipment. In reality, the share of the industrial equipment can be larger, as there are likely to be special industrial smoke detectors, heating regulators and thermostats. In Section 3.3.1 the impacts of this option to the quantities of hazardous substances put on the market were estimated assuming that 75% of the Cat. 9 is industrial equipment and that this same ratio applies to the hazardous substances within this category.

In Figure 4, it can be observed that Option 5 (which should be compared with Option 2 in this figure), even assuming the compliance by 2018[36], has little effect on the quantities of lead and cadmium, while having a more significant impact on mercury and hexavalent chromium. However, the figure overestimates the quantities, as the compliance date of 2018 does not mean that the use of hazardous substances in industrial Cat.9 products stays at their current level until 2018 (as implicitly assumed in Figure 4).

Over time more and more products will be redesigned and the quantities of hazardous substances will go down. According to T&M Coalition, 2018 marks the date when all the products will be compliant and industry thus advocates this compliance date. Industrial Cat.9 equipment manufacturers point out that 2018 is the date when all industrial equipment in this category can be made RoHS compliant with limited cost, but as the product conversion is gradual process a significant share of products, or most of the components of a product will already be RoHS compliant long before this date.

Regarding economic impacts, industrial Cat.9 equipment manufacturers consider compliance before 2018 to lead to many products to be withdrawn from the market and consequent loss of sales. Test & Measurement Coalition has estimated the cost as loss of sales, corresponding to the value of the products that will not be RoHS compliant if the industrial Cat.9 are brought into the scope of RoHS in 2012, 2015 and 2018. Due to confidentiality reasons the estimated costs can only be expressed in relative terms in this report (Table 14). According to these estimates the compliance date has a very significant impact to the costs incurred by the industry.

[36] Option 5 deals with a deferred deadline: 2018 is considered the latest acceptable date, but other intermediary date (e.g. 2015) could also be envisaged

Table 14 - Estimated relative costs (due to loss of sales) to the industry of Cat.9 industrial equipment depending on the compliance date

Compliance date	**2012**	**2015**	**2018**
Relative costs	9	5	1

Furthermore, according to the industry, a compliance date earlier than 2018 for these appliances would lead to a high number of individual exemption requests, which would place an administrative burden on both industry and public authorities.

This option would require a definition of "industrial equipment" to be included in the test of the Directive to avoid confusion. Test & Measurement Coalition has put forward two possibilities:

- Adapt the definition from the Battery Directive to: 'Industrial electrical and electronic equipment' means any electrical and electronic equipment designed for exclusively industrial or professional use[37];
- Use standard EN61010:1993 as a basis for differentiation. This standard covers three types of equipment intended for professional, industrial and educational use: test and measurement equipment, control equipment and laboratory equipment.

As for Cat.8&9 equipment in general, lead in solders is the biggest issue in making industrial Cat.9 RoHS compliant. It has been pointed out that general exemption for lead in solders (Option 4) could avoid delayed implementation dates for industrial Cat.9. But such a general exemption would give the exemption for all the Cat.8 and 9 products without technical justification, as for the more simple products the conversion can be achieved if not already done. Thus, a more specific, later compliance date is considered more appropriate.

3.3.8. OPTION 6 VS. "NO OPTION 6"

IVD and AIMD were highlighted in [Goodman 2006] as product groups which could hardly meet the general 2012 (or 2014) as a date of compliance.

The worldwide sales of an In Vitro Diagnostics (IVD) instrument model are typically around 500 per year. About 38% of these sales are estimated to be in the EU. [Goodman 2006] IVD instruments are reported to represent 3500 tonnes WEEE per year[38] [COCIR et al. 2007].

In-vitro diagnostics equipment is completely different to other medical equipment discussed above. Sales of a product model continue typically 10 years before a new

[37] AEA Europe has expressed their support for this definition (comment 11/07/2008). Other stakeholders have not commented on these definitions.

[38] using figures from 6 major manufacturers

design is launched. New products introduce relatively small internal changes while external appearance may be quite different. Due to the complexity of these products and the fact that they need to be very accurate and reliable, changes are minimised and only fully tested components and circuit designs are utilised. New products may contain circuit designs with associated software that was developed 20-30 ago.

Design, testing, validation and licensing costs are significant and very time consuming for IVD instruments. Members of EDMA[39] have estimated that to convert, re-test and validate all products to comply with RoHS could take eight years or longer. [Goodman 2006] considers this a rather generous estimate, but agrees on the need to allow significant time to comply, considering many of the complex products.

RoHS related cost examples for one IVD manufacturing site [COCIR et al. 2007]:

- Conversion of two instruments to RoHS in progress with budgets of 2 to 3 million dollars per year
- Costs for RoHS compliant parts up 10-20%
- End of Life buys for non RoHS components roughly 2 million dollars to sustain the older products on the market / spares.

RoHS budget costs, example from an US site [COCIR et al. 2007]:

- 2007: $840,000 to cover reliability testing, headcount and effort to change PCB components
- 2008: $2,800,000 to cover RoHS conversion cost of one instrument (on the market):
- $100,000 covers compliance software to track and collect data of all planned instruments
- $1,100,000 covers 4 each PWB redesigns with new test fixtures and headcount
- $600,000 covers mechanical part assessments, testing and conversions
- The rest is document services and verification testing
- 2009: $1,989,000 to finish out other PWB's and components of the second instrument

It should be noted that the current RoHS Directive is already impacting even IVD manufacturers e.g. PWB manufactures, and new instruments are already being designed with RoHS compliant components. While many instruments currently contain RoHS compliant components and subassemblies, only few products themselves are RoHS compliant (examples include some small self test instruments e.g. glucose monitors).

[39] European Diagnostic Manufacturers Association, trade association representing IVD instrument manufacturers

In Vitro Diagnostics provide critical health information, influencing more than 60% of the clinical decisions and contributing significantly to the quality of healthcare. IVDs allow earlier and more appropriate treatments, thus helping to shorten length of hospital stays, rule out expensive treatments and reduce costs of treatment of complications. Moreover they assist to keep under control the spread of infectious diseases in the community. [EDMA 2007]

Active Implanted Medical Devices (AIMD) are safety critical instruments, and consequently the design cycle for new products or a redesign cycle is very long. The time from concept to clinical trials is 6 to 8 years with a further 1 year for EU Medical Devices Directive (MDD) licensing. Reliability data is required to obtain approval for sale in the EU under the MDD. Usually, reliability statistics are based on field data from existing but very similar products. Until there is field data from lead-free soldered products available (which is not yet the case) the manufacturers of AIMD cannot guarantee the reliability of their products and will thus face difficulty in obtaining a licence. [Goodman 2006]

The cost of changing AIMD products to comply with RoHS will be relatively expensive and it is possible that many manufacturers will phase out products earlier rather then make necessary changes. Manufacturers have said that inclusion of AIMD within the scope of the RoHS Directive is impractical before 2020.

As for the other option in this factsheet, the industry has been unable to provide estimates of the costs of not allowing for later compliance date for IVD and AIMD. Again, it is stated that unless sufficient time is given many products will be withdrawn from the EU market. The medical industry proposes AIMD to be excluded from the RoHS Directive, but this exclusion could be reconsidered in the next review of the Directive. However, from the point of view of providing an incentive to manufacturers, it would seem better to include them in the scope from 2020 onwards – this date can be revised in the next review of the Directive if it is deemed necessary.

As illustrated in Figure 4, allowing a later compliance date for IVD and AIMD has a negligible impact on the quantities of hazardous substances in Cat. 8 and 9 equipment as a whole.

3.4 SUMMARY AND CONCLUSIONS

Environmental impact potentials of the hazardous substances in Cat. 8 and 9 products were assessed based on the life cycle analysis methodology. However, this assessment contains many uncertainties, as for example the end-of-life step of Cat.8 and 9 cannot be appropriately modelled with available data. Hence quantities of hazardous substances used in equipment seem to be a better, surrogate measure to estimate the potential environmental and public health impacts of the different options.

Of course, considering only the quantities does not take into account that if the products are effectively collected and treated in the end-of-life, as industry claims, most of the

hazardous substances would not be released to the environment. On the other hand, restriction of these substances will not only avoid their emission to the environment at the end-of-life, but also potential emissions at the production phase.

There are many anecdotal or case study-like data on the costs related to the RoHS compliance of Cat. 8 and 9 products. But, even the overall cost to the relevant sectors has turned out to be difficult to estimate. Industry associations have been unable to provide detailed information on the economic impacts. This confirms the experience of Ms Bogaert in the context on their study [ARCADIS & RPA 2008], where it was extremely difficult to obtain costs data per product category.

Based on available market data and assumptions, indicative overall compliance costs for Cat. 8 and 9 were estimated in the range of €400 to €1600 million. But these figures should be treated with great caution. Comments have been sought from relevant industrial associations on this estimate, but to date no comments have been received.

A survey covering extensively the producers in Cat. 8 and 9 would seem necessary to estimate the compliance costs in more detail for these categories. But that has unfortunately been out of the scope of this study.

Considering the difficulties in deriving an overall estimation of compliance costs, it has been rather impossible to compare the impacts of the different options in monetary terms. And, as pointed out by industry, the costs in Euros to industry do not provide a full picture of the impacts. Availability and reliability of products have important implication to public health and other important domains.

The comparison of options in terms of quantities of hazardous substances put on the market in Cat. 8 and 9 product in a ten year period (2010 – 2020) reveals that there is only marginal difference between the compliance date in 2012 and 2014. The later date would, however, ease the compliance costs for industry and avoid market disruptions, which industry considers significant if compliance date is set at 2012.

Existing exemptions are being assessed by Öko-Institut in a separate project[40], which will also consider the eventual requirements of Category 8 and 9 regarding these exemptions. Thus, they have not been looked at within this project. Regarding exemptions requested specifically for Category 8 and 9, ERA exemptions have been re-assessed. “Table 71” are still considered justified and hence their inclusion in the provisions of the revised Directive would avoid significant administrative burden related to exemption process. For “Table 72” no convincing evidence was found that they would still be justified after 2012. Additional new exemption request were presented by the Medical Industry. They have been presented in this report, but these latest industry requests have not been reviewed by any study or stakeholder consultation; it was out of the scope of this study to examine them.

[40] http://rohs.exemptions.oeko.info/

General exemption for lead in solders seems poorly justified if compliance date is 2014. It could avoid the need for deferred dates for industrial Cat.9 equipment, IVD and AIMD, but it seems more appropriate to create specific provisions to these product groups rather than provide a general exemption for all products in these categories. Lead in solders being the biggest issue to achieve RoHS compliance, a general exemption for it would seem to compromise the environmental objectives. A life cycle assessment on solders [Geibig and Socolof 2005] has suggested that there may not be clear environmental or health benefit of replacing lead in solders with the currently available alternatives. But the results have been contested and the there seems to be no agreement on the overall environmental performance of the different solders.

General exemption for lead could be combined with compliance date of 2012, but it could then halt the redesign of lead-free products and thus also compromise the environmental objectives.

Based on the comparison of options in terms of hazardous substances over ten year period reveals that the later dates for Cat. 9 industrial, IVD and AIMD product groups would not greatly compromise the environmental goal. These options would ensure availability and reliability of these safety critical appliances for European end-users, and would avoiding disproportionate compliance costs for industry.

Note on definitions:

It has been out of the scope of this study to draft precise definitions or wording of the policy options. However, according to number of stakeholders, one of the reasons for the lack of verifiable data for Category 8 & 9 products is the confusion over the scope. If these categories are to be included in the scope of the RoHS Directive, it seems important to define them to improve clarity and consistency in regulatory interpretations among Member States.

3.5 CONTACTS & REFERENCES

3.5.1. CONTACTS

Following person/organisations contributed to the study through personal communication and/or written comments.

- Advanced Medical Technology Association (AdvaMed)
- AeA Europe
- Bell, S., General Electrics
- Beynon, G., AMETEK
- Bogaert, S., ARCADIS
- COCIR, EDMA, Eucomed (representing Cat. 8 equipment) Goodman, P., ERA

- Gordon, P. Technology Forecasters Inc.
- Hamm, U., Zeiss
- Koyama, K., Horiba Ltd.
- Jemima, Japan
- Nimmo, K., ITRI
- Somes, E., Thermo Fisher Scientific Inc.
- Sonneshine, J. and Brugge, P., CEA
- Test & Measurement Coalition
- Willems, G., IMEC & SIRRIS
- Zangl, S. et al., Öko-Institut

3.5.2. REFERENCES

[AeA 2008] AeA (2008) Europe Response to European Commission Consultation on Policy Options for a Revised RoHS Directive

[AMCHAM 2008] AMCHAM EU (2008) Response to DG Environment's consultation on the political options for the revision of the RoHS directive

[ARCADIS & RPA 2008] Bogaert, S., Van Acoleyen, M., Van Tomme, I., De Smet, L., Fleet, D. and Salado, R. (2008) Study on RoHS and WEEE Directives. By ARCADIS & RPA for the DG ENTR, European Commission.

[CEA 2008] CEA (2008) Economic Impact of the European Union RoHS Directive on the Electronics Industry

[COCIR] http://www.cocir.org, Facts & Figures, viewed 25/06/2008.

[COCIR 2006] COCIR (2006) Appendix 2: Overview and Rationale of RoHS restricted substances in Medical Devices as controlled by Directive 2002/95/EC (RoHS), 21 March 2006

[COCIR et al. 2007] COCIR, EDMA and Eucomed (2007) Meeting between DG Environment, DG Enterprise and Healthcare Industry representatives – presentation. 11 September 2007 in Brussels.

[COCIR et al. 2008a] COCIR, Eucomed, EUROM VI and EDMA (2008) Use of RoHS Substances in Medical Devices - Joint Industry Statement

[COCIR et al. 2008b] COCIR, Eucomed and EDMA (2008) Joint Medical Device Industry data on economic and social impact of bringing Medical Devices into scope of RoHS without the proposed exemptions, June 12, 2008

[Deubzer 2007] Deubzer, O. (2007) Explorative Study into the Sustainable Use and Substitution of Soldering Metals in Electronics. Ecological and Economical Consequences of the Ban of Lead in Electronics

and Lessons to Be Learned for the Future. Thesis Delft University of Technology, Delft, the Netherlands. Design for Sustainability program publication no. 15. ISBN 978-90-5155-031-3

[COWI 2002] COWI (2002) Heavy Metals in Waste, Final Report, February 2002, European Commission DG ENV. Available at: http://www.weee-forum.org/att/literature/2002_Heavy%20Metals%20in%20Waste%20_COWI%20Denmark.pdf?weeeforum=918f3197b4ea4da2982e6917178749ac

[EC 2008] European Commission (2008) The Review of Directive 2002/95/EC – Invitation for comments on policy options and for information supply.

[EDMA 2007] EDMA (2007) European IVD Market Estimates 2005 – Press release 12 January 2007. Available at: http://www.edma-ivd.be/index.php?id=89

[ERM 2006] ERM (2006) Battery Waste Management Life Cycle Assessment – Final Report

[Eucomed 2007] Eucomed (2007) Medical Technology Brief, Key facts and Figures on the European Medical Technology Industry, http://www.eucomed.be/~/media/pdf/tl/2008/portal/aboutindustry/medtechbrief2007.ashx

[Geibig and Socolof 2005] Geibig, J.R. and Socolof, M.L. (2005) Solders in Electronics: A Life-Cycle Assessment. By the University of Tennessee for US EPA. Available at: http://www.epa.gov/dfe/pubs/solder/lca/lfs-lca-final.pdf

[Goodman 2006] Goodman, P. (2006) Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report. ERA Technology Ltd for the European Commission, DG ENV, http://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

[Medical Products Agency 2008] Medical Products Agency (2008) Comments on the policy options and for the information supply

[Norwegian Pollution Control Authority 2008] Norwegian Pollution Control Authority (2008) Norwegian comments to the review of directive 2002/95/EC

[Orgalime 2008] Orgalime (2008) Policy options for the review of Directive 2002/95/EC (RoHS)

[Pammolli et al. 2005] Pammolli, F. et al. (2005) Medical Devices Competitiveness and Impact on Public Health Expenditure, Study prepared for the Directorate Enterprise of the European Commission, http://ec.europa.eu/enterprise/medical_devices/c_f_f/md_final_report.pdf

[Rreuse 2008] Rreuse - Re-use and Recycling European Union Social Enterprises (2008) Comments on the policy option for the review of RoHS

[Test & Measurement Coalition 2008] Test & Measurement Coalition (2008) Consultation on Political Options for RoHS Revision

[UNU 2007] United Nations University (2007) 2008 Review of Directive 2002/96 on Waste Electrical and Electronic Equipment (WEEE) –

3.6 ANNEXES OF THE FACT SHEET

Estimation of compliance costs: Category 8

	Total annual sales (2005) [million €]		
	Europe	**Global**	**Reference**
Medical technology	€63600	€187000	[Eucomed 2007]
IVD	€8712	*€25615*	[EDMA 2007]
Medical imaging equipment	€5000	€20000	
Healthcare IT (inlc. software)	€17600	€55000	[COCIR], G. Ahlbom (pers.comm.)
Total Cat. 8 sales	**€94912**	*€287615*	

The market figures above are reported by different sources. In principle, the figure for "medical technology" does not include the specific figures for the IVD and Medical Imaging & Healthcare IT devices. But it includes a wide variety of non-EEE medical devices (e.g. orthopaedic shoes, spectacles and contact lenses, insulin pens, hip prostheses, pregnancy tests, etc.). Similarly 'IVD' sales include chemical test kits etc. which do not belong to EEE.

A medical industry presentation in the RoHS context [COCIR et al. 2007] estimates the global market of medical devices at 100 billion, which is assumed to exclude the non-EEE part of the sales. Using this assumption and the figures above, it is possible to derive an estimate for Europe, corresponding to Cat.8 equipment relevant to RoHS.

	[million €]	
Share of the EEE within total Cat.8 sales (derived)		*35%*
Electric&electronic Cat. 8 sales	€33000	€100000

[COCIR et al. 2007] also estimates the compliance costs to Cat.8 to be 1-4% of the medical industry turnover. Based on this a rough minimum and maximum estimation can be calculated.

COMPLIANCE COSTS	**Europe**	**Global**
Min	**1%**	
Max	**4%**	
MIN Estimation of the overall costs of RoHS implementation	€330	€1000
MAX Estimation of the overall costs of RoHS implementation	€1320	€4000

Estimation of compliance costs: Category 9

	Total annual sales (2005) [million €]		
	Europe	**Global**	**Reference**
Industrial test and measurement equipment	€7234	€28937	T&M Coalition (pers.comm)
Industrial automation equipment	?		
Non industrial monitoring and control equipment	?		
Total known Cat. 9 sales	***€7234***	***€28937***	

Comprehensive market data for Cat.9 was not available. An estimate for the industrial test and measurement equipment was provided by T&M Coalition, but no data was available for industrial automation and non industrial equipment. Thus the figure provided above and the compliance costs estimated below are underestimations. On the other hand, the costs of conversion of non-industrial products is deemed to low compared to industrial Cat. 9 equipment and to a large extent this conversion has already been carried out for non-industrial products. Yet, this may not be the case for industrial automation equipment.

The compliance costs are calculated using the Cat.8 estimate of 1 - 4% of turnover.

COMPLIANCE COSTS	**Europe**	**Global**
Min	**1%**	
Max	**4%**	
MIN Estimation of the overall costs of RoHS implementation	€72	€289
MAX Estimation of the overall costs of RoHS implementation	€289	€1157

4. FACT SHEET ON CLARIFICATION OF THE SCOPE: SPARE PARTS AND COMPONENTS & "REPAIR AS PRODUCED PRINCIPLE" & CONSUMABLES

4.1 ISSUE

Issue/problem addressed:

The present work intends to evaluate the impact of possible technical changes to the scope of the RoHS Directive in order to clarify it. The issues considered in this fact sheet are:

- Include explicitly spare parts and components

- "Repair as produced" principle: exclude parts for repairing and the reuse of products lawfully placed on the market

- Clarify status of consumables

Background:

RoHS Directive 2002/95/EC aims to approximate the laws of the Member States as regards the restriction of the use of hazardous substances in electrical and electronic equipment and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment.

In implementing the Directive, differences and uncertainties concerning the interpretation of the scope have been identified. It may be possible to clarify these issues as part of the review of the Directive.

The overall objective is to have a clearer outline of products being covered by the RoHS Directive.

Options and summary of analysis:

This factsheet considers separately the three issues identified above against the business as usual option.

4.1.1. CURRENT PRACTICE/SITUATION

- **Spare parts and components**

The Article 2 of the RoHS Directive defines the scope of the Directive as follows:

*1. Without prejudice to Article 6, this Directive shall **apply to** electrical and electronic **equipment** falling under the categories 1, 2, 3, 4, 5, 6, 7 and 10 set out in Annex IA to*

Directive No 2002/96/EC (WEEE) and to electric light bulbs, and luminaires in households.

2. ...

*3. This Directive **does not apply to spare parts** for the repair, or to the reuse, of electrical and electronic equipment **put on the market before 1 July 2006**.*

The Directive thus explicitly covers 'equipment' while excluding explicitly 'spare parts' for EEE put on the market before the Directive came into force. The exclusion suggests that spare parts for the equipment put on the market after July 2006 would be in the scope, and this interpretation was published in the FAQ [EC 2005]:

"It is permissible to put on the market spare parts - containing the hazardous substances - for the repair of old equipment (put on the market before 1 July 2006), but not to repair new equipment (put on the market after 1 July 2006). In fact, the marketing of spare parts containing banned substances for the repair of new equipment would prolong the existence of hazardous substances in the waste stream and hamper efforts to increase recycling."

However it is not always clear whether some equipment should be considered 'part' or 'final product'.

Furthermore, many 'parts' for repair/reuse are actually 'components' which are just sold separately. Yet, 'components' are not mentioned at all in the scope of the RoHS Directive.

While B2B 'components' that are incorporated into other products that are later put on the market in the EU already need to (implicitly) comply with RoHS provisions, the status of B2C 'components' (sold separately to the end-user) seems to be truly unclear. They can be considered out of the scope (e.g. in France they seem to be considered out of WEEE and thus out of RoHS). On the other hand, the IT B2C components put on the market individually and marketed as individual products could also be considered to fall under 'other products and equipment for the collection, storage, processing, presentation or communication of information by electronic means' in Category 3.

Figure 9 – Examples of IT components (processors) sold as individual parts for end-users

- **"Repair as produced" principle**

As was explained above, the current scope of the Directive either excludes (explicitly) or includes (implicitly) parts for repair and reuse of product based on the date when the product was put on the market: before or after 1 July 2006. However, this is a "static" criterion and does not take into account changes in the Directive for example due to changes in the exemptions and the differing compliance dates (e.g. if Category 8 and 9 appliances are included in the scope).

- **Status of consumables**

'Consumables' are not mentioned in the RoHS Directive. Questions have been raised as to whether for example ink cartridges fall within the scope the Directive.

The FAQ published by the Commission provides the following clarification concerning ink cartridges [EC 2005]:

"According to the definition of EEE, the printer itself is EEE because it falls under Category 3 of Annex IB to the WEEE Directive. If a printer is discarded, it becomes WEEE. This means that if an ink cartridge is inside a discarded printer, the cartridge becomes part of the WEEE because it is a consumable which is part of the printer at the time of discarding. However, the cartridge itself does not fall under the definition of EEE, but is considered to be a consumable. Therefore the RoHS Directive does not apply to ink cartridges."

4.1.2. ISSUES/PROBLEMS TO EXPLORE

In order to achieve clarification of the scope of the RoHS Directive, the impacts of clarifying the scope regarding the above mentioned issues need to be considered.

Based on the preliminary policy options presented in the 2nd Consultation Document [EC 2008], the present work considers the following options regarding the technical changes to the scope of the Directive, which can be compared to the common "no change in the Directive" (i.e. business as usual) option:

- **Business-as-usual**

The scope stays as it is now; no further clarification or changes to the Directive are introduced.

- **Option 1: Include explicitly spare parts & B2C components**

It was clarified with the Commission that purpose of this option is to look at the parts/components put on the market individually to end-users, i.e. the intention of the option is not to explicitly cover B2B components/parts of EEE.

Hence, this options refers to including spare parts and components explicitly in the scope of the Directive, for example by adding a clause to Article 2, stating that "this Directive applies to components of EEE and spare parts and components for the repair, or to the reuse, of EEE, put on the market individually to end-users..." or by adding 'components and parts of EEE' to Article 2.1.

The 'spare parts' is understood to be linked to a given equipment and meant for its repair ; 'component' is understood to be a part/element to be used in EEE, but which is not specific to one given equipment and which cannot be used individually. Thus, 'spare parts' are relevant for all equipment categories, whereas 'component' rather refers to electronic (IT) parts such as processors, fans, CD/DVD drives, internal hard disks, mother boards, etc. (sold individually to end-user).

It is worth noting that the EuP Directive provides a definition for 'components and sub-assemblies', which in this context means "parts intended to be incorporated into EuPs, and which are not placed on the market and/or put into service as individual parts for end-users or the environmental performance of which cannot be assessed independently". This definition of a 'component' is the opposite from the meaning considered in the context of this option. This shows that to avoid confusion, 'component' needs to be properly defined within the RoHS Directive, if relevant provisions are introduced to the Directive.

- **Option 2: "Repair as produced" principle: exclude parts for repairing and for the reuse of products lawfully placed on the market**

Recast the Article 2.3 of the Directive, or add a clause that the Directive does not apply to spare parts for the repair, or to the reuse, of EEE lawfully placed on the market.

[Goodman 2006] has proposed following wording to amend Article 2.3 which is intended to capture changes in exemptions over time:

"This Directive does not apply to spare parts containing 'certain hazardous substances' for the repair and/or upgrade of EEE which fall inside the scope of this Directive where these 'certain hazardous substances' were permitted to be used by an exemption when the equipment was put on the market".

- **Option 3: Clarify status of consumables**

Based on the consultation document [EC 2008], this option refers to excluding consumables explicitly from the scope of the Directive unless they are part of the product when it is placed on the market, e.g.

"This Directive does not apply to consumables unless they are part of the product when it is placed on the market".

The abovementioned policy option put forward in the Consultation document is somewhat different from the guidance provided by the FAQ [EC 2005], where it is simply stated that the "RoHS Directive does not apply to consumables".

Thus for the purpose of this assessment two sub-options are considered:

Option 3a: Excluding explicitly consumables unless they are part of the product when it is placed on the market. Inversely, this could also be expressed as "this Directive shall apply to consumables that are part of the product when it is placed on the market, other consumables are excluded".

Option 3b: Excluding explicitly consumables regardless on the way they are placed on the market, for example by adding a new Article 2(4) to the Directive stating, "This Directive does not apply to consumables".

To clarify the status of consumables, T&M Coalition has suggested to include a definition in the "whereas" section in the beginning of the Directive. According to this proposal, for example the "whereas 12" could be modified from:

As product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available.

To:

As product reuse, refurbishment and extension of lifetime are beneficial, spare parts ***and consumables*** *need to be available* ***to maximise lifetime****.*

Consumables have shorter working life than products they are used with due to exhaustion of released chemicals, mechanical wear, chemical change, leakage, blockage or contamination.

T&M Coalition is convinced that this clarification would bring more clarity and legal certainty. According to them, they have shared this suggestion with several major trade associations and so far have received only positive reactions.

However, in the context of this work, this option is considered to have limited power to clarify the issue and it is more of a wording option[41]. Thus it is not assessed in this factsheet.

4.2 PROS & CONS

Business-as-usual i.e. non-action

Pros:

- No legislative changes, i.e. no change to established interpretations

Cons:

- Continuing possible differences in the interpretations and practises between

[41] A stakeholder has also pointed out that while consumables are simply necessary to use certain products, it may be difficult to argue that they can "maximise lifetime".

Member States

- Difficulty of new producers to know whether they product falls in the scope or not

Option 1: Include explicitly spare parts & B2C components

Pros:

- Clarifies the scope and thus increases the efficiency of regulation.

Cons:

- May cause some additional administrative costs to firms, who would have to provide compliance certificates for the B2C components

Option 2: "Repair as produced" principle: exclude parts for repairing and for the reuse of products lawfully placed on the market

Pros:

- Would ensure the availability of spare parts for appliances put legally on the market and thus not artificially reduce their lifetimes.

Cons:

- Slows down the elimination of hazardous substances from the products.

Option 3a: Clarify status of consumables (excluding explicitly consumables unless they are part of the product when it is placed on the market)

Pros:

- Clarify explicitly the status of consumables.

Cons:

- Introduces an inconsistency to legislations, a same consumable would be treated differently depending on the way it is placed on the market.

Option 3b: Clarify status of consumables (Excluding explicitly consumables regardless on the way they are placed on the market)

Pros:

- Clarify explicitly the status of consumables and enforce the current interpretation that was published in the FAQ.

Cons:

- Without including a well-though definition of 'consumable' in the Directive, the meaning of consumable is open for interpretation as it is not always clear whether something is a consumables or a spare part.

4.3 ANALYSIS OF OPTIONS

The table below presents the comparison of the different options to the Business-as-usual scenario, which by definition would have no, i.e. zero effect on the different impact assessment criteria. The results and the thought process behind the ratings will be explained in the subsections following the matrix. The analysis is mostly qualitative due to the lack of qualitative data on the relevant issues.

Table 15 – Summary of assessed impacts

	BAU	Option 1	Option 2	Option 3a	Option 3b
Environmental impacts					
Level of environmental protection/improvement	0	0 to +	0 to +	0	0
Economic impacts					
Firms: costs & competitiveness	0	0 to -	+	0 to -	0
Innovation and research	0	0	0	0	0
Consumers and households	0	0	+	0	0
Public authorities	0	0	0	0	0
Social Issues					
Employment and labour markets	0	0	0	0	0
Public health and safety	0	0 to +	0 to +	0	0
Other Impacts					
Clarity and consistency	0	+ to -	+	+	+ to -
Severity of barriers to be expected	0	0 to -	+	-	0 to -
Administrative effort	0	0	0	0 to -	0
Practical workability and enforceability	0	+	0 to --	+	0 to -

4.3.1. OPTION 1: INCLUDE EXPLICITLY SPARE PARTS & COMPONENTS (PLACED ON THE MARKET AS INDIVIDUAL PARTS FOR END-USERS)

Currently spare parts and components placed on the market individually are not explicitly under the scope of RoHS Directive. However, spare parts for the equipment placed on the market after July 2006 can be considered implicitly in the scope, while components are rather considered out of the scope of the Directive in the current situation.

Specifying that spare parts are within the scope would increase legal certainty and this would rather enforce the current interpretation than to change the scope. Yet, to avoid further problems, this option would call for a definition of 'spare part'.

As explained previously in Section 4.1.1, the status of B2C components seems to be rather unclear. An amendment to the Directive specifying that they are within the scope could marginally enlarge the scope and thus environmental benefits.

However, as all parts and components integrated in finished products must be RoHS-compliant, the components sold separately to end-users are also likely to be compliant. This is explained by the fact that economically it makes little sense to produce small series of non-compliant components or parts only to be sold separately. Hence environmental impacts of this option are likely to be negligible. Intel and AMD have confirmed at in general they do not make any difference in terms of RoHS-compliance between components that are part of an end-product (already in the scope) and components sold individually (currently out of scope). They are not aware of any other semiconductor companies differentiating between components in or out of scope [pers. comm. Mr. Lageard][42].

It has been impossible to quantify the spare parts for repair and components sold individually; much less the share of RoHS compliant and non-compliant spare parts and components on the market, in order to estimate the potential environmental impact in more detail. But, as stated above, this impact is considered marginal.

For the abovementioned reasons, the economic impacts of the redesign of components/parts due to this option are also considered minimal. However, as pointed out in the Consultation document of the Commission [EC 2008], this option could entail additional cost and limited administrative burden for some component manufacturers, who would have to provide conformity certificates for their B2C products. It has not been possible to quantify these costs, which are also linked with conformity assessment procedure(s). This subject is being considered as part of this project in as a separate factsheet: the costs related to self declaration would be lower compared to the situation where third party verification was required.

The social impacts of this option are also considered negligible.

This option would remove the uncertainties as to whether some equipment should be considered "part/component" or "final" product. Some stakeholders have claimed, as a barrier to this option, that the inclusion of 'components' would change the fundamental principle of RoHS that it applies on finished products. However, this argument seems to be more relevant for B2B components, which are not concerned by this option. B2C

[42] An effort was made to verify the issue with a few other IT component manufacturers whose products are also sold individually to end-users (NEC and Hitachi) but it was not possible to get further clarification on this issue. The companies contacted were selected based on previous established contacts.

components placed on the market individually are marketed as individual products and thus their inclusions in the scope would not seem to change the general philosophy of the Directive.

4.3.2. OPTION 2: "REPAIR AS PRODUCED" PRINCIPLE: EXCLUDE PARTS FOR REPAIRING AND FOR THE REUSE OF PRODUCTS LAWFULLY PLACED ON THE MARKET

At present if an exemption is removed, any product put on the market after 1 July 2006 cannot be repaired using a spare part which made use of this exemption. This will result in equipment reaching end of life prematurely. While, many consumers EEE are discarded more due to trends than technical failure and/or since repair costs more than a new product, the repair plays a significant role in the more complex EEE. Furthermore, the exemptions are more relevant for the complex equipments than for simple consumer appliances. Therefore this option would contribute to extending life time and avoiding untimely disposal of equipment, thus bringing environmental and social benefits due to avoidance/ reduction in the overall amount of WEEE disposed. These benefits are likely to balance or even outweigh the negative impacts of the slower elimination of hazardous substances from the products.

It is considered that replacing the single date in Article 2.3 by a principle "exclude parts for the repair, or to reuse, of equipment lawfully place on the market" would enhance legal clarity and security. However, the legal text needs to be carefully formulated and adequate enforcement practises put in place to prevent abusive generalisation of use of non-compliant parts and components. This may be challenging.

In practise, it seems to be extremely difficult to make sure that spare parts are only used for appliances 'legally placed on the market'. But as has been pointed out by industry, this is already the case with the current provision that exempts spare parts for appliances put on the market before July 2006 from the scope of the Directive. The industry considers that there is no practical means to verify or enforce this. Thus, the enforceability of this option is rather poor but not necessarily worse than the enforceability of current situation. But it should be admitted that creation of more categories than just products placed on the market before or after July 2006 can make the enforcement even more complicated.

4.3.3. OPTION 3: CLARIFY STATUS OF CONSUMABLES

It was agreed with the Commission that the objective of the current study was not to develop or analyse the definition of 'consumable' itself, but rather to provide an inventory of the consumables that are relevant for RoHS, identify which equipment categories are concerned, what RoHS restricted substances are likely to be found in these consumables and in what quantities.

However, without a clear definition of 'consumable' it was extremely difficult to properly assess the abovementioned issues, as:

- The difference between a 'consumable' and 'spare part' is not clear, e.g. filters in some Category 9 appliances need to be replaced over the life time of a product, depending on the technical characteristics of a filter this could be rather a spare part or a consumable.[43]
- It is not clear whether the intention of the legislator is to capture only consumables, which can be considered EEE components/parts themselves, case (A), or all the parts/materials that are used in appliances covered by the RoHS Directive, case (B). Case (B) would cover consumable like water and detergents (consumables of washing machines), paper (consumable of printers and copy machines), etc. The use of Category 8 equipment involves often kits of reactants, test tubes, test tube trays, sample cartridges, etc. It does not seem reasonable to even consider such non-EEE consumables for the scope of the RoHS Directive. Hence, case (B) is considered inappropriate interpretation in the context of this Directive.

Even case (A) poses problems, as can be illustrated by the ink/toner cartridges. Some inkjet cartridges have a printhead involving an electronic chip and such a cartridge would be considered an EEE consumable in case (A). However, other inkjet cartridges and especially toner cartridges do not contain a printhead and are rather ink/toner containers made of plastic than electronic parts themselves.

What could be considered consumables of EEE?

The table below provides examples of some products/substances that could be considered as EEE consumables. Without clear definition, the industry was unable to provide a clear list of consumables [pers. comm. with COCIR, EDMA, Eucomed, Test & Measurement Coalition].

In general, RoHS substances do not seem to be a concern in the potential consumables of EEE.

[43] The EU Guidelines on the application of the Directive 89/336/EEC (EMC) define 'spare part' as "any item intended to replace a defective or worn out item of apparatus, equipment or system previously placed and put into service on the EEA market", but this does not seem to allow easy differentiation between spare part and consumable.

Example	"Potential consumable"	Relevant for products	Placed on the market together with EEE?	Can be considered an EEE component/ part in itself?	Likely to contain RoHS regulated substances?	Comments
1	Ink/toner cartridge	Printers, copiers (Cat. 3)	Yes & No	Yes: print head (& housing)	No	Print head is integrated only in some cartridges; housing is made of bulk plastics.
				No: toner/ink	Not likely, but if so, in minute quantities in specific pigments	Toner/ink is a chemical substance rather than EEE part.
2	Head of electric toothbrush	Body care appliances (Cat. 2)	Yes & No	?	No	
3	Chain of the chain saw	Saws (Cat. 6)	Yes & No	?	No	Spare part or a consumable?
4	Batteries	Portable products in most Categories	Yes & No	N/A	N/A	Hazardous substances in batteries are regulated separately.
5	Sample trays	Analysis equipment (Cat. 8, 9)	Yes & No	No	No	
6	Chemical reactants	Analysis equipment (Cat. 8, 9)	No (usually)	No	Possibly, if needed in a particular reaction.	Reactants are chemical substances rather than EEE parts.
7	Paper	Printers, copiers (Cat. 3)	No	No	No	Clearly not relevant for RoHS Directive.
8	Bag of a vacuum cleaner	Vacuum cleaners etc. (Cat. 2)	No	No	No	Clearly not relevant for RoHS Directive.
9	Liquid and solid fuels	Stoves etc. (Cat. 1)	No	No	Possibly (e.g. lead as a contaminant in coal)	Clearly not relevant for RoHS Directive.
10	Water	Washing machines (Cat. 1)	No	No	No	Clearly not relevant for RoHS Directive.

Closer look on the printer cartridges

The ink/toner cartridges of printers are at the heart of the consumables issue. To clarify this particular issue, responses to the following questions were looked for:

- What are the current amounts of RoHS restricted substances in cartridges? / How feasible it is technically to make RoHS compliant cartridges?

According to Mr. Van Dijk (pers. comm.) from ETIRA, the bulk of the cartridges, i.e. the housing is made of standard plastics that should currently not contain RoHS restricted substances. The cartridges with an integrated print head (only a part of all cartridges) contain an electronic chip which could in principle contain RoHS restricted substances although this is unlikely at present.

A cartridge is provided full of ink/toner. Their detailed composition is confidential and proprietary knowledge [Stobbe et al. 2007]. Ink/toner being a chemical i.e. non-EEE consumable (see case B described in the section above) it can be argued that the content of the cartridge is out of the scope of RoHS.

The Material Safety Data Sheets (MSDS) of Canon, Epson, HP[44] and Dell[45], verified in the context of this work do not report RoHS restricted substances. Dell and Lexmark have confirmed that their cartridges (housing) do not contain any RoHS restricted substances. They, and also EPSON confirm that inks or toner in their cartridges do not contain RoHS restricted substances above the maximum concentration values [pers. comm. Mr. Furkel, Mr. Moreau and Mr. Stutz].

Thus cartridges themselves and even the ink/toner seem already to be RoHS compliant.

- What percentage of ink/toner cartridges put on the EU market is actually sold together with a printer?

Based on the data on representative products[46] from the EuP preparatory study on Imaging equipment [Stobbe et al. 2007] and the typical capacities of standard ink/toner cartridges, 18 cartridges are used over a lifetime of a printer/copier on average. Only the first cartridge is provided with the printer, the others are purchased separately (OEM, “no brand” or refilled/-manufactured cartridges). Based on this estimation, on average only 5 percent of the cartridges are supplied/sold together with a printer.

From the point of view of printer manufacturer, according to the estimation by Dell, the distribution between OEM cartridges sold with the printer and sold separately as supply is something like 1:5.

- Is it possible to quantify the cost of having cartridges in the scope?

---

44 http://www.ciwmb.ca.gov/wpie/electronics/InkAndToner.htm#MSDS

45 http://www.dell.com/content/topics/global.aspx/corp/environment/en/prod_design?c=us&l=en&s=corp&~section=001

46 The EuP preparatory studies are built upon so-called ‘base-cases’ i.e. representative products/ product categories for the whole of the EU-27.

Based on the fact that the cartridges themselves (ink/toner not considered here) are already RoHS compliant, the inclusion of the cartridges into the scope would not seem to inflict costs related to R&D or product re-design. However, the compliance verification process would place an additional burden on manufacturers; testing, gathering data etc. would be the most important cost driver. These costs are likely to be rather limited, due to the relatively simple design and composition of the cartridges. But this burden could nevertheless be disproportionate with the health and environmental gains as RoHS substances are not likely to be present in the cartridges in the first place.

Environmental and economic impacts

Based on the FAQ, consumables are already considered out of the scope of the Directive. Hence, excluding them explicitly (Option 3b) is estimated to have negligible environmental impacts. Similarly, economic impacts are considered negligible.

Option 3a could increase the administrative burden to companies as they would need to create compliance certificates for the consumables supplied with an appliance as opposed to the current approach where this is only done upon request. Environmentally, the compliance of the consumables supplied with an appliance would have a negligible impact, as many seem to already be RoHS compliant due to voluntary measures (e.g. cartridges) and since majority of consumables are bought separately during the life time of the appliance.

Other impacts

An explicit exclusion of consumables would seem to clarify the scope of the Directive. However, amending the Directive on this issue could lead to new confusion or inconsistencies, depending on the sub-option.

Option 3a would provide that all the parts that are provided with the equipment falling into the scope of the Directive when it is placed to the market have to be RoHS compliant. This would have the advantage that it can avoid defining 'consumable' (which can be problematic, see Option 3b below). However, the concern about this option is that it treats differently same consumable products depending on the way they are placed on the market. An exactly same cartridge, for example, could fall in and out of the scope of the Directive depending whether it is supplied with the product or sold separately. Based on the estimation calculated above, only about 5% of cartridges are supplied with the printer and would be covered by the Directive according to this option. 95% of the cartridge market would stay out of the scope. This would introduce a regulatory inconsistency. Furthermore it would inflict RoHS compliance costs only on those manufacturers that place consumables in EEE market, not by those selling them separately which could lead to distortion of the market. The option would have a small effect on the environmental impact of cartridges on the whole.

Option 3b would avoid the discriminatory effect (i.e. all the consumables would be out of the scope, even if they are part of the product when it is placed on the market). However, in order to avoid further confusion and ambiguity, this option would require a

clear definition of consumables to be incorporated in the Directive. Otherwise, this clause may be abused and wearing parts of an appliance claimed as consumables. For example, discussion with Cat. 9 industry revealed that they would consider parts that have to be regularly changed due to mechanical ware as consumables (e.g. saw blade, valves, etc.). Clearly such interpretation would create further confusion between 'spare parts' (which are in the scope of the Directive) and 'consumables' (which would be out of the Directive).

AEA Europe has suggested the following definition of consumables[47]:

"Consumables are items used in combination with electrical and electronic equipment (EEE), the contents or parts of which are intended to be used up or consumed and which are intended to be replaced to re-supply the EEE with what is consumed during the use phase of the EEE."

Please note, that other definitions could surely be envisaged and neither the contractors of this study nor the European Commission have any preference for this definition at this stage.

4.4 SUMMARY AND CONCLUSION

In the first phase of the project, a lack of data on all of the issues was identified and in the second phase of the project, additional data was looked for on key issues that have been outlined in the above sections. Yet, it has not been possible to clarify the issue to the extent that would allow quantitative assessment of the impacts. Firstly, due to the lack of agreed definitions it has been difficult to discuss these issues with the industry. Secondly, the time constraints have not allowed carrying out an extensive new research on these issues.

All the proposed option would seem to clarify the scope of the Directive, while having limited or negligible environmental, economic and social impacts. The biggest risk with these options is to create further interpretation issues if the status of spare parts, B2C components and consumables are clarified in the Directive, without providing proper definitions for them.

Option 2 would be in line with the current spirit of the Directive, but instead of a static date, it would introduce a more dynamic provision regarding the spare parts, thus ensuring a full lifetime for products currently placed on the market using an agreed

[47] AEA Europe has suggested first thinking "a contrario" to make sure that defined consumables can in all circumstances be excluded from the scope of the RoHS Directive, without ambiguity. Hence, a consumable is not EEE, a component of an EEE, a spare part of an EEE or a subassembly of an EEE. Further, AEA Europe recommends a consumable to be defined by reference to the fact that is "consumed", e.g. used repeatedly for the purpose of the good functioning of a given product that can be easily replaced by the consumer/end-user.

exemption. A serious handicap of Option 2 is its poor enforceability, which however is already true for the current provision on spare parts.

For legal coherency, Option 3b would seem more preferable over Option 3a.

4.5 CONTACTS & REFERENCES

4.5.1. CONTACT

Following person/organisations contributed to the study through personal communication and/or written comments.

- AeA Europe
- Bogaert, S., Arcadis
- COCIR, EDMA, Eucomed (representing Cat. 8 equipment)
- Goodman, P., ERA
- Gordon, P., Technology Forecasters Inc.
- EICTA
- Furkel, M, Lexmark
- Hermanns, S., AMD
- Holmberg, J., Hitachi
- Lageard, J., Intel
- Moreau, P. EPSON Europe
- Nimmo, K., ITRI
- Sherwood, C., US Mission to the EU
- Sonneshine, J. and Brugge, P., CEA
- Stutz, M., Dell
- Test & Measurement Coalition (representing industrial Cat. 9 equipment)
- Van Dijk, V., European Toner & Ink Remanufacturers' Association (ETIRA)
- Willems, G., IMEC & SIRRIS

4.5.2. REFERENCES

[EC 2005] European Commission (2005) Frequently Asked Questions on Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), http://ec.europa.eu/environment/waste/pdf/faq_weee.pdf

[EC 2008]	European Commission (2008) The Review of Directive 2002/95/EC – Invitation for comments on policy options and for information supply.
[Goodman 2006]	Goodman, P. (2006) Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report. ERA Technology Ltd for the European Commission, DG ENV, http://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf
[Orgalime 2008]	Orgalime (2008) Policy options for the review of Directive 2002/95/EC (RoHS)
[Rreuse 2008]	Re-use and Recycling European Union Social Enterprises (2008) Comments on the policy option for the review of RoHS
[Stobbe et al. 2007]	Stobbe et al. (2007) EuP Preparatory Studies "Imaging Equipment"(Lot 4) - Final Report on Task 4 "Technical Analysis"
[Test & Measurement Coalition 2008]	Test & Measurement Coalition (2008) Consultation on Political Options for RoHS Revision

5. FACT SHEET ON CLARIFICATION OF THE SCOPE: FINISHED PRODUCTS ENDING UP IN FIXED INSTALLATIONS & LSIT & ELECTRICITY PRODUCING EQUIPMENT

5.1 ISSUE

Issue/problem addressed:

This factsheet deals with possible options to improve the delineation of products falling under the RoHS Directive, by explicitly including or excluding specific products or categories.

Background:

Difficulties and differences in the interpretation of the scope of the RoHS Directive have lead to confusion to both industry and authorities.

The confusion is caused by both referring to the WEEE Directive in the scope of the RoHS Directive and the (non-)limitative character of the Annexes of the WEEE Directive. Moreover, the obligation for periodically reviewing the exemption for LSIT is not clear.

The overall objective is to have a clearer outline of products being covered by the RoHS Directive. The assessment of explicitly including or excluding products from the scope of the RoHS Directive forms a substantial contribution to reaching this objective.

Options and summary of analysis:

The options analysed in this factsheet consider:

- Business as usual
- Explicit inclusion of 'finished products ending up in fixed installations' in the scope of the RoHS Directive
- Abandon the general exemption for LSIT
- Explicit inclusion of electricity producing equipment in the scope of the RoHS Directive

5.1.1. CURRENT PRACTICE/SITUATION

Current confusion about the scope of RoHS Directive is caused by several reasons:

- the reference to WEEE Directive in the scope of RoHS Directive;
- the uncertainty about the (non-)limitative character of the Annex IB of WEEE Directive, that lists products falling under the categories of Annex IA, which sets out the scope of RoHS (and WEEE) Directive;

- lack of clarity about the obligation for periodical reviewing the exemption(s) on LSIT (Large-scale Stationary Industrial Tools) present in Annex IA, category 6.

Due to the reference to Annex IA of the WEEE Directive in the scope of RoHS Directive, there is confusion about products or installations falling under RoHS Directive or not, leading to different implementation modes in Member States.

The scope of WEEE and RoHS Directive is similar for a lot of product categories, but nevertheless there are several differences.

As explained in the FAQ document, **fixed installations** are out of the scope of WEEE Directive, but as the article that is causing this exclusion (Article 2.1) is not applicable to the scope of RoHS Directive, fixed installations are not excluded of the scope of RoHS Directive. However the FAQ document mentions 'The opinion of the Commission is that excluded from the scope of the RoHS Directive is the equipment which part of another type of equipment that does not fall within the scope of this Directive', implying that fixed installations are also out of the scope of RoHS Directive.

Article 5.1(c) states the requirements for periodical review of exemptions to the scope of RoHS Directive, which is 'carrying out a review of each exemption in the Annex at least every four years or four years after an item is added to the list with the aim of considering deletion…'.

As **large-scale stationary industrial tools (LSITs)** are mentioned as an exception on the scope in Annex IA of WEEE Directive, it is unclear if a periodic review is obliged for LSIT[48].

The scope of RoHS Directive is delineated as 8 categories of Annex IA of WEEE Directive. Annex IB of WEEE Directive gives a detailed overview of EEE falling under the categories defined in Annex IA.

As RoHS Directive makes no reference to Annex IB of WEEE Directive (and as Annex IB is only a non-limitative list), equipment that is covered by the definition of EEE in RoHS Directive and that belongs to the indicated categories is falling under RoHS Directive. **Electricity producing equipment** is equipment that is covered by the definition of EEE and can fall under the categories of Annex IA of WEEE Directive, depending on its actual function.

Most Member States consider only the products of categories 1 to 7 and 10 in Annex IB of WEEE Directive as scope for RoHS Directive, and exclude electricity producing equipment of the scope of RoHS Directive.

According to Emerson Electric, fixed installations, LSIT and electricity producing equipment are not considered being in the scope of the RoHS Directive due to the potential catastrophic consequences that a failure of this type of equipment could cause.

[48] Exempted equipment is subject of a periodic review; excluded equipment is not.

5.1.2. ISSUES/PROBLEMS TO EXPLORE

In order to achieve clarification of the scope of the RoHS Directive, for each product group or category considered, an assessment has to be done regarding environmental, economic and social impacts comparing the actual situation with the new situation where a product group is explicitly included in or excluded from the scope.

The assessment is based on a qualitative approach and is founded with quantitative data as much as possible. Relevant quantitative data for the assessment refer to:

- quantities of relevant products involved, both
  - the current situation: amount of product currently falling under the scope
  - situation after explicit inclusion or exclusion of product (group)
- presence and quantities of the 6 hazardous substances covered by the RoHS Directive in the products
- the economic importance of the products and the market situation
- the environmental impact of the products over the production, use and waste phases of the lifecycle
- the innovation pace of the sector or the innovative potential of the products.

5.2 POLICY OPTIONS

Besides the business-as-usual (BAU) scenario as reference, the policy options defined consider each the explicit inclusion or exclusion of a product group which causes confusion on the actual scope of the RoHS Directive.

This also means that for the review of the RoHS Directive the options are not mutually exclusive, so they can be combined.

Options considered in this factsheet:

- Option 1: Business-as-usual
- Option 2: Explicit inclusion of finished products ending up in fixed installations in the scope of the RoHS Directive
- Option 3: Abandon the general exemption for LSIT
- Option 4: Explicit inclusion of electricity producing equipment in the scope of the RoHS Directive

5.3 AVAILABLE INFORMATION ON THE IMPACTS OF OPTIONS

5.3.1. AVAILABLE INFORMATION ON THE IMPACTS FOR ALL OPTIONS

With respect to the impact on the operating costs of businesses, the extent of the divergence in the current interpretation and the numbers of products (and associated costs to producers) affected is not clear. Individual producers have raised this issue in respect of their own products, but lack of information in terms of consolidated interpretations across Member States is currently not available.

Businesses will benefit positively from a clarification of the scope as they will no longer be required to investigate the scope of products being covered in each Member State.

There will be benefits in clarifying the scope of the directive in terms of competition through harmonisation but some of the impacts are highly uncertain, as the current scope varies across Member States significantly therefore imposing additional costs to businesses and authorities in some while compared to the other countries.

Differing interpretations of the scope of RoHS Directive across Member States have led to the situation where certain products are being treated as being covered by the Directive in some countries but not in others.

This implies an unequal treatment of producers and therefore has implications for the competitive position of those companies which are placing products on the market in Member States where they are included within scope as compared to those companies placing the same products on the market in Member States where they are not included. Clarification of the scope would lead to a common interpretation and equal treatment of producers.

5.3.2. AVAILABLE INFORMATION ON THE IMPACTS FOR OPTION 2 (FINISHED PRODUCTS IN FIXED INSTALLATIONS)

Based on the definitions of fixed installation in the FAQ document and of finished product in the Official Guidelines for the implementation of Directive 89/336/EEC, a (preliminary) list is made up with finished products that can end up in fixed installations and that belong to one of the categories that are in the scope of RoHS Directive.

The products concerned are: personal computers, surveillance camera (webcam), lighting equipment, emergency lighting, (loud) speakers, videophone/intercom, (pre)amplifier, timer, antennas, transportable electronic tools (robot arm, drill, mill…), refrigeration unit/system, etc. [49]

[49] If these products are integrated into equipment that does not fall in the scope of the RoHS Directive (e.g. in a spacecraft), RoHS does not apply while the manufacturer that puts the equipment on the market as such, is responsible for meeting the relevant material restrictions in order to comply with RoHS.

This list is made by listing fixed installations and finished products ending up in it, and dividing the finished products list into products respectively in and out of the scope of RoHS.

These lists are based on information from the FAQ document, some guidance documents (Rohsservice, Orgalime) and (critically reviewed) stakeholders contributions on the second consultation document.

List of fixed installations:

- Heating plants
- Industrial installations/plants (petro-chemical processing, automobile manufacturing, pharmaceutical, material handling, power generation, water treatment, paper manufacturing)
- Electrical installations in buildings
- Airport luggage transport systems
- Power transmission networks
- Cable TV networks (other than separately operable equipment)
- Airport runway lighting installations
- Storm surge barrier installations
- Ship elevators
- Railway infrastructure
- Fire and life security control systems
- Large automatic water pump installations
- Automatic warehouse transport systems
- Centralized air conditioners
- Refrigerated display cabinets connected with centralized cooling station
- Refrigerated cold stores
- Traffic light installations
- Airport runway lighting installations
- Radio telescope installations
- High voltage substations
- Wind turbine stations
- Radiotherapy equipment
- Nuclear medicine equipment
- Electric energy distribution system
- Etc.

List of finished products in fixed installations **belonging** to one of the RoHS product categories:

- personal computer
- surveillance camera/webcam
- lighting equipment, emergency lighting
- videophone/intercom
- (pre)amplifier
- (loud)speakers
- antenna
- timer
- transportable electronic tool (robot arm, drill, mill, etc.)

- refrigeration unit/system
- …

List of (finished) products in fixed installations that **do not belong** to one of the RoHS product categories:

- switch
- dimmer
- socket
- thermostat
- smoke/gas detector
- transformer
- UPS
- battery charger
- adaptor
- PLC
- electric motor
- frequency convertor
- switchgear and control gear products
- programmable controller
- sensor
- transducers (e.g. pressure, flow and temperature)
- control panels
- operator consoles
- power supplies
- fuse
- interfaces
- contactor
- data logger
- measuring equipment
- oscilloscope
- GC
- laboratory equipment
- medical equipment
- LSIT
- equipment for gates or shutters, automation or door/gate opening detection system
- safety system
- counting system
- device for metering and billing electric energy
- computers not able to perform its function outside the equipment it is provided with
- …

Although the lists with finished products ending up in fixed installations and respectively in and out of the scope of RoHS Directive look already quite elaborated, several products probably have to be added to make them complete.

The list with fixed installations contains some broad categories as 'industrial installations', and can be considered as quite exhaustive.

As this option is more a clarification of the scope, rather than the inclusion of new equipments, quantification of the impacts of this clarification is not feasible as it would mean quantifying the number/type of products for which their producers made a mistake in their interpretation of the scope of the Directive. As no reasonable estimation of the affected number of products is possible based on existing data, the quantification of the impacts has not been performed for this option.[50]

To prevent abusing the definition of fixed installations to exclude equipment out of the scope of the RoHS Directive, a limitative list of fixed installations falling out of the scope of RoHS Directive can be included in the Directive.

5.3.3. AVAILABLE INFORMATION ON THE IMPACTS FOR OPTION 3 (LSIT)

Based on the definition of LSIT in the FAQ document, a (preliminary) list is made up of products falling under the LSIT definition: machine tools, paper machines, printing presses, packaging machines, textile machines, (stationary) car assembly robot arms, industrial robots, industrial measurement and monitoring platforms, oil rigs, large dockyard cranes.

In the UNU-study on the review of WEEE Directive, an estimation is made of the total numbers of products and the composition of these products for different product categories falling under the scope of the RoHS Directive, including Electrical and Electronic Tools (category 6 of Annex IA of WEEE Directive). Although LSIT belong to this category (but are exempted), LSIT's composition and annual production numbers will probably differ from typical category 6 products.

This study [UNU 2007] also provides more specific information about the products or equipment falling under LSIT:

- LSIT cover a specific stream of electrical and electronic appliances put on the market. The German Machine Tool Industry (VDW, producing both LSIT and other tools) accounts for more than 10 billion EUR of production value, representing the second country after Japan in respect of production, and exports more than 50% of its production outside Germany, according to 2005 sales data. About 66% of German Machine Tool Industry has less than 250 employees (thus Medium sized). Such appliances are machines or systems designed to be used in industry only, ranging from 100 kg to over 100 tonnes in weight. They are installed by specialized personnel and permanently located during their use phase.
- LSIT machine tools are not found in the general household environment and do not end up in the MSW stream due to their size and value: typically they still have a considerable value even after being used in production for more than 20 years.

[50] Stakeholders (e.g. AEA Europe and ERA) stress the need to support possible extensions of or explicit inclusions in the scope of the RoHS Directive by a quantitative assessment; all available data have been included in the factsheet.

There is a well-organised international market for used machine tools. These are refurbished and updated with modern technology and can still be in use in Europe or sold to countries all over the world. Machine tools are definitely not found in household waste. As a result no appliances falling into LSIT definition have been anyway found in the WEEE stream of appliances collected and treated across EU by neither Compliance Schemes, nor EERA members or in the sampling exercise in UK.

- For machine tools more than 50% of the commercial value is produced outside the manufacturer's premises from different suppliers. For this reason, the inclusion of such appliances in the scope of the RoHS Directive hints specific problems related to the supply chain fragmentation.

CECIMO (European Committee for Cooperation of the Machine Tool Industries) covers 15 EU MS, with its production of €19.6M, and represents 44% of the world-wide value of machine tools production.

No information was found to estimate the total market of LSIT, its share in the total tool industry or market, nor the specific composition of LSIT (see also previous footnote [50]).

If the part of LSIT in total tool industry was known or could be estimated, total compliance costs could be calculated using a total cost of RoHS compliance globally of 1.1% (of industry revenue) and requiring annual maintenance of 0.12% of revenue (source: CEA).

5.3.4. Available information on the impacts for Option 4 (Electricity producing equipment)

Electricity producing equipment, designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current, is covered by the definition of the scope of the RoHS Directive, as far as this equipment also belongs to the product groups in Annex of the WEEE Directive that are in the scope of the RoHS Directive.

Listing up this electricity producing equipment leads to (small) portable generators and EEE on solar cells (such as calculators, watches, lights or toys) as products belonging to the RoHS categories.

Other electricity producing equipment (as large and stationary generators, UPS, fuel cells, batteries, alternators) do not belong to the RoHS categories.

All generators fulfill the definition of EEE. In general they (could) fall under Category 6 (Electric and electronic tools), although some generators are marketed for special purposes, as being camping and/or household products, so also categories 1, 2 or 7 could be appropriate.

Theoretically also all solar cells (or panels) comply with the definition of EEE.

But as the scope of RoHS Directive is limited to equipment falling under the categories set out in Annex IA of the WEEE Directive, only **portable generators and EEE running on solar cells**[51] are considered in this factsheet.

Solar modules/panels are not covered by the RoHS Directive because they are not included in the categories set out in annex 1A of the WEEE Directive.

Portable generators

To assess the impacts of the inclusion of portable generators in the scope of the RoHS Directive, relevant data to estimate the European market of portable generators and their composition with regard to hazardous substances is searched.

European market for generators

Following Eurostat's Prodcom list, the total number of generators put on the European market is divided into categories according to their capacity and working principle as in Table 16. The available quantitative data on generators in the Prodcom list is summarized in Table 17.

Table 16 – Prodcom categories for generators

Prodcom Label	Description
31102610	Alternators of an output < 75 kVA
31102630	Alternators of an output > 75 kVA but ? 375 kVA
31102650	Alternators > 375 kVA but < 750 kVA
31102670	Alternators of an output > 750 kVA
31103113	Generating sets with compression-ignition internal combustion engines, of an output < 7.5 kVA
31103115	Generating sets with compression-ignition internal combustion piston engines, of an output > 7.5 kVA but < 75 kVA
31103130	Generating sets with compression-ignition internal combustion piston engines of an output > 75 kVA but < 375 kVA
31103150	Generating sets with compression-ignition internal combustion piston engines of an output > 375 kVA but < 750 kVA
31103173	Generating sets with compression-ignition engines: 750 kVA < output < 2000 kVA
31103175	Generating sets with compression-ignition engines : output > 2000 kVA
31103233	Generating sets with spark-ignition internal combustion piston engines of an output < 7.5 kVA
31103235	Generating sets with spark-ignition internal combustion piston engines of an output > 7.5 kVA
31103250	Generating sets including turbo-generators, generating sets for welding equipt. without heads/appliances excluding previous types

[51] EEE running on solar cells use these cells as electricity generating components, and such EEE are an not electricity producing equipment in itself. The solar cell is not part of the "primary function" of the EEE it delivers energy to. Thus an EEE would therefore be categorized based on its primary function (calculator, mobile phone, etc.) rather than based on its power source (solar cells or other) So, a solar cell in itself is not a finished product; it is a component. Nevertheless EEE on solar cells are considered in following paragraphs.

Table 17 – Generator market figures in the Prodcom

Prodcom Label	Capacity	Value EU27 (in k€)	Sold volume (in thousands)
31102610	< 75 kVA	451962	confidential
31102630	> 75 kVA - < 375 kVA	240901	95
31102650	> 375 kVA - < 750 kVA	129995	20
31102670	> 750 kVA	1192077	22
31103113	< 7,5 kVA	122807	73
31103115	> 7,5 kVA - < 75 kVA	607446	110
31103130	> 75 kVA - < 375 kVA	834381	51
31103150	> 375 kVA - < 750 kVA	520237	15
31103173	> 750 kVA - < 2000 kVA	560913	6
31103175	> 2000 kVA	140468	0
31103233	< 7,5 kVA	172851	237
31103235	> 7,5 kVA	confidential	15
31103250		4720517	25
Total		9694555	668

Total = sum of available figures, confidential information not included

Based on the Prodcom figures, the total European generator market amounts up to about €10 billion and (probably) more than 700,000 units. However, another source estimates the European market for small portable generators < 3 kW at 380,000 units. The latter figure is used to calculate the total amount of hazardous substances in generators annually put on the European market in this factsheet.

Hazardous substances in generators

No specific information on the composition of generators with regard to hazardous substances is found. As assumption the composition of Category 6 Equipment (Tools) (Table 18) is used to calculate the total content of hazardous substances.

Table 18 – Hazardous substance content of a Category 6 equipment (Tools) [UNU 2007]

Hazardous substance	Quantity per unit
Cd	8.57 g
Hg	0.000001 g
Pb	0.21 g
Cr	0.0058 g

This composition of Category 6 Equipment is based on an average weight of 6.141 kg per unit. The average weight of a small portable generator <3 kW is typically higher than 6.141 kg (in the range of 12 – 20 kg), but assuming that most of this extra weight is caused by the housing/casing of the generator and that this housing/casing is not containing hazardous substances, no correction is made for the higher average weight of generators.

Total amount of hazardous substances in generators

For a total generator market of 380,000 units, the weight of hazardous substances in the annual sales of small portable generators amounts to the levels presented in Table 19.

Table 19 – Estimation on the hazardous substances contained in the small portable generators sold annually[52]

Hazardous substance	Total amount in generators sold annually
Cd	3260 kg
Hg	0.38 kg
Pb	80 kg
Cr	2.2 kg

Due to the many uncertainties in the transformation of the amount of hazardous substances to environmental impacts, only an assessment of the substances is made.

Solar cells

In assessing the impact of EEE powered by solar cells, a distinction is made between the solar cells and the EEE they are powering. Assuming that the EEE themselves will have the same composition as if their power supply were provided by the electrical network, no additional environmental impact is expected with respect to the EEE. Therefore, the focus of this section is on the composition of the solar cells supplying EEE with electricity (called consumer applications). Solar cells or modules for off- or on-grid applications are not included.

The total market of solar cell technology can be divided in two segments, namely wafer-based crystalline silicon technology and thin film technology. There are 4 types of thin film PV modules:

- Dye + others
- CIS
- CdTe
- crystalline silicon based

Of these thin film PV modules crystalline silicon represents the major part (about 90% of total production), and only CdTe and CIS PV modules contain (one of the) RoHS substances, namely cadmium.

In the market of PV consumer applications 2 categories can be distinguished: power modules and indoor modules (Table 20). Consumer power modules can be found in lighting, personal electronics, battery chargers and automotive applications. Category 'indoor modules' comprises calculators, watches and other instrumentation on PV modules.

[52] For the purpose of this factsheet, the environmental impact is in a first approach focused on the use of hazardous substances as a proxy for the risks presented during the use and end of life of the products

Table 20 – PV consumer applications [Navigant Consulting]

PV Category	Application segments	Application sub-segments
Consumer power modules	Consumer power	Lighting Personal Electronics Battery Chargers Automotive
Indoor modules	Consumer indoor	Solar calculator Watch Etc.

Global market

Consumer applications accounted for less than 2% of the worldwide photovoltaic market in 2007, or 34 MW (Navigant Consulting). The relative share of consumer applications is expected to decrease over the next decades [EPIA 2007], but as the photovoltaic industry is expected to grow significantly, the absolute amount of consumer applications will probably also increase slightly.

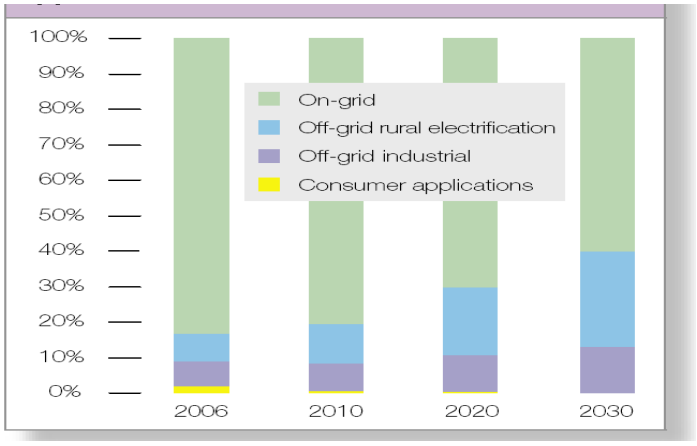

Figure 10 – Annual PV installations by application [EPIA 2007]

European market

At European level, both consumer power (including lighting, personal electronics, battery chargers, and automotive applications) and consumer indoor (including calculators, watches, and other instrumentation) is estimated to represent less than 1% of the EU photovoltaic market: 0.001383 % and 0.00002 %, respectively.

Consumer Power uses about 60% crystalline silicon and 40% thin film technologies, while consumer indoor uses about 95% thin film. Solar toys use close to 100% crystalline silicon. (Source: Navigant Consulting)

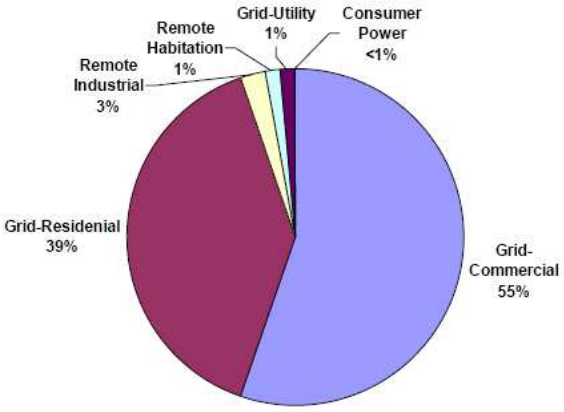

Figure 11 – European PV market by application, 2006 [Navigant Consulting]

Examples of multi-crystalline applications include: chargers, toys and fans. Examples of thin film applications include: watches, blue tooth for cellular phones, scales, pocket calculators, and sun roofs on cars.

Thin film technologies used in consumer applications are mostly amorphous silicon. None of the largest CdTe or CIS photovoltaic manufacturers provide PV to any consumer applications.

Due to their cadmium content CdTe and CIS PV modules are not compliant with the RoHS Directive, and therefore they can never be used in consumer applications.

5.4 PROS & CONS

For each option the pros and cons are briefly explained.

Option 1: Business-as-usual i.e. non-action

Pros:

- Regulatory stability

Cons:

- "Business as usual" would mean "burden as usual" and also distribution of the burden as usual. None of the problems of the current situation would be solved. Differences would remain in terms of the burden placed on different actors and interpretation will remain dependent of the Member States.

Option 2: Explicit inclusion of finished products ending up in fixed installations

Pros:

- The explicit inclusion of finished products ending up in fixed installations is in line with the goal of RoHS Directive; it will avoid interpretations problems and create a more level playing field. Currently the exclusion of fixed installations is being abused regularly to keep (finished) products and installations out of the scope of RoHS Directive.

Cons:

- Because of the clarification of the scope some producers will be confronted with some additional administrative burden/costs.

Option 3: Abandon general exemption for LSIT

Pros:

- An inclusive approach would enhance clarity and transparency. Maintaining the general exemption risks to prolong uncertainty and diverging interpretations.

Cons:

- Some effort would be needed in case it is deemed necessary to exclude products; however this effort would not be substantial: the products could be named in a list, on the basis of the definition already available in the Guidance document (accompanied by several examples) which has been discussed in the last years. If needed, a quantitative criterion (for example number of such products manufactured per year in the EU) could be used.

Option 4: Explicit inclusion of electricity producing equipment

Pros:

- The explicit inclusion of electricity producing equipment will avoid interpretations problems and create a more level playing field.

Cons:

- Because of the clarification of the scope some producers will be confronted with some additional administrative burden/costs and some compliance costs.

5.5 ANALYSIS OF OPTIONS

The table below presents a summary of options' analysis in the form of a matrix in order to compare the advantages and disadvantages of each option.

Table 21 – Summary of assessed impacts

	Option 1: BAU	Option 2: inclusion of fixed installations	Option 3: inclusion of LSIT	Option 4: inclusion of electricity producing equipment
General impacts				
Legislative changes	0	+	+	++
Environmental impacts				
Level of use of hazardous substances	0	?	?	+
Level of environmental protection/improvement	0	0 to +	0 to +	++
Economic impacts				
Firms: costs	0	- to 0	- to 0	- to 0
Innovation and research	0	0	0 to +	0 to +
Public authorities (budget; resources)	0	- to 0	- to 0	-
Social Issues				
Impact on consumers (availability / price)	0	0	- to 0	- to 0
Public health and safety	_	+	+	+
Other Impacts				
Clarity and consistency (e.g. with other legislation)	_	+	+	+

5.5.1. GENERAL IMPACTS

All of the proposed options would lead to legislative changes at both European and national levels. For Options 2 and 3 concerning clarification of the scope, the changes to the provision of the RoHS Directive will be of the same order of magnitude. As Option 4 considers an extension of the scope the legislative changes will be bigger.

5.5.2. ENVIRONMENTAL IMPACTS

- **Level of use of hazardous substances**

For options 2 and 3 the level of use of hazardous substances could not be quantified, mainly because of the lack of adequate data as the definition on the considered product groups is very broad and specific at the same time.

For option 4, small portable generators put on the European market contain a significant amount of hazardous substances and inclusion under RoHS Directive would imply non-compliant components to be replaced by compliant components, so reducing the

amount of hazardous substances in the equipment. For solar cells, currently no RoHS substances are used in consumer applications. CdTe and CIS thin film PV modules (containing cadmium) are not compliant with the RoHS Directive, but they are currently not used in PV cells powering consumer applications.

- **Level of environmental protection/improvement**

Option 1, no action, does not improve environmental protection, compared to the present situation.

Although the use of hazardous substances could not be quantified for Options 2 and 3, both options will probably protect the environment better than the BAU option.

The level of environmental protection for option 4 depends merely on the end-of-life scenario for portable generators, but as at least some of them inevitably will end up in MSW, there will be a significant improvement for the environment if the presence of hazardous substances will be limited in these applications. For solar cells, it should be assured that CdTe and CIS PV modules will never be used in consumer applications, as these modules contain cadmium and do not comply with the RoHS Directive.

5.5.3. Social Issues

- **Impact on consumers**

As option 2 includes only finished products that already belong to the product categories in the scope and that end up in fixed installations, RoHS compliant finished products are available, and the price and availability for consumers should not be changed.

Options 3 and 4 consider equipment that is currently not included in the scope. So for these options both price and availability will be influenced negatively, but probably only limited.

- **Public health and safety**

Clarification or extension of the scope will for all options (2, 3 and 4) have a positive effect on public health as it always would decrease the amount of hazardous substances used and as alternative materials are available or for similar product categories is proven that the use of hazardous substances can be avoided or at least limited.

5.5.4. Economic Impacts

- **Firms: costs**

For option 2, the costs for firms to make their products RoHS compliant, are limited, as these products already belong to product categories under RoHS Directive and for these products is proven that the compliance costs globally amounts to 1.1% of industry revenue and requires annual maintenance of 0.12% of revenue.

For option 3 and generators (option 4), the same reasoning can be followed, as LSIT and generators can be considered a special category within Electric and Electronic Tools, already being covered by RoHS Directive.

- **Innovation and research**

For option 2 and solar cells in option 4, inclusion in RoHS Directive will not contain a driving force for more innovation or research, as the concerned products easily can be replaced by already existing RoHS compliant products.

For option 3 and generators in option 4, innovation and research is expected to increase only in a very limited way, as for these products already available knowledge and infrastructure for RoHS compliant Electric and Electronic Tools can be used.

- **Public authorities**

For the public authorities, only option 4 concerning the extension of the scope of RoHS with electricity producing equipment will have a significant impact, as this would mean that the inspection campaign approach has to be extended and/or reconsidered.

5.5.5. OTHER IMPACTS

- **Clarity and consistency**

The purpose of the proposed options is specifically to clarify the scope of the RoHS Directive compared to the current situation. So compared to the BAU option, the explicit inclusion (or exclusion) of product groups will increase clarity and consistency.

5.6 SUMMARY

This factsheet deals with possible options to improve the delineation of products falling under the RoHS Directive, by explicitly including or excluding specific products or categories. The product groups concerned are:

- 'finished products in fixed installations' (option 2)
- LSIT (option 3)
- Electricity producing equipment (option 4).

For each product category a specific, but different, reason exists to include it in the scope of the RoHS Directive.

To support the inclusion (or exclusion) of the product categories, the social, economic and environmental impacts are assessed per option.

Although for option 2 (finished product in fixed installation) the impacts of a possible inclusion could not be quantified, including this equipment seems reasonable as only

(finished) products that belong to one of the product categories that are already in the scope of the RoHS Directive are affected.

Also for the inclusion of LSIT in the scope of RoHS Directive (option 3), the possible impacts could not be quantified because of a lack of specific data on this product group. Because their affinity with electric and electronic tools (product group currently covered by the RoHS Directive) however, an inclusion in the scope of the RoHS Directive seems not insurmountable[53].

For option 4 (electricity producing equipment) the focus is set on portable generators and EEE supplied with power by solar cells, as product category complying with the definition of EEE and falling under the categories of Annex IA of the WEEE Directive (= the scope of RoHS Directive). For portable generators quantification of the impacts learns that the total amounts of hazardous substances being involved are significant, and that an inclusion in the scope of the RoHS Directive seems appropriate in terms of environmental protection. For EEE powered by solar cells, CdTe and CIS thin film PV modules are not compliant with the RoHS Directive, but they are currently not used in PV cells powering consumer applications. Also in the future, CdTe and CIS PV modules cannot be used in consumer applications.

When explicitly including fixed installations, LSIT or electricity producing equipment in the scope of the RoHS Directive, equivalent alternatives should exist in order not to increase potential catastrophic consequences of a failure of this type of equipment. It has not been in the scope of this study to carry out a detailed technical assessment on the reliability of alternatives in these applications.

5.7 CONTACTS & REFERENCES

5.7.1. PERSONAL CONTACT

- Mr. Steven Andrews, BERR
- Ms. Abigail Cotrell, AEA Europe
- Mr. Marcel Dutrieux, Honda Europe
- Mr. Geert Willems, IMEC/Sirris
- Ms. Sarah Bogaert, Arcadis
- Ms. Susan Bell, GE
- Mr. Goran Gablin, KEMI
- Mr. Jan Clyncke, PV Cycle
- Ms. Florence Limet, EPIA

[53] According to stakeholders (ERA and AEA Europe), this statement may be true but is in their opinion an oversimplification of a complex issue

- Ms. Eleni Despotou, EPIA

5.7.2. REFERENCES

ADEME 2007	ADEME (2007) Etude sur la mise en oeuvre des directives DEEE et RoHS en Europe
ARCADIS & RPA 2008	Bogaert, S., Van Acoleyen, M., Van Tomme, I., De Smet, L., Fleet, D. and Salado, R. (2008) Study on RoHS and WEEE Directives. By ARCADIS & RPA for the DG ENTR, European Commission.
COWI 2005	COWI (2005) RoHS substances (Hg, Pb, Cr(VI), Cd, PBB and PBDE) in electric and electrical equipment in Belgium. Study for the Federal Public Service Health, Food Chain Safety and Environment. Directorate-General Environment, Brussels.
Navigant consulting	Analysis of Worldwide Markets for Photovoltaic Products & Five-Year Application Forecast 2007/2008
Sander 2008	Study on the development of a take back and recovery system for photovoltaic systems, Ökopol, 2008
EPIA 2007	EPIA (2007) Solar Generation IV, http://www.epia.org/fileadmin/EPIA_docs/publications/epia/EPIA_SG_IV_final.pdf
EU PV Platform 2007	EU Photovoltaic Platform (2007) A strategic Research Agenda for photovoltaic solar energy technology, http://cordis.europa.eu/technology-platforms/pdf/photovoltaics.pdf
Jäger-Waldau 2007	Jäger-Waldau, A. (2007) PV status report 2007, Research, solar cell production and market implementation of photovoltaics. EC, DG JRC, http://re.jrc.ec.europa.eu/refsys/pdf/PV_StatusReport_2007.pdf
UNU 2007	2008 Review of Directive 2002/96 on WEEE, R. Kuehr et al.
VDW	The German Tool Industry in 2006
WTCM-CRIF	De RoHS-richtlijn, een antwoord op uw vragen, WTCM-CRIF, Geert Willems
Fthenakis 2003/1	Fthenakis, V.M. (2003) Overview of potential hazards, Practical handbook of photovoltaics, Elsevier 2003
Fthenakis 2003/2	Fthenakis, V.M. (2003) Life cycle impact analysis of cadmium in CdTe PV production, Renewable and sustainable energy reviews, December 2003
Fthenakis and Kim 2006	Fthenakis and Kim (2006) CdTe photovoltaics: Life cycle environmental profile and comparisons, European Material Research Society Meeting, May 2006

6. FACT SHEET ON THE INCLUSION OF DEFINITION FOR 'HOMOGENEOUS MATERIAL'

6.1 ISSUE

Issue/problem addressed:

This factsheet deals with the inclusion of an appropriate definition for 'homogeneous material' in the RoHS Directive.

Background:

The maximum concentration values for hazardous substances, as in Annex of the RoHS Directive, are expressed as weight percentage in homogeneous materials, but the definition of homogeneous material is not included in the Directive. Furthermore, the definition in the FAQ document, that is generally used, is rejected by some stakeholders, specifically with regard to small components and the presence of chromium VI in metallic coatings.

The overall objective of this factsheet is to have an appropriate and enforceable definition for 'homogeneous material' in relation with RoHS Directive. The assessment of the inclusion of an appropriate definition in the Directive forms a substantial contribution to reach this objective.

Options and summary of analysis:

The options analysed in this factsheet consider 3 topics related to the definition of 'homogeneous material':

1. Inclusion of the definition in RoHS Directive
2. Dealing with small components
3. Dealing with metal concentrations in metallic coatings

For every topic several options are analysed:

1. Inclusion of definition
    a. Business-as-usual (= definition in FAQ document)
    b. Inclusion of the definition in RoHS Directive
    c. Inclusion of the definition in an international standard
2. Small components
    a. Business-as-usual
    b. Maximum size limit of 4 mm^3
    c. Maximum size limit of 40 mm^3
3. Metallic coatings
    a. Business-as-usual
    b. Ban all intentionally added HS

6.1.1. CURRENT PRACTICE/SITUATION

As a total avoidance of heavy metals and brominated flame retardants is in some instances impossible to achieve, certain concentration values in materials should be tolerated.

Therefore, the Commission adopted the Decision 2005/618/EC, which adds the following note to the Annex of RoHS Directive:

'For the purposes of Article 5(1)(a), a maximum concentration value of 0.1 % by weight in homogeneous materials for lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) and of 0.01 % by weight in homogeneous materials for cadmium shall be tolerated.'

But due to the lack of clear definition (in the RoHS Directive) on what is 'homogeneous material', this resulted in considerable confusion with regard to how the term was to be interpreted and applied.

The FAQ, last updated on August 2006, contains the following definition of homogeneous material:

> "Homogeneous material" means a material that cannot be mechanically disjointed into different materials.
>
> The term "homogeneous" means "of uniform composition throughout". Examples of "homogeneous materials" are individual types of plastics, ceramics, glass, metals, alloys, paper, board, resins and coatings.
>
> The term "mechanically disjointed" means that the materials can, in principle, be separated by mechanical actions such as: unscrewing, cutting, crushing, grinding and abrasive processes.

As noted by ERA, the clarification and wording in FAQ is intended only as a definition of a homogeneous material and is not intended as instructions for analysis, as has been assumed by some manufacturers and analysts. Hence, the objective of this factsheet is to assess if and how the interpretation of 'homogeneous material' could be clarified rather than assess current testing practices.

6.1.2. ISSUES/PROBLEMS TO EXPLORE

In general for compliance testing of electrotechnical products a 2-step approach is used: first a (qualitative) screening with XRF is performed to determine 'suspicious' parts or materials[54]; secondly, in the verification test procedure, these parts or materials are tested using a variety of test methods. Depending on the size and the form of the

[54] during screening the material does not have to be mechanically disjointed prior to testing, as the definition states 'can, in principle, be separated'.

sample it can also be decided to skip the screening and only perform the verification test procedure. [IEC 62321, SJ/T 11365-2006, RoHS EGD 2006]

Currently it is difficult in practice to control the "homogeneous material" concept as a basis for checking compliance with the maximum concentration values, because of limited enforceability (as the definition of 'homogeneous material' is only described in the FAQ document) and because in practice it may be extremely difficult and very costly to apply this definition in the verification test procedure to very small components and to metallic surface conversion applications. [ARCADIS & RPA 2008, Daojun & Zhengyun 2006, EICTA 2008, Koskinen & Terho 2008a-b, VITO/COWI 2007]

Therefore, in the review of the RoHS Directive following aspects with respect to 'homogeneous material' have to be assessed:

- Inclusion of the definition in RoHS Directive
- Practical and efficient definition of 'homogeneous material' with regard to small components and HS concentrations in metallic coatings

Typically EEE is composed of hundreds, even thousands of individual components, such as integrated circuits (ICs), discrete components (resistors, capacitors, diodes, etc), wires, cables, printed circuit boards, connectors, fasteners, sensors, enclosures, etc. And each electronic component has a unique mixture of parts which are made from a variety of materials. The task of obtaining a representative sample for compliance testing in the verification test procedure can be very onerous and challenging. For small components the costs/time for taking a representative sample, taking into account the definition of homogeneous material, can be disproportionate to the environmental gain.

As a matter of fact, it can be practically impossible to gain homogeneous materials through disjointment especially for the electronic components which have tiny size or complicated structure. [Daojun & Zhengyun 2006, Koskinen & Terho 2008a-b] The small components illustrated in Figure 12 each contain at least 22 homogeneous materials that have "uniform composition throughout, part of which are depicted in Figure 13.

Figure 12 – Small electronic components [Koskinen & Terho 2008a]

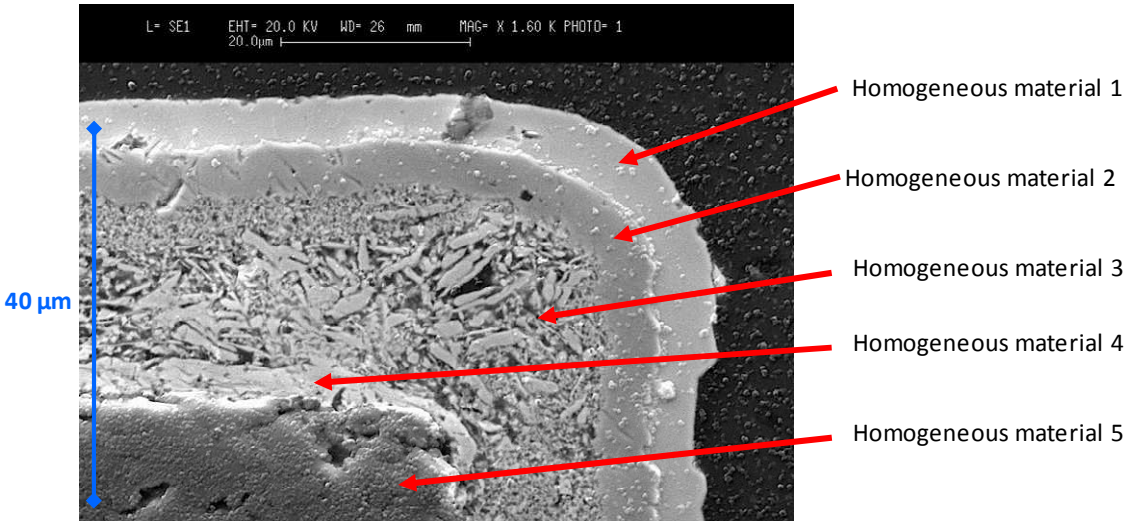

Figure 13 – Cross section of a small electronic component showing layers of five different homogeneous materials that have "uniform composition throughout" [Koskinen & Terho 2008a]

For chromate coatings on metallic samples, representative sampling in the verification test procedure according to the definition of homogeneous material is hard to apply for 2 reasons:

1. sampling of a metallic coating
2. quantitative analysis of Cr(VI) in a coating

As a metallic coating typically consists of a very thin layer of the metal on a sample or product (for example to protect it from corrosion), the mechanical disjointment of this coating always will lead to problems to get a representative sample because it is not possible to remove the coating 100% quantitatively from the bulk sample, and so it is difficult to express the results in mg/kg of the coating layer.

When the coating is removed for sampling, part of the underlying material may be included in the sample, and it should be ensured that only the very thin metallic conversion layer is removed. [COWI 2007, VITO/COWI 2006] This is a problem that exists for all metallic coatings but while common metallic coatings can easily be screened by XRF (without disjointing), analysis of concentration as weight % of Cr(VI) in coatings is difficult[55].

If the metallic coating is anyhow disjoint from the bulk sample, it can be analysed for hazardous substances. The sample is then digested in an appropriate solution and analysed with specific instrumentation.

For Cr(VI), the test methods described in the IEC 62321 standard cover two procedures for the determination of the presence of Cr(VI) in colourless and coloured chromate

[55] Confidential comment received 09/07/2008 and comment from Dr. Goodman (received 02/07/2008)

coatings on metallic samples. However, both procedures can be applied to detect the presence of Cr(VI) *only qualitatively*, because due to its highly reactive nature, during the digestion some (or even all) Cr(VI) will convert very easily to Cr(III). Moreover the concentration of hexavalent chromium in a chromate layer can change drastically with time and storage conditions because of the highly reactive character of Cr(VI). [VITO/COWI 2007]

So, both the representative sampling and the highly reactive nature of hexavalent chromium pose problems for chromate coatings to comply with the maximum concentration values from the RoHS Directive.

The definition of 'homogeneous material' provided by the FAQ document can serve as a start for a better definition taking into account the difficulties to perform tests on very small components or to decompose them further into homogeneous materials and measuring the presence and concentrations of hazardous substances (as Cr(VI)) in metallic surface conversion applications.

6.2 POLICY OPTIONS

For the elaboration of policy options, a distinction is made between 3 topics related to the inclusion of the definition of 'homogeneous material' in RoHS Directive:

1. Inclusion of the definition in RoHS Directive
2. Dealing with small components
3. Dealing with metal concentrations in metallic coatings

For every topic several options are defined and analysed.

The options considered in this factsheet are:

Option 1: Inclusion of definition

a. Business-as-usual (= definition in FAQ document)
b. Inclusion of the definition in RoHS Directive
c. Inclusion of the definition in an international standard

Option 2: Small components

a. Business-as-usual
b. Maximum size limit of 4 mm^3
c. Maximum size limit of 40 mm^3

Option 3: Metallic coatings

a. Business-as-usual
b. Ban all intentionally added HS

Concerning the inclusion of the definition of 'homogeneous material', it can be considered to include the definition in the RoHS Directive (option 1b), or to have an international standardisation working group (such as WG 3 of IEC TC 111) dealing with it and including it in an international standard (option 1c), or to leave the situation as it is (business-as-usual, option 1a).

To deal with the problem of small components, the Chinese RoHS legislation (China RoHS) [SJ/T 11363-2006] has introduced a limit value of 4 mm³. Any component smaller than this limit value needs to be treated as a homogeneous material if it is not possible to disjoint the component mechanically (option 2b)[56].

Furthermore, even a higher limit value can be considered as long as it enhances the practicability of the sampling for compliance testing and the increased environmental impact is negligible or only limited (option 2c)[56]. A very recent study by Nokia shows that a size limit of 40 mm³ could be applied based on full material declarations and without risk to change the compliance criteria from the current RoHS Directive. [Koskinen & Terho 2008a]

To deal with the problems regarding metallic coatings, China RoHS also has introduced the concept of banning all intentionally added Cr(VI) in metal treatment, without imposing concentration limits (option 3b). [SJ/T 11363-2006]

Chinese RoHS Directive classifies EEE (or EIP, electronic information products) in 3 categories, EIP-A, EIP-B and EIP-C, as in Table 22.

Table 22 - Classification of materials (unit) in EIP

Classification of Materials (Unit)	Definition of Materials (Unit)
EIP-A	Each homogeneous material composing EIP
EIP-B	Metallic coating of each part in EIP
EIP-C	Small components or materials that cannot be further disassembled under existing conditions in EIP. They generally refer to the products of equal to or less than 4 mm³ in size.

In case of overlapping or contradictions in the classifications, they should be classified according to the EIP-A/EIP-B/EIP-C sequence, that is, if it can be classified to the category of EIP-A, it is not desirable to be classified to the category EIP-B or EIP-C.

[56] Some stakeholders (Imec and another confidential pers. comm.) consider that the introduction of any size limit will introduce (serious) loopholes in the control of the RoHS Directive and that such options should not be considered at all. They think that the current situation is very much workable and enforceable using analysis techniques that do not need disjointment. However, other stakeholders (VITO laboratory, Nokia) have confirmed that with non-disjointment techniques it is possible to show that a component or appliance clearly IS NOT compliant, but it is not possible to prove that a component IS compliant/appliance as complex components can hide non-compliant homogeneous materials in them, which can only be detected by disjointment.

The corresponding requirements for each classification category are summarised in Table 23.

Table 23 - Requirement for concentration limits for toxic or hazardous substances

Classification of Materials (Unit)	Limit Requirements
EIP-A	The contents of lead, mercury, hexavalent chromium, polybrominated biphenyl, polybrominated diphenyl ether (exclusive of decabromodiphenyl ether) in this category shall not exceed 0.1 % and the content of cadmium shall not exceed 0.01%.
EIP-B	The hazardous substances including lead, mercury, cadmium, hexavalent chromium in this category shall not be added intentionally.
EIP-C	The contents of lead, mercury, hexavalent chromium, polybrominated biphenyl, polybrominated diphenyl ether (not decabromodiphenyl ethers) in this category shall not exceed 0.1%, and the content of cadmium shall not exceed 0.01%.

The purpose of bringing in the concept of "intentionally added" is to resolve the problem of metal coating that is difficult to disassemble, based on homogeneous materials, for testing or determination. In actual operations however, "intentionally" and "unintentionally" can often not be distinguished. To prevent people from using the "unintentionally" as an excuse, the use hazardous substances in quantity above a given limit must be punished.

6.3 AVAILABLE INFORMATION ON THE IMPACTS

6.3.1. AVAILABLE INFORMATION ON THE IMPACTS FOR OPTION 1 A, B AND C (INCLUSION OF DEFINITION)

- **Environmental impacts**

Not applicable.

- **Economic impacts**

Relevant economic impacts cover the creation of a level-playing field by improving the definition of 'homogeneous material' and the improved enforceability. No quantitative data were found.

Social impacts

Due to the different interpretations of the homogeneous material concept, there is a lack of harmonisation of supplied components testing and sample disjointment for assessing the concentration of the restricted substance within a homogeneous material. Where producers need to rely on produced test results or certification presented by second parties to ensure compliance, this uncertainty in process continues to challenge industry in its ability to confirm the levels of compliance in their products. [Arcadis&RPA 2008]

Small and medium sized enterprises are not active in standardisation. Their sector organisations seem to be in favour of EU standards instead of ISO international standards, on which the European Union lacks control. [Arcadis&RPA 2008]

IEC WG3 Task Force is producing a PAS document ('Guideline for sampling procedure for chemical analysis of Restricted Substances in Electrotechnical products') for sample preparation for RoHS testing but due to the very challenging definition of the homogeneous material in RoHS Directive it is extremely difficult to give instruction on how to separate components to the homogeneous materials in the verification test procedure.

6.3.2. AVAILABLE INFORMATION ON THE IMPACTS FOR OPTION 2 A, B AND C (SMALL COMPONENTS)

Environmental impacts

One of the principles behind the introduction of a volume size limit is that introducing the size limit should not influence the environmental impact (by definition): the size limit is actually chosen as the maximum size that does not change the compliance criteria for homogeneous material and therefore has no environmental impact.

However, a detailed analysis of the study of Doajun and Zhengyun (2006) that introduced the size limit of 4 mm^3 in the Chinese RoHS legislation (cf. option 2a), reveals that this limit should have only a very small environmental impact. The 4 mm^3 size limit is based on a chip resistor with a solder containing lead, provided that the thickness of the solder coating is 2 µm, the lead content in the solder is 10% and the ratio of the volume of the component to the volume of the coating is 3.75/0.06 (mm^3/mm^3). If any of these three parameters is lower, it is possible that the hazardous substance content of the coating of a 4 mm^3 (sub)component is higher than 0.1% but that it passes the compliance criteria for a 4 mm^3 component[57,58].

[57] A stakeholder (confidential pers. comm.) has noted that "there may be many other similar examples, especially for coatings, where such a definition would permit the use of the banned substances", but this stakeholder does not provide any more specific data of such cases.

[58] According to Geert Willems, Imec-Sirris (pers.comm.), an example that proves this statement concerns the use of SnPb finish (3-10% Pb), that may become acceptable again, in small components

However, quantifying the total environmental impact for the European EEE market if this limit was adopted is quite impossible.

Based on full material declarations, a recent study by Nokia [Koskinen & Terho 2008] determined a maximum size limit of 40 mm³ (option 2c) without changing the current compliance criteria. 51 non-compliant components were studied, and in total 4 of them falsely passed the current compliance criteria. From this study the smallest cut off point where these false compliant results were first detected (i.e. 40 mm³) sets the limit. It is claimed that when this cut off point sets the limit there is no risk that the compliance criteria are falsely passed.

It can be reasoned that a size limit of 40 mm³ could have a somewhat higher environmental impact than the 4 mm³ size limit, but the impact is nevertheless estimated low, considering that even this limit is claimed not to allow compliance criteria to be falsely passed.[59]

Material data used in this study was collected before the RoHS Directive was in force. At the moment it is not possible to acquire the components used in this study because they are RoHS non-compliant and no longer available from the manufacturers. Therefore it is not possible to verify these results experimentally.

The introduction of a size limit also influences the current exemptions in RoHS Directive as the homogenisation of components for compliance testing will make it impossible to apply certain exemptions.

Many small components are ceramic based and are allowed to use Pb (exemption 7) in their ceramic body (e.g. ceramic capacitors, ceramic film resistors) but they are not allowed to use lead in the solderable finish on their terminals. When homogenised, these components will always exceed the 0.1% Pb limit. Either this is acceptable based on exemption 7 and implicitly will allow the use of Pb for other purposes than exemption 7 has intended, or it is not allowed making exemption 7 inapplicable for a large and important group of components.

(China RoHS does not have this problem because it has no exemptions.)

Economic impacts

EEE producers will benefit most from introducing a volume size limit, as in the verification test procedure the sample preparation for analytical laboratories performing compliance testing for RoHS Directive becomes less time consuming. The bigger the

(< 4mm³) in Printed Board Assemblies; typically, several hundred of these components are used in a PBA, and make up a significant amount of Pb in the PBA.

59 According to some stakeholders (Doajun, Nokia and EICTA) the maximum size limit of 4 or 40 mm³ is determined not to increase the environmental impact; others (Imec, Sirris, 1 confidential source) argue that the introduction of a maximum size limit will increase the environmental impact and should be carefully considered to ensure it does not open the door to general abuse of the aims of the RoHS Directive.

volume size limit, the bigger the economic benefit. To estimate the total avoided costs by introducing a maximum size limit, the total amount of small components (smaller than the size limit) that would be further disjointed to the homogeneous material level if there was no maximum size limit, should be known. As the mentioned specifications are not commonly used specifications for classifying components, estimating this amount of small components could/has not be done.

Taking over the China approach is considered to have both practical and economic benefits: harmonisation between EU and China RoHS legislation should lead to less confusion and would allow the same compliance testing for the two markets. Thus, the total market for RoHS compliant EEE products increases without extra compliance costs. This is an advantage for European EEE producers, but it also opens simplified access to the European market for Chinese EEE producers.

According to Mr. Willems (pers. comm.), the introduction of a 4 mm^3 size limit also would mean that for the majority of electronic components (in volume) the pre-RoHS situation can be restored since all passive components up to resistors & capacitors size could again use SnPb as a finish and still be RoHS compliant, which is cheaper (but also introduces an increased use of Pb). However, Nokia considers that that even components of 40 mm^3 are so small that intentional use of lead finishes or solders with them would lead to exceeding the RoHS limits in homogeneous material.

- **Social impacts**

Compliance testing would be enhanced considerably, as the introduction of a volume size limit makes it easier to perform analytical measurements on homogeneous materials in EEE in the verification test procedure and to compare them with the maximum concentration values. So a bigger level playing field is created.

6.3.3. AVAILABLE INFORMATION ON THE IMPACTS FOR OPTION 3 A AND B (METALLIC COATINGS)

The impacts with regard to banning all intentionally added HS in metallic coatings are in first instance focussed on Cr(VI), and the analysis for Cr(VI) is extrapolated to other HS.

The principal application area for Cr(VI) is chromate conversion coatings. The corrosion resistance of a wide range of metals including zinc, cadmium, aluminium, copper and steel can be improved by treatment with chromate based passivation solutions [EC 2006].

To deal with the problem of representative sampling and of quantitative analysis of Cr(VI) in conversion coatings the option to ban all intentionally added Cr(VI) in metallic coatings is introduced. To quantify the impacts of this option it is necessary to have quantitative data on the amount of Cr(VI) that is currently used in metallic coatings EEE in Europe.

Environmental impacts

Amount of Cr(VI) in metallic coatings [COWI 2005, EC 2006, VITO/COWI 2007]

The consumption of Cr(VI) in EEE in Belgium around 2000 is roughly estimated at 3-15 tonnes/year, of which chromate passivate coatings account for the main part. The stock of Cr(VI) in EEE in 2005 is estimated at 30-300 tonnes.

Chromate coatings are used for lots of applications, of which components of EEE account for only a minor part.

Chromium coatings typically consist of a thin layer of amorphous trivalent chromium Cr(III) with Cr(VI) incorporated in the layer. The Cr(III) content of the coating varies but is typically 70-90%.

The Cr(VI) content in zinc passivated components ranges from approximately 0.03 to 0.7 g Cr(VI) per m^2. The thickness of the layer ranges from 0.025 µm for the clear/blue up to 1.5 µm for the olive tinge.

Whereas the Cr(VI) content of individual components in many cases may be less than 0.1%, the Cr(VI) content of the passivate coating will be significantly higher.

So for chromate coating, if Cr(VI) is applied, the Cr(VI) content will always[60] be higher than the current maximum concentration value for Cr(VI) for homogeneous materials in the RoHS Directive. In this way, a complete ban of all intentionally added Cr(VI) would not be a real change compared to the current situation.

Adequate substitutes for Cr(VI) are available for most chromate coating applications[61], although the development of some of the alternatives is still on-going[62].

Economic impacts [EC 2006, VITO 2007]

Alternatives to hexavalent chromium are generally more expensive than Cr(VI) itself – purchase prices for trivalent chromium systems are 2-3 times higher and the application costs for the passivation process are also higher, by approximately 50%.

The market structure for total surface treatment industry, including chromate coatings, is approximately (in volume): automotive 22%, construction 9%, food and drink containers 8%, electric industry 7%, steel semi product 7%, electronic industry 7%, industrial equipment 5%, aerospace industry 5 %, unspecified 30%.

Surface treatment is carried out in more than 18300 installations in Europe, ranging from small private companies to facilities owned by multinational corporations. The large majority are small or medium enterprises; in Germany the typical number of

[60] This statement was contested by a stakeholder (confidential pers. comm.), according to who good quality Cr plating processes do not result in coatings where Cr(VI) can be detected.

[61] One such substitute is coating starting as Cr(III) where Cr(VI) will never be present but chromium will be.

[62] According to Mr. Willems (Sirris-Imec, comment received 11/07/2008), Cr(VI) substitutes are still less effective for corrosion protection than Cr(VI) itself.

employees is between 10 and 80. Altogether, the industry for the surface treatment of metals and plastics employs about 440000 people in Europe. These figures include manufacturers of printed circuit boards. More than 10000 (55%) are specialist surface treatment installations (known as job or jobbing shops). The remaining 8300 (45%) are surface treatment shops within another installation typically also an SME.

- **Social impacts** [COWI 2005]

The use of substitutes for Cr(VI) probably will have effect on the number of companies or people involved in conversion coating processes: although the Cr(VI)-free processes are also conversion coating processes, they are much more difficult to control and require investment in new equipment (accurate temperature control and chemical analysis). Cr(VI) conversion coatings are currently produced with very low cost facilities and are very easy to apply. It is therefore likely that many of the organisations that carry out Cr(VI) conversion coating will not invest in the alternative processes due to the technical skills required and the higher cost.

6.3.4. EXTRAPOLATING THE TOTAL BAN TO OTHER HAZARDOUS SUBSTANCES CURRENTLY COVERED BY ROHS

Banning all intentionally added Cr(VI) in metallic coatings provides a solution for RoHS compliance testing as both the problems of representative sampling of coatings and the quantitative analyses are by-passed, through performance of existing, qualitative analyses for Cr(VI) in metallic coatings.

For other hazardous substances currently covered by RoHS (as lead, mercury and cadmium), it also can be considered (as in the Chinese RoHS Directive) to ban all intentional adding in metallic coatings, as similar problems occur for these substances in metallic coatings and qualitative analysis methods (XRF) for these substances exist and are already stated in the IEC 62321 standard.[63]

6.4 PROS & CONS

For each option the pros and cons are briefly explained.

[63] A stakeholder has noted that consideration should be made to the possible inclusion of new substances in RoHS. These may be organic materials for which XRF testing may not be feasible. In such a case, full chemical analysis would still be needed.

Option 1: Inclusion of definition of homogeneous materials in RoHS Directive

a. Business-as-usual

No pros.

Cons:

- Limited legal enforceability of definition in FAQ document.

b. Include definition in RoHS Directive

Pros:

- Clarification; streamlining implementation; creation of better testing conditions; remaining detailed problems could be further explored by the appropriate technical bodies. Definition in FAQ document is widely accepted (and implemented).

Cons:

- Limited flexibility regarding adaptations to scientific and technical progress. Difficult to update, if and when needed.

c. Include definition in international standard

Pros:

- Clarification; streamlining implementation; creation of better testing conditions; remaining detailed problems could be further explored by the appropriate technical bodies. Definition in FAQ document is widely accepted (and implemented).
- Extensive consultation of stakeholders possible/mandatory. Standardization can play its part and support industry and its supply chain with workable solutions with regard to testing of equipment on the homogeneous material level.

Cons:

- Delay before having a final definition because of the extensive consultation.

Option 2: Small components

a. Business-as-usual

No pros.

Cons:

- Problems with application of current definition for small components

b. Introduce maximum (volume) size limit of 4 mm³

Pros:

- Practical solution to improve sampling for compliance testing, with no (or

limited) increased environmental impact[64].

- Harmonisation between European and Chinese RoHS legislation, with both practical and economic benefits.

Cons:

- Many components of a volume bigger than 4mm³ have extremely complex inner parts and cannot be tested if the limit is set as low as 4mm³. This limit solves only part of the problem.

  The introduction of a size limit is not compatible with the current exemptions in RoHS Directive.

c. <u>Introduce maximum (volume) size limit of 40 mm³</u>

Pros:

- Practical solution to improve sampling for compliance testing, with no (or limited) increase in environmental impacts (see also footnote [64]).

Cons:

- Extension of material declarations necessary (for concentrations lower than maximum concentration values).
- The introduction of a size limit is not compatible with the current exemptions in RoHS Directive.

Option 3: Metallic coatings

a. <u>Business-as-usual</u>

No pros.

Cons:

- Problems with application of current definition in metallic surface conversion applications

b. <u>Ban all intentionally added hazardous substances (covered by RoHS)</u>

Pros:

- Analytical standards can be used to control level of HS qualitatively; environmental impact because of the HS decreases.

Cons:

- Alternative techniques and materials for replacing HS must be available at economic price and without increased environmental impact.

[64] Some stakeholders (Imec pers. comm.. and confidential pers. comm.) state that the introduction of a size limit will increase the environmental impact significantly . However, the 4 and 40 mm^3 limits were set, by definition, so as not to have environmental impact.

6.5 ANALYSIS OF OPTIONS

The tables below present a summary of options' analysis for option 2 and option 3 (in separate tables) in the form of a matrix in order to compare the advantages and disadvantages of each option.

Because it is quite clear what the advantages and disadvantages are for option 1 and because the matrix used for summarizing the option analysis is not a very adequate tool for option 1, no further analysis in the form of a matrix is performed for option 1.

Table 24 – Summary of assessed impacts-option 2 'Small components'

	Option 2a: no change	Option 2b: size limit of 4 mm³	Option 2c: size limit of 40mm³
General impacts			
Legislative changes	0	-	-
Environmental impacts			
Level of environmental protection/improvement[65]	0	0 to -	0 to -(-)
Economic impacts			
Firms: costs	0	+	+
Firms: competitiveness (internal & external market)	-	+	+
Innovation and research	0	0	0
Public authorities (budget; resources)	NA	NA	NA
Social Issues			
Impact on consumers (availability / price)	NA	NA	NA
Public health and safety	NA	NA	NA
Other Impacts			
Clarity and consistency (e.g. with other legislation)	-	++	+
Practical workability and enforceability	-	- to +	- to +

GENERAL IMPACTS

Compared to the current situation, the introduction of a maximum size limit for homogeneous material would cause legislative changes, irrespective of the exact limit size.

ENVIRONMENTAL IMPACTS

[65] In this context related to level of use of hazardous substances

Level of environmental protection/improvement

As no end-of-life scenario's are estimated or calculated, a higher level of use of hazardous substances is assessed to have a negative impact on the environmental protection.

Although the use of hazardous substances should be the same when a size limit is introduced, a small increase of the environmental impacts can be expected, as the 4 mm^3 size limit is deducted for specific resistors; for some components the hazardous substances content can be higher if the maximum concentration values are set on a 4 mm^3 size limit than on the homogeneous material level (current situation).

Due to the higher limit, for a size limit of 40 mm^3 the environmental impacts could be somewhat higher, but they are nevertheless considered to remain low.[66]

To assess the exact increase of the environmental impact by introducing a maximum size limit, a quantitative impact assessment involving testing of a significant number of products would be needed. This has been out of the scope of this study.

ECONOMIC IMPACTS

Firms: costs

As the total analysis cost for RoHS compliance is proportionate with the number of analyses to be performed, the introduction of a size limit lowers the costs for compliance testing, because as compared to the current situation it can only happen that fewer analyses have to be performed. When using material declarations to prove compliance testing, the accumulated number of analyses will be the same as for option 2b, but probably spread over several suppliers.

As noted by a stakeholder (confidential pers. comm.), introduction of any clear definition could require changes in the working procedures of some test laboratories, bringing additional expenses. Also, from the point of view of test laboratories, contrary to the industry view, the more straightforward testing could reduce the revenue.

Firms: competitiveness

As the introduction of a size limit enhances RoHS compliance testing, it will also improve the competitiveness between companies on the European market.

Innovation and research

No significant effect is expected for innovation and research, provided that the introduction of a maximum size limit does not require definitions and new methods of volume measurement to determine the maximum size.

[66] Some stakeholders have contest this. See footnotes [57] and [58].

OTHER IMPACTS

Clarity and consistency

Because of current difficulties with the application of the definition of homogeneous material, the specific goal of this topic is to bring more clarity in the definition of homogeneous material and its application, so positive effect is expected for options 2b and 2c, compared to the current situation.

Harmonisation between European and Chinese RoHS legislation (i.e. introducing a size limit of 4 mm^3, option 2b) would lead to a higher clarity and consistency in the international level.

Workability and enforceability

In terms of practicability and enforceability, options 2b and 2c are easily manageable and will decrease misinterpretations considerably[67].

However the incompatibility of homogenisation with current exemptions in the RoHS Directive undermines this enhanced workability and enforceability seriously.

Table 25 – Summary of assessed impacts-option 3 'Metallic coatings'

	Option 3a: no change	Option 3b: ban intentionally added HS
General impacts		
Legislative changes	0	-
Environmental impacts		
Level of use of hazardous substances	0	0 to +
Level of environmental protection/improvement	0	0 to +
Economic impacts		
Firms: costs	0	0
Firms: competitiveness (internal & external market)	-	0
Innovation and research	0	+
Public authorities (budget; resources)	0	0
Social Issues		
Impact on consumers (availability / price)	NA	NA
Public health and safety	NA	NA

[67] According to a stakeholder, the current situation is also manageable and achieves the highest environmental protection (confidential pers. comm.), but this is contested by a number of stakeholders reporting confusion under the current situation (e.g. pers. comm. with EICTA, ERA, Technology Forecasters Inc., etc.).

Other Impacts		
Clarity and consistency (e.g. with other legislation)	-	++
Practical workability and enforceability	-	++

GENERAL IMPACTS

Compared to the current situation, any proposed option with respect to clarification of the definition of homogeneous material, will lead to possible changes to the legislation.

ENVIRONMENTAL IMPACTS

Because of the specific composition and function of metallic coatings on EEE, currently the maximum concentration values are in most cases violated when using hazardous substances in metallic coatings[68]. So banning all intentionally added hazardous substances in metallic coatings would not implicate a drastic decrease of the use of these hazardous substances for this purpose, or only to a very little extent.

As the (possible) exposure of the environment to hazardous substances is estimated to be proportionate to the use of the hazardous substances in metallic coatings, also the difference in level of protection of the environment is very limited.

ECONOMIC IMPACTS

Regarding economic impacts, banning all intentionally added hazardous substances will have a very limited positive effect, if any, compared to the current situation and require changes in the working procedures of some test laboratories, bringing additional expenses to them.

OTHER IMPACTS

Most expected impact related to banning all intentionally added hazardous substances comes from creating a more clear and enforceable situation where RoHS compliance testing is supported by appropriate analysis techniques.

6.6 SUMMARY

The maximum concentration values for hazardous substances, as in Annex of the RoHS Directive, are expressed as weight percentage in homogeneous materials, but the definition of homogeneous material is not included in the Directive. Furthermore, the definition in the FAQ document, that is generally used, is rejected by some stakeholders,

[68] This statement was contested by a stakeholder (confidential pers. comm.), but no further information was provided on this issue.

specifically with regard to small components and the presence of hazardous substances in metallic coatings.

To cope with these problems, this factsheet deals with the inclusion of an appropriate definition for 'homogeneous material' in the RoHS Directive.

For the elaboration of policy options, a distinction is made between 3 topics related to the inclusion of the definition of 'homogeneous material' in RoHS Directive:

1. Inclusion of the definition in RoHS Directive
2. Dealing with small components
3. Dealing with metal concentrations in metallic coatings

For every topic several options are defined and analysed:

Option 1: Inclusion of definition
- a. Business-as-usual (= definition in FAQ document)
- b. Inclusion of the definition in RoHS Directive
- c. Inclusion of the definition in an international standard

Option 2: Small components
- a. Business-as-usual
- b. Maximum size limit of 4 mm^3
- c. Maximum size limit of 40 mm^3

Option 3: Metallic coatings
- a. Business-as-usual
- b. Ban all intentionally added HS

The possible manners to deal with the inclusion of the definition of 'homogeneous material' focus on the difference in enforceability and flexibility between the considered options. The inclusion of the definition in the RoHS Directive (option 1b) is from a legislative point of view the most enforceable option, but at the same time from a technical point of view the least flexible option, whereas for option 1c (definition in international standard) it is the opposite way, and option 1a (current situation, definition in FAQ document) being in between[69].

As for small components the costs/time for taking a representative sample in the verification test procedure, according to the current definition of homogeneous material (option 2a), can be disproportionate to the environmental gain, setting a maximum size limit of 4mm^3 in the case where (further) disjointment is reasonably not possible can be an appropriate way to meet both the needs for environmental protection and for a

[69] A stakeholder (confidential pers. comm.) has noted that increasing flexibility translates to increase in possible loopholes, but the possibility of taking advantage of loopholes of course depends on the enforcement of legislation in any case. Further, as noted by industry, under the current definition the verification of compliance is so complicated that some companies are likely to take advantage of that already.

more practical sampling requirement for compliance testing (as to control sampling and analysis costs). Additionally, as the Chinese RoHS legislation uses already a maximum size limit of 4 mm^3, introducing this size limit in the European RoHS Directive would enhance clarity and consistency.

Nevertheless it has to be stressed that introducing a maximum size limit of 4 mm^3 will decrease, although probably to a limited extent, the environmental protection compared to the current situation.

By using full material declarations, even allowing a maximum size limit of 40 mm^3 (option 2c) can be considered, provided that there is no change of the current compliance criteria. Material data used to set the size limit on 40 mm^3, was collected before the RoHS Directive was in force. At the moment it is not possible to acquire the components used in this study because they are RoHS non-compliant and no longer available from the manufacturers. Therefore it is not possible to verify these results experimentally.

The decrease of the environmental protection (as discussed for a 4 mm^3 maximum size limit) is estimated to apply even more to the higher maximum size limit of 40 mm^3. But again, the effect on the environmental protection in absolute terms is estimated limited. Some stakeholders[70] have pointed at the risk of allowing the use lead solders and finishes by setting a size limit at 4 or 40 mm^3. However, this could be avoided by specifying that any solder or finish on a component should be considered as a homogeneous material in itself and the size limit considers the individual, bare components[71].

Furthermore, the introduction of a maximum size limit is not compatible with the current exemptions in the RoHS Directive as the homogenisation of components for compliance testing will make it impossible to apply some of these exemptions.

Currently (option 3a) for metallic coatings on EEE, representative sampling according to the definition of homogeneous material is hard to apply because of representative sampling of a metallic coating (due to the nature of the plating) and because of performing a quantitative analysis of Cr(VI) in a coating (due to the nature of Cr(VI)).

To cope with these problems an option is to ban all intentionally added Cr(VI) in metallic coatings, as for most (or all) purposes a Cr(VI) free chromate coating (so only containing Cr(III)) exists as alternative. In this way the existing method to analyse Cr(VI) qualitatively can be used for compliance purposes.

---

70 Mr. Willems (pers. comm.) and confidential stakeholder contribution (pers. comm.)

71 This is in the matter of fact reflected in the proposal made by Koskinen & Terho (2008a) where "disjointment into homogeneous material [or otherwise testing separately] shall always be considered as the first and preferred approach when conducting RoHS compliance testing; only in cases where disjointment is not possible, components with the minimum achievable dimensions (but in any case no larger than 40 mm^3) can be tested for RoHS compliance without further disjointment".

In a similar way all intentionally added lead, mercury and cadmium can be banned in metallic coatings.

6.7 CONTACTS & REFERENCES

6.7.1. PERSONAL CONTACT

- Mr. Geert Willems, IMEC/Sirris
- Ms. Sarah Bogaert, ARCADIS
- Mr. Markus Stutz, Dell
- Ms. Kaisa-Reeta Koskinen & Ms. Salla Ahonen, Nokia
- Mr. Malte Becker, Electrolux
- Mr. Kristof Tirez, VITO (analytical laboratory)

6.7.2. REFERENCES

ARCADIS & RPA 2008	Bogaert, S., Van Acoleyen, M., Van Tomme, I., De Smet, L., Fleet, D. and Salado, R. (2008) Study on RoHS and WEEE Directives. By ARCADIS & RPA for the DG ENTR, European Commission.
UNU 2007	2008 Review of Directive 2002/96 on WEEE, R. Kuehr et al.
RoHS EGD 2006	RoHS Enforcement Guidance Document, version 1 - issued May 2006, developed by EU RoHS Enforcement Authorities Informal Network
SJ/T 11363-2006	Standard of the Electronics Industry of the People's Republic of China, SJ/T 11363 – 11/06/2006: Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Products
SJ/T 11365-2006	Industrial Standard of the People's Republic of China, SJ/T 11365-11/06/2006: Testing methods for Hazardous Substances in Electronic Information Products
COWI 2005	COWI (2005) RoHS substances in electric and electrical equipment in Belgium
COWI 2007	COWI (2007) RoHS inspection campaign, draft
VITO/COWI 2007	VITO/COWI (2007) Support to a RoHS inspection campaign in Belgium
EC 2006	European Commission (2006) Reference Document on Best Available Techniques for the Surface Treatment of Metals and

Plastics.

Daojun & Zhengyun 2006 — Daojun, L. and Zhengyun, B. (2006) Study on Minimal Size of Component unnecessary to further disjoint in RoHS testing, 2nd International Eco-electronics Conference, 7-9th December, 2006, Beijing, China.

IEC 62321 — Standard for test methods determining RoHS substances in electronics (IEC 62321), Markus Stutz, Mike Loch

EICTA 2008 — EICTA position on the definition of homogeneous material, June 27th, 2008

Koskinen & Terho 2008a — Koskinen, K.-R. and Terho, M. (2008) New approach for homogeneous material definition in EU RoHS – How to keep things practical without compromising results?, Nokia, Electronics Goes Green 2008+, September 7 – 10, 2008, Berlin.

Koskinen & Terho 2008b — Koskinen, K.-R. and Terho, M. (2008) Practical problems with homogeneous material definiton in EU RoHS – Limitations on RoHS compliance testing in the case of the small and complex systems, Nokia, Electronics Goes Green 2008+, 7 – 10 September, 2008, Berlin.

VITO 2007 — VITO (2007) Beste Beschikbare technieken (BBT) voor oppervlaktebehandeling van metalen en kunststoffen, finale versie.

JIG-101 A — Joint Industry Guide, Material Composition Declaration for Electronic Products, September 2008

7. FACT SHEET ON BURDEN OF PROOF AND THE PROVISION OF A SUBSTITUTION PLAN WHEN REQUESTING EXEMPTIONS

7.1 ISSUE

Issue/problem addressed:

There is a need to streamline and improve the quality of the exemptions approval process. The industry is already required to provide information to those reviewing the exemptions on the availability of alternatives. It is also common practice for the reviewer to contact the company and ask them of a roadmap of how and when they are able to substitute the harmful substance for which an exemption is sought. So even if substitution plans are not currently a legal requirement the industry is already required to provide the reviewer with this information if they want their exemption application to be successful. Hence any legal requirements of a substitution plan do not move the burden of proof to the industry, because this is already the case. However, a legal requirement for a substitution plan as part of the exemption application would clarify the necessity of considering this aspect as well as bringing to the forefront the role of exemptions being a temporary solution. As the exemption process and any requirements of a substitution plan are interlinked, both issues will be addressed within this fiche.

Background:

Currently the approval process for exemptions is complicated, involving an initial screening by a subcontracted consultant, followed by the comitology procedure. The process has led to an expanding list of exemption requests. Furthermore, there have been a number of repeated requests for exemptions which have already been denied, as well as requests for more specialised applications which cover limited numbers of products. Some of the exemption requests are still unresolved even if they have been processed for over two years.

Whereas the RoHS Directive bans or limits the use of hazardous substances in EEE products, the Directive allows for exemptions from its provisions where the benefits of retaining certain hazardous substances until an effective substitute can be identified outweigh the perceived drop in performance of certain products or the environmental benefits for phasing out the hazardous substance.

Options and summary of analysis:

Option 1: Business-as-usual – exemption processes remain as they are

Option 2: Introduction of a basic "light" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS.

Option 3: Introduction of a basic "light" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS with a maximum validity period of 4 years for granted exemptions.

Option 4: Introduction of a comprehensive "full" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS.

Option 5: Introduction of a comprehensive "full" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS with a maximum validity period of 4 years for granted exemptions.

7.1.1. CURRENT PRACTICE/SITUATION

- **Exemption Process**

The Annex to the RoHS Directive lists a limited number of applications of lead, mercury, cadmium and hexavalent chromium, which are exempted from the requirements of Article 4(1). Pursuant to Article 5(1): "Any amendments which are necessary in order to adapt the Annex to scientific and technical progress for the following purposes shall be adopted in accordance with the procedure referred to in Article 7(2)", which refers to the comitology procedure.

Since the RoHS Directive came into force, 120 exemption requests have been made to the Commission (33 are outstanding) with only 21 of them having been approved. A Checklist for Requests for Additional Exemptions was issued by the Commission in 2004 in response to the number of requests for exemptions from industry that the Commission services felt were not substantiated by scientific and technical advice. The purpose of the checklist was to enable the Technical Advisory Committee (TAC) to carry out a first screening of the requests received, with those passing the screening stage being considered for a possible exemption. The TAC is chaired by the European Commission and consists of representatives from all the Member States. Exemptions are for specific applications of the restricted substances and once agreed through a vote in the TAC followed by publication of a Commission Decision, will apply to everyone. There is no requirement to register.

The criteria required for the checklist is listed in Table 26.

Table 26 - RoHS checklist

Criteria	Information Please provide supporting technical and scientific evidence
1. Please describe the material / component of the electrical and electronic equipment that contains the hazardous substance. Please indicate the type and quantity of the hazardous substance used in the homogeneous material. Please indicate the quantity of the substance in absolute numbers and in percentage by weight in homogeneous material. Please indicate the functionality of the substance in the material of the equipment. Please also provide an estimate of the annual quantities of the hazardous substance used in this particular application.	
2. Please explain why the elimination or substitution of the hazardous substance via design changes or materials and components is currently technically or scientifically impracticable.	
3. Please indicate if the negative environmental, health and/or consumer safety impacts caused by substitution are likely to outweigh the environmental, health and/or consumer safety benefits. If existing, please refer to relevant studies on negative impacts caused by substitution.	
4. Please indicate if feasible substitutes currently exist in an industrial and/or commercial scale. Please indicate the possibilities and/or the status for the development of substitutes and indicate if these substitutes will be available by 1 July 2006 or at a later stage.	
5. Please indicate if any current restrictions apply to such substitutes. If yes, please quote the exact title of the appropriate legislation/regulation.	
6. Please indicate the costs and benefits and advantages and disadvantages of such substitutes. If existing, please refer to relevant studies on costs and benefits of such substitutes.	
7. Please provide any other relevant information that would support your application for an additional exemption.	

However, despite the issuing of this Checklist, the number of requests for exemptions has continued to grow.[72]

In 2004 the Commission issued a call for technical expertise to assist the TAC with specialist knowledge to approve or reject exemptions requests and this additional stage in the process had been continued to date. This contract was given to Öko- Institut together with Fraunhofer IZM in order to assess whether requests for exemptions are justified in line with the exemption criteria given in Article 5 (1) (b) of the RoHS Directive In order to do this the reviewers have followed the following technical and scientific proceedings shown in Table 27[73].

Table 27 - Technical and scientific proceedings by the exemption reviewers

Work packages	**Tasks**	**Procedure, methodological background**
(A) Basics: first assessment of exemption request & stakeholder comments	Check: • Specific application described? • Application covered by RoHS Directive? • Wording proposed? Wording precise and clear? • Quantity of substance, need for its use, substitution / elimination efforts described in comprehensive and detailed manner? • Justification in line with criteria of Art. 5 (1) (b)? • Additional evidence / information provided in stakeholder comments?	• Analyses of data and information gathered from documents downloaded from Commission online database • Elaborate questionnaire with need for clarification and further information • Consultation with applicants of exemptions (inter alia on possibly new or changed wording) • Review of literature • Contacting competitors • Exchange with external experts
(B) Assessment of technical specifications & substitution or elimination possibilities	• Identify alternative materials and components including adaptability of substitutes in similar applications to the application in question • Determine possible substitution through alternative materials: effects on characteristics and performance (e.g., reliability, manufacturing	• Analyses of data and information gathered from documents downloaded from Commission online database • Confrontation of applicants and stakeholders with opposing views on substitution possibilities • If necessary: hold meeting bringing different stakeholders together in

[72] Bogaert, S., Van Acoleyen, M., Van Tomme, I., De Smet, L., Fleet, D. and Salado, R. (2008) Study on RoHS and WEEE Directives. By ARCADIS & RPA for the DG ENTR, European Commission.

[73] Öko-Institut and IZM (2007), *Adaptation to scientific and technical progress under Directive 2002/95/EC*, Monthly Report 1. Freiburg 29 November 2006.

	yield, appearance) • Determine possible substitution through alternative production processes: effects on characteristics and performance (e.g., reliability, manufacturing yield, appearance) • Determine alternative product design providing the same function • Assessment of the availability of alternatives within the next four years	order to clarify diverging statements • Review of scientific and patent literature • Consultations with relevant scientific and research bodies within and outside the EU • Expert consultation, esp. component and equipment manufacturers • Check (safety) standards and other related legislation • Check if substitutes have undergone a risk assessment
(C) Assessment of possible environmental, health and / or consumer safety impacts	Comparing potential assets and drawbacks caused by substitution regarding • Environmental impacts (energy use, toxicity, impact waste stream) • Impacts on occupational health • Consumer safety and protection	• Analyses of data and information gathered from documents downloaded from Commission online database; especially check whether LCA or similar has been provided as evidence • Consultation with applicants, stakeholders and external experts • Analyse hazardous properties of substances as well as expected exposure situation; main elements: human health hazard assessment, environmental hazard assessment, assessment of bioaccumulation potential and persistency, exposure assessment, risk characterisation • Regarding working place safety and environmental protection: application of standard or enterprise specific risk management measures can be included in the exposure assessment if sufficient information is available • Relay on publicly available information on potential negative impacts of substitution

(D) Other criteria going beyond Art. 5 (1) (b)	• Identify arguments used by applicant NOT in line with Art. 5 (1) (b) (e.g. economic aspects, supply chain problems, phase-out periods etc.) • Assess whether these arguments are nevertheless valid from a general environmental, health or safety perspective • Include statement on those arguments in evaluation	• Compare argumentation line with criteria from Art. 5(1) (b) • Consultation with applicants, stakeholders and external experts • Assess validity of arguments with regard to Community environmental, health and safety policy

The above table shows that much of the technical work is already focused on alternatives and the assessment of alternatives. It also requires considering any developments regarding new alternatives during the next four years.

Substitutions

Substitution Requirements under RoHS

Article 5b exempts materials and components from the requirements of the Directive if their elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to therein is technically or scientifically impracticable, or where the negative environmental, health and/or consumer safety impacts caused by substitution are likely to outweigh the environmental, health and/or consumer safety benefits thereof;

Article 5c requires that at least every fourth year or four years after an item has been added to the Annex a review is to take place to consider the deletion of materials and components of EEE from the Annex, if their elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to in Article 4(1) is technically or scientifically possible, provided that the negative environmental, health and/or consumer safety impacts caused by substitution do not outweigh the possible environmental, health and/or consumer safety benefits thereof.

Substitution Plan under REACH

An application for an authorisation shall include a technical and economic feasibility of substitution and if appropriate, information about any relevant research and development activities by the applicant. When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures and the technical and economic feasibility of alternatives for the applicant.

Where the analysis shows that suitable alternatives are available, a substitution plan including a timetable for proposed actions by the applicant is required. In its review decision the Commission may, if circumstances have changed and taking into account the principle of proportionality, amend or withdraw the authorisation. Authorisations are subject to a time-limited review and are normally subject to conditions, including monitoring. Authorisations may be reviewed at any time if the circumstances of the original authorisation have changed (risks or socio-economic impact) or if new information on possible substitutes becomes available. In its review the Commission may amend or withdraw the authorisation. In cases where there is a serious and immediate risk for human health or the environment, the Commission may suspend the authorisation pending the review.

7.1.2. ISSUES/PROBLEMS TO EXPLORE

- **Exemption Process**

It is important to understand the current exemption process in assessing the impacts of a mandatory substitution plan.

The increasing number of exemption requests

As a consequence of the expanding list of exemptions and the potential for withdrawing exemptions, the list of exemptions is no longer stable, leading to a situation of uncertainty. Furthermore, there have been a number of repeated requests for exemptions which have already been denied, as well as requests for more specialised applications which cover limited numbers of products. The reason for this is that companies are not aware what type of exemption applications are in the pipeline or have been earlier declined. This constant submission of applications for exemptions makes the Directive less effective in achieving its environmental objectives and could reduce the level of incentives for industry to concentrate on research and development of alternative products.[74]

Currently there are no guidelines available on how an applicant can find out at what stage an application is. The lack of easily available information on submitted exemption applications does not only increase the number of exemption requests but makes it difficult for companies to plan ahead.

Design of a request for exemption

According to the ARCADIS & RPA report respondents (based on a sample of 17 companies) indicate the design of a request for exemption as the most important activity related to exemption procedures. The length of the decision-making process and the withdrawal of an existing exemption are perceived as much less important. Furthermore, facing the need to provide technical evidence, it was highlighted that

[74] Bogaert, S., Van Acoleyen, M., Van Tomme, I., De Smet, L., Fleet, D. and Salado, R. (2008) Study on RoHS and WEEE Directives. By ARCADIS & RPA for the DG ENTR, European Commission.

dealing with exemption procedures requires a lot of internal communication as well as the management of legal uncertainty on definitions for which legal services may need to be used.

Length of the decision-making process

Trade associations mention the long waiting periods between a request for exemption and the decision. Furthermore, they mention the lack of communication to industry during this process. Products awaiting approval are not allowed to be put on the EU market, which hinders competitiveness. In some cases, uncertainty remains, despite the complete handling of an exemption request.

During a RoHS workshop organised by BERR on 26 October 2007 on the RoHS exemptions process, applicants complained that they have experienced long periods of uncertainty with no indications of progress. At the same time the Commission has found it difficult to reach decisions because of the technical complexity of many of the requests. Also the possibility of the creation a notified body (funded by the applicant), to review exemption requests, was discussed during the meeting. It was argued that this would shorten the time for applications.[75]

During the TAC meeting in July in 2007 the UK expressed concerns over the length of time it takes to process exemption requests with some being still unresolved after nearly two years.

Comments within in response to the Second Consultation

Many of those respondents to the second consultation, who opposed the shifting of the burden of proof and costs towards the industry referred to the comitology process. It was argued that the Commission, along with the Member States, has the overall responsibility for resource and financial management of the exemption process. The other occurring argument against this proposal was the "already high costs for the industry to manage the Directive". JMC for Trade and Investment in Japan assumed it would become more difficult to ensure fairness, transparency and accountability to every business due to the influence of the interests of individual sectors. NEMA (National Electrical Manufacturers Association) also pointed out that there are already administrative and resource costs associated with the exemption process.

Those in favour of the shift of costs and burden of proof towards the industry referred to the polluter pays principle and the speeding up of the exemption process. SFT Norway (Pollution Control Authority) argued that it is the industry and not the Member States that should assume the burden of proof and the cost of quality-checking the application. The Ministry of Environment of Finland felt that it is currently very simple for companies to send the exemption request and some companies are sending the same applications again to the Commission after the request has be rejected.

[75] http://www.era.co.uk/news/rfa_feature_16d.asp

Substitutions

According to a number of stakeholders, not only the issue of technology availability is valid. There is a time gap between the availability of a substitute and the RoHS conformity of an EEE. When the substitute becomes available in the beginning of the supply chain, it takes considerable time before it arrives in the end product and the product is considered free of RoHS substances. Therefore, industry argues that there should be a sufficient buffer period between the arrival of a substitute and the abolishment of an item from the annex of exemptions. This period may however not be too long, because it is not intended for using up an existing stock of supplies containing RoHS substances.[76]

Whilst these hazardous substances are still allowed under exemptions, the ARCADIS & RPA report finds it difficult to ascertain how much effort and investment companies will put into the development of alternative products with less environmentally damaging substances.

Initially, the Commission intended the review and evaluation work to be carried out only on the basis of the documentation available from the applicant as well as from documents made available by stakeholders during the public stakeholder consultations (this is the mandate which the contractor has been given). This is not realistic and it has appeared to be impossible if a sound recommendation shall be given. In several cases it would have resulted in positive recommendations for exemption requests, where RoHS-compliant solutions are available. In other cases, there was a suspect or even hints that RoHS-compliant solutions are available, but the time and budget restrictions of the contractor did not allow further investigations.[77] Consequently a mandatory substitution plan might alleviate the workload of those reviewing the exemption applications.

ITIR points out that any measures addressing the technical feasibility of an alternative within a substitution plan would be based on the reliability of the data, which could be interpreted in different ways. Hence ITRI emphasises the importance of a robust approach for any alternatives in substitution plan.

Comments within in response to the Second Consultation

Those respondents who were against substitution plans did not provide any reasoning for their opposition. Eucomed was of the opinion that possible substitution plans could be introduced at a later stage.

EPPA supported substitution plan as the requirement to provide a substitution plan when requesting an exemption is already applicable in practice. It also pointed out that

[76] Bogaert, S., Van Acoleyen, M., Van Tomme, I., De Smet, L., Fleet, D. and Salado, R. (2008) Study on RoHS and WEEE Directives. By ARCADIS & RPA for the DG ENTR, European Commission.

[77] Öko-Institut and IZM (2007), *Adaptation to scientific and technical progress under Directive 2002/95/EC*, Final Report. Freiburg 22 October 2008.

this is also in line with requirements under REACH. The Federal Government of Belgium supported substitution plans as it would make the exemption process more transparent.

7.2 POLICY OPTIONS

The Commission has not specified what might be included in a substitution plan. This section aims to explain what is understood by a substitution plan and hot the distinction between a light and comprehensive substitution as policy options have been made.

Under a REACH Technical Assistance contract with DG Enterprise and Industry, RPA consultants were commissioned to provide technical support and targeted advice to the appraisals of various REACH provisions. The report looks at the relationship between the identification of alternatives (as part of the authorisation procedure) and the substitution plan. Substitution is defined in the report as replacement of one chemical with another, where this replacement can be undertaken with little reformulation required in order to deliver the desired functionality. The report gives also a broader definition for substitution, which also covers the adoption of an alternative technology or product which involves no reliance on the chemical of concern.

The report identifies two potential starting points for developing a substitution plan. The first is when the analysis of alternatives is unable to clearly identify a technically feasible alternative. In this case, the substitution plan is likely to focus on the R&D required to identify potential alternatives amongst those substances not yet analysed or to develop a new substance, processing method or product. When a technically feasible alternative is identified, then there would need to be a further round of time planning with regard to its adoption. The second starting point is when suitable alternatives have been identified. In this case, the substitution plan would be aimed at undertaking any further R&D required and setting out the time frame for adoption of the alternative(s). Thus, in identifying the costs associated with a mandatory requirement for substitution plans in all cases, it is important to separate out what would be undertaken for the analysis of alternatives as opposed to the substitution plan.

The analysis of alternatives is not described as part of the substitution plan under REACH. Instead the analysis of alternatives is the stage that triggers the requirement for a substitution plan (in case alternatives do exist). Consequently the “second starting point” in the RPA report is normally the stage that follows the identification of alternatives under REACH, and hence not always a starting point but the next step. However, even if the “analysis of alternatives” is not part of the substitution plan under REACH, it is clear that they are very closely linked and overlap. Because of this relationship between “analysis of alternatives” and the “adaptation of a substitution plan”, it is important to decide to what level and detail applicants are required to focus on analysis and/or adaptation.

It is suggested that the "light" version of a substitution plan would cover a basic analysis of alternatives and the "full" version of a substitution plan would cover a comprehensive analysis of alternatives with both versions covering the same adaptation requirements.

We have also added to the "light" ad "full" options the requirement of a maximum validity period of granted exemptions of four years, as options 3 and 5.

Option 1: Business-as-usual – exemption processes remain as they are

Option 2: Introduction of a basic "light" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS.

Option 3: Introduction of a basic "light" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS with a maximum validity period of 4 years for granted exemptions.

Option 4: Introduction of a comprehensive "full" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS.

Option 5: Introduction of a comprehensive "full" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS with a maximum validity period of 4 years for granted exemptions.

7.3 PROS & CONS

The information collected on the likely impacts is based on research on the cost and benefits of REACH substitution plans as well as the ARCADIS & RPA report. Valuable information about the exemption process was obtained from Otmar Deubzer, technical evaluator of exemption request at IZM .

Note that any costs or benefits linked to a substitution plan are only indicative as they are highly dependent on what substance/process is being substituted and the specific requirements of the substitution plan.

Option 1: Business-as-usual i.e. non-action

Pros:

- The current lack of a mandatory substitution plan may be beneficial for some applicants who are able to use the flexibility within the system in a creative way. The maintenance of current status quo might also be perceived by the industry as a way to avoid any further administrative burdens through mandatory substitution plans, even if the submission of similar information to a substitution plan is already necessary during the exemption process.

Cons:

- It is unclear to what detail one has to assess any alternatives. The system where the "substitution plan" is not legally required means that the reviewers have to chase this information from the applicant.

Option 2: Introduction of a basic "light" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS.

Pros:

- Would clarify the requirements of what is required under the analysis of alternatives and the adaptation to these. It would lessen the administrative burden of the reviewers and might also reduce the administrative burden for industry as a consequence of not having to correspond in an ad hoc manner to requests of providing information, which now would be included in the substitution plan.

Cons:

- In some cases, depending on the criteria used, the administrative burden for some companies might increase.
- The light substitution plan might not be sufficient to move from a risk reduction approach to a hazard reduction approach.
- The option would be unable to address the other procedural problems linked to the exemptions.

Option 3: : Introduction of a basic "light" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS with a maximum validity period of 4 years for granted exemptions.

Pros:

- The addition of maximum validity period of 4 years for granted exemptions are likely to increase the effort by industry to identify alternatives. It would also be a further incentive to continue their research for alternatives after an exemption has been granted and would enhance innovation in the long run.
- There is a possibility that the 4 year maximum validity period would complement the "light" substitution plan by encouraging further analysis of alternatives (this is not necessarily the case, see also Cons).

Cons:

- Likely to increase funds required for R&D in the short term and might favour larger companies who are capable to release funds for this,
- As the "light" substitution plan is less focused on alternatives and more on adaptation, it might be less suitable to be combined with the 4 year maximum validity period.

Option 4: Introduction of a comprehensive "full" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS.

Pros:

- The greater focus on the analysis of alternatives would increase innovation and move the onus from the reduction of risks towards the elimination of risks. It is likely to reduce the administrative burden of the technical experts

reviewing the exemptions. This approach would potentially provide for greater consistency and coordination with processes under REACH and possible efficiency gains over time in terms of completing substitution plans.

Cons:

- Likely to increase the administrative burden for industry as well as require greater investments towards R & D in the short term. It would be unable to address the other procedural problems linked to the exemptions.

Option 5: Introduction of a comprehensive "full" substitution plan with set criteria based on the requirements of REACH but adapted to RoHS with a maximum validity period of 4 years for granted exemptions.

Pros:

- The addition of maximum validity period of 4 years for granted exemptions would fit well with the greater emphasis on the analysis of alternatives within this option. It would also be a further incentive to continue the research for alternatives after an exemption has been granted and would enhance innovation. It would further reduce the impact of the hazardous substances covered by RoHS on the environment and human health. It is likely to reduce the administrative burden of the technical experts reviewing the exemptions.

Cons:

- Likely to increase the administrative burden for industry as well as require greater investments towards R & D.
- This option would be unable to address the other procedural problems linked to the exemptions.

7.4 ANALYSIS OF OPTIONS

Table 28 below presents a summary of options' analysis in the form of a matrix in order to compare the advantages and disadvantages of each option.

Table 28 – Summary of assessed impacts

	Option 1	Option 2	Option 3	Option 4	Option 5
Environmental impacts					
Level of use of hazardous substances	0 to -	0 to +	+	+ to ++	++
Level of environmental protection/improvement	0 to -	0 to +	+	+ to ++	++
Economic impacts					
Firms: costs[78]	-	-	- to --	--	--
Firms: competitiveness (internal & external market)	0 to +	+	+ to ++	++	++
Innovation and research	0 to +	+	++	++ to +++	++ to +++
Public authorities (budget; resources)	-	0 to +	+	++	++
Social Issues					
Impact on consumers (availability / price)	0 to -	0 to -	-	- to --	- to --
Public health and safety	0 to -	0 to +	+	+ to ++	++
Other Impacts					
Clarity and consistency (e.g. with other legislation)	-	+	+	+	+
Practical workability and enforceability	-	+	+	+	+

ENVIRONMENTAL IMPACTS

The earlier mentioned RPA report argues that if substitution is strictly defined as the replacement of hazardous substances in products and processes by less hazardous or non-hazardous substances, then this is equivalent to adopting a hazard based approach to chemical risk management. Consequently, the more weight is placed on the substitution plan within the authorisation procedure, the greater the extent to which the authorisation procedure will become based on hazard reduction rather than on risk reduction. In other words it would move the focus from managing risks to removing them. It is therefore likely that a requirement of a substitution plan as part of the RoHS exemption procedure would reduce the negative impacts on the environment and health. However, there might be some secondary impacts that are not beneficial for the environment. A literature review was performed as part of the ARCADIS & RPA study to look into the effects of Pb substitution in solders. The report concludes that substitution of Pb in solders by other substances (lead-free solders) could also have negative environmental effects, besides the positive environmental effects of Pb substitution, such as greater energy use.

[78] Short term costs

The REACH Implementation Project 3.9-1[79] addresses questions that may help determine the importance of considering indirect environmental and human health effects from the adoption of substitutes. These are:

- Could adoption of the substitute result in increased dependence on a scarce raw material?
- Could it lead to significant changes in the usage of other inputs, such as energy or water?
- Could adoption of the substitute lead to a shift in risks across life-cycles?
- Could adoption of the substitute lead to changes in effluent or waste treatment requirements?
- Could adoption of the substitute lead to changes in worker protection requirements?
- Could adoption of the substitute lead to changes in the final disposal requirements?

From the above it is evident that any environmental impact is highly dependent on the hazardous substance in question but it is likely that options 4 and 5 are the most beneficial for the environment.

Social Issues

According to the RPA study companies may or may not be able to pass changes in costs on to their customers (or may decide to retain the benefits) and it may be especially difficult for companies to pass on increases in costs where global competition prevents a company from being able to do this while still retaining its market share. In such cases, companies may experience reduced profits or may be forced to withdraw from a market. In other cases, companies will raise the price of their output to downstream customers. The significance of any changes in the costs of a chemical or product to downstream users or consumers will depend on the nature of the chemical under investigation. It is assumed that the impacts on consumers correlate more or less with the short term costs incurred on industry but are likely to be reduced when/if these measures lead to innovation, successful substitutions and a competitive edge.

Economic Impacts

Ten companies have given quantitative information on costs and/or time spent for exemption procedure activities. Costs made for exemption procedures make up only about 1% of total costs related to RoHS. However, absolute figures can be important. Concerning the costs related to or resulting from exemption measures, two different cost margins can be distinguished. On the one hand, total costs are given in a range of € 100 - 1000. Other companies state having incurred total costs between € 20,000 -

[79] Postle, M. Salado R. Bradley, P. Irpola, E. Salonen, H. 2006 *Reach Implementation Project3.9.1*, DG Joint Research Centre, European Commission

2,000,000 spread over several years. We tend to believe that the first group of companies only refers to the costs of the exemption handling, without the process of technical evidence collection which is included in the second range. Unfortunately, this could not be confirmed through individual contacts.[80]

The cost of the technical evaluation of exemptions conducted by the Öko-Institut and IZM varies from couple of days to couple of weeks, depending on the exemption.[81]

The RPA report identifies three different levels, reflecting the level of effort that might be put into the technical, cost and risk assessments carried out as part of an analysis of alternatives. These are described below:

Level 1 – Basic analysis: using readily available information and discussions with users but no further investigations or research into alternatives;

Level 2 – Detailed analysis: using readily available information, discussions with users, and additional research aimed at identifying alternatives and collecting information on the implications of their adoption; scope would cover alternatives available on the market in the EU and elsewhere, and those under development;

Level 3 – In-depth analysis: as for Level 2, although this level may also include the use of downstream user questionnaires or some modelling with regard to both the cost and hazard/risk assessment activities; it would also involve a more detailed consideration of alternatives likely to come to the market in the near future (i.e. in the next 2 to 3 years). Some may also expand the type of assessment carried out at this level to consideration of the life-cycle environmental and social impacts associated with the adoption of alternatives. The report points out that those making applications for authorisations may adopt an approach which involves different levels of detail for different aspects of their analysis.

Here level 1 could correspond to option 1, level 2 to options 2 and 3, and level 3 to options 4 and 5.

The resulting Table 29 below sets out a matrix of possible combinations of these aspects and the associated costs based on an average fee rate of €875 per day (in line with the assumptions of the extended Impact Assessment of REACH). These cost estimates are based on the consultants experience in preparing Risk Reduction Strategies under the Existing Substances Regulation, translated to the context of authorisations. The three aspects distinguished in the table are the assessment of technical feasibility; the cost assessment; and the assessment of the human health and environmental hazards posed by the alternatives, respectively.

[80] Bogaert, S., Van Acoleyen, M., Van Tomme, I., De Smet, L., Fleet, D. and Salado, R. (2008) Study on RoHS and WEEE Directives. By ARCADIS & RPA for the DG ENTR, European Commission.

[81] Communication with Otmar Deubzer, technical evaluator at IZM

Table 29 - Costs of analysis of alternatives at different levels of detail

Level of detail	Technical	Costs of Alternatives	HH & Env Hazard/Risk	Total
Level 1	€ 875	€ 1 750	€ 1 750	€ 4 375
Level 2	€ 2 188	€ 8 750	€ 10 938	€ 21 875
Level 3	€ 8 750	€ 35 000	€ 13 125	€ 56 875

These cost estimates are based on RPA's experience in preparing Risk Reduction Strategies under the Existing Substances Regulation, translated to the context of authorisations.

The RPA report states that in cases where an alternative was identified during the analysis of alternatives, and where the supply chain effects are straightforward, it may be possible to prepare a substitution plan in days. But in cases where clear alternatives have not been identified, and the supply chain effects could be significant, developing the plan may take several person months. Based on this the report estimates that the costs of preparing a substitution plan may be an average of similar magnitude or greater to those quoted for an analysis of alternatives. And finally, the costs will depend on what is required by the substitution plan and to what detail.

Some of the costs (or savings in them) may not be immediately obvious but may nevertheless be significant. One example is the effect that regulations may have on innovation by reducing the options open to a company as part of new product or process development. Other examples are the costs associated with staff training, changes in administrative systems, and changes in product labelling requirements. The adoption of a less 'hazardous' substance may lead to a reduction in costs, i.e. due to the substitute technologies being more efficient with regard to their use of certain inputs (raw materials, recycling of materials, energy, etc.).

The approach proposed to utilising substitution planning techniques developed under REACH (as proposed in options 3 through 5) within ROHS may lead to costs, however, these will potentially be tempered by the complementarity of the systems under the linked measures leading to efficiency gains. ROHS manufacturers may potentially be required to submit substitution plans under REACH for substances not yet covered by ROHS – but potentially will be in future – easing the burden over time of introducing further measures. As REACH is steadily implemented the approaches and requirements set out will naturally permeate the EEE industry and require manufactures to develop substitution plans and approaches etc. It is therefore, potentially efficient to ensure that these complementary regimes have compatible and reinforcing enforcement mechanisms generating time savings in the longer term for both industry and potentially overseeing authorities.

Consequently it is very difficult to estimate the overall cost/benefits in the long run. As a result the costs for industry in the assessment table are assessed as short term costs and the possible benefits in the long term are covered by impacts on competitiveness and innovation.

7.5 SUMMARY

For the purpose of this IA we divided substitution plans into two versions; light and full. It is suggested that the "light" version of a substitution plan would cover a basic analysis of alternatives and the "full" version of a substitution plan would cover a comprehensive analysis of alternatives with both versions covering the same adaptation requirements.

We have also added to the "light" ad "full" options the requirement of a maximum validity period of granted exemptions of four years.

Based on the analysis the options 3-5 seem most promising. However, any costs or benefits linked to a substitution plan are only indicative as they are highly dependent on what substance/process is being substituted and the specific requirements of the substitution plan. It has also become clear that the relationship between "analysis of alternatives" and the "adaptation of a substitution plan" are closely linked and it is important to decide to what level and detail applicants are required to focus on analysis and/or adaptation before more detailed estimations of impacts can be made.

8. FACT SHEET ON THE INCLUSION OF CONFORMITY ASSESSMENT PROCEDURES

8.1 ISSUE

Issue/problem addressed:

A lack of a formal compliance assessment approach under the RoHS Directive has led to different interpretations of some aspects of the Directive across Member States. This in turn has resulted in difficulties related to the free movement of goods, uncertainty for manufacturers and additional costs due to differing requirements for demonstrating compliance. Importantly and fundamentally, without formal compliance assessment procedures it is impossible to ensure that product on the EU market place comply with the requirements of ROHS hence, that the environment and human health are protected. The latter is essential as good law making is more than simply setting out rules to be followed it requires their effective implementation to deliver the desired change.

Background:

The Directive does not set any requirements for compliance documentation or the compliance and enforcement process. This is partly a consequence of the Directive having originally been conceived as an element of the WEEE Directive. Consequently there is a lack of standardised approaches across Europe to the monitoring of ROHS implementation making it impossible to identify compliance with the law and ensure that the environment and human health are protected effectively.

Options and summary of analysis:

There is clearly a need to alter the approach to ensuring compliance under the Directive as this is leading to significant barriers, costs and problems. The assessment of the Business as Usual option identifies potentially negative impacts environmentally, in terms of costs and competitiveness of industry and socially associated with health and safety and consumer confidence. There are two alternatives options to the BAU outlined these are:

- Option 2 - Self Declaration by producers – based on the presumption of compliance and supported by effective reporting by producers, systems for checking of suppliers and a robust approach to market surveillance
- Option 3 – Third Party Verification – essentially requiring upfront assessment before a product can be allowed access to the market place with producers paying for the services

The conclusions of this research are that both could potentially lead to an improved system of conformity assessment. However, their effectiveness would fundamentally depend upon a robust and transparent approach to implementation, adequate checks to ensure the systems in place are effective and resources. Importantly the difference in terms of impact from the BAU will vary across the EU given that different approaches adopted in Member States.

Self declaration is the option preferred by industry and most closely reflects the approaches adopted in many of the leading Member States. This would require limited burden to be placed on businesses but potentially would require significant public resources to review efforts and also ensure in parallel a rigorous market surveillance system. Importantly, in order for market surveillance to be delivered effectively the requirements for industry must be consistent across all Member States and the approaches to checking of supplier information and good practice clearly defined.

8.1.1. CURRENT PRACTICE/SITUATION

The RoHS Directive (2002/95/EC) does not prescribe any requirements regarding the use of compliance documentation that needs to be maintained by operators or Member States nor more broadly concerning the compliance and enforcement process[82]. At present the Directive simply states in Article 4 that:

'Member States shall ensure that, from 1 July 2006, new electrical and electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE). National measures restricting or prohibiting the use of these substances in electrical and electronic equipment which were adopted in line with Community legislation before the adoption of this Directive may be maintained until 1 July 2006.'

As a consequence of this lack there are no standardised approaches across Europe to ensuring compliance under the Directive with a multitude of approaches emerging on an ad-hoc, Member State led basis. This causes problems given the nature of the EU market place, potentially distorting trade across the internal market. Fundamentally it means that there is no mechanism for ensuring the goals of the ROHS Directive are being met in practice i.e. that the bans on the content of EEE are being enacted.

In response to these difficulties, in 2006, non binding guidance was adopted by the EU ROHS Enforcement Authorities Informal Network. This was intended to:

- assist Member States with national enforcement of the RoHS Directive; and
- provide clarity to industry on how producers may demonstrate compliance with its requirements.

It was also intended to become part of a wider, voluntary initiative to develop administrative co-operation between those Member State enforcement authorities that have responsibility for the implementation of the RoHS Directive. The guidance starts from the principle that under RoHS there is a 'presumption of conformity' i.e. that producers are operating in line with the prescribed bans and do not have to prove this before their produce enters the market, and that self declaration from producers is the

[82] RoHS Enforcement Guidance Document, Version 1 – issued May 2006, EU RoHS Enforcement Authorities Informal Network

key enforcement process. The figure below sets out the compliance process as prescribed in the guidance. The guidance also then goes on to set out sampling methodologies and the types of documents that need to be held.

The document appears to have received widespread support, according to the ARCADIS & RPA work, from Member States and interviews with enforcement officials conducted by Martin et al revealed that Denmark, The Netherlands, Estonia, Finland, France, Hungary, Slovakia, Slovenia and UK all intended to fully or partially follow the document when implementing market surveillance systems. (At the time of interviewing by Martin et al, officials from other countries were unable to confirm whether or not they would be following the guidance).

Examining the conformity systems established in different Member States reveals that there are definite differences in the approach taken by different authorities. Note that the ARCADIS & RPA report contains some limited analysis of approaches in Member States.

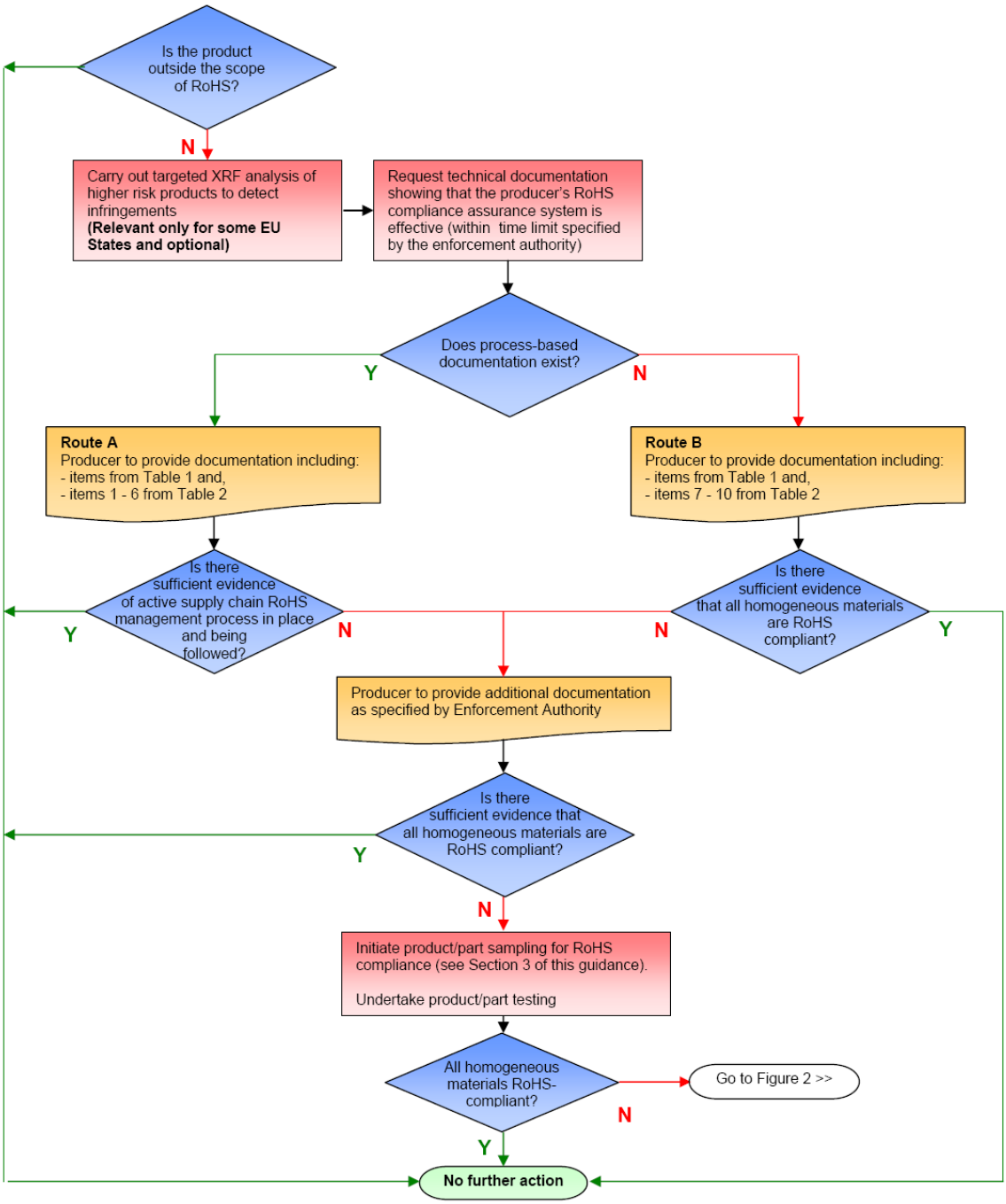

Figure 14 - Flow chart for RoHS Compliance Assessment Using Documentation

8.1.2. ISSUES/PROBLEMS TO EXPLORE

Detailed information is supplied below regarding the issues. However, in summary research appears to show that compliance requirements are currently uncertain with differences in approach across Member States. This leads to difficulties in terms of the free movement of goods, uncertainty for manufacturers and additional costs due to differing requirements for demonstrating compliance.

Fundamentally, the lack of a compliance mechanism means that there is no clear way of ensuring that the Directive is effectively implemented. It is considered to be ineffective policy making to put in place requirements but with no means of proving compliance and this leads to difficulties for industry and governments. For any EU legislative measure to be effective it must be properly transposed by Member States, implemented and then compliance with measures must be ensured. The lack of a clear approach to this had lead to some of the challenges associated with ROHS.

In terms of costs associated with the implementation of the RoHS Directive the ARCADIS & RPA work highlights the compliance costs, which are particularly associated with the proof of conformity for homogeneous materials within EEE. The ARCADIS & RPA report recommends specific options for amending the Directive in relation to addressing the approach to "homogeneous materials" (materials of uniform composition). Currently enforcement authorities in different Member States apply different methods of testing and analysis in relation to the composition of homogeneous materials. This is a potential area for internal market distortions since it might be possible that the same product, being tested under different methods in different countries, might be deemed in compliance in one Member State but not in the other.

The challenge of regulating products in Europe

As set out in the IA on the marketing of products, legislation can only achieve its objectives if it is effectively enforced. The IA highlights that the enforcement of EU product legislation is generally acknowledged to be unsatisfactory and a considerable number of non-compliant (and potentially dangerous) products reach the market. The share of non-compliant products can only be estimated and the situation differs very much from sector to sector and from Member State to Member State. Nevertheless, the available information[83] indicates that a significant proportion of the products on the market do not comply with the legal requirements. In 2004, in Germany as many as 33% industrial products were found not to be in conformity with the legislation and the market surveillance authorities were unable to identify the country of origin of 35% of these products.[84]

It is commented in the IA on marketing of products that there is a further complexity in relation to the import of products; 'distributors do not sufficiently check the conformity of the products which they are supplying and rely on the fact that this, is in principle, the task of the manufacturer. This is a particular problem in relation to imports from third countries. Manufacturers outside the EU are often less aware of the European legal requirements than European manufacturers. Furthermore, products manufactured outside the EU may not necessarily be intended for the European market and hence

83 In some sectors which are strongly concerned by this problem industry has carried out its own research, e.g. results of CELMA market surveillance forum, April 2006 – federation of luminaire manufacturers: http://www.celma.org/pages/CELMA%20Market%20Surveillance%20Forum%20L+B%202006.asp

84 Technische Überwachung Bd.47 (2006) Jan/Febr.

need not comply with European regulations. Therefore, it cannot be assumed that conformity to European legislation has already been guaranteed during the manufacturing process. Consequently importers must ensure that the manufacturer has actually complied with the European legislation'.

The challenge of a lack of compliance structure

According to the ARCADIS & RPA report the lack of established procedures to monitor and enforce the Directive has been found by Martin et al to be a potential barrier to trade across the internal market as Member States introduce different requirements and procedures. According to ARCADIS & RPA, interviews with representatives of Member States indicated differences in the expectations of officials responsible for enforcement with respect to evidence that producers will be expected to provide in order to demonstrate compliance.

Martin et al concluded that countries such as Portugal, Ireland, Germany, the Netherlands and Scandinavian countries have adopted stricter approaches than in other Member States, with officials indicating that producers are expected to compile and retain a variety of technical documents for their products. This being the case, they may also be obliged to produce different documentation and undergo different market surveillance procedures in each of the Member States where they are placing products on the market. For example, officials in Ireland indicated that producers would need to provide documented self certifications from their materials and component suppliers confirming that they were RoHS compliant. In Greece, Hungary and Latvia, producers are expected to provide corporate commitments to RoHS compliance in their registrations under the WEEE Directive. In Germany and Portugal, those officials interviewed for the study indicated that technical documentation in national languages will be required and producers are expected to use laboratories certified to international standards when they undertake destructive testing of their products to demonstrate RoHS compliance. Officials in Denmark, the Netherlands, Estonia, Finland, France, Hungary, Slovakia, Slovenia and the UK indicated that they would be adopting the approach of checking documentation in the first instance with testing being considered as a last resort.

The Martin et al study concludes that barriers to trade such as those illustrated above would be less likely to occur or be reduced if the RoHS Directive were to be based on the New Approach to technical harmonisation and standardisation. Directives based on the New Approach involve the development of harmonised standards which producers can follow in order to demonstrate compliance with the requirements of the Directive. The study points to the fact that whilst a number of standards have been developed for electrical and electronic equipment, RoHS enforcement officials in Member States still have the flexibility to choose which, if any, will apply in their own jurisdiction, thereby creating the possibility of technical barriers to trade. This will, of course have an influence over the technical documentation that producers may be required to produce to accompany their products in demonstrating compliance.

Research in Finland[85] into company level implementation of ROHS highlighted how, at present, companies rely heavily on assurances of compliance provided by materials and component suppliers and that the cost of materials component testing limits its use. It highlighted that the small size of electronics components and their complexity, in particular, cause testing problems. It has also been shown that different testing measures can produce very different results. The research does however, highlight that different approaches and practices for demonstrating and ensuring conformity are beginning to evolve (based on Mustonen 2005):

• Assurance from the component manufacturers or suppliers that the products do not contain forbidden substances beyond the established maximum concentration values. The assurance can be given in the form of a declaration of conformity or a materials safety data sheet (MSD).

• Product markings to prove conformity (labels, e.g. RoHS compliant or leadfree). The markings vary between companies since no official standards have yet been established.

• A certification of RoHS conformity by a third party that proves that the production can produce RoHS compatible materials and components.

• Testing of new components and random analysis of components in production.

Difficulties associated with the guidance on compliance

During their research ARCADIS & RPA identified several problems associated with the guidance document approach. Firstly, within the Directive itself there is no definition as to when a product is deemed to be 'put on the market', and this is not clarified further in the guidance. This leads to a situation whereby the scope of what is covered by the Directive is open to interpretation across Member States with the consequent implications for the functioning of the internal market outlined above. In addition, enforcement authorities in all Member States do not have limitless budgets to carry out market surveillance activities and, as a result, selective targeting will be the main method to verify the compliance status of products. The precise nature of implementation and criteria used in targeting strategies will be very influential in determining a level playing field at the Member State level, whereas significant differences may well have implications across the EU for the operation of the internal market.

There are concerns over the availability of infrastructure to carry out any detailed testing that might be required for targeted products. Additionally, with a lack of consistency over when and what testing should be used there will be higher costs associated with demonstrating compliance in Member States who place a greater emphasis on testing. This leads to a disincentive for companies to operate/enter into that market. According to ARCADIS & RPA work producers identified the cost of product

[85] Petrus Kautto and Anna Karna, Finnish Ministry of the Environment, Experiences on the implementation of environmental product policy in the Finnish electrical and electronics industry, 2006

compliance testing as one of the most significant factors in influencing whether they choose to place products on the market in a given country.

A further issue is that the guidance, by its very nature, is not compulsory. The title page of the guidance Document makes this clear by stating: “It should be noted that this document is informative and advisory, but has no legal authority. Individual Member State RoHS enforcement authorities are bound by their own national legal structures and can only apply this guidance within the confines of those structures.“

As long as the advisory actions and procedures included remain as guidance only there will be scope for different approaches to the implementation of market surveillance and conformity assessment procedures maintaining variation across Member States and the potential for distortions of the internal market. CECED (European Committee of Domestic Equipment Manufacturers), in a critique of the Guidance Document, generally welcomed the effort but stated that it would like to see a stronger emphasis on cooperative dialogue between national enforcement authorities and producers in establishing market surveillance procedures; arguing that such co-operation is essential for effective and uniform market surveillance.

CECED further stressed the guidance should make clear that requests for detailed documentation should only be made when enforcement authorities have “substantiated indications that a particular product does not comply with the requirements.” The document list described should be indicative only, CECED argues, since it may not be necessary in all cases to produce the complete set of documents in order to demonstrate conformity. An area of particular concern to CECED is that of testing and the fact that the Guidance Document leaves significant scope for ‘enforcement authorities in different member states to apply different methods of testing and analysis in relation to the composition of “homogeneous materials”’. This is a potential area for internal market distortions since it might be possible that the same product being tested under different methods in different countries might be deemed in compliance in one Member State but not in the other.

Orgalime has welcomed suggestions that there could be a greater harmonisation of compliance procedures across Member States and is in favour of “integrating a uniform mechanism for demonstrating compliance, including alternative mechanisms on the basis of accomplished work to minimize the risk of diverging interpretation practices in member states.” It also promotes the view that market surveillance procedures and tools across Europe should take into consideration work ongoing at the IEC13 level, since producers of EEE are operating in global markets.

A further criticism of the guidance document is that it does not choose a position over which standards to apply. The document suggests that both producers and RoHS enforcement officials keep up to date with the different standards developed across the world in deciding which ones to apply. This inevitably creates administrative burden for producers and officials and will likely still lead to, and could even exacerbate, a situation where different standards are applied across the Community.

Stakeholder concerns and opinion on compliance assessment (taken from responses to the 2nd consultation on the ROHS review)

The second consultation posed the question of should compliance assessment be improved and if so what mechanism for demonstrating compliance is appropriate i.e. self assessment by industry or third party verification. There were mixed responses as to which approach to compliance assessment might be considered best practice. However, there was clearly a desire that the situation regarding compliance be addressed and clarified. A summary of the different views regarding the best approach to compliance assessment are set out below.

AeA Europe (American Electronics Association, Europe) stated that they consider the self certification approach currently employed to be satisfactory and that third party verification would only add complexity. Verification was also not considered to be acceptable across all product categories. AEA state they support the BERR (Department for Business, Enterprise and Regulatory Reform, UK government) RoHS Guidance Notes on taking a risk-based approach. Importantly, they highlight that BERR's guidance states that due diligence cannot expect analysis of every component/material as this would be unreasonable.

Amcham also comment that they do not consider third party verification to be appropriate for all sectors and that it would add complexity. However, they do support a more consistent approach to ensuring compliance and consider the lack of no clear compliance system is a current failing. They would like to see RoHS converted into a New Approach Directive. They also provide a detailed analysis on the existing problems due to the current lack of consistency in terms of compliance. Meanwhile, CECED (European Committee of Domestic Equipment Manufacturers) commented that they support ***the inclusion of a conformity assessment procedure into RoHS but one '****based on the* principle of "Presumption of Conformity" and self declaration of conformity'. They strongly advocate the use of *internal production* control without involvement of a third party. They oppose mandatory third party certification. JBCE (Japan Business Council in Europe) also support the application of the principle of conformity and the use of producer self declaration, rejecting verification. JEITA (Japan Electronics and Information Technology Industries Association) also feel the same way. JMC comment that if conformity assessment is to be clarified self declaration approaches should be strengthened. NEMA also feels the same way considering verification would add administrative burdens. However, Nokia supports third party verification as a starting point.

Several respondents favour the application of the presumption of conformity (EICTA and EPPA), along with an approach for self declaration. EPPA comments that this should be as per the manufacturer's due diligence process. It also commented that it is late in the policy cycle to be adding a new compliance approach. Ericsson also supports self declaration but specifically focused on processes rather than measurements.

Respondents were divided over the issue of adopting ROHS as a new approach Directive. Several respondents commented that they don't believe RoHS should become a New Approach Directive, as REACH is not one.

Meanwhile the NGOs clearly favour the introduction of conformity assessment and would favour third party verification. Meanwhile, SFT Norway comments that both self declaration and third party verification approaches would be a positive development. However, the MS enforcement authorities must have the right to challenge this i.e. check that compliance is indeed achieved.

More broadly questions were raised regarding the ability to appropriately test final product and assess compliance. Various respondents raised the issue that it is very difficult and costly to test a final EEE product for elicit substances once placed on the market. Meanwhile others commented that in fact it was impossible to ascertain conformity via end of pipe testing given the rules on homogeneous materials, you can prove non compliance but not compliance given that there are so many substances and potentially very small quantities in different components.

8.2 POLICY OPTIONS

Based on the research and discussions with the commission the following policy options have been identified

- **Option 1: Business-as-usual**

As per today this would mean that the current approach to conformity assessment would continue whereby there are no formalised requirements for assessment and enforcement under ROHS and any coordination between Member State approaches would be completed via informal channels i.e. enforcement best practice groups and non binding guidance.

- **Option 2: Self Declaration – based on the presumption of compliance and supported by effective reporting by producers, systems for checking of suppliers and a robust approach to market surveillance**

Option 2 as proposed is that self declaration be adopted as an approach to checking conformity. This would build on the most commonly used approaches to compliance assessment currently in operation – although in an uncoordinated manner. For this option to be robust there are certain caveats that need to be considered and addressed. These are set out below

Under this option EEE on the market place would be assumed to be in compliance with the Directive's requirements. Producers would have to declare to the authorities that there products are in compliance with the ROHS Directive. The validity of this statement would be based on assurances from all suppliers that materials, components and equipment do not contain any of the banned substances. Producers should assess the

validity of supplier statements by appropriate testing. Many consider it would be prohibitively expensive to test all component parts, however, in cases deemed as higher risk supplier statements should be checked by taking 'reasonable steps' to ensure compliance including a range of actions from lab based testing to discussions with suppliers to ensure quality procedures are in place[8687]. The risk associated with a given supplier could be assessed based upon for example: the stability of the relationship with the supplier; the risk of contaminants based on their processes and form of operation; the risks associated with potential contaminants; and the potential quantities of a product entering the market place[88] . Producers would need to keep a permanent record of the assurances received from suppliers and the checks undertaken in order to inform the authorities.

Reporting formats would need to be developed to be applied by Member States within which producers should set out their statement of compliance with the provisions of ROHS and the information upon which this is based. In house assurance procedures for ensuring adequate controls on suppliers hence contamination with hazardous substances should be set out. The quality and appropriateness of procedures and the information base should be assessed by regulators with recommendations for improvements made if necessary. There should be mechanisms built in to ensure that pressure is maintained to continue with good practice

The self declaration approach must be coupled with a robust and rigorous market surveillance approach. There should be a clear link between the compliance assessment process, as the market surveillance approach for example if concerns are raised regarding the nature of an organisations assurance process this should be investigated using market surveillance approaches. There needs to be a system whereby positive feedback is possible between the two approaches to ensure adequate environmental protection.

Option 3: Third Party verification

Under third party verification each producer's basis for declarations related to their compliance with ROHS's requirements would be independently assessed in order to ensure that this is accurate. Verifiers would review quality assurance and mechanisms

86 Further research and discussions relating to good practice approaches to ensuring adequate oversight of suppliers and what methods under what circumstances is considered to be reasonable are needed. A clear approach to this should be set out in order to avoid confusion and provide clarity for producers

87 Goodman et al. 2004 comment that Self-declaration is used for many of the EC New Approach Directives and would be appropriate even though RoHS is not a New Approach Directive. Two main approaches are available to producers: Obtain an assurance from suppliers that no banned substances are present. These could take many formats but ideally a permanent record will need to be kept allowing the producer to demonstrate due diligence; and carry out limited analysis to verify declarations; analysis of every component by all producers would be hugely expensive and can be considered rather unreasonable

88 Based on proposals within the ERA study on possible compliance approaches for Directive 2002/95/EC. Further elaboration of the list of risk factors needed to provide clarity for producers.

for ensuring supplier compliance with the requirements of the Directive to ensure that approaches adopted were rigorous and deliver products in compliance with ROHS. Essentially this would be an upfront assessment to determine if a product to be placed upon the market complies with ROHS's requirements. Verification would be undertaken periodically to ensure that standards of compliance were maintained.

Similar to approaches in the regulation of other product requirements a verifier would accredit a product as in compliance with requirements operating under the oversight of an accreditation body. Verifiers would charge producers for their services and access to the market would be denied unless compliance could be demonstrated to verifiers.

Third party verification can be established in a number of ways i.e. MS level, EU level etc. This could be based on one of the following methodologies:

I – Tiered approach with requirements varying depending upon the needs associated with different electrical products, hazardous substances and associated risks

II – EU wide standards for verification and accreditation bodies i.e. one scheme applicable in all Member States

III – Requirement for verification and key features set out in EU legislation but implemented at the Member State level with national approaches and by national accreditation bodies, similar to approaches set out in the market surveillance Regulation.

8.3 PROS & CONS

Option 1: Business-as-usual i.e. non-action

Pros:

- Requires no prescriptive changes at this stage in the implementation of a complex piece of legislation

Cons:

- Current situation means that there is no adequate approach to ensuring the compliance with the Directive undermining the achievement of the measures objectives and the protection of human health and the environment
- The current approach leads to a lack of clarity on the part of producers and regulators regarding which are the best methodologies to follow. This means that there is uncertainty within the market place
- As a consequence different Member States have adopted differing approaches to implementing the Directive potentially leading to additional costs and trade barriers within the internal market
- The current approach based on informal guidance is insufficient for ensuring consistent compliance across the EU.

Option 2: Use of Self Declaration combined with a presumption of compliance and regulatory oversight

Pros:

- There is a clear need to move to a more robust system for ensuring compliance with the Directive
- If appropriately included within the Directive with clear procedures and requirements set out this would provide clarity in the market place and a consistent approach to ensuring compliance with the Directives requirements and the achievement of its aims in a proportionate way.
- Self declaration appears to clearly be supported by industry as is the need to provide a better approach to ensuring compliance.
- Industry appears to consider costs associated to be acceptable in order to deliver the benefits of clarity and consistency in approach and reduce the need for understanding differing approaches to compliance assessment across the EU.

Cons:

- Unless accompanied by appropriate support procedures i.e. clarity regarding the documentation to be submitted, timing for submission, checks by regulators, robust and compatible approaches to market surveillance etc this may lead to little difference in terms of environmental protection and consistency in the market place when compared to the BAU. It should be noted that this may not need to be placed within the Directive at this stage but could perhaps be defined in comitology procedures or as binding guidelines from the Commission at a later date – as per the model of the EU ETS monitoring and reporting guidelines.
- There is still a reliance on industry taking the initiative, and an emphasis on trust in the systems in place within companies to deliver adequate protection with potentially little regulatory oversight.
- This will require approaches procedures for monitoring, checking and enforcing to be developed in all Member States to support self assessment and market surveillance. There are potentially increased costs for administrators, in particular those who do not have appropriate compliance assessment and market surveillance mechanisms in place.
- The ARCADIS & RPA work highlights ongoing concerns about the definition of homogeneous materials and terms such as put on the market. These will remain as difficulties under a renewed regime unless addressed separately during the review of the measure.

Option 3: Third Party Verification

Pros:

- There is a need to alter the current system to be improved
- Would provide a higher degree of independence regarding the compliance of products on the European market place and is supported by environmental

groups

- Potential for more rigorous checks on compliance by both producers and their suppliers
- May reduce the burden upon national regulators in terms of assessing compliance, self declared materials and the need to establish market surveillance.

Cons:

- Industry considers that this would add unnecessary costs and complexity to the system
- Unlikely to have industry support were it implemented
- Would require accreditation and verification infrastructure to be established potentially at significant cost and clarity as to how these might operate at an EU wide level. There is evidence from other product policy[89] that verification approaches can become corrupted as they are themselves operated as commercial activities and there is evidence of inconsistent standards and undercutting in terms of prices.
- A system of third party verification may be disproportionate to the compliance assessment needs
- Requires potential preconditions to be met in order to deliver effectively i.e. effective verification requires strong overseeing bodies i.e. accreditation bodies to ensure that verifiers are of an adequate standard and that verifiers approaches are continually improving
- Would still require many of the questions and problems set out under option 2 to be addressed.

8.4 ANALYSIS OF OPTIONS

Table below presents a summary of options' analysis in the form of a matrix in order to compare the advantages and disadvantages of each option.

Table 30 – Summary of assessed impacts

	Option 1: NO ACTION	Option 2: Self declaration	Option 3: third party verification
General impacts			
Legislative changes	N	Y	Y
Environmental impacts			
Level of use of hazardous substances	-- to 0	0 to ++	0 to ++
Level of environmental protection/improvement	-- to 0	0 to ++	0 to ++

[89] IA for the marketing of products package

Economic impacts			
Firms: costs	-- to 0	- to +	-- to -
Firms: competitiveness (internal & external market)	--	0 to ++	- to +
Innovation and research	--	0 to +	- to +
Public authorities (budget; resources)	- to 0	-- to 0	- to 0
Social Issues			
Employment and labour markets	-	0 to +	0 to +
Impact on consumers (availability / price)	0 to – over time in terms of value for money	0 to +	- to +
Public health and safety	-	0 to +	0 to +
Other Impacts			
Added value for the efficiency of regulation	--	+	+
Clarity and consistency (e.g. with other legislation)	---	+	+
Added value for stakeholders	N/A	N/A	N/A
Severity of barriers to be expected	0	-	--
Administrative effort	0	-	-
Practical workability and enforceability	---	+ to +++	+ to +++

8.4.1. General Impacts

Given the lack the inclusion of any wording within the ROHS Directive on the assessment of conformity and enforcement by Member States both options proposed to clarify this would require legislative change i.e. the amendment of the existing Directive. The extent to which, especially for option 2, new provisions are prescribed in the Directive itself or referenced in the Directive and set out in supporting binding guidelines drawn up at a later date can be adapted to ensure that the approach is achievable given existing timetables for the ROHS review and that necessary research is completed to ensure the most appropriate and workable approach is adopted for both regulators and industry.

8.4.2. Environmental Impacts

According to research by ARCADIS & RPA 'environmental supply chain management' improved a great deal because of ROHS. Accordingly communication massively increased across the supply chain, e.g. on materials data and this development complements the data needs for example under REACH and other product based measures. The achievement of ROHS's goals and associated environmental benefits can,

however, only be ensured when there is certainty over the compliance of products with the Directive. At present there is a lack of clarity over how compliance is assessed and whether this is adequate in many Member States to ensure the effective protection of the environment.

In terms of assessing the environmental impacts of the different options two specific subcategories were considered of relevance i.e. the level of use of hazardous substances and the level of environmental protection/improvement. The adoption of ROHS should have delivered both of these; however, without adequate compliance assessment it is impossible to establish whether it did in fact deliver on its promise. Additionally, a lack of a compliance assessment approach also leads to a lack of consistency in enforcement and a lowered 'fear of enforcement' reducing the inducements to comply with the Directive's requirements. For this reason it is considered that the adopting option 1 i.e. remaining with the BAU approach would either have no impact on the environment or over time it may have a negative impact. This is because as the threat of enforcement and the need to comply apparently recedes standards may fall leading to negative environmental impacts.

Both option 2 and 3 are believed to have a neutral to a substantial positive effect upon both reducing the use of hazardous substances and the level of environmental protection. The scales recognise that the beneficial impacts will vary depending upon how effectively the systems for implementing these options are designed, the ability to develop a European wide approach and importantly on the nature of conformity assessment currently being implemented in a specific Member State. The latter point recognises, as set out in the information above, that some Member States have already implemented approaches for dealing with conformity assessment while other approaches are less rigorous.

Both options 2 and 3, if implemented in a rigorous, transparent and consistent way should be able to deliver - if twinned with adequate enforcement action/market surveillance - better conformity assessment, more effective implementation of ROHS and better environmental protection. Option 3's obvious benefit over option 2 is that it delivers an additional level of independent oversight. The key for both options is, however, the approach to implementation. Verification approaches have been shown to be flawed under other product assessment regimes and so too have centralised regulator lead approaches. Option 2 should be able to deliver a rigorous system but this will rely on regulators having sufficient resources to deliver the required level of oversight, producer's in house systems for reviewing supplier information and assessing associated risks and the link to an effective market surveillance approach.

8.4.3. Economic Impacts

Research by ARCADIS & RPA identified that the cost of product compliance was considered to be the most important factor in determining where and whether to place a product on the market. Therefore, a consistent mechanism is necessary across all

Member States to ensure adequate access to market and to ensure costs and competition are comparable for all. The following sections examine the economic impacts of each option in detail.

For information and aiding interpretation of this assessment it should be noted that the IA of the Marketing of Products package states that "in general, the costs for conformity assessment are mainly determined by personnel costs, travelling costs and overhead for testing equipment. ... On average, conformity assessment costs constitute only 1% to 2% of the overall unit production costs (even less for large scale production)." Further information on costs of current practice is provided in the following section.

- **Business as usual**

At present there is a lack of consistency in approaches to compliance assessment across Europe potentially distorting trade (given the statements above) and causing inconsistent levels of costs for producers. The BAU approach in option 1 is therefore considered to be inappropriate with inconsistency potentially causing increased costs for business, impacting on competitiveness (as different companies may experience different market conditions) and potentially complicating the picture for enforcement authorities leading to excess costs. For this reason the impact of adopting the BAU option has been classed as predominately negative (although it may be neutral for some companies and Member States given the variability in the existing system). Importantly, the current system is deemed to have a negative impact on innovation as the inefficiency of the compliance assessment process may prevent new products entering the market place or limit the attention paid to new products designed with to achieve lower contaminant levels.

At present there is only an informal system of self declaration in place in Europe in order to systematically register and assess the compliance of ROHS placed upon the European market. There are also concerns that different notification bodies and Member State authorities adopt different approaches to assessing the conformity of products on the market place. This leads to costs for legitimate businesses, unfair and unbalance competition and a lack of compliance on the market place. There are resultant implications in terms of lost revenue for businesses and a danger that inappropriate and polluting products may enter the market place leading to costs associated with clean up operations etc.

During the implementation of ROHS thus far, according to research completed by ARCADIS & RPA, compliance costs have made up 67 per cent of the costs incurred by industry. This includes one off costs for registering products and also ongoing costs such as the provision of information on a regular basis. In a survey of 30 companies ARCADIS & RPA identified that in future of the total compliance costs 68 per cent are anticipated to be attributable to proving compliance i.e. collecting and reviewing information. This research also suggests that effort is currently split in terms of information and collection and review as per the figure below.

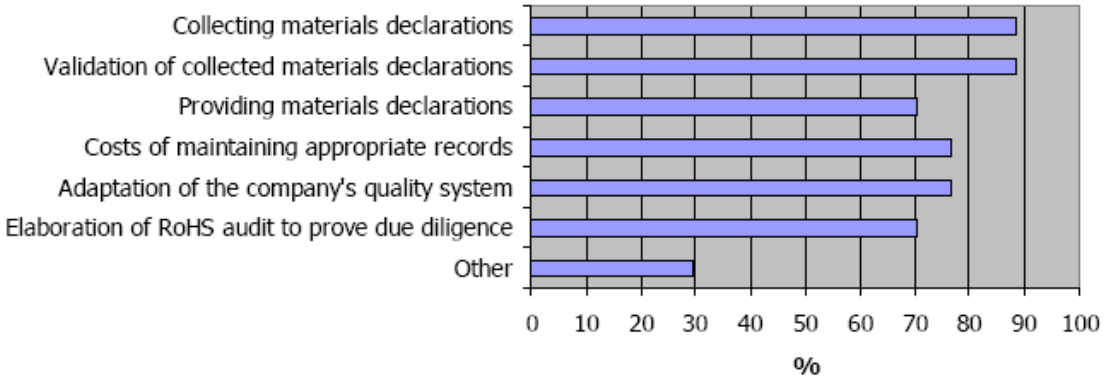

Figure 15 – Detail of activities related to collecting and reviewing of information on a sample of 20 companies

Additionally, ARCADIS & RPA have also estimated actual costs for time dedicated to collecting and reviewing information in relation to ROHS compliance, based on information from twenty three companies. Accordingly past costs and future one off costs were estimated to amount to a maximum of €35 million with an average of € 5.5 million and a weighted average of € 11.5 million. Future yearly costs amount to a maximum of € 3.5 million, with an average of € 1.1 million and a weighted average of € 550,000. Information on the personnel time spent collecting and reviewing information is estimated to lead to an equivalent of 0.20% of total personnel per company. This average drops to 0.03% when the expected yearly costs in the future are assessed. In absolute figures, on average approximately 8 full time employees per company will be dedicated globally in the future to collecting and reviewing information activities.

Option 2 – Self Declaration

Option 2 proposes a unified European approach to self declaration under ROHS be adopted across the EU. This would lead to greater standardisation and consistency. The impact on administrative costs for industry will depend on the information requirements set out under the new system and also the current baseline within their Member State(s) of operation. Overall, however, this approach would provide greater predictability of information needs. Additionally, it should streamline requirements as this would be consistent for all suppliers to the EU. This should mean that all suppliers and component manufacturers will be under greater pressure to provide information but requests will be more consistent. In turn, while this may initially lead to costs, over time the consistency should lead to a more streamlined and efficient process. For these reasons the impacts of self declaration on competitiveness and innovation have been deemed to be either neutral or positive – depending to the BAU under which the firm is operating. Costs to firms have been seen as potentially negative in the first instance, again depending upon current circumstance, ranging to positive impacts more widely particularly in the longer term.

Administrative costs should not only consider the costs to business but also to the public sector of implementing a given action. The impact of self declaration is considered to be relatively high for the public sector given the need the emphasis on implementing a robust and consistent approach across Europe. The costs are considered to be higher given the need for this to operate in tandem with an effective market surveillance approach. Again costs will of course vary depending upon the current regime applied within each Member State.

- **Option 3 – Third Party Verification**

For this analysis it is assumed that verification would be a cost additional to self declaration and/or the time and effort currently spent on the collation and review of information. This is because these processes would still have to be undertaken in a rigorous way in order to ensure that the verifiers could be provided with the appropriate information. As verification by third parties is not currently undertaken in relation to ROHS it is unclear the exact impact this would have both in terms of costs to industry, but also in terms of reduced burden for Member State authorities. There has been extensive experience under the EU ETS of third party verification and thus far the use of verification has not reduced the checks conducted by the competent authorities who continue to review compliance.

Third party assessment of products has been analysed within the IA supporting the marketing of products package. This is essentially the cost associated with getting a third party to verify that a product meets a certain standard. Research to support the IA noted that there is a considerable variation in the price of this service, between 30 and 70 per cent variability. The 'normal' cost of a conformity assessment was considered to be between €2500 and €3000, although some bodies offered the same service for as little as €500 – with evidence that these lower prices are associated with less stringent approaches to assessment. Third party verification under ROHS would probably be akin to that for third party assessment of other products. However, this would most likely vary depending exactly on the type and potential contaminants associated with a product. Annex 1. It was commented that if full testing of a finalised product under ROHS were required under third party verification these figures would be a major underestimate given the potential number of different elements and substances that might need to be tested.

In order to make a full assessment of the additional costs of verification it is necessary to understand how often verifiers would be required to assess compliance and the nature of the proposed methodologies. Some brief assessment of the potential sub approaches is set out below.

- Sub option 3I, would allow requirements to be more directly tailored to the specific needs of a particular product or group of products. This may lead to reduced costs for simple or lower risk products and may reduce costs of verification (compared to one standard approach) for certain elements of industry. Tailoring of requirements would help minimise any wasted administrative effort over time.

- Sub option 3 B, would lead to a totally consistent approach across the EU. It has been shown that implementation has varied thus far in terms of ROHS requirements and the application of third party assessment of products. Both have then resulted in distortions in trade and risks in terms of non compliance. An EU wide approach would provide overall consistency meaning that costs are comparable for all. It has been shown by experiences in terms of product policy and verification under the EU ETS that it is important to have consistent approaches across Europe to avoid confusion, ensure consistent standards and maintain the integrity of the market. However, there needs to be clarify over how this would be managed at an EU wide approach to avoid increasing bureaucracy.

- Sub option 3 C, would mean that Member States would develop their own approaches to third party verification under ROHS. This would seem to lead to increased administrative costs, as has been seen more widely from experiences relating to product policy more generally.

In conclusion the costs associated with verification are considered to potentially be significant for industry and additional to other ongoing activities. However, the impact on competitiveness has been classed as negative to positive. This will depend upon the balance of costs for verification compared to benefits in terms of consistency in approach and access to new markets. Additionally, there is a potential for positive feedbacks within the verification system if operated effectively allowing improvement and efficiency gains by producers. The impact on public authorities is considered to be from negative to neutral. This is because there will be costs associated with setting up a robust system. Meanwhile, however, this may reduce the burden upon them in terms of checking conformity.

8.4.4. Social Issues

The social impacts associated with amendments to the conformity assessment approach relate directly to job creation, consumer confidence and public health. The BAU approach (option 1) is considered to have a negative impact in relation to all three aspects. This is due to the negative impacts of a lack of consistency across the European market place and inadequate provisions to assess conformity. This may lead to a lack of consumer confidence and most importantly the endangering of health by unidentified non compliant products.

The adoption of self declaration is considered to have a neutral to positive impact on the labour market given the potential benefits of a more consistent internal market place assuming requirements are adequately implemented. Verification is consider neutral to positive for the same reasons, with the addition that the introduction of verification may require the establishment of new jobs to provide for the verification needs.

In terms of health and safety both are considered to have a neutral impact moving to positive assuming adequate implementation and the BAU conditions in the different Member States. In terms of impact on consumers self declaration's impact is considered to be neutral to positive as it is unlikely to impact on price but may increase availability

of products by opening up the internal market place. Meanwhile verifications impact is considered to be from negative to positive. The negativity is created by the potential increase in costs to producers associated with the verification process. Meanwhile the positive is generated by the perceived increase in independent oversight over the market place.

8.4.5. OTHER IMPACTS

Other impacts are central to this assessment. The BAU approach is inappropriate due to its failure to protect the environment and human health, but importantly due to its inconsistency and lack of clarity. Adopting both option 2 and 3 is considered for this reason to have a positive impact on the clarity and consistency of EU policy and increasing the efficiency of environmental regulation. There are considered to be greater barriers to implementing verification given the lack of industry support and also the failings of past approaches to third party assessment within the products field. Both options are considered to have a positive impact upon the workability and enforceability of the ROHS Directive and the strength of this positive impact will depend upon the effectiveness in terms of implementation.

Importantly, while many favour self declaration an additional knock on benefit of an effective verification regime should be noted. This is that this may in turn reduce the need for market surveillance and shift the burden of proof from regulators to producers.

8.5 CONCLUSIONS

There is clearly a need to alter the approach to ensuring compliance under the Directive as this is leading to significant barriers, costs and problems. The two key approaches for achieving this are self declaration by producers i.e. that there product complies with ROHS and third party verification to ensure a product complies. The former is based upon a presumption of conformity within the market place, while the latter would require conformity to be assessed. They are two fundamentally quite different approaches.

The conclusions of this research are that both could potentially lead to an improved system of conformity assessment. However, their effectiveness would fundamentally depend upon a robust and transparent approach to implementation, adequate checks to ensure the systems in place are effective and resources.

Self declaration is the preferred option by industry and most closely reflects the approaches adopted in many of the leading Member States. This would require limited burden to be placed on businesses but potentially would require significant public resources to review efforts and also ensure in parallel a rigorous market surveillance system. Importantly, in order for market surveillance to be delivered effectively the requirements for industry must be consistent across all Member States and the approaches to checking of supplier information and good practice clearly defined.

There is potentially an option whereby third party verification could be used as a constituent part of the self declaration process to review checks in place, identify if these are adequate and recommend improvements. This would however, need further investigation in terms of viability.

8.6 ANNEX TO THE FACT SHEET

Analysis on the costs of third party verification taken from the impact assessment on the marketing of products package

Within the impact assessment for the marketing of products package the issue of accreditation and third party assessment is discussed in detail. It is commented that:

'Feedback received from targeted surveys and studies[90] indicates that notified bodies often take different approaches in assessing the conformity of products with the legislation. Manufacturers have reported that the interpretation of safety requirements as well as procedural requirements vary significantly from body to body. Manufacturers can therefore shop around for the lowest price which is not always linked to the consistency of service.'

This argues towards having some centralised control over procedures for third party assessment, but also could be applied to assessment of self declared information i.e. that different bodies tend to take differing approaches when centralised guidance is absent. This may, however, be more pronounced for third party notification or verification bodies as this is a commercial activity meaning that there is competition between the different bodies.

In terms of the costs of third party notification or approval figures quoted in the IA for the products package are as follows:

'While a variation in price of up to 15% is usually considered as a standard competition situation, notified bodies reported cases of between 30% and 75% lower prices, whereas SMEs report an average variation of 48%.[91] Where a normal price for conformity assessment was approximately €2500-3000, the same services were offered by other bodies at €500. Hence there are strong indications that "dumping rates" or unrealistically low prices for services offered are frequently linked to a less stringent approach applied during the assessment. This could apply to fewer inspections or controls, cases of lax or incomplete testing, acceptance of test results from the manufacturer himself or acceptance of test results from another third party which itself does not adequately apply conformity assessment procedures.

Information from the responses to the questionnaire also informs us that notified bodies frequently lose projects or clients due to such unfair practices. They are, therefore, put

[90] E.g. Medical Devices: Report on the functioning of the medical devices directive, 2002

[91] Several SMEs replying to the SME test panel indicated that rates charged by notified bodies for comparable services vary throughout EU.

under market pressure to cut their costs. This results in a downward spiral in terms of both their turnover and their quality of service'.

9. FACT SHEET ON THE INTRODUCTION OF COST / BROADER SUSTAINABILITY CRITERIA FOR GRANTING EXEMPTIONS

9.1 ISSUE

Issue/problem addressed:

The argument being that sustainability is not just about the environmental and health impacts but ought to take into consideration economic and social costs as well.

Background:

Currently only environmental and health impacts are taking into consideration as criteria in the exemption process.

Options and summary of analysis:

Exemptions should be tailored to specific circumstances and justified on a case by case basis. There is a president for the inclusion of economic considerations into decisions aimed to meet an environmental end. Examples of such criteria are for example under the EU ETS Directive the provision of unreasonable cost is applied to monitoring requirements and the level at ambition that monitoring of a particular installation must achieve. Meanwhile provisions such as BATNEEC also take into consideration the practicability of achieving an environmental end based on economic costs. However, the appropriateness of the use of additional clauses will vary depending on the substances, their use and the nature of the product in question.

According to REACH an authorisation can still be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies.

This clause introduces an element whereby economics and practicability can be taken into account. However, it should be noted that this may weaken the environmental credentials of the exemption process. In addition concepts such as what costs are practicable or unreasonable are notoriously difficult to apply and leading to inconsistent application.

We do not feel that it is possible to assess the impacts of such an inclusion given the huge variety of circumstances that might be experienced and variability of substances being dealt with. It was therefore proposed that the approach to introducing costs/broader sustainability consideration in other measures would be examined in more detail along with the responses to the consultation document and how the issue has been dealt under REACH.

Based on this analysis it seems likely that any inclusion of socio-economic analysis into the exemption procedure would require a considerable increase in staff reviewing the quality of

the exemption applications as well as a considerable burden of proof and administrative costs for the industry, when submitting an exemption application based on socio-economic analysis.

9.1.1. CURRENT PRACTICE/SITUATION

Criteria for exemptions only take into account environmental and health criteria, not socio-economic issues.

9.1.2. ISSUES/PROBLEMS TO EXPLORE

Comments within in response to the Second Consultation

Many of the respondents were not quite clear with what was meant by broader sustainability criteria. EICTA (European Information and Communications Technology Industry Association) did not oppose to the introduction of broader criteria as such but would like to see a clear definition of the concept of "broader sustainability criteria".

EPPA strongly feels that integrating of economic, environmental and social aspects is very important to achieve balanced assessment. Orgalime (European Engineering Industries Association) also felt that this option would enhance consistency with REACH and EuP.

RREUSE (Re-use and Recycling European Union Social Enterprises) does not support this as it would make the exemption process very difficult, less transparent, open for subjective interpretations, etc. Also the SFT Norway (Norwegian Pollution Control Authority) opposes socio-economic criteria as it would create a very burdensome additional step which might take additional time.

9.2 POLICY OPTIONS

Exemptions should be tailored to specific circumstances and justified on a case by case basis. There is a president for the inclusion of economic considerations into decisions aimed to meet an environmental end. Examples of such criteria are for example under the EU ETS Directive the provision of unreasonable cost is applied to monitoring requirements and the level at ambition that monitoring of a particular installation must achieve. Meanwhile provisions such as BATNEEC also take into consideration the practicability of achieving an environmental end based on economic costs. However, the appropriateness of the use of additional clauses will vary depending on the substances, its use and the nature of the product in question.

According to REACH an authorisation can still be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies.

This clause introduces an element whereby economics and practicability can be taken into account. However, it should be noted that this may weaken the environmental credentials of the exemption process. In addition concepts such as what costs are practicable or unreasonable are notoriously difficult to apply and leading to inconsistent application.

We do not feel that it is possible to assess the impacts of such an inclusion given the huge variety of circumstances that might be experienced and variability of substances being dealt with. It is proposed that the approach to introducing costs/broader sustainability consideration in other measures be examined in more detail along with the responses to the consultation document. These will be used to develop a list of possible approaches and pros and cons. Also, we will consider how this issue was dealt with in the REACH impact assessment. However, a formal impact assessment is impractical at this stage.

9.3 ANALYSIS

Detailed Description of the Socio-Economic Analysis under REACH

Substances of very high concern are subject to authorisation by the Commission with regard to particular uses. The aim of the authorisation procedure is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations are required to analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

Once a substance is included in the system, those using or making available such a substance will need to apply for an authorisation for each use of the substance. The Commission is responsible for granting such authorisations. An authorisation is granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is considered to be *adequately controlled* in accordance with section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the Committee for Risk Assessment. When granting the authorisation the Commission will take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision. However, the adequate control route does not apply to certain compounds of very high concern, criteria of which are listed in the Directive.

If an authorisation cannot be granted under the adequate control route or for substances listed above, an authorisation may still be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from

the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of the following elements:

- the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;
- the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;
- the analysis of the alternatives submitted by the applicant or any substitution plan submitted by the applicant, and any third party contributions submitted; and available information on the risks to human health or the environment of any alternative substances or technologies

In addition the opinions of the Committee for Risk Assessment and the Committee for Socio-Economic Analysis have to be taken into account. When assessing whether suitable substances or technologies are available the Commission needs to consider whether the transfer to alternatives would result in a reduced overall risk and the technical and economic feasibility of alternatives for the applicant. Authorisations are subject to a time-limited review and shall normally be subject to conditions, including monitoring. Authorisations may be reviewed at any time if the circumstances of the original authorisation have changed (risks or socio-economic impact) or if new information on possible substitutes becomes available. In its review the Commission may amend or withdraw the authorisation. In cases where there is a serious and immediate risk for human health or the environment, the Commission may suspend the authorisation pending the review.

The above issues are part of the authorisation procedure. However, REACH includes also a restriction procedure where the socio-economic analysis is of importance. Restrictions are a safety net to address unacceptable risks to human health or the environment, arising from the manufacture, use or placing on the market of substances. Any substance on its own, in a preparation or in an article may be subject, where justified, to restrictions.

If the Commission or Member States consider that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, the Agency (asked by the Commission) or the Member State needs to prepare a dossier which conforms to the requirements of Annex XV. Annex XV requires Information on hazard and risk, Information on alternatives, justification for restrictions at Community Level, socio-economic assessment and Information on stakeholder consultation.

The socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI (this may also be used for the authorisation application). To this end, the net benefits to human health and the environment of the proposed restriction may be

compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

Annex XVI states that a socio-economic analysis may include the following elements:

- Impact of a granted or refused authorisation on the applicant(s), or, in the case of a proposed restriction, the impact on industry (e.g. manufacturers and importers). The impact on all other actors in the supply chain, downstream users and associated businesses in terms of commercial consequences such as impact on investment, research and development, innovation, one-off and operating costs (e.g. compliance, transitional arrangements, changes to existing processes, reporting and monitoring systems, installation of new technology, etc.) taking into account general trends in the market and technology;

- Impacts of a granted or refused authorisation, or a proposed restriction, on consumers. For example, product prices, changes in composition or quality or performance of products, availability of products, consumer choice, as well as effects on human health and the environment to the extent that these affect consumers;

- Social implications of a granted or refused authorisation, or a proposed restriction. For example job security and employment;

- Availability, suitability, and technical feasibility of alternative substances and/or technologies, and economic consequences thereof, and information on the rates of, and potential for, technological change in the sector(s) concerned. In the case of an application for authorisation, the social and/or economic impacts of using any available alternatives;

- Wider implications on trade, competition and economic development (in particular for SMEs and in relation to third countries) of a granted or refused authorisation, or a proposed restriction. This may include consideration of local, regional, national or international aspects;

- In the case of a proposed restriction, proposals for other regulatory or non-regulatory measures that could meet the aim of the proposed restriction (this shall take account of existing legislation). This should include an assessment of the effectiveness and the costs linked to alternative risk management measures;

- In the case of a proposed restriction or refused authorisation, the benefits for human health and the environment as well as the social and economic benefits of the proposed restriction. For example, worker health, environmental performance and the distribution of these benefits, for example, geographically, population groups; and

- A socio-economic analysis may also address any other issue that is considered to be relevant by the applicant(s) or interested party.

Thus, part of the aim in developing a strategy or plan for further data collection should be to ensure that the above types of issues, and the degree to which they hold for a given chemical, can be addressed within a socio-economic analysis under RoHS.

In terms of conducting the socio-economic analysis the Technical Guidance Document on socio-economic analysis for Restrictions under REACH suggests the following five stage approach to a socio-economic analysis:

• Stage 1: Set the aims of the SEA (why is the SEA being developed?)

• Stage 2: Set the scope of the SEA (what is the continued use ("baseline") scenario and the "proposed restriction" scenario? Which manufacturing process and whole supply chains are affected in the "proposed" restriction scenario and how are they affected?)

• Stage 3: Identify and assess the impacts (what are the impacts of the proposed restriction compared to the continued use scenario i.e. what are the differences between the two scenarios?)

• Stage 4: Interpretation & conclusion drawing (bring the human health, environmental, economic, social and other impacts together to assess the net benefits and net costs of the proposed restriction)

• Stage 5: Present the results (prepare a report that transparently documents the results and assumptions used in the analysis)

Socio-Economic Analysis adapted to RoHS

REACH allows authorisations to be granted where the socio-economic benefits of a particular use of a substance outweigh the costs, even where safe use cannot be demonstrated. There is no such provision in RoHS; instead exemptions apply only where substitution is not possible from a scientific or technical viewpoint. There are potential implications of differing approaches under two such closely linked regimes.

Under RoHS any application of socio-economic analysis would be part of the review of exemptions. In this case it is assumed that, as in the case of the current procedure, the industry would be responsible to justify the use of a hazardous substance under RoHS based on socio-economic benefits outweighing those inflicted on the environment and human health.

A proper socio-economic analysis is a highly complicated task. A report[92] by IMV reviewed 22 EU Risk Reduction and socio-economic analysis under existing Chemical Substance Regulation 793/93 and under six US economic assessments under the US Toxic Substance Act.

Based on the findings the report concludes, in relation to REACH, that that even with more resources devoted to analysis, ensuring a balanced, and truly well-informed socio-economic analysis is bound to remain a complicated task.

In providing recommendations for the European Chemicals Agency the report points out future socio-economic analysis need to have a sound logic and well applied methodology that makes important assumptions and limitations visible for the Agency.

[92] IVM (2007), *Challenges for Economic Analysis under REACH, What can we learn from previous experience?,* May 2007.

However, even with this in place, stakeholders would still be expected to have a wide discretion for how to carry out socio-economic analysis in practice. The report therefore recommends that all analysis would have to be subjected to an obligatory quality assessment. Any quality assessment could be financed through public funds or alternatively by the applicant, who would be required to stand for the cost of an independent, approved reviewer.

Based on the above, any inclusion of socio-economic analysis into the exemption procedure would require an increase in staff reviewing the quality of the exemption applications as well as a considerable burden of proof and administrative costs for the industry in order to submit an exemption application based on socio-economic analysis. This impact might be reduced through the provision of good guidance, but there is also a limit to this, as any socio-economic analysis guidance would still have to be quite general in its nature to allow for the degree of flexibility needed to allow for a more specific analysis suitable for the broad range of possible issues to be analysed.

10. FACT SHEET ON THE INSERTION OF A REVIEW CLAUSE

10.1 ISSUE

Issue/problem addressed:

What approach to follow in terms of including a review clause within RoHS in terms of achieving good regulation and an effective outcome for the Directive?

Background:

Currently a review clause exists within the RoHS Directive stating that the Commission shall review the Directive to take into account new scientific evidence. Since the publication of the original proposal for the RoHS Directive, the Commission adopted a Communication on 'Simplifying and improving the regulatory environment' (COM(2002) 278) that sets out the importance of review clauses. Additionally, different models of review clause exist in measures linked to the RoHS Directive from simple references to the need to monitor impacts, report and revise a Directive if needed to very specific review periods for the review of important and controversial elements of legislative measure. Therefore, a decision must be made as to what is the most appropriate approach to pursue within a revised RoHS Directive in terms of review, what might or is realistic to cover. Within the 2nd consultation it was proposed that review clauses might be linked in some way to the substances covered by the Directive or to technical changes in the scope of RoHS. Additionally it was discussed as to whether reviews might be linked to the inclusion of a substance into RoHS by a given deadline.

Summary of analysis:

It does not appear appropriate to impact assess the inclusion of a review clause. The inclusion of a review clause is essentially a political decision by the Commission based on the needs and requirements to amend a Directive along with future knowledge and understanding. The benefits of a review clause setting out specific items for consideration by a specific date would be to increase certainty; however, this would also commit the Commission to a set cycle of review. A review clause could be included setting out a specific timetable. Alternatively, however, the Directive can simply require that impacts and approaches to implementation be monitored and reported and based on the findings of this research the Directive will be reviewed as and when considered appropriate to meet the needs of the market.

The review process is essentially a legislative tool and it is good practice to include such a clause in a Directive. Decisions to undertake a review should be based on robust monitoring and reporting. Any indicators or criteria used to establish when a review should take place must reflect the aims of the Directive and its potential impacts both positive and negative.

Details are provided on possible indicators and criteria for triggering a review. The most commonly used is time elapsed since the adoption of the legislation based deadlines for the completion of specified tasks. Alternatively, if monitoring provisions are sufficient, a review might be triggered if it is found that levels of non compliance are rising rapidly or that new potentially hazardous material is appearing on the EU market within EEE that need controlling. The linkage with the importance of information provision for enabling effective review is highlighted.

10.1.1. CURRENT PRACTICE/SITUATION

In its current form the RoHS Directive contains the following references to a review. In the prelims to the Directive, paragraph 8 states that:

'The measures provided for in this Directive take into account existing international guidelines and recommendations and are based on an assessment of available scientific and technical information. The measures are necessary to achieve the chosen level of protection of human and animal health and the environment, having regard to the risks which the absence of measures would be likely to create in the Community. The measures should be kept under review and, if necessary, adjusted to take account of available technical and scientific information'.

In addition Article 6 of the Directive sets out current requirements for the review of the Directive:

Article 6 of the RoHS Directive as stands

Before 13 February 2005, the Commission shall review the measures provided for in this Directive to take into account, as necessary, new scientific evidence.

In particular the Commission shall, by that date, present proposals for including in the scope of this Directive equipment which falls under categories 8 and 9 set out in Annex IA to Directive 2002/96/EC (WEEE).

The Commission shall also study the need to adapt the list of substances of Article 4(1), on the basis of scientific facts and taking the precautionary principle into account, and present proposals to the European Parliament and Council for such adaptations, if appropriate.

Particular attention shall be paid during the review to the impact on the environment and on human health of other hazardous substances and materials used in electrical and electronic equipment. The Commission shall examine the feasibility of replacing such substances and materials and shall present proposals to the European Parliament and to the Council in order to extend the scope of Article 4, as appropriate.

In 2002, after the proposal of the text of the current RoHS Directive (in 2000), the European Commission has adopted its Communication on simplifying and improving the regulatory environment[93]. This document sets out good practice in terms of the development of legislation. It specifically recommends the inclusion of a review clause in legislative acts stating as follows.

'Without prejudice to its right of initiative, the Commission will take steps to add, where appropriate, a review clause, or even a revision clause, to its legislative proposals, particularly those which are subject to rapid technological change, so that legislation can be updated and adjusted regularly. The Commission will draw up a report using the information provided by the Member States and the parties concerned and will, where necessary, propose that the legislation concerned be amended. Action of this kind should be based on effective cooperation with the national authorities (cf. Part IV), particularly when it comes to the ex post evaluation of how the legislation has been applied in the Member States. In appropriate cases, the Commission will seek to identify ways of simplifying the substantive aspects of legislative acts after they have been reviewed. In proposing a review clause, the Commission will seek to preserve legal certainty for operators.'

In addition subsequent to the adoption of the RoHS Directive and the 2002 Communication different approaches to review have been put forward in measures in some way linked to the RoHS Directive. Set out below are details of review clauses from the proposal for a Directive on waste, the REACH Regulation and the Directive on batteries and accumulators. It can be seen from this that different models of review are used in these different measures. Within REACH a very specific approach is taken whereby given factors relevant to the measure must be reviewed at set time periods. Specific dates for each review and monitoring and reporting requirements, closely linked to the review cycle, are set out. Within the Batteries Directive it is set out that an implementation report will be produced by the Commission and with this there will be particular focus on the key topics highlighted. Meanwhile the proposal for a Directive on waste simply states that a report on the implementation of the Directive will be published by the Commission at a given time and based on this report presents proposals for revision if appropriate. The WEEE Directive currently does not contain a specific clause for review.

93 Communication from the Commission Action plan "Simplifying and improving the regulatory environment", COM(2002)278

Table 31 - Table setting out the review clauses in key relevant Directives

Directive	Review Clauses
Proposal for a Directive on waste	[94]At intervals of three years Member States shall inform the Commission of the implementation of this Directive, in the form of a sectoral report. The report shall be drawn up on the basis of a questionnaire or outline established by the Commission in accordance with the procedure referred to in Article 6 of Directive 91/692/EEC16. The report shall be made to the Commission within nine months of the end of the three year period covered by it. Member States shall include in these reports information on their progress in the implementation of their waste prevention programmes. In the context of the reporting obligations, data shall be collected on catering waste, enabling the establishment of rules on its safe use, recovery, recycling and disposal. The Commission shall send the questionnaire or outline to the Member States six months before the start of the period covered by the report. The Commission shall publish a Community report on the implementation of this Directive within nine months of receiving the reports from the Member States in accordance with paragraph 1. In the first report that intervenes five years after the entry into force of this Directive the Commission will review the implementation of the Directive and will present a proposal for revision if appropriate.
Regulation on REACH	Article 117 Reporting[95] 1. Every five years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 127. The first report shall be submitted by 1 June 2010. 2. Every five years, the Agency shall submit to the Commission a report on the operation of this Regulation. The Agency shall include in its report information on the joint submission of information in accordance with Article 11 and an overview of the explanations given for submitting information separately. The first report shall be submitted by 1 June 2011.

[94] Article 34, Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on waste, COM(2005) 667, 21.12.2005

[95] Article 117, Regulation (EC) No 1907/2006 Of The European Parliament And Of The Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

	3. Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation. The first report shall be submitted by 1 June 2011. 4. Every five years, the Commission shall publish a general report on (a) the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1, 2 and 3 and (b) the amount and distribution of funding made available by the Commission for the development and evaluation of alternative test methods. The first report shall be published by 1 June 2012. Article 138 Review[96] 1. By 1 June 2019, the Commission shall carry out a review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. However, for substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2, in accordance with Directive 67/548/EEC, the review shall be carried out by 1 June 2014. When carrying out the review the Commission shall take into account all relevant factors, including: (a) the costs for manufacturers and importers of drawing up the chemical safety reports; (b) the distribution of costs between actors in the supply chain and the downstream user; (c) the benefits for human health and the environment. On the basis of these reviews, the Commission may, if appropriate, present legislative proposals to extend this obligation.

[96] Article 138, Regulation (EC) No 1907/2006 Of The European Parliament And Of The Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

	2. The Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following: (a) the risks posed by polymers in comparison with other substances; (b) the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other. 3. The report, referred to in Article 117(4), on the experience acquired with the operation of this Regulation shall include a review of the requirements relating to registration of substances manufactured or imported only in quantities starting at 1 tonne but less than 10 tonnes per year per manufacturer or importer. On the basis of that review, the Commission may present legislative proposals to modify the information requirements for substances manufactured or imported in quantities of 1 tonne or more up to 10 tonnes per year per manufacturer or importer, taking into account the latest developments, for example in relation to alternative testing and (quantitative) structure-activity relationships ((Q)SARs). 4. The Commission shall carry out a review of Annexes I, IV and V by 1 June 2008, with a view to proposing amendments, if appropriate, to them in accordance with the procedure referred to in Article 131. 5. The Commission shall carry out a review of Annex XIII by 1 December 2008, to assess the adequacy of the criteria for identifying substances which are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, with a view to proposing an amendment to it, if appropriate, in accordance with the procedure referred to in Article 133(4). 6. By 1 June 2012 the Commission shall carry out a review to assess whether or not to amend the scope of this Regulation to avoid overlaps with other relevant Community provisions. On the basis of that review, the Commission may, if appropriate, present a legislative proposal. 7. By 1 June 2013 the Commission shall carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 60(3) to substances identified under Article 57(f) as having endocrine disrupting properties. On the basis of that review the Commission may, if appropriate, present legislative proposals. 8. By 1 June 2019, the Commission shall carry out a review to assess whether or not to extend the scope of Article 33 to cover other dangerous substances, taking into account the practical experience in implementing that Article. On the basis of that review, the Commission may, if appropriate, present legislative proposals to extend that obligation. 9. In accordance with the objective of promoting non-animal testing and the replacement, reduction or refinement of animal testing required under this Regulation,

	the Commission shall review the testing requirements of Section 8.7 of Annex VIII by 1 June 2019. On the basis of this review, while ensuring a high level of protection of health and the environment, the Commission may propose an amendment in accordance with the procedure referred to in Article 133(4). 4. Every five years, the Commission shall publish a general report on (a) the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1, 2 and 3 and (b) the amount and distribution of funding made available by the Commission for the development and evaluation of alternative test methods.
Batteries and Accumulators Directive	[97] 1. The Commission shall review the implementation of this Directive and the impact of this Directive on the environment and the functioning of the internal market after receiving reports from Member States in accordance with Article 22(4) for the second time. 2. The second report that the Commission publishes in accordance with Article 22(5) shall include an evaluation on the following aspects of this Directive: (a) the appropriateness of further risk management measures for batteries and accumulators containing heavy metals; (b) the appropriateness of the minimum collection targets for all waste portable batteries and accumulators set out in Article 10(2), and the possibility of introducing further targets for later years, taking account of technical progress and practical experience gained in Member States; (c) the appropriateness of the minimum recycling requirements set out in Annex III, Part B, taking account of information that Member States provide, technical progress and practical experience gained in Member States. 3. If necessary, proposals for revision of the related provisions of this Directive shall accompany the report.

10.1.2. ISSUES/PROBLEMS TO EXPLORE

In response to the consultation several responded more generally as to whether they support or do not support the insertion of review clauses more generally.

AEA (Association of Electoral Administrators), Amcham (American Chamber of Commerce), COCIR (the European Coordination Committee for the Radiological, Electromedical and Healthcare), EICTA (European Information and Communications Technology Industry Association) all stated they do not support the use of review clauses. AEA commented that they feel review clauses add to uncertainty.

A number of consulted stakeholders highlighted that RoHS already has a review clause and that adding indicators etc. could over complicate this. EPPA commented that the

[97] Article 23, Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC

RoHS Directive already has a review clause and that they do not support the use of criteria or indicators as it would add complexity and be difficult to find measurable indicators. JMC commented that they could see no disadvantages with the current approach while more specifically and echoed concerns from EPPA about the difficulty of finding measurable indicators. JMC also raised concerns that a review clause for the purpose of identifying candidate products and substances could cause uncertainty and confusion. Orgalime also felt that existing review obligations are sufficient in tandem with obligations to review exemptions every four years. They felt that for any new substances restrictions under REACH would apply.

Finally EEB (European Environmental Bureau) and Nokia support the use of review clauses, although did not comment in detail. EUCOMED (a medical technology association) commented that given that medical devices will no longer be exempt it would be useful to monitor progress and benefits of their inclusion in RoHS. The Belgian Federal Government commented that review clauses can simplify legislation making it more flexible. RREUSE (Re-use and Recycling European Union Social Enterprise) echoed these sentiments commenting that inserting a new review clause into the revised Directive is a very good option, as products, scientific knowledge on hazardous substances, technologies evolve steadily and legislation must be open to being adapted.

From the consultation response it seems that the majority do not object to some form of review clause within RoHS, although there are concerns about making these too ambitious in terms of including criteria and indicators and that this may lead to uncertainty. However, some do support the review being focused on monitoring impacts and implementation in relation to specific element of the Directive.

10.2 POLICY OPTIONS

- **Option 1: Business-as-usual – Review clause to remain similar to the existing RoHS Directive Article**

There are some objections to the overall approach to using reviews in legislation; however, this is established practice in terms of better regulation and simplification.

- **Option 2: Review based on the use of indicators and criteria**

Based on the consultation responses there are concerns that this might over complicate the process and lead to uncertainty. There are particular concerns regarding the use of indicators/criteria and the ability to develop measurable factors.

- **Option 3: Develop a review clause that contains specific actions and elements of the Directive to be reviewed by a specified date**

This is a proposed third way and may be more akin to efforts under REACH. This would go slightly further and into more detail than existing review clauses specifying particular areas of concern to be reviewed and by when.

- **Option 4: Totally unspecified review clause as per the waste framework Directive proposal**

This would specify the timing of a review but leave the content open to allow consideration based on implementation reports. The downside of this broad approach is that with a Directive dealing with specific substances and products such as RoHS this may lead to a lack of clarity as to what might be expected.

10.3 INDICATORS, REVIEWS AND GOOD PRACTICE

10.3.1. TRIGGERING REVIEWS

Legislative requirements for review within the European environmental Directives (see examples in section 1.1) are predominately triggered by time factors for example when 3 years have elapsed since the entry into force of the measure or from a specified reporting period. Therefore the key indicator triggering a review, cited in existing legislation, is time elapsed.

Within the guidelines on review published within the 2002 Communication on better regulation it is stated that review clauses should be added to legislative proposals '*particularly those which are subject to rapid technological change'* - as is the case in the EEE sector. It is however, relatively difficult to identify at what point technological changes are sufficient to trigger a review.

One option would be that technological change within the EEE sector be monitored e.g. via some proxy such as new products and product types placed on the market. If the rate of new product adoption were too significantly rise i.e. rise by 30 per cent per annum, this could trigger an investigation into the market place in more detail. If this investigation were to identify a significant shift in the nature of EEE and risks related to ROHS this in turn could trigger a review.

Alternatively, a system similar to that set out in the proposal for a Decision on a common framework for the marketing of products might be adopted. Under the proposed Decision if a Member State performs an evaluation of a product and deems that, although it complies with the Decision's requirements, it still presents a significant risk to health or the environment they must take all appropriate measures to ensure the product no longer presents and risk. IN addition they must immediately inform the Commission of the risks. This same approach could be applied to ROHS in order to identify any novel or emerging pollutants or products that might present a risk in terms of the hazardous substances they contain. Were it identified that there is a trend towards substances outside the scope of ROHS becoming an increasing risk, or ROHS compliant products still being deemed a risk, this could trigger a review.

Finally, at present there is a system whereby a review of a piece of legislation can be triggered informally based on monitoring results or reported concerns. If the Commission has significant concerns regarding a particular area of a measures

implementation, resulting from Member State reports, industry or information from civil society they can trigger a more in depth review. This appears to have been the case for the current review of the Seveso II Directive.

In terms of practice the most common approach to triggering a review is a time factor. This is used for the sake of simplicity but also as it provides industry and others with clarity as to when reviews will take place. In terms of ROHS, given the rapidity of technology shifts in the market place it would be useful to also have a system whereby significant shifts in terms of novel products and importantly increased risk to health and the environment can trigger a review. The approaches set out above seem to be the most appropriate, however, it is important to note that these will only be possible if appropriate monitoring mechanisms and reporting structures are set up to support them.

10.3.2. ISSUES TO BE REVIEWED

During a review there are certain factors that should be taken into account and criteria that should be considered[98]. Generally for reviews to work effectively the following should be applied:

- Requirements, tasks and information upon which a review will be based should be clearly spelt out in the legislation i.e. it should be clear upon what the review will be based;
- There should be a clear link between the triggers of the review and the objectives of the measure i.e. the review should be aimed at improving the effectiveness with which the aims of the legislation are achieved;
- There must be clear, appropriate and proportionate mechanisms in place for monitoring the achievements under the measure.

There are two types of indicators for the success of a measure. Firstly whether the measure is improving the actual situation on the ground i.e. reducing the use of hazardous substances, and is appropriate to prevailing market conditions i.e. the scope reflects the types of products on the market place. Secondly, it should consider whether implementation is appropriate.

In the case of the former, for ROHS assessing the level of compliance with the Directive's requirements is particularly problematic. The best indicator of the success of the Directive would be figures on compliant versus non compliant products on the market place. These are almost impossible to collect given the emphasis of presumed conformity. The best proxy for this under ROHS would likely be, assuming in the future there will be a more consistent and robust monitoring and market surveillance approach

[98] Informed by work by IEEP for the IMPEL network on the practicability and enforceability of legislation, IMPEL Project - "Developing a checklist for assessing legislation on practicability and enforceability"

to products, the percentage of products assessed that proved to be non compliant. Such reporting on the level of compliance should also indicate the level of risk posed by the non compliant products i.e. in terms of anticipated level of market penetration and levels of hazardous substances. This could then be used, in conjunction with figures on the percentage of products on the market checked during surveillance activity, to develop an understanding of whether the trend is towards increased or decreased compliance and the achievement of the Directive's aim. If this shows an increasing level of non compliance or continued high levels of non compliance this should trigger a more fundamental evaluation of the approach to ROHS.

Importantly, in terms of reviewing the achievements of the ROHS Directive a review should also look towards the future as well as what is happening in the present. Therefore, the following should also potentially be considered:

- the extent of and approach to exemptions and the availability of substitutes (potentially in future based on substitution plans)
- innovations within the industry which might lead to:
    - less hazardous products in the future and the reduction in exemptions
    - future sources of risk i.e. new products containing novel materials
    - new categories of EEE that need to be more explicitly covered by ROHS

The second strand of monitoring success is assessing achievements in terms of governance structures. While it is essential to understand overall compliance with the objectives of the Directive, it is also important that within reviews the approach to achieving compliance is assessed. This aids understanding as to why objectives are or are not being met and whether Member States are performing the tasks asked of them. Within ROHS there are key policy processes that need to be completed and could be monitored. These include:

- Transposition of amendments into national laws
- Monitoring and reporting on approaches for compliance assessment and enforcement
- Monitoring and report on market surveillance activities i.e. are these occurring, when, how is it decided which product to check, what methods are used to conduct the assessment, what percentage of products are being checked within the Member State
- What, if any, enforcement actions have been carried out and have these been pursued against all products identified as non compliant
- The time taken and costs associated with achieving compliance with the Directive, both for industry and the authorities

10.4 CONCLUSIONS REGARDING IA ON THIS ISSUE

It does not appear appropriate to impact assess the inclusion of a review clause. The inclusion of a review clause is essentially a political decision by the Commission based on the needs and requirements to amend a Directive along with future knowledge and understanding. The benefits of a review clause setting out specific items for consideration by a specific date would be to increase certainty; however, this would also commit the Commission to a set cycle of review. A review clause could be included setting out a specific timetable. Alternatively, however, the Directive can simply require that impacts and approaches to implementation be monitored and reported and based on the findings of this research the Directive will be reviewed as and when considered appropriate to meet the needs of the market.

The review process is essentially a legislative tool and it is good practice to include such a clause in a Directive. Decisions to undertake a review should be based on robust monitoring and reporting. Any indicators or criteria used to establish when a review should take place must reflect the aims of the Directive and its potential impacts both positive and negative.

Details are provided on possible indicators and criteria for triggering a review. The most commonly used is time elapsed since the adoption of the legislation based deadlines for the completion of specified tasks. Alternatively, if monitoring provisions are sufficient, a review might be triggered if it is found that levels of non compliance are rising rapidly or that new potentially hazardous material is appearing on the EU market within EEE that need controlling. The linkage with the importance of information provision for enabling effective review is highlighted.

11. FACT SHEET ON THE INTRODUCTION OF MARKET SURVEILLANCE MECHANISMS

11.1 ISSUE

Issue/problem addressed:

There are currently no specific market surveillance requirements in relation to the RoHS Directive, although there are systems for this set up under the WEEE Directive. The current Directive contains relatively vague requirements in relation to what Member States must achieve in order to ensure the prevention of products non compliant with RoHS entering the market place. This has lead to difficulties in terms of inconsistency in approach across Europe, uneven cost distribution for industry, potential for non compliant product to remain on the market place and not face enforcement action, and importantly potentially undermines efforts to protect the environment and human health using the ROHS Directive.

To complement existing requirements within ROHS and other product focused policy, in 2007 the Commission proposed a Decision on the marketing of products (COM(2007)53) and a Regulation on accreditation and market surveillance for the marketing of products (COM(2007)37). These proposed measures would put in place systems for the monitoring and assessment of the qualities of products on the European market place more generally. However, the proposed Regulation would still contain relatively vague requirements for the actions to be conducted by Member States in relation to market surveillance.

Background:

According to the second consultation document 'effective market surveillance mechanisms at national level would greatly enhance the environmental benefit of RoHS by minimising the number of non-compliant products; a major disincentive for free riding, it would contribute to a level playing field for producers'. An Informal Enforcement Bodies Network already exists however, while efforts have been of use Member State uptake of the outputs is widely varied. Within the second consultation responses there was overwhelming support for the introduction of measures to deliver better market surveillance and consequently better monitor the compliance of products on the market place.

Options and summary of analysis:

There is clearly a need to have clarity over the approach to market surveillance. This is the foundation of assessing the conformity of products on the market place, enforcing against non compliance and fundamentally delivering the aims of the ROHS Directive.

There are different approaches possible. One option would be to simply abide by the rules

under the proposed Decision and Regulation on marketing of products – what will become the BAU upon their adoption. However, while focusing on the surveillance of products on the market place these measures do not specifically consider EEE nor the requirements of ROHS. The forthcoming requirements may, therefore, lack specificity in terms of implementing the complex requirements of RoHS.

An alternative, and option 2 considered within this assessment, is for requirements to be included in ROHS. These would build upon those new provisions set out in the forthcoming Decision and Regulation, but take them a step further as is appropriate for a specific and important legislative measure such as ROHS. This approach could involve simply a brief reference within the Directive accompanied by binding guidelines agreed at a later date - based broadly on the provisions Article 14 of the 'Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products'. Or alternatively full details could be included in an annex to the ROHS Directive itself.

The impacts of adopting new provisions on market surveillance under ROHS are considered to be broadly positive in terms of environmental benefit, social impact, the costs and competitiveness of industry, innovation and the workability and clarity of legislation. The only negative impact, primarily in terms of cost, is considered to be for the regulatory authorities who would have to implement a more rigorous assessment system. Importantly, given the current variability in approach by Member States to market surveillance, the impacts will vary in strength depending upon the existing situation.

11.1.1. CURRENT PRACTICE/SITUATION

There are currently no specific market surveillance requirements in relation to the RoHS Directive, although there are systems for this set up under the WEEE Directive. The current Directive contains relatively vague requirements in relation to what Member States must achieve in order to ensure the prevention of products non compliant with RoHS entering the market place. For further analysis please see the fact sheet on compliance assessment, please note that the conclusions of the sheets are integrally as market surveillance approaches will be influenced by the choice of compliance assessment approach and vice versa.

To complement existing requirements within RoHS and other product focused policy, in 2007 the Commission proposed a Decision on the marketing of products (COM(2007)53) and a Regulation on accreditation and market surveillance for the marketing of products (COM(2007)37). These proposed measures would put in place systems for the monitoring and assessment of the qualities of products on the European market place more generally. A summary of the Decision and the Regulation can be found in the below boxes.

Proposal for a Decision on the marketing of products (COM(2007)53):

The Proposal for a Regulation will reinforce Market Surveillance structures to protect citizens from unsafe products (including those coming from outside of the EU) and levelling the playing field for compliant businesses, by removing those products from the market and taking action against fraudulent manufacture. The Regulation is also designed to enhance confidence in the conformity assessment of products by strengthening the role of Accreditation for testing, certification and inspection bodies.

Proposal for a Regulation on accreditation and market surveillance for the marketing of products (COM (2007)37):

The Proposal for a Decision contains a toolbox of additional measures which will be integrated into the future legal framework as either new sector specific directives are brought forward or existing sectoral directives are revised or updated. This will clarify commonly used procedures and terms (which are often used differently) so that all stakeholders can be clear on relative responsibilities. In addition there are new rules to enhance confidence and trust in CE marking which will help to increase transparency and strengthen the system.

The proposals are intended to provide harmonised requirements for a raft of different Directives. The proposal for a Regulation would establish formal accreditation bodies and importantly would also help to clarify issues surrounding definitions which have proved difficult in relation to RoHS for example when a product is deemed to be 'placed on the market' or 'available on the market'

However, the proposed Regulation would still contain relatively vague requirements for the actions to be conducted by Member States in relation to market surveillance. In chapter III, Article 14 of the measure it is stated:

'Member States shall organise and perform surveillance in order to ensure that products on the Community market, or entering that market, which are covered by Community harmonization legislation, satisfy the provisions of the relevant Community harmonisation legislation and that they do not, under the condition that they are properly installed, maintained and used, compromise health or safety or other issues of public interest protection set out in the relevant Community harmonisation legislation.'

Full details of the Regulation's requirements can be found in the Annex. It is considered that while the provisions in the Directive may be a useful starting point for requirements under RoHS this would not provide a clear European wide approach.

11.1.2. ISSUES/PROBLEMS TO EXPLORE

In order for legislation to be effective progress and compliance must be effectively monitored and failures enforced against; if these are lacking policy will not be implemented in a robust nor rigorous way.

At present only informal and non explicit approaches to market surveillance exist under RoHS. The proposal for a Decision on marketing of products and the regulation of market surveillance sets out only a broad approach to this. The latter could however, be adapted for application to RoHS. The links between the different dossiers need to be clarified.

An academic study reviewing implementation of RoHS in Member States, based on interviews with officials, identified several issues and problems that impact upon market surveillance and the ability to consistently apply ROHS requirements[99]. The study revealed clear differences in the implementation of ROHS in different Member States. A key issue, also identified in other studies as a problem, is the differing approach to dealing with the phrase 'put on the market'. According to community guidance this should mean the first transfer of a product onto the European Community market, however, in July 2006 interpretation of this term still differed in several Member States or there was no clarity as to exactly how this is interpreted in the Member State laws – Greece, Cyprus, Hungary, Poland, Latvia and Slovakia all either adopted different interpretation or were unclear as to how the term has been interpreted in the legislation. This lack of clarity causes a problem in relation to understanding what has been placed on the European market, hence regulating it. Within the proposed package of measures on the marketing of products the 'placing on the market' of products would be defined as the 'making available of a product on the Community market'.

Importantly the same study also highlighted the differences in the requirements for checking compliance in different Member States, while some only require corporate commitments to RoHS compliance, others require documentary evidence of compliance from material and component supplies and others still require the use of specific testing procedures to prove compliance. Additionally, the importance countries place upon market surveillance seems appears to vary. As of the 1 July 2006 the ROHS Directive has been in effect. Several Member States planned to commence market surveillance operations upon the date of entry into force, meanwhile others were proposing a transitional phase and others stated that they have no immediate plans for market surveillance. Additionally different approaches to testing the compliance of products inspected were anticipated to be adopted. These differences are considered in the paper to undermine the directive in terms of environmental protection, to potentially lead to trade barriers. The lack of clarity and consistency was also considered to lead to unnecessary repetition of effort and burden.

[99] Martin, A; Mayers, C; France, C; The EU Restriction of Hazardous Substances Directive: problems arising from implementation differences between Member States and proposed solutions., RECIEL, 16(2)2007

- Conclusions on the Problems Faced in Tracking and Surveying Products on the Market – based on the IA for the marketing of products package

Within work to support the marketing of products proposals it was identified that a significant proportion of products on the European market place are not considered to be compliant with EU rules. Based on survey results the following results of relevance were identified.[100] In addition 96 per cent of respondents to the survey felt that market surveillance is insufficiently rigorous in relation to products on the EU market place. Surveillance of products on the market can different between Member States with 94% feeling that there is a significant difference between the level of surveillance in different Member States with the most common differences being: the number and frequency of checks, resources allocated and degree of detail.

The IA for the marketing of products Directive provides information on the baseline scenarios and additionally contains a set of options focusing on how the enforcement of EU Directives might be improved including a sub-option that would require a Common EU framework for market surveillance with minimum criteria.

Source	Share of non-compliant products on the market
SME Test panel	The majority of SMEs could not provide figures. Where figures were given, they differed considerably from sector to sector as well as between Member States. The figures ranged from 4%-51%, the average being 24%.
Enterprise questionnaire	Most respondents could not provide figures but indicated that the problem was important. However, below is an overview of the estimates provided: Electro-technical sector: 10-30% (up to 50 % in the luminaires sector) Mechanical sector: 5-7 % Medical devices: 10-30%
Market surveillance authorities	Electro-technical 10-70 % Medical Devices 2-20 %,

According to the IA on the marketing of products under ***business as usual there is a lack of efficient market surveillance mechanisms impairing the competitiveness of European industry.*** 'As it is difficult to estimate the share of non-compliant products on the market, it is equally difficult to estimate the loss of industry due to non-compliant products. For this reason most enterprises ***could not quantify these damages. Only a***

[100] From the IA on the marketing of products proposals pp19-20

few enterprises actually indicated figures. These ranged in general between 4-25%[101] of the annual turnover. There is however widespread agreement amongst enterprises that the situation undermines their competitiveness compared to operators, which benefit from the current weaknesses in the enforcement and do not observe the rules.

The unhindered entry of non-compliant products on the market can seriously endanger the health and safety of their users, consumers, workers and professionals. Due to lack of an EU wide database linking accidents with their cause it is not possible to give figures on the accidents caused by non-compliances of a product. Apart from any attempt to allocate a certain proportion of such accidents to the lack of market surveillance would not make sense, since it forms part of a broader policy on accident prevention. However, the fact that more and more products presenting serious non-compliances are found on the market[102] gives an indication on the potential danger arising from the current situation.

Leaving the situation unchanged would also mean to accept obstacles for a real internal market. Despite the fact that EU law has harmonised the conditions for the marketing of products, markets will still remain fragmented due to national differences in the enforcement of the rules.

A system of technical harmonisation for products requires a well functioning control mechanism in order to ensure an even level of safety for all users and consumers and a level playing field for economic operators throughout the European Union (cf. chapter 2.2). A solution has to be found which balances burden between Member States and economic operators'[103].

Under proposals a common European framework approach to the market surveillance of all products would be introduced. In addition there would be increased cooperation and communication between national bodies. This is reflected by two options within the impact assessment for the marketing of products proposals. The impacts, as presented in the impact assessment are as follows.

A common framework for market surveillance (option B4 within the marketing of products IA)

It is stated that the majority of enterprises are in favour of reinforcing market surveillance with 95% of enterprises surveyed responding that reinforced market surveillance would contribute to ensure a level playing field for companies. The vast majority also do not anticipate additional costs associated with such mechanisms. Market surveillance authorities considered that a common framework would improve the effectiveness of their work, with 41% suggesting that the system suggested would

101 Figures are taken from the SME panel and the enterprise questionnaire and reflect the general tendency.

102 Rising number of RAPEX notifications. Annual Report on the Operation of the Rapid Alert System for non-food consumer products (RAPEX) 2005 http://ec.europa.eu/consumers/reports/report_rapex_05_en.pdf

103 Marketing of products impact assessment p.46

bring significant improvement. Although it is difficult to estimate the share of non compliant products on the market, hence quantify the damages, a few enterprises did so within the SME panel and enterprise questionnaire. These estimates ranged from between 4 to 25 per cent of annual turnover. There was, however, widespread agreement amongst industry that the current situation undermines competitiveness due to weak enforcement and a lack of compliance with the rules. Additionally, this can seriously endanger the health and safety of used, consumers and workers etc. The RAPEX notifications[104] record is recording greater numbers of serious non compliances on the market indicating the potential dangers.

Enhancing cooperation between MS (option B1 within the marketing of products IA)

According to the IA, 68 percent of respondents believe that the enhanced cooperation mechanisms proposed in relation to the marketing of products package would lead to significant improvement, all agreed that it would enable more effective controls and 91 per cent commented that it would lead to an efficient sharing of resources. It was predicted that this cooperation system would lead to costs for the Commission and public authorities. The Commission had allocated a budget of 1200000€ per year for this activity. Meanwhile there was uncertainty concerning additional costs among public authorities regarding the cost impact, 21 per cent commented they would expect significant additional costs while 60 per cent expected an overall reduction in costs.

- Second consultation responses

The majority of consulted stakeholders support the introduction of market surveillance mechanisms; however, they have specific views about how this might be approached. While some specifically highlight their support of the transformation of this measure into a New Approach Directive others are much more sceptical of the benefits of this approach.

Below are presented the key responses on this issue in the second consultation document.

AEA	Supports the introduction of a market surveillance mechanism. Agreed sampling and testing methodologies should be used (e.g. application of IEC TC111 standards – IEC 62321once finally adopted). Noted that they support the approach adopted by specific Member State governments that documentation is checked in the first instance with actual testing being considered as a last resort.

[104] Annual pa.eu/consumers/reports/report_rapex_05_en.pdf

Amcham	Supports the introduction of a market surveillance mechanism. RoHS test equipment needs to be specified. Wants that RoHS is made into a New Approach Directive. Argues that the New Approach is a proven, successful way to demonstrate compliance and to facilitate enforcement of the RoHS Directive. By changing the RoHS Directive into a New Approach Directive there will be benefits not only for the companies and the enforcement authorities but also for the environment.
CEA USA	Wants to ensure that the process for complying is made more easily understood (currently enforcement and conformity requirements are unclear and vary from member state to member state)
CECED	Supports the introduction of a market surveillance mechanism.
COCIR	Supports the introduction of a market surveillance mechanism.
Danish Ministry of the Environment	Is of the opinion that the proposals are very general, need more specific proposals, before making more specific comments. Support compliance-assessment procedures and administrative cooperation.
EEB	Supports the introduction of a market surveillance mechanism in principle as a greater verification checking is needed
EICTA	Expects Member States to firstly rely on examining the documentation provided by manufacturers as indicated in the "RoHS Enforcement Guidance Document". Where there is a need for testing, International standards exist or are in preparation for such purposes.
EPPA	A harmonized approach by national authorities to check product compliance would provide industry with certainty. Agreed sampling and testing methodologies should be used (e.g. application of IEC TC111 standards, i.e., IEC 62321 when adopted) to demonstrate compliance and the international standardization work on test methods needs the support of Member States and the Commission.

Ericsson	All regulation should be monitored by the authorities to ensure that all players comply with the rules. We expect the market surveillance to concentrate on examination of the processes, given in documentation (as indeed is indicated in the informal "RoHS Enforcement Guidance Document").
Eucomed	Welcomes a 'common' approach to market operation surveillance with clear statements on the actual mechanism and respective responsibilities.
Belgium Ministry of the Environment	Supports the introduction of a market surveillance mechanism.
Gambica	Does not support the introduction of a market surveillance mechanism.
JBCE	JBCE believes in the usefulness of the "New Approach" in relation to market surveillance.
Japan Machinery Center	The Enforcement Guide for the RoHS Directive published by the informal network should be respected, and JMC requests that the administrative procedures be unified throughout the EU member states.
Medical Product Agency	Supports the introduction of a market surveillance mechanism. Proposes a mechanism similar to market surveillance mechanism found in the New Approach Directive
Romanian Ministry of the Environment	Supports the introduction of a market surveillance mechanism.
Finish Ministry of the Environment	Supports the introduction of a market surveillance mechanism.
Nokia	The introduction of a market surveillance mechanism should be conducted according to the New Approach
Orgalime	Support for all areas of market surveillance and enforcement. The principles of the New Approach should be applied, i.e.: presumption of conformity and harmonised standards for test methods.

RREUSE	Supports, in general, the introduction of effective market surveillance mechanisms at national level is needed to enhance the environmental benefit and create a level playing field for producers.
Norwegian Pollution Control Authority	The Informal Enforcement Bodies Network that already exists is supportive for the different MS enforcement bodies, but enforcement will always be a national issue.

11.2 POLICY OPTIONS

- **Option 1: Business-as-usual**

This would mean that the current systems would be relied upon for the time being. Upon the adoption of the proposed measures on the marketing of products the existing requirements would be complemented by the vague and potentially unclear requirements set out. Note that with adoption of the marketing of products proposals the current business as usual will shift. Details of how this new system would relate to market surveillance are set out in the Annex

- **Option 2: Introduce market surveillance requirements under RoHS**

There are various approaches that could be adopted in order to deliver market surveillance under RoHS. However, given the imminent introduction of requirements within the Regulation on accreditation and market surveillance relating to the marketing of products it would seem good practice to adapt the provisions included to RoHS making requirements more specific to the circumstance of RoHS.

Importantly, the requirements and approaches must be clearly set out in the new RoHS measure to ensure consistent understanding and interpretation by the different Member States. Furthermore, there must be mechanisms for ensure consistent implementation of this surveillance process including the proportion of products to be checked and the basis for determining which products to review i.e. based on risk posed or on a more arbitrary factor e.g. that all products be tested at least every 3 years per se. It was commented by stakeholders that while market surveillance and associated enforcement is a matter for Member States this should be actively supervised by the Commission and clearly laid down within legislation to ensure more consistency of approach across Europe.

This approach could either be adopted as provisions within the revised ROHS Directive or within formal, binding guidelines in support of the marketing of products package or the Regulation on accreditation and market surveillance.

It should be noted that any approach to market surveillance should be developed in close coordination with efforts to improve compliance assessment under ROHS. These

two elements are integrally linked and must operate efficiently together in order to deliver better RoHS compliance across the EU.

11.3 PROS & CONS

Option 1: Business-as-usual i.e. non-action

Pros:

- Requires no investment or resources from the administrator or business
- The situation may improve in light of the adoption of the broader marketing of products package, once this has been approved.

Cons:

- There is a lack of consistency in Member State approaches leading to uncertainty on the part of producers, imbalanced costs and associated competitiveness impacts for firms operating in different countries
- Market surveillance in fundamental to delivering compliance on the market place hence achieving the protection of the environment and human health. Without surveillance there is no basis for enforcement action and no pressure to comply
- Industry has clearly identified that the current legislative situation is impacting negatively upon business and needs to be rectified
- There is no guarantee that broad proposals within the marketing of products package will deliver the clarity needed for a measure as specific as ROHS especially given that ROHS is not a new approach Directive.

Option 2: Adopting a market surveillance approach based on the marketing of products package

Pros:

- Adopting a market surveillance approach would allow a basis for assessing compliance of products on the market and delivering the protection of the environment and human health.
- If appropriately implemented clear requirements within the Directive would ensure a consistent approach across the EU to market surveillance and also that all Member States do in fact adopt this important provision – not currently the case based on research.
- It would become more clear what products are being placed upon the market with an efficient market surveillance mechanism enabling the more effective development of future policy
- There is clear support from stakeholders for improving market surveillance provisions and increasing consistency.

Cons:

- If inappropriately conceived this approach may replicate efforts under WEEE or other measures
- This would potentially require significant resources on the part of the regulatory authorities if no market surveillance system currently exists
- There may be difficulties in terms of gaining Member State support for a totally harmonised European wide approach.

11.4 ANALYSIS OF OPTIONS

Table below presents a summary of options' analysis in the form of a matrix in order to compare the advantages and disadvantages of each option.

Table 32 - Summary of assessed impacts

	Option 1: NO ACTION	Option 2
General impacts		
Legislative changes	N	Y
Environmental impacts		
Level of use of hazardous substances	--	0 to ++
Level of environmental protection/improvement	--	0 to ++
Economic impacts		
Firms: costs	--	- to +
Firms: competitiveness (internal & external market)	--	- to +
Innovation and research	--	++
Public authorities (budget; resources)	- to 0	0 to --
Social Issues		
Impact on consumers (availability / price)	--	+ to++
Public health and safety	--	0 to ++
Other Impacts		
Clarity and consistency (e.g. with other legislation)	--	0 to ++
Practical workability and enforceability	--	+ to +++

Please note that the scales used within the table reflect uncertainty. In relation to option 2 this reflects that Member States have adopted different approaches to market

surveillance and as such the change seen will vary depending on the BAU applicable to a given area of operation. Secondly, option 2's effectiveness will depend heavily upon how effectively measures are implemented. As a consequence the impact varies with more positive impacts reflecting more effective implementation.

11.4.1. ENVIRONMENTAL IMPACTS

As set out in the previous section benefits associated with product and market based measures can only be achieved if there is certainty about the compliance of products on the market place. Therefore, to achieve the substantial, potential environmental benefits associated with RoHS a system for effectively monitoring the market place and ensuring non compliant products and producers are enforced against is essential.

Arguably the BAU option, despite potential improvements in future associated with the marketing of products package, is insufficient to deliver an effective analysis of the products on the market place specifically in relation to requirements under ROHS. The ratings in the table reflect that if the BAU were allowed to persist there would most likely be a significant negative impact upon environmental protection. As it becomes clear that there is no mechanism for ensuring compliance and the threat of enforcement recedes, this situation will worsen over time. Assuming a new tailored approach to market surveillance were implemented effective, option 2 is believed to deliver significant positive impacts for the environment – both in terms of the reduction in the use of hazardous substances and environmental protection more generally. The scales in the table reflect uncertainty regarding the exact nature of the system to be put in place and the need for effective implementation.

11.4.2. ECONOMIC IMPACTS INCLUDING ADMINISTRATIVE COSTS

According to consulted stakeholders the possibility for free riders or lack of enforcement was an unimportant factor in their decision to place a product on the market (although arguably no company is going to say the most important factor in making a decision about putting a product on the market is if they can get away with non compliance). However, cost of product compliance testing was considered to be the most important. Arguably a clearer compliance system and a more harmonised approach could reduce this.

The impact assessment for the marketing of products package suggests a broad estimate that improvements in market surveillance, in the absence of significant data, might increase costs by around 5% to 10% including initial set up. These costs will be incurred by the administrations/regulators in charge of market surveillance and would not affect manufacturers. However, what the IA does not comment upon is that there would potentially also be cost reductions over time for producers. This would result from increased clarity over requirements and greater consistency reducing the need to replicate efforts. Competition would be made more equitable as free riders, and the

associated costs of their activities, would be reduced. Below a more detailed assessment of cost impacts for the two options reviewed within this factsheet are set out.

Business As Usual – Option 1

At present there is an informal system for market surveillance under the ROHS Directive; the current business as usual situation. However, there are concerns that the lack of consistency in terms of market surveillance of products more generally is leading to non compliant material being placed on the European market. There is also a lack of consistency in approach adopted between Member States. Both of these factors lead to costs for industry associated with unfair competition from products that fail to comply or must meet less stringent requirements given the variability of the approach across Europe. In addition there is an administrative burden for multinational groups given that there is no one European wide approach. The latter is associated with the need to repeatedly identify requirements and comply with multiple and varied regimes. While there are no figures held on the number of non compliant products on the market work, based on surveys for the Commission, has estimated that non compliance of products within the Electro-technical sector is between 10 and 30% (up to 50 % in the luminaires sector)[100]. In terms of turnover industry has estimated non compliant products in Europe to cost them between 4 and 25 per cent of their annual turnover[101].

Based on these figures there is clearly a case for improving the market surveillance of products on the European market place and in response the Commission has proposed a package of legislation on the marketing of products in Europe. This will deal with the market surveillance of products in Europe in a more general way improving the quality of and standardising market surveillance in Europe. This approach of greater coordination between Member States and the standardisation of rules has been widely welcomed by industry; very positive responses were reported in the IA for the package.

Assuming the proposed measures on the marketing of products are adopted this system would become the business as usual for the EU. This shift would, in itself, have administrative cost implications for business and government departments when compared to the existing situation. In terms of the former the impacts are more limited associated with requirements to provide documentation to the authorities and accommodate site visits. Meanwhile Member State authorities need to establish systems for monitoring the market place, recording information, conducting checks of products on the market place and with drawing non compliant products. The costs associated with implementing this package for both industry and the authorities will vary depending on the quality and nature of each Member State's existing approach to surveillance.

In the assessment of economic impacts the impact of remaining with the BAU, or even and altered BAU, is considered to be negative. This is because firms are anticipated to still face costs associated with inconsistent implementation, free riders and challenges impacting on their broader competitiveness. The consequent impact on innovation in the sector is also considered to be negative if the boundaries for market entry remain

unclear, there is little pressure to comply and develop new products that replace non compliant existing ones etc. For public authorities the costs are anticipated to be negative to neutral as, while they will have to implement the marketing of products package, there would be few additional costs in terms of administrative efforts – as at present little is being undertaken in way of market surveillance.

- **Option 2 – Introducing market surveillance measures specific to RoHS**

The marketing of products package contains generalised requirement for market surveillance for all products on the European market place; it does not specifically focus on EEE or testing for the hazardous substances set out in ROHS. Without further specification regarding how surveillance mechanisms should be applied to EEE, in line with ROHS, this could lead to differing approaches in the Member States, potential lack of clarity and confusion. This in turn would mean distortions in the internal market will remain. Additionally, without appropriate checks there would still be potential for non compliant products to remain on the market. There would, therefore, potentially be a continuation in the current imbalances in terms of competitiveness and costs to industry.

Option 2 would require the development of market surveillance mechanisms, building on the marketing of products proposals, but clarifying the exact requirements in relation to ROHS.

Were more detailed ROHS market surveillance requirements to be adopted there could potentially be administrative costs for industry associated with:

- more detailed reporting requirements;
- the requirement to provide documentation to the authorities in the event that their product is reviewed;
- the requirement that authorities might visit their establishment to investigate compliance;
- costs associated with any testing that must be conducted during the process of market surveillance, assuming costs are recovered from industry by the authorities.

Most of these conditions would apply as a consequence of the implementation of the marketing of products package. However, having specific requirements for ROHS might make the process more intensive hence costly. Meanwhile, clarity over what is required will avoid wasted energy and potentially streamline the process keeping these impacts to a minimum. Additionally, the extent of additional costs will depend on the current approach and systems in place within particular Member States. If a rigorous approach is already applied, as in some countries and companies, the associated additional costs will be limited or negligible. The costs to industry associated with option 2 are, therefore, considered to range from slightly negative, to neutral to slightly positive dependant on the current conditions in the Member State.

Administrative costs are likely to be most pronounced for the authorities/regulator, if no formal system of market surveillance is currently in operation. As for industry these will be similar to those for the broader marketing of products package but potentially more pronounced if specific additional requirements are applied for ROHS. Again additional costs will depend upon the current approach adopted and may be negligible in some Member States. As a consequence the impact on public authorities is considered to be neutral to negative.

For Member State authorities it is Important to note that adopting an effective approach to market surveillance may reduce costs in the longer term. This is because non compliance on the market place will be reduced, hence the negative environmental and health impacts will also be minimised.

It is considered that option 2, if appropriately implemented, will have a significant positive impact on innovation in the sector. This is because it would send a very strong message that non compliant products would not be tolerated and set the basis upon which firms can have the confidence to innovate more environmentally friendly products without the fear of being undercut by non compliant product.

11.4.3. SOCIAL IMPACTS

The BAU option is considered to have a significant negative impact on both consumers and public health and safety. This is because potentially significant non compliant product could remain on the market place. Given that ROHS was implemented to address some highly hazardous materials this potentially leaves the public at risk. Over time, if there is a failure to implement and non compliant products lead to problems of health consumer confidence in the sector will reduce.

The impact of option 2 on consumers is considered to be positive to significantly positive, as increased market surveillance would increase confidence in the products on the market place. The impact on health and safety is considered to be neutral to significantly positive. This is range is because there are major uncertainties regarding the product actually on the European market at present and its content. Additionally, the variability in terms of current implementation will also impact on the level of benefit achieved.

11.4.4. OTHER IMPACTS

The insertion of clear, consistent requirements on market surveillance into the legislation related to EEE and ROHS would clearly have benefits in terms of law making. It would create a more robust legislative measure, increase consistency of implementation and the ability to enforce against non compliance. To ensure implementation you need to be able to monitor what is on the market place and only once you have this information can you produce a robust compliance response. There are clear precedents for the formal insertion of requirements for example from the review of the IPPC Directive which included new provision on compliance assessment.

11.5 PRELIMINARY CONCLUSIONS REGARDING IA ON THIS ISSUE

There is clearly a need to have clarity over the approach to market surveillance. This is the foundation of assessing the conformity of products on the market place, enforcing against non compliance and fundamentally delivering the aims of the ROHS Directive. More over the current situation leads to costs for industry due to inconsistencies in approach and potential negative competition from cheaper non compliant product.

There are different approaches possible. One option would be to simply abide by the rules under the proposed Decision and Regulation on marketing of products – what will become the BAU upon their adoption. However, while focusing on the surveillance on products on the market place these measures do not specifically consider EEE nor the requirements of ROHS. The forthcoming requirements may, therefore, lack specificity in terms of implementing the complex requirements of RoHS.

An alternative, and option 2 considered within this assessment, is for requirements to be included in ROHS. These would build upon those new provisions set out in the forthcoming Decision and Regulation, but take them a step further as is appropriate for a specific and important legislative measure such as ROHS. This approach could involve simply a brief reference within the Directive accompanied by binding guidelines agreed at a later date based broadly on the provisions Article 14 of the 'Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products'. Or alternatively full details could be included in an annex to the ROHS Directive itself.

The impacts of adopting new provisions on market surveillance under ROHS are considered to be broadly positive in terms of environmental benefit, social impact, the costs and competitiveness of industry, innovation and the workability and clarity of legislation. The only negative impact, primarily in terms of cost, is considered to be for the regulatory authorities who would have to implement a more rigorous assessment system. Importantly, given the current variability in approach by Member States to market surveillance, the impacts will vary in strength depending upon the current approach adopted.

11.6 ANNEX TO THE FACTSHEET

Provisions within the proposed Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products – from chapter III of COM(2007)37 .

General principles for market surveillance

Member States shall organise and perform surveillance in order to ensure that products on the Community market, or entering that market, which are covered by Community harmonisation legislation, satisfy the provisions of the relevant Community harmonisation legislation and that they do not, under the condition that they are properly installed, maintained and used, compromise health or safety or other issues of public interest protection set out in the relevant Community harmonisation legislation.

Information obligations

Each Member State shall inform the Commission and the other Member States of the authorities competent to perform market surveillance on its territory, hereinafter "the market surveillance authorities".

Obligations of the Member States as regards organisation

1. Member States shall ensure communication and co-ordination between all the different market surveillance authorities.

2. Member States shall establish adequate procedures in order to follow-up complaints or reports on issues related to risks arising from products falling under Community harmonisation legislation, monitor accidents and damage to health which are suspected to have been caused by those products and follow up and update scientific and technical knowledge concerning safety issues.

3. Member States shall ensure that their market surveillance authorities have the necessary powers and resources in order to properly perform their tasks.

4. Member States shall establish, implement and periodically update market surveillance programmes.

5. Member States shall periodically review and assess the functioning of their surveillance activities.

Market surveillance measures

1. The market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, through documentary, and, where appropriate, physical and laboratory checks on the basis of representative samples.

The authorities shall be entitled to require economic operators to make available such documentation and information as appear to them to be necessary for the purposes of

They shall also be entitled to enter the premises of the economic operators concerned where it appears to them to be necessary for the purposes of Article 14.

2. The market surveillance authorities shall take appropriate measures in order to alert the users in their territory about any product they have identified as presenting a risk. They shall co-operate with economic operators on actions which could prevent or reduce risks caused by products made available by them.

3. The market surveillance authorities shall carry out their duties with due independence and observe confidentiality and professional secrecy.

Products presenting a serious risk

Member States shall ensure that products which present a serious risk, including a serious risk the effects of which are not immediate, requiring a rapid intervention are recalled or withdrawn or that they are prohibited from being made available on the market and that the Commission is without delay informed in accordance with Article 20.

Restrictive measures

1. Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the making available of a product, to withdraw it from the market or recall it, states the exact grounds on which it is based.

2. Such measures shall be communicated without delay to the economic operator concerned, who shall at the same time be informed of the remedies available under the national law in force in the Member State concerned and of the time limits to which such remedies are subject.

3. Prior to the adoption of a measure as referred to in paragraph 1, the economic operator concerned, shall be given the opportunity to put forward his viewpoint, unless such consultation is not possible because of the urgency of the measure to be taken, as justified by health or safety requirements or other public interests covered by the relevant Community harmonisation legislation.

Exchange of information – Community Rapid Information System

1. Where a Member State takes measures under Article 18 and considers that the reasons which prompted the measures or the effects of the measures taken go beyond its territory, it shall, immediately, notify the Commission, in accordance with paragraph 4, of the measures taken or those it intends to take. It shall also inform the Commission without delay of modification or withdrawal of any such measure.

2. Member States shall also notify to the Commission any voluntary measures taken by an economic operator in the case of a serious risk presented by a product which he has made available on the market.

3. The notification under paragraphs 1 and 2 shall provide all available details, in particular as regards the necessary data for the identification of the product, the origin and the supply chain of the product, the related risk, the nature and the duration of the national measure taken and any voluntary measures taken by economic operators.

4. For the purposes of paragraphs 1, 2 and 3 of this Article the market surveillance and information exchange system provided for in Article 12 of Directive 2001/95/EC shall be used. Paragraphs 2, 3 and 4 of Article 12 of Directive 2001/95/EC shall apply mutatis mutandis.

Information support system

1. The Commission shall develop and maintain a general archiving and exchange of information system on issues relating to market surveillance activities.

2. For the purposes of paragraph 1, Member States and the Commission shall provide information at their disposal on products presenting a risk, in particular, identification of risks, results of testing carried out, provisional restrictive measures taken, contacts with the economic operators concerned, and justification for action or lack thereof.

The safeguard of confidentiality and professional secrecy with regard to the information content shall be ensured. The protection of professional secrecy shall not prevent the dissemination to the market surveillance authorities of information relevant for ensuring the effectiveness of market surveillance activities.

Principles of cooperation between the Member States and the Commission

1. Member States shall ensure efficient co-operation and exchange of information on all issues relating to products presenting a risk between their market surveillance authorities and those of the other Member States and between their own authorities and the Commission and the relevant Community Agencies.

2. For the purposes of paragraph 1, the market surveillance authorities of one Member State shall provide, on request, assistance to market surveillance authorities of other Member States by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measure or by participating in investigations initiated in other Member States.

Sharing resources

1. The Commission shall draw-up and coordinate market surveillance initiatives for which expertise and cooperation of two or more Member States are required in order to share resources and expertise.

2. For the purposes of paragraph 1, the Commission, in cooperation with Member States shall:

(a) develop and organise training programmes and exchange of national officials;

(b) set up appropriate programmes for the exchange of experience, information and best practice, programmes and actions for common projects, information campaigns, joint visit programmes and the sharing of resources.

3. Member States shall ensure that their national authorities participate in the activities referred to in paragraph 2, where appropriate.

12. FACT SHEET ON THE ASSESSMENT OF ADMINISTRATIVE COSTS OF THE AMENDMENT OF THE ROHS REVIEW

According to the Impact Assessment Guidelines of the Commission, the administrative costs imposed by legislation should be assessed whenever a measure is likely to impose significant administrative costs on business, the voluntary sector or public authorities.

Administrative costs are defined as the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties. Information is to be construed in a broad sense, i.e. including costs of labelling, reporting, monitoring and assessment needed to provide the information and registration. In some cases, the information has to be transferred to public authorities or private parties. In others, it only has to be available for inspection or supply on request.

The assessment of the costs is subject to the principle of proportionality, i.e. the effort of assessment should remain proportionate to the scale of the administrative costs imposed by legislation. Moreover, the degree of detail will depend on the availability of reliable and representative data.

One of the principle objectives of RoHS Directive revision is to reduce the administrative burden. The following revision issues have been identified as bringing an overall positive impact on the administrative burden from RoHS implementation, if retained.

1) Clarification of the scope, including
    a. Clarification of spare parts and “repair as produced principle”
    b. Clarification of excluded equipment
        i. Equipment which is part of another type of equipment that does not fall within the scope
        ii. Equipment which is intended for specifically military purposes
    c. Changing the indicative annex regarding the scope to a non-exhaustive binding one
    d. Adding/modifying definitions
2) Introduction of market surveillance mechanisms (including common procedures for withdrawing non-compliant products from the market and for administrative cooperation)
3) Harmonisation of methods for demonstrating compliance
    a. Including conformity assessment

b. Use of (international) standards for presumption of conformity

4) Modification the exemptions procedure, including

a. Introduction of substitution plans

b. Introduction of 'availability' and 'reliability' of a substitute as criteria for granting exemptions

c. Introduction of standard format for exemption requests

d. Setting a maximum validity period of granted exemptions to 4 years

Companies affected by the administrative burden due to the RoHS Directive are not only producers of EEE as defined by the WEEE Directive, but also the EEE's components manufacturers, assemblers, etc. who have to check RoHS compliance of their suppliers' products and prove compliance to their clients, all along the equipment supply chain.

12.1 GENERAL DATA

An effort has been made to try to assess the administrative costs generated by the implementation of the RoHS Directive and their expected reduction thanks to the review on the basis of analysis of information available in the literature. The results of this task are presented in this chapter.

It should already be noted that there is no data available enabling to calculate administrative costs using the core equation of the cost model presented in the EC IA guidelines Annex 10, which basically calculates the average cost per action by multiplying a tariff (based on average labour cost per hour including prorated overheads) and the time required per action. Administrative costs are rather expressed in available studies in Euros / company or % of turnover. Therefore the crucial data necessary to estimate the total administrative costs due to the RoHS Directive are the number of companies affected by RoHS and their turnover in the EU.

12.1.1. NUMBER OF EU COMPANIES AFFECTED BY ROHS

Estimate on the number of companies affected by RoHS is a crucial data in order to evaluate the administrative costs, as many figures on these kinds of costs are given in €/company.

Estimations are available in the literature (i.e. [ARCADIS & RPA 2008] and [CEA 2008] reports mainly), but they differ by a factor near 3, so further investigation is necessary.

The following paragraphs present a critical analysis of the figures presented in the literature, as well as further research carried out in this study to find relevant figures. In the end a range of figures is estimated.

ARCADIS & RPA data

[ARCADIS & RPA 2008] estimates that in EU-27 around 250,000 companies are active as producers of EEE, noting that this estimation is rather approximate. Further, the report provides information on the distribution of companies by the number of employees, noting that there are significant differences between the MS. It is concluded that 90-95% of the companies active as EEE producers have less than 20 employees. Based on the data by MS provided in the ARCADIS & RPA report (pp 5-6), the share of companies by the number of employees was calculated:

Share of the EEE companies in Europe by numbers of employees				
zero[105]	**1 - 4**	**5 - 9**	**10 - 19**	**> 20**
56%	15%	5%	3%	5%

There are many issues regarding the methodology of estimation:

- Most importantly the use of PRODCOM statistics include products which are not in the scope, as they consider all companies under the DL code "Manufacture of electrical and optical equipment". For example, they include "manufacturers of medical and surgical equipment and orthopaedic appliances", which are out of RoHS scope.
- Second, they include more than 125 000 "one-man" companies with zero employees, which may not be that affected by RoHS.
- Finally, data are not available for all EU-27 countries, so extrapolations were made for countries were data is missing, using population to do the ratio.

Besides, Eurostat figures were updated since ARCADIS & RPA report was produced, and using the same methodology with the new figures, the updated estimation of the number of EEE companies in the EU-27 is more around **260,000**.

Based on the 2 first arguments above, there is a high probability that the figure of 250,000 (or 260,000 companies) is an overestimation.

Data from the UK Regulatory Impact Assessment on the transposition of RoHS Directive

The UK Regulatory IA on the transposition of the RoHS Directive estimates that there may be around 7,500 EEE manufacturers in the UK. Standard Industrial Classification (SIC) data suggests that there may be as many as 15,000 businesses affected by the RoHS Directive. Given the exemptions on certain applications, and the scope of the RoHS Directive in relation to the EEE products it covers[106], it is estimated that around 50% of total UK businesses producing EEE may be affected directly by the RoHS Regulations.

[105] Only one entrepreneur

[106] Medical devices, monitoring and control equipment, and military and aerospace equipment are outside the scope, or considered to be outside the scope of the RoHS Directive. [DTI 2006] states UK to be a leading player in the manufacturing of EEE in these sectors.

This implies that some 3750- 7500 UK businesses are possibly being affected by the RoHS Directive. [DTI 2006]

The extrapolation of this data to EU27, based on a simple population ratio, provides an estimate of **30,400 – 60,900** businesses being affected directly by the RoHS Directive. Without the factor of 50%, the number of businesses would seem to be 140,000 at maximum. Of course, such an extrapolation is extremely rough, as the number of EEE companies is likely to vary greatly between the MS. However, this estimate suggests that the number given by ARCADIS & RPA may be too high a figure.

CEA data

The study made by CEA on the economic impacts of RoHS on the electronics industry estimates the number of "global electronics companies" at **90,000**.

Communication with Ms P. Gordon, from Technology Forecasters Inc., who realised the study, enabled to have more information on the methodology used. Basically, US data are a mix of estimates from US Census Bureau[107] statistics on the number of US companies in the NAICS codes 334 "Computer & Electronic product manufacture" and 335 "Electrical equipment, appliance & component manufacture", and from TFI own estimates. Then US data were extrapolated to the world by dividing them by the fraction of dollar output of total US manufacturers over worldwide industry revenues.

As regards the scope of this estimation, it seems that it could be a bit overestimated as some manufacturers of products out of the scope of RoHS included (e.g. batteries, electricity generators).

In order to obtain the European part out of this global number, the market share of Europe in the total production of electronic equipment in 2006 was used (Figure 16)[108]. This gives an estimate of 15,000 companies for the EU, which seems very low.

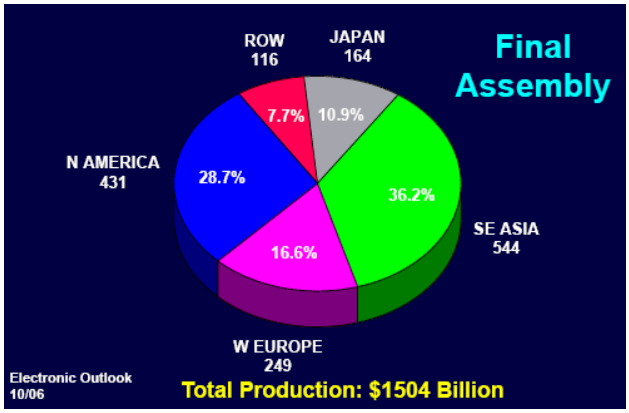

Figure 16 - World Electronic Equipment Production per geographical area, 2006

107 http://www.census.gov/econ/census02/data/us/US000_31.HTM#N334

108 Electronic Outlook Corporation 2006, quoted in http://www.ttiinc.com/object/me_custer_20061023.html

Data on the Engineering Industry (DG ENTR)

DG ENTR web site provides data on the Engineering Industry, in a 2007 report about the competitivity of the sector[109]. Unfortunately the scope is limited to "machines and other mechanical equipment and electrical apparatus and installations" most of which are out of the scope of RoHS (e.g. Electric Motors, Generators and Transformers), and does not include other EEE which are in RoHS scope, e.g. electronic equipments. So the figure of **18,000 companies** covered by this study is quite far from the scope of the RoHS Directive.

Eurostat data

An extraction was made from Eurostat database, from the Annual detailed enterprise statistics on manufacturing subsections DF-DN (incl. coke, chemicals, plastics, minerals, metals, machinery and transport equipment) and total manufacturing (NACE D) (part of Annex 2). NACE codes corresponding (or best approaching) to RoHS scope were selected. The total amounts to 75,586 companies (Table 33). In addition, two categories – manufacture of optical instruments, photographic equipment and manufacture of games and toys were considered to be partly in RoHS scope, as the manufactured products can either be EEE (e.g. video games) or not (e.g. dolls). A rough 50% of the total number of companies within these two categories was estimated to be under the scope of RoHS. Finally, two other categories – manufacture of pumps and compressors and manufacture of insulated wire and cable – were considered, though not directly under RoHS scope, these companies may produce components / parts included in equipments in the scope, therefore affected by the Directive. Again, it was roughly estimated that half of these companies would be affected. Table 33 below summarises the results found.

[109] EU Engineering Competitive Update, 2007, http://ec.europa.eu/enterprise/electr_equipment/engin/engineer_compet_june2007.pdf

Table 33 - Estimation of the number of companies affected by RoHS administrative burden in EU-27, Eurostat

NACE codes	Number of entreprises, EU-27, 2004
Companies in RoHS scope	
dk2941 Manufacture of portable hand held power tools	***2 370***
dk2971 Manufacture of electric domestic appliances	***3 000***
dl30 Manufacture of office machinery and computers	***10 394***
dl315 Manufacture of lighting equipment and electric lamps	***9 000***
dl3162 Manufacture of other electrical equipment n.e.c.	***20 433***
dl32 Manufacture of radio, television and communication equipment and apparatus	***29 189***
dl335 Manufacture of watches and clocks	***1 200***
Companies which can partly be affected by RoHS, either because some of their products are EEE (e.g. video games) or because their products may end up in equipments covered by RoHS. A rough estimate was made that 50% of these companies would be affected by an administrative burden linked to RoHS.	
dl334 Manufacture of optical instruments, photographic equipment	***4 000***
dn365 Manufacture of games and toys	***3 300***
dk2912 Manufacture of pumps and compressors	***2 923***
dl313 Manufacture of insulated wire and cable	***1 150***
TOTAL	86 959

The geographical completeness of the figures presented in the above table is quite good as data is missing from only a few new Member States (e.g. Malta, Latvia…) and sometimes also from Ireland and Portugal.

The different estimates available are summarised in the table below:

Table 34 - Summary of available estimates of number of EU companies affected by RoHS administrative burden

Source	**Estimate number of companies affected by RoHS**	**Comment**
ARCADIS & RPA 2008	250,000	Probably overestimated, include categories not in the scope
UK RoHS RIA	30,400 – 60,900	Very rough extrapolation of UK data to the whole EU-27
CEA 2008	90,000 (global) 15,000 (EU, BIO estimation)	The global figure could be a bit overestimated.
DG ENTR, stats on engineering industry	18,000	Underestimated
Eurostat	87,000	Data missing from a few new Member States, limited accuracy of the scope

Even if data from ARCADIS & RPA report is excluded, the range of figures is very large, from **15,000 to 87,000 companies**.

12.1.2. ESTIMATES OF THE TURNOVER OF EU COMPANIES AFFECTED BY ROHS

[ARCADIS & RPA 2008] providing administrative cost estimates in the form of % of turnover of EEE companies, the total turnover of EU companies was sought for. Eurostat data were used, extracting figures for NACE codes similar to the ones described in Table 35.

Table 35 - Estimation of turnover of companies affected by RoHS in EU-27, Eurostat

NACE codes	Turnover, EU-27, 2004 *million euros*
Companies in RoHS scope	
dk2941 Manufacture of portable hand held power tools	***5 000***
dk2971 Manufacture of electric domestic appliances	***43 000***
dl30 Manufacture of office machinery and computers	***59 500***
dl315 Manufacture of lighting equipment and electric lamps	***20 000***
dl3162 Manufacture of other electrical equipment n.e.c.	***30 990***
dl32 Manufacture of radio, television and communication equipment and apparatus	***200 770***
dl335 Manufacture of watches and clocks	***1 520***
Companies which can partly be affected by RoHS, either because some of their products are EEE (e.g. video games) or because their products may end up in equipments covered by RoHS. A rough estimate was made that 50% of these companies would be affected by an administrative burden linked to RoHS.	
dl334 Manufacture of optical instruments, photographic equipment	***N/A***
dn365 Manufacture of games and toys	***3 500***
dk2912 Manufacture of pumps and compressors	***17 084***
dl313 Manufacture of insulated wire and cable	***10 681***
TOTAL	392 045

12.1.3. ADMINISTRATIVE COSTS

[ARCADIS & RPA 2008] defines administrative costs in the framework of the RoHS Directive as part of compliance costs, and include the following items:

- Costs of training and information measures (both personnel and resource costs)
- Costs of collecting and reviewing information (both personnel and resource costs)
- Costs related to exemption procedures

Both the ARCADIS & RPA and CEA studies [ARCADIS & RPA 2008, CEA 2008] show that future yearly costs are low compared to the amount of past costs and one-off future costs made. This indicates that most companies have completed the changes required for RoHS. CEA indicates that the burden of RoHS is higher for smaller companies compared to large or multinational companies.

Revision of the Directive may have an effect on the future yearly costs (named annual maintenance costs in CEA report), but it may also incur new one-off costs. For example, administrative burden related with the scope of RoHS has included tracking the transposition of the Directive in all 27 MS due to large variation in transposition

(differences in enforcement methodologies and in interpretation of the scope and applicability due to lack of clear definitions such as 'put on the market', 'lead free' and 'homogeneous material). However, at this stage, most of the companies have already dealt with this issue and further changes may incur additional costs due to the need to reconsider the new scope and its implications.

Both ARCADIS & RPA and CEA studies provide estimations on the total compliance costs to companies and more or less detailed view on the different cost components. See tables on the following pages.

CEA does not consider costs to administration or other stakeholders e.g. trade associations. ARCADIS & RPA provides only some very anecdotal information for trade associations: trade organisations both within and outside the EU (with members exporting to the EU) keep their members well informed on RoHS. In most cases permanent new jobs were created dedicated to these information activities. Some associations could cope with RoHS without additional staff; often they had to make use of consultants. Examples: 3 permanent jobs at JBCE since 1999, 2 temporary posts at JEMIMA since 2004. [ARCADIS & RPA 2008]

The tables below summarise the cost data available in both ARCADIS & RPA and CEA reports. Figures in pink cases are what could be identified as administrative costs. In case of data from ARCADIS & RPA, administrative costs were clearly designed; as for CEA data, we selected from the different types of costs available the ones that could relate to administrative burden.

Table 36 - Data provided on RoHS compliance costs in [ARCADIS & RPA 2008]

Total costs related to ROHS [Arcadis 2008]		"Past costs and one-off future costs"				"Future yearly costs"			
			€ / company	% of turnover	€ / employee		€ / company	% of turnover	€ / employee
High			€59 600 000	16.00%	€32 590		€4 700 000	0.20%	€225
Low			-	0.01%	€9		-	0.00%	€0.6
Weighted average			€21 000 000	0.05%	€191		€660 000	0.00%	€22
Average			€10 000 000	1.90%	€3 185		€950 000	0.04%	€65
Technical costs of phase-out		33%	€3 300 000						
*Compliance costs**		67%	€6 700 000						
* *of which Administrative burden*	Highest		€42 700 000	1.23%	1450.001		€4 700 000	0.15%	176.471
	Lowest			0.00%	0.992			0.00%	2.046
	Weighted average		€13 200 000	0.02%	96.481		€675 000	0.01%	23.828
	Average		€5 900 000	0.18%	272.809		€265 500	0.04%	56.575
	Training and information measures	45%	€2 629 348			26%	€69 030		
	Collecting and reviewing information	53%	€3 142 391			68%	€180 540		
	Exemption procedures	2%	€128 261			6%	€15 930		
	Admin burden of total compliance costs	88%							
	Admin burden of total costs related to RoHS	59%							

Further note: More than 90% of the costs of RoHS training and information measures are personnel costs. The remainder consist of resource costs for the organisation of training and information sessions, meetings, workshops, active customer and supplier education and the development of special information packages and courses. [ARCADIS & RPA 2008]

NB: regarding future yearly costs, the samples of interviewed companies are not exactly the same for estimates of total costs and administrative costs, which should explain the differences in average figures.

So this gives average administrative costs of €5,900,000/ company (0.184% of turnover) for past costs and one-off future costs, and €265,500/company (0.042% of turnover) for future yearly costs.

Table 37 - Data provided on RoHS compliance costs in [CEA 2008]

Compliance costs [CEA 2006]		**"Initial compliance costs"**			**"Annual maintenance costs"**		
			€ / company	% of turnover		€ / company	% of turnover
Weighted average			€4 334 185			€1 050 711	
Median costs			€526 085			€86 100	
Average			€1 926 304	1.10%		€351 696	0.12%
Capital costs		47%	€413 499		48%	€176 337	
Software costs			€91 208			€12 163	
Consulting			€72 966			€30 405	
Cost of extra inventory			€510 762			€0	
Written-off inventory			€547 246			€0	
Other compliance expenses			€376 994			€0	
*Personnel***		53%	€547 246		52%	€170 230	
** of which	*R&D*	18.5%	€101 240			€31 493	
	BOM/product design	30.9%	€169 099			€52 601	
	Update internal processes	17.3%	€94 673			€29 450	
	Material testing	11.6%	€63 480			€19 747	
	Inventory rework	6.0%	€32 835			€10 214	
	Legal	7.2%	€39 402			€12 257	
	Other	8.5%	€46 516			€14 470	

So this gives average administrative costs of €254,000/ company for initial compliance costs, and €87,000/company for annual maintenance costs.

The data found on administrative costs is summarised in Table 38. It is clear from the differences observed in the above table that these figures must be taken with extreme care.

Table 38 - Summary of available estimates of administrative costs

Source	Past costs and one-off future administrative costs[110]	Future yearly administrative costs
ARCADIS & RPA 2008	€5,900,000/ company 0.184% of turnover	€265,500/company 0.042% of turnover
CEA 2008	€286,000/ company	€97,000/company

If we apply the above figures to the previous estimate of 15,000 to 87,000 EU companies affected by RoHS, we obtain the figures presented in Table 39.

Table 39 - Estimates of past and future administrative costs due to the RoHS Directive for European companies

Source	Past costs and one-off future administrative costs *million Euros*	Future yearly administrative costs *million Euros*
ARCADIS & RPA 2008	89,000 – 513,000 * 721 **	4,000 – 23,000 * 165 **
CEA 2008	4,000 – 25,000 *	1,400 – 8,000 *
* based on the administrative costs estimated in €/company (Table 38) and the estimation on the number of companies (15,000 – 87,000) ** based on the administrative costs estimated as % of turnover (Table 38) and the turnover estimated in Section 12.1.2, e.g. for Future yearly administrative costs: 0.042% * 392045 million Euros		

If we focus on future yearly costs, assuming that the 87,000 figure for the total number of EU companies affected by RoHS is the best estimate, and consider only cost estimates from [ARCADIS & RPA 2008], we come up with an extremely large range of **165 to 23,000 million Euros**, depending whether the estimation is based on the administrative costs estimated in €/company or % of turnover. The higher estimate of 23,000 corresponds to 5% of the total turnover of EU companies affected by RoHS (in comparison with the 0.042%).

Considering this, contact was taken with ARCADIS, to try to understand these very broad results. ARCADIS stressed that, due to the low overall response rate to their survey, the sample cannot be considered as representative and cannot be used for extrapolation. The figure of 265,500 €/company of future administrative costs is only valid for

[110] 'Past costs and one-off future administrative costs' include all costs incurred up to the present plus one-off costs companies are projected to face in the near future. According to [ARCADIS & RPA 2008] they can be considered to correspond to 'total compliance costs' of [CEA 2008]. Similarly 'future administrative costs' [ARCADIS & RPA] correspond to 'annual maintenance costs' [CEA].

international companies, whereas the percentage of 0.042% of turnover is not representative either as, basically, administrative costs are proportionally higher for SMEs than for large companies. So both figures of 165 and 23,000 million Euros are wrong, because either under- or overestimated, and the right range is "somewhere in the middle".

Conclusion of this task is that it appears in the end not feasible to assess the total future costs due to the administrative burden of the RoHS Directive for European companies, as data available is not consistent enough.

12.2 ADDITIONAL DATA PER ISSUE

12.2.1. CLARIFICATION OF THE SCOPE

While the different interpretations of scope across the MS have been identified as an important cause of administrative burden to companies, there is hardly any quantitative data on this issue.

In a small sample of individual companies consulted by ARCADIS & RPA (14 responses), only 7% (1 company) had experienced any difficulties in placing product on the market due to differences in MS legislation. However, one further comment suggested that for one large manufacturer, the differences in product scope interpretations in the MS have cost $3 million. [ARCADIS & RPA 2008]

12.2.2. INTRODUCE MARKET SURVEILLANCE MECHANISMS

(Including common procedures for withdrawing non-compliant products from the market and for administrative cooperation)

The market surveillance provisions to be possibly included in the RoHS would follow the proposal for the framework for market surveillance, COM(2007)37. The impact assessment on this proposal outlines that "some of the market surveillance requirements are linked to administrative costs, for example the complaint management". Further, the provisions for enhanced co-operation and information exchange at European level will lead to initial additional costs in terms of personnel, training and travelling costs. On the other hand, reinforced co-operation is also expected to lead to considerable efficiency gains through sharing of information and resources.

In the absence of significant data, the IA makes a broad estimate that the increased costs in relation to initial set-up to comply with the requirements will be around 5% to 10% [EC 2007, p.58]. These costs will be incurred by the administrations in charge of market surveillance and would not affect manufacturers.

The IA does not provide estimation on the possible positive effects (avoided administrative burden) for economic operators.

12.2.3. HARMONISE METHODS FOR DEMONSTRATING COMPLIANCE

■ **Include 'self declaration' as the conformity assessment procedure**

The IA of the Marketing of Products package states that "in general, the costs for conformity assessment are mainly determined by personnel costs, travelling costs and overhead for testing equipment. ... On average, conformity assessment costs constitute only 1% to 2% of the overall unit production costs (even less for large scale production)" [EC 2007, p.58].

[Goodman et al. 2004] Self-declaration is used for many of the EC New Approach Directives and would be appropriate even though RoHS is not a New Approach Directive. Two main approaches are available to producers:

- **Obtain an assurance from suppliers that no banned substances are present.** These could take many formats but ideally a permanent record will need to be kept. If and enforcement authority finds a banned substance then the producer will need this information to show that he has taken reasonable steps to comply with legislation. ("Due diligence")
- **Carry out limited analysis to verify declarations.** Many manufacturers are currently carrying out at least some analysis to check the accuracy of their suppliers' declarations. However, analysis of every component by all producers would be hugely expensive and can be considered rather unreasonable.

"All stakeholders acknowledged the need for strengthening market surveillance, administrative cooperation and some form of conformity assessment, through additions in the legal text of the revised RoHS. Several of them supported the idea to integrate elements from the New Approach Directives (dealing, for example, with safety and electromagnetic compatibility of EEE products and machines) with which EEE manufacturers are by and large familiar, for demonstrating compliance.

Concerning conformity assessment procedures in particular, industry unanimously and strongly opposes product conformity to be assessed through a declaration issued by a third party and seems to favour self-declaration based on "due diligence" (producers not responsible for non-compliance if they can prove that all necessary measures to comply had been taken) and use of standards (fostering also worldwide harmonised implementation of requirements related to HS in EEE)." [EC 2008]

■ **Use of (international) standards for presumption of conformity**

This option would introduce to the RoHS Directive a clause similar to Article 13 of the (proposal for a) Decision on a common framework for the marketing of products [COM(2007) 53]:

Presumption of conformity

Products which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in ...[reference to the relevant part in the legislation].

According to [Goodman et al. 2004] a small number of standards exist that are suitable for analysis of parts used for or within electrical equipment to determine the concentrations of the banned substances. They recommend that some new standards are developed where sampling and analysis are difficult or where a technique has significant limitations that could lead to erroneous results. The issue of conformity assessment procedures is further discussed in Section 8 of this report.

12.2.4. MODIFY THE EXEMPTIONS PROCEDURE

- **Introduce substitution plans**

This option would introduce to the RoHS Directive a clause similar to Article 62 4(f) of the REACH regulation, which could for example be formulated as:

An application for exemption shall include an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant.

Where the analysis referred to the above point shows that suitable alternatives are available, a substitution plan including a timetable for proposed actions by the applicant shall be provided.

Any costs or benefits linked to a substitution plan are only indicative as they are highly dependent on what substance/process is being substituted and the specific requirements of the substitution plan.

The RPA report [RPA 2006] identifies three different levels, reflecting the level of effort that might be put into the technical, cost and risk assessments carried out as part of an analysis of alternatives (Table 40).

Table 40 - Costs of analysis of alternatives at different levels of detail

Level of detail	Technical	Costs of Alternatives	HH & Env Hazard/Risk	Total
Level 1	€ 875	€ 1 750	€ 1 750	€ 4 375
Level 2	€ 2 188	€ 8 750	€ 10 938	€ 21 875
Level 3	€ 8 750	€ 35 000	€ 13 125	€ 56 875

As indicated in the Factsheet on this issue, the possible administrative costs could be estimated on the basis of the above table, but these would of course vary considerably based on what the actual substitution plan would look like and the substance/process in question.

- **Introduce 'availability' and 'reliability' of a substitute as criteria for granting exemptions**

This could involve additional administrative costs to companies, who would have to provide proof to support the exemptions claims on the basis of availability and reliability.

- **Introduce standard format**

This option would ease the administrative burden of all the actors. Accordingly, all stakeholders agree that asking the regulatory committee to elaborate a standard format for exemptions' request is a good idea [EC 2008].

- **Set a maximum validity period of granted exemptions to 4 years**

This would reduce the administrative burden to authorities related to the exemption review process, but would to some extent increase the administrative costs to industry that would have to file new exemption requests. However, while re-request would likely require additional evidence to be gathered, the administrative costs are assumed to be lower than for the first request. Furthermore, due to the on-going developments, increasing number of exemptions will become redundant.

This option would reduce the administrative costs to the administration as it would only be necessary to evaluate (the declining number of) new requests rather than carry out a full analysis of all the exemptions.

12.3 QUESTIONNAIRE: REDUCTION OF ADMINISTRATIVE BURDEN FOR COMPANIES

As illustrated by Section 4, above, there is very little data available to allow estimating the impacts, in terms of administrative burden, of the different policy options. In order to try to obtain more precise information regarding the impact on the administrative burden for a group of specific options, a short questionnaire was sent to some major industry associations (see list in Section 12.4.1).

The short questionnaire is not to be considered a formal consultation of the Commission on the revision of the Directive. It was a tool aimed at facilitating the data gathering exercise made by the contractors in charge of assisting the Commission with the impact assessment of the revision.

The set of policy options which were identified as options which could decrease the administrative burden of RoHS for companies and which were included in the questionnaire were (the numbering of options is derived from the 2nd Consultation Document[111] on the RoHS review):

III.1 Separate WEEE from RoHS scope + IV5: updating explanatory annex IB through comitology

III.2 (a) Include explicitly spare parts

III.10 "Repair as produced principle": exclude parts for repairing and for the reuse of products lawfully placed on the market

III.3 Insert in RoHS a clause similar to WEEE Art. 2.1 (excluding equipment which is part of another type of equipment that does not fall within the scope)

III.4 Insert in RoHS a clause similar to WEEE Art.2.3 (excluding equipment which is intended for specifically military purposes)

IV.1 Insert definitions in line with the "Marketing of products" package, based on COM(2007)37 and 53, e.g. definition for "placing on the market, economic operators, etc.

V(a)1 Harmonise market surveillance

V(a)2i Include conformity assessment procedures: use of standards, self declaration and CE marking

V(a)2ii Include conformity assessment procedures: use of standards, external declaration and CE marking

V(b)5 Exemptions: introduce requirement for analysis of substitutes

V(b)7 Exemptions: introduce broader criteria (such as reliability and availability of substitutes as reasons for granting exemptions

V(b)6 Exemptions: introduce standard format and validity period

12.3.1. RESPONSE RATE

Within the given delay, 13 specific responses to the questionnaires were received:

Organisation	Type of organisation	Response from
Bell Helicopter Textron	Manufacturer	USA
Christie Digital Systems Canada	Manufacturer	Canada
Electrolux Major Appliances Europe	Manufacturer	EU
Freescale Semiconductor Inc.	Manufacturer	USA

[111] http://ec.europa.eu/environment/waste/weee/pdf/2nd_consultation.pdf

Honeywell Aerospace	Manufacturer	USA
JEMIMA[112]	Association	Japan
Liebherr Hausgeräte Ochsenhausen GmbH	Manufacturer	EU
Motorola	Manufacturer	EU
Power-One, Inc.	Manufacturer	USA
Rantec Power Systems Inc.	Manufacturer	USA
Siemens Switzerland AG	Manufacturer	Switzerland
Telex Communications, Inc.	Manufacturer	USA
Test & Measurement Coalition	Association	EU

One further association referred to their response to the 2nd Consultation, but no specific data could be extracted from it. Two more associations have promised to provide their response by the 27 of June, 2008.

The list above shows that the respondents cannot be considered to be representative of the European market and the small number of the responses hampers an effective statistical treatment of the responses.

12.3.2. RESPONSES

The questionnaire asked the respondent to evaluate the decrease in the administrative burden compared to current level, in the scale of small-medium-high, if the option is adopted. The responses are provided in Table 41.

Table 41 - Summary of responses to the questionnaire concerning the decrease of administrative burden to companies

Option	No. of responses	Number of responses of the opinion that the option would result in				
		Small	Medium	Important	*None**	*Additional administrative burden**
		decrease in administrative burden				
III.1	13	**10**	2		1	-
III.2 (a)	11	**8**	2			1 response: "additional administrative

[112] Japan Electric Measuring Instruments Manufacturers' Association

						costs"-
III.10	12	**7**		5		-
III.3	12	**8**	3		1	-
III.4	12	**9**	1	2		-
IV.1	12	**8**	4			-
V(a)1	13	**7**	1	4		1 response: "additional administrative costs"
V(a)2i	14	2	4	**7**		1 response: "additional administrative costs"
V(a)2ii	11	**5**	2			4 responses: "additional administrative costs"
V(b)5	12	**8**		2		2 responses: "additional administrative costs"
V(b)7	13	3	4	**6**		-
V(b)6	13	**5**	**5**	3		-

In the questionnaire, the respondents were also asked to further quantify, if possible, the decrease in the administrative burden on each of the issues. Only 4 respondents filled in this section for each option; two more respondents provided estimates for some options. The estimations are extremely variable. While some respondents quantify the "small" decrease to be in the range of 0-2%, others correlate "small" with 10% decrease. Furthermore, for option, for example, V(b)5 one respondent estimates the administrative burden to be decreased by 20% while another thinks that the administrative costs can increase up to 50%, yet two other respondents estimated the decrease in 0% and 2% respectively.

When asked to evaluate the extent of the decrease in the administrative burden, if all the options were adopted, the responses provide estimations of 5%, 20% in long term ("if options having negative impact excluded"), "increase in administrative burden and cost".

Considering such variation, there are too few responses to allow any meaningful quantitative conclusions to be made on the administrative costs on the basis of them.

The qualitative arguments provided for (or against) the different options are summarised below:

III.1	- In general, it makes easier for manufacturers to determine if a product falls within the scope or not. But it will require further investigation to evaluate the effectiveness of this option on Category 9 products because of its huge variety. - Small burden reduction improvements could be expected due to reduced need to respond to scope-related inquiries for out-of-scope products. - It's unclear why this should lead to a decrease of administrative burdens. - The location of scope and index has no impact on administrative burden. Separation might simplify RoHS interpretation, but does not change the compliance activities.
III.2 (a)	- It's unclear why this should lead to a decrease of administrative burdens. - Burden would not be reduced because non-compliant parts would still be available for purchase and in case of out-of-scope products need to be available for repairs.
III.10	- As the products lawfully placed on the market are subject to Article 2.3, they are outside of the scope. So, no reduction is expected. - It's unclear why this should lead to a decrease of administrative burdens. - Beyond just the reduction of administrative burden, this option's significant savings would come from reducing premature scrap costs, both in repairable equipment and parts on hand. - RoHS already excludes parts for repairing products lawfully put on the market 'before July 1, 2006". At this time, removal of the date would have no impact on administrative burden for semiconductor component manufacturers.
III.3	- Insertion of the clause in RoHS makes easier for manufacturers to determine if a product falls within the scope or not. - Making this clause from the WEEE / RoHS FAQ binding is beneficial in supporting common interpretations and reduces the administrative burdens of inquiry response and unnecessary supply chain interactions. - Regardless of the statement, all semiconductor components have already been certified for hazardous substance content to allow a single component to be used in various consumer applications. This change would have negligible impact on RoHS administrative burden for semiconductor components.
III.4	- Would provide consistency with WEEE and simplify interpretation, but would not change the compliance activities for semiconductor components. - No direct benefit would be realized as test and measurement products purchased by the military are not designed exclusively for military use. However, we support binding clarification of the scope within RoHS.
IV.1	- Creating common definitions binding upon all member states will reduce

	administrative activities needed to ensure free movement of compliant, in-scope goods. - New Approach definitions clarify and reduce compliance risk, but do not change the compliance activities. The definition of product in COM(2007)53 Article 1 still does not clearly distinguish between a unit of product (serial number) or an item (SKU).
V(a)1	- No impact, as market surveillance currently does not exist. - A harmonized approach would be helpful in maintaining the common market interpretations mandated by the basis on Article 95 of the treaty. This would prevent much of the confusion we have seen from member states' variable interpretations with respect to WEEE. - New Approach definitions clarify and reduce compliance risk, but do not change the compliance activities. The instructions for market surveillance in COM(2007)37 require cross-boundary cooperation and consistency. This clarifies expectations and reduces compliance risk, but does not change our company's compliance activities. Furthermore, if producer hazardous substance testing is mandated, it would be a major cost rather than a savings, potentially multiplying current testing activities up and down the supply chain.
V(a)2i	- Self declaration is very effective for reduction of administrative burden. - Projected savings might be lowered or negated if costlier standards for showing compliance are mandated. - There is no decrease of administrative burden expected. Self declaration (compared to external declaration) is considered also to have the least increase in administrative burden - Current RoHS allows each company to determine conformity assessment procedures. Depending on the adopted standard, this proposal could add cost for changing current procedures and updating documentation. It would eventually reduce risk, but with a high operating cost in the initial years.
V(a)2ii	- External declaration is not appraisable because it requires additional cost and time. - External declaration means external certification (in any form) and this means additional costs. - Will not reduce costs but rather create additional burden. - This approach would add administrative as well as incremental external declaration costs without reducing the internal burden of compliance via self-declaration. - Current RoHS allows each company to determine conformity assessment procedures. Depending on the adopted standard, this proposal could add cost for changing current procedures and updating documentation. Forced external certification is very expensive. - External compliance certification not only adds additional cost from both the manufacturers and government agencies, but also delays the introduction time for new products in the EU market compared to the other regions. - For our company, the all important monitoring and production control is a vital

	part of a company's strategy how compliance with a given legislation shall be achieved and maintained. This internal task of a company, to also meet its obligations for instance related to product liability, has to be performed by a company in any case independently whether documentation is requested by third parties. It is furthermore very much linked to the risk, a company wants to take when it comes to the question, whether and how much to rely on Supplier declarations. Therefore, the level of monitoring and production control may widely vary among companies. This means that for the time being the administrative costs of our company may be limited to the storage of supplier declaration or issuing of company compliance declaration. Administrative costs to proof compliance towards national authorities or third parties could substantially increase if harmonised enforcement activities would start in the EU. In that sense harmonised documentation requirements - as mentioned in options "Va) 2i" and "Va) 2ii" may certainly help to reduce additional costs, but will more likely create higher costs at least for external verifications.
V(b)5	- Analysis of substitute increases the burden and often involves competition among manufacturers. - Will not reduce costs but rather create additional burden. - Depending on implementation, this proposal may create market confusion, delay new product development or even increase costs. - Though we support this option, reduction of administrative burden would be small as it is already the general practice to require a substitution plan when requesting exemptions. Consideration of additional criteria beyond those allowed by RoHS might improve the savings as it would allow a more realistic consideration of potential substitute materials. - Official EU analysis might provide market consistency and prevent premature removal of materials from the market, but adds cycle time and delays NPI entry to the EU market. Industry analysis could drive conflicting answers from different OEM manufacturers for semiconductor components going into different applications or sold to different OEM customers.
V(b)7	- Introduction of broader sustainability criteria including economic aspects would help reducing the burden for industry. - Category 9 products sometimes require electronic equipments mandatory from safety reasons, in transportation and process plant operation for example, with no substitutes available or with long period of evaluation required for substitution. - Integrating environmental, economic (availability) and social (reliability) considerations into decision making will result in significant savings well beyond administrative savings alone, especially in sectors where product volumes are small. In such cases, failure to consider other factors leads to a disproportionate administrative burden when compared to the environmental benefits that can be achieved.
V(b)6	- This option eases paperwork. - There is already to a certain extent use of a standard format for providing

	information in support of requested exemptions. Formalization of this is welcomed. A guaranteed minimum validity period would also enable more effective administrative planning in order to improve efficiency of transitions away from materials being phased out. - The standard exemption format is a good change. The validity period should only be introduced based on identified potential solutions, and should always include a final TAC review for replacement availability and reliability before implementation. Any validity period that is not justified by commercially available alternative solutions will drive exponential cost increase. The current supply chain is specialized and demands its suppliers to develop technologies; unjustified termination of exemptions would create an exponential cost increase, with most research yielding no value, especially where the technology provides no clue for future success.

Some more general comments were also provided regarding the list of options:

- As an equipment manufacturer and exporter, we would view these options as continuous improvement activities that are consistent with other actions we take on a daily basis to remain competitive in a global market.
- Many of the listed options will have a beneficial effect on administrative burden overall. Where some are not listed as significantly impacting the burden of our sector, we still feel they are important in order to ensure common interpretation and legal certainty for producers and member states as is mandated by the Article 95 basis of RoHS (e.g., exclusion of products intended for purely military use as these customers are highly concerned about long-term reliability.) It should also be noted that some of the options above would have a negative impact on our administrative burden if enacted in isolation. For example, the explicit inclusion of spare parts within the scope of RoHS would actually increase the burden of supply chain management and inquiry response. While the simultaneous binding inclusion of the repair-as-produced principle may possibly ameliorate this effect, it would need to be sufficiently clear to all parties that repair-as-produced takes precedence over the inclusion of spare parts to head off potentially differing interpretations.
- For our firm, the infrastructure to administer the RoHS initiative (and other EU environmental legislation) has been put in place long ago and is an on-going cost of doing business in the EU market. The adoption of these options would not have a significant impact to our budget.
- I fail to see how any of these reduce the administrative burden, with the exception of making improvements to the exemption process.
- It should be noted that regardless of the improvements made, there will still be high costs associated with administrative systems and resources required to show due diligence in ensuring end products placed on the market are RoHS compliant, especially as the Directive is subject to constant review and revision. This burden can never be eliminated as long as the producer is far removed in the supply chain from the original formulators of the components used in manufacture. Thus, any method of reducing this burden is appreciated.
- We would like to stress that the reduction of administrative costs is considered an issue of minor importance in comparison to major question, to improve RoHS in terms of practicability and the possibility to enforce RoHS compliance in a harmonised and unambiguous way all over Europe.

12.3.3. CONCLUSIONS BASED ON THE QUESTIONNAIRE

Based on the view of industry on the different options presented in the questionnaire, the reduction in administrative costs to the industry is expected to be modest. Nevertheless, as pointed out by some of the respondents, many of the options would reinforce the current interpretations and practices and would thus support better regulation.

One respondent thought that harmonising market surveillance would result in additional administrative costs rather than reduce the burden. This can reflect the fact that up to now the RoHS market surveillance and enforcement activities in the Member States have been rather limited i.e. many companies have had no concrete consequences due to market surveillance. From this standpoint, harmonised and possibly more "active" procedures could increase the administrative cost for a company. Similar motives may explain the one "higher costs" answer for the Option V(a)2i, as well. On the other hand such harmonisations can bring about reduction in the administrative costs of public authorities and contribute to the proper implementation of the Directive.

Regarding options V(a)2ii, four of the ten responses on this option indicated that the administrative costs would rather be higher than lower for this option due to external declaration. Thus from the point of view of administrative costs, self declaration is seen as a preferable option.

For V(b)5, two responses also indicated higher administrative costs, but they have not be substantiated with proper arguments and are opposed by other opinions that consider the option to have positive effects.

12.4 CONTACTS & REFERENCES

12.4.1. EEE INDUSTRY ASSOCIATIONS/FEDERATIONS WHO RECEIVED THE QUESTIONNAIRE

EEE industry associations/federations who replied to the 2nd Consultation of the Commission on the RoHS review and to whom the short questionnaire about the administrative costs was sent.

- AEA
- CECED
- CECIMO
- Cocir
- EDMA
- EICTA
- EPIA
- EPPA

- Eurometaux
- Orgalime
- RREUSE
- Eucomed
- JBCE
- JAIMA(Japan Analytical Instruments Manufacturers Association), JIRA (Japan Industries Association of Radiological Systems), JMED (Japan Medical Devices Manufacturers Association), JMOIA (Japan Medical-Optical Equipment Industrial Association)
- JEMA (The Japan Electrical Manufactures' Association), JEMIMA (Japan Electric Measuring Instruments Manufacturers Association), JMIF (Japan Measuring Instruments Federation), NECA (The Nippon Electric Control Equipment Industries Association)
- ITI
- IPC
- ASTM International
- CEA

12.4.2. REFERENCES

[ARCADIS & RPA 2008] Bogaert, S., Van Acoleyen, M., Van Tomme, I., De Smet, L., Fleet, D. and Salado, R. (2008) Study on RoHS and WEEE Directives. By ARCADIS & RPA for the DG ENTR, European Commission.

[CEA 2008] CEA (2008) Economic Impact of the European Union RoHS Directive on the Electronics Industry

[DTI 2006] Department of Trade and Industry, UK (2006) Full Regulatory Impact Assessment (RIA) for the Department of Trade and Industry's regulations transposing Directive 2002/95/EC (the RoHS Directive), as amended, in the United Kingdom.

[EC 2007] European Commission (2007) Commission staff working document, SEC(2007) 173.

[EC 2008] European Commission (2008) The Review of Directive 2002/95/EC (the "RoHS" Directive) – Invitation for Comments on options and for information supply, December 2007 – February 2008: Summary of comments and information received. http://ec.europa.eu/environment/waste/weee/pdf/2nd_consultation_comments.pdf

[Goodman et al. Goodman, P. et al. (2004) Possible Compliance Approaches for Directive 2002/95/EC (The RoHS Directive), ERA Technology Ltd.

2004] For the UK Department of Trade and Industry.

[RPA 2006] Industry and Risk & Policy Analysts Ltd (2006) Technical Assistance for REACH Impact Assessment Updates – Summary Report