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COMMISSION STAFF WORKING PAPER

accompanying the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the restriction of the use of certain hazardous substances in electrical and electronic equipment

(recast)

Impact Assessment

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COMMISSION STAFF WORKING PAPER

Impact Assessment for a Commission Proposal on the review of Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment

EXECUTIVE SUMMARY

RATIONALE FOR THE REVIEW

Directive 2002/95/EC aims to restrict hazardous substances in electrical and electronic equipment so as to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment. Its review is being carried out for two main reasons:

1. The Commission is committed to developing a **better regulatory environment**, one that is simple, understandable, effective and enforceable. The regulatory environment in which businesses operate influences their competitiveness, and their ability to grow and create jobs. The aim for better regulation is an important element in the EU's Partnership for Growth and Jobs (Lisbon) strategy. There is room to improve the Directive in terms of implementation, enforcement and coherence.

2. The RoHS Directive calls on the Commission to review the measures provided for in the Directive in particular with regard to the inclusion of two additional categories of equipment in the scope (categories 8&9 : medical devices and monitoring and control instruments) and the adaptation of the list of restricted substances.

PROBLEM AND OBJECTIVES

Achievement of the RoHS Directive's objectives is hindered and made more costly by problems related to uncertainties in implementation such as lack of harmonisation in interpretation of definitions and diverging requirements for demonstration of product compliance; problems with enforcement such as suboptimal market surveillance activities; and problems related to perceived inconsistency with other Community legislation or technical/scientific progress, such as potential overlaps with REACH or EuP and need for extending the scope to cover medical devices and control and monitoring instruments. .

The objectives of the review are: improved implementation and enforcement of the Directive, enhanced consistency with related Community product legislation, improvements in cost effectiveness of the Directive and increased environmental benefit.

THE REVIEW PROCESS

Two stakeholder consultations and several studies were carried out. These dealt with the topics of the review as well as the policy options within each topic. These consultations and studies helped define and analyse a number of specific options as outlined below.

OPTIONS

The options are grouped in three main classes:

1. Clarify and simplify the Directive

2. Improve enforcement at national level

3. Adapt the Directive to technical and scientific progress

Within each of these main groupings a number of options were considered and an analysis of costs and benefits was carried out for each option.

A common feature of both consultations and studies launched by the Commission services was the difficult access to quantitative data. Possible reasons include the inability of stakeholders to provide data and information and the fact that the Directive is quite young (entry into force of the ban in July 2006, enforcement activities started in 2007) as well as the absence of formalized compliance/reporting mechanisms.

SELECTED OPTIONS

In summary, the following options are recommended:

Changes in the legal text to clarify scope and definitions, in particular by creating a list of products defining the scope of the RoHS Directive which is binding and not dependent on the scope of the WEEE Directive

Introduction of all relevant provisions already used in the EU "Marketing of products" package of legislation concerning:

- national market surveillance activities;
- mechanisms for assessing the conformity of the product prior to its placing on the market based on the self declaration by the producer;
- presumption of conformity of the product on the basis of harmonised standards and CE marking.

Adaptation of the procedure for exemptions, for instance by introducing through comitology a requirement for applicants to analyse the substitutes before submitting a request, and the introduction of additional criteria for granting an exemption;

Inclusion in a staged manner in the scope of RoHS of medical devices and control and monitoring instruments; no changes in the list of restricted substances.

BENFITS and COSTS

An overview of the costs and benefits of these options is as follows:

- There is little experience of actual **compliance costs in industry;** for products currently included in RoHS estimates are it would vary from 1-4% of turnover. More recent surveys give an average overall cost related to RoHS of 1,9% of turnover (past cost and one-off future costs).

In the case of medical devices and control and monitoring instruments some of which are produced in low numbers or have critical applications and hence increased testing and reliability requirements, approximate yearly compliance cost is estimated to 400-1600 million €; it is even claimed that cost of RoHS compliance for some complex products could be as high as 7-10% of turnover (new product) or 1-10% (modification of existing product). A large part of this cost is attributable to the long development, testing and approval cycles of the more complex products. This is why a **staged introduction** for these products is proposed allowing the compliance conversion to take place in the framework of existing resources and product development cycles.

The RoHS Directive does not foresee explicit reporting obligations for Member States or information supply requirements by manufacturers and in most cases Member States have not introduced such legal obligations at national level. The process for granting exemptions is considered lengthy for products with short innovation cycles; harmonising the requirements for the contents of the application and clarifying the period of validity of exemptions will **speed up the process**, increase legal security and reduce administrative burden for both authorities and the applicants.

The introduction of harmonised requirements for scope, definitions, assessment of product conformity and market surveillance which are in line with other product-related EU legal requirements will **increase legal certainty** and thus **reduce the administrative burden.**

Initial implementation of these revised provisions could create **additional administrative burden** for Member States and producers dependent on the Member State's current level of preparation for proper enforcement and on the adequacy of measures taken by producers for ensuring product compliance.

The Commission services estimate that overall net benefits, albeit modest, will ensue. Moreover, the recommended options will have an important cumulative effect in clarifying the Directive and harmonising its implementation and enforcement with a positive contribution to better regulation.

Environmental benefits are likely to be significant: several tonnes of the heavy metals banned under RoHS (>1400 tonnes of lead, approximately 2,2 tonnes of cadmium) are used in medical devices and control and monitoring instruments, which account for 0,2-03% of waste from electrical and electronic equipment by weight; these substances by improper waste management may be released to the environment (only 49,7% of waste medical devices and 65,2% of waste control and monitoring instruments are separately collected); restricting the use of these substances through RoHS will in the medium to long term eliminate their presence in the products and in the waste thereof; further analysis shows that even in scenarios assuming much higher recycling rates there is some environmental benefit from including these categories of equipment in the scope of RoHS.

Taking into account that current Member States checks revealed that up to 44% of EEE checked were not fully compliant, effective market surveillance mechanisms at national level and enhanced cooperation among Member State authorities for removal of non-compliant

products are expected to increase considerably the environmental benefit of RoHS by minimising the number of non-compliant products on the market.

Concerning the adaptation of list of hazardous substances regulated by RoHS, the preparatory studies identified candidate substances, but given the lack of sufficient information on substitutes, which does not allow a clear view on whether they are environmentally safer or, in cases where environmentally safer alternatives do exist, whether replacement costs are proportionate to environmental benefits, **it is not considered feasible to propose new hazardous substances in the scope of RoHS.**

INTRODUCTION

Background

Electric and electronic equipment (EEE) is a product group characterized by extreme diversity and increasingly fast innovation cycles. Its production supports one of the fastest growing domains of manufacturing industry in the western world. In the EU alone an estimated 9,3 million tonnes of EEE are sold annually, the biggest share of which are large household appliances and IT and telecommunication equipment.

As the market continues to expand and innovation cycles become even shorter, the replacement of equipment accelerates, making waste electrical and electronic equipment (WEEE) the fastest growing waste stream. WEEE arisings are estimated to be 14-24 kg/head for EU 15 Member States and 6-12 kg/head in the new Member States. This is estimated to total 8,3 to 9,1 million tonnes per year, growing to 12,3 million tonnes by 2020.

WEEE is a complex waste stream of different materials and components, including several hazardous substances that can be released into the environment and damage human health if not treated appropriately. Potential risks for the environmental and human health are further increased by sub-standard recycling/recovery operations in developing countries, driven by a rising demand for raw materials and often supplied by illegal shipments of WEEE[1].

These risks can be significantly reduced by sound management of WEEE. Elements of sound management include: separating WEEE from other waste to facilitate targeted and technically adequate treatment, applying treatment standards that minimize the release of harmful substances and recovering as much as feasible materials and energy embodied in the waste. These measures can be complemented by innovative design of EEE. This can help to avoid to the extent possible the use of hazardous substances, reduce possible exposure of workers and consumers, and favour the efficient dismantling and sorting of waste.

In principle, such an approach offers opportunities for the waste management sector, equipment manufacturers and producers of EEE (first mover advantage). However, historically market forces alone have not been strong enough to promote significant improvements to the management of WEEE – as recently as the 1990s more than 90% of WEEE was still landfilled, incinerated or recovered without pre-treatment. Some of the main reasons seem to include:

– The high number of EEE manufacturers on the (global) market makes voluntary design changes in the interest of recycling unlikely as it may entail extra cost and benefits often cannot be linked to individual producers;

– Hazardous substances are often the cheapest technical solutions in the short term;

[1] Environment and human health concerns in the processing of electrical and electronic waste, Greenpeace Research Laboratories, University of Exeter, Technical note 04/2006, May 2006; "High-Tech Trash" by C.Caroll, National Geographic, published January 2008; The recycling and disposal of electrical and electronic waste in China – legislative and market responses, Environmental Impact Assessment review 25 (2005), p.461, 462; Heavy metals concentrations of surface dust from e-waste recycling and its human Health implications in Southeast China, Anna W.Leung et al, January 2008.

– Inadequate disposal of WEEE has no extra costs or may even have price incentives (low-cost landfilling in many countries; illegal exports for sub-standard treatment);

– Low prices for raw materials in previous decades discouraged investment in collection and recycling infrastructure. Even the present raw materials prices enable profitable operations in the EU for only few waste materials and fears of cyclical price changes keep holding back investment.

In reaction to this, in the late 1990s several Member States introduced national laws to address environmental concerns related to the management of WEEE. In 2000, the Commission proposed EU legislation in this field, in response to rapidly growing amounts of WEEE and associated possible environmental and health problems, and to approximate product-related legislation across Member States. As a result, the WEEE and RoHS Directives[2] were adopted in 2002.

Objectives and rationale of the WEEE and RoHS Directives

The WEEE Directive aims to prevent WEEE, and where this is not possible to recycle and recover it to reduce its disposal. It requires Member States to ensure that collection and treatment schemes are set up, sets collection and recovery targets, and makes producers[3] responsible for the financing of the WEEE management. So far, no negative effects on consumption levels have been reported although, during a transitional period, the costs of collection and treatment are clearly indicated on new equipment. The Directive thus enables market mechanisms and financial incentives in favour of efficient collection, treatment and "design for recycling".

The RoHS Directive prohibits the use of certain hazardous substances in EEE, approximating national legislation across Member States to ensure the free movement of goods. Its environmental objective is to protect humans and the environment against the release of these substances and to facilitate recycling and recovery of materials from WEEE. While establishing binding minimum requirements for all producers, it enables competitive advantages for innovative products and technologies that can comply with the substance ban more efficiently.

Recent research has confirmed the rationale of the Directives[4]. For example, the total prevented global warming potential by treating waste fridges is more than 2000 kg CO2 equivalent per fridge and energy savings from recycling metals contained in WEEE can be significant; recycled copper requires 85% less energy and recycled steel requires 74% less energy than the extraction and refining of virgin materials.

While the RoHS Directive contributes effectively to reducing hazardous substances in new EEE, hazardous substances such as mercury, cadmium, lead, hexavalent chromium PBBs and PBDEs will still be present in WEEE for many years. Reasons are, among others, waste from "pre-RoHS" equipment, exemptions under the RoHS Directive and non-compliant equipment placed on the market illegally. Separation, recovery and treatment of WEEE will therefore remain necessary for the foreseeable future.

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2 Directives 2002/96/EC and 2002/95/EC respectively

3 "Producers" are manufacturers of EEE in the EU as well as first-time importers of EEE into the EU.

4 UNU study

Experience with implementing the Directives

Both Directives had to be transposed by the Member States by 13 August 2004. By 13 August 2005, collection and treatment systems needed to be in place and producers of electrical and electronic equipment needed to start providing for their financing. The collection and recovery targets needed to be achieved by 31 December 2006 and the substance ban entered into force on 1 July 2006. Practical experience with implementing the Directives is therefore still building up but significant results have already been achieved:

– Compared to the 1990s, in 2005 about 2 million tonnes of WEEE have been diverted from disposal without any pre-treatment, by separate collection followed by treatment operations

– The RoHS Directive has resulted in reducing the quantities of the banned substances being disposed of and potentially released into the environment by 89800 tonnes of lead, 4300 tonnes of cadmium, 537 tonnes of hexavalent chromium, 22 tonnes of mercury and 12600 tonnes of Octa-BDE[5].

Significant investments were made in treatment facilities (15 new facilities in the EU-15 plus treatment facilities serving several new Member States at the same time) and the WEEE recycling business increased to a multi billion industry, employing several ten thousands of persons. However, there are indications that the Directives are not yet achieving their objectives as efficiently as possible. Some of the main reasons for this are unclarity or lack of definitions, resulting in legal uncertainty or sub-optimal solutions at national levels. Furthermore, there is now sufficient experience and knowledge to design more effective collection and recycling/recovery targets, streamline the process of granting exemptions under the RoHS Directive and efficiently widen the scope of the RoHS Directive to strengthen its environmental benefits.

Issues for Review

The Directives themselves call for a review of certain provisions, notably the list of substances banned under RoHS, the list of equipment covered by the substance ban (possible inclusion of control and monitoring and medical equipment), and the collection and recycling targets for 2008, with the aim of adapting the provisions to scientific evidence as well as to technical and economic experience in the Member States.[6]

Furthermore, a review of the Directives is foreseen by the Commission's simplification strategy, which should contribute to better implementation and enforcement of the Directives at national level.

Also based on the experience with implementation and enforcement of the two Directives at national level the following issues appear to request particular attention: Clarifying the scope, reviewing the substance ban, streamlining procedures, strengthening collection and recycling targets (WEEE), improving enforcement, clarifying definitions and clarifying relations between the two directives and with other relevant Community legislation.

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5 Arcadis report (See Annex I)

6 See Articles Articles 4(3) and 6 of the RoHS Directive and Articles 5(5), 7 (4) and 17 (5) of the WEEE Directive.

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Organisation and timing

The elaboration of policy options started after the end of the first stakeholder consultation identifying topics for the review of the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) (late spring 2007); following the conclusion of the second consultation on policy options (February 2008) drafting of the Impact Assessment started in spring 2008.

An Inter-Service group on the review of the two related WEEE and RoHS Directives was created in early 2007; it was regularly informed on and provided input to all important milestones of the review (preparation of study reports, stakeholder consultations); in particular during 2007 it was extensively consulted and provided comments on the background documents for the two stakeholder consultations on the RoHS Directive review. It was also convened in May 2008 to discuss the policy options to be presented in the impact assessment.

1.2. Consultation and expertise

- *Studies*

A comprehensive study (referred to below as the "ERA report") regarding the possibility of including medical devices monitoring and control instruments, as requested by Article 6 of RoHS, was carried out in 2006[7].

A study[8] (Ökoinstitut) examining the need and feasibility of regulating under RoHS additional hazardous substances (HS) used in electrical and electronic equipment (EEE) as required by Articles 4(3) and 6 of RoHS Directive.

A service contract related to adaptation to scientific and technical progress of RoHS, aiming primarily at reviewing existing exemptions granted in its current annex is underway (finalisation foreseen end November 2008).

A service contract (BIO Intelligence) to assist the Commission services with technical aspects of the impact assessment was finalized in July 2008.

A study focusing on innovation and competition aspects of the WEEE and RoHS review ("Arcadis study")[9].

In the context of the WEEE Directive review, two studies[10] have been executed which are relevant for the RoHS review as well, in particular with regard to the scope, the definitions, the EEE quantities and composition (content in HS and materials) the separate collection of WEEE as well as the structure of the EEE markets and development of cost/prices.

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7 http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf.

8 http://hse-rohs.oeko.info/.

9 http://ec.europa.eu/enterprise/environment/reports_studies/index.htm

10 http://ec.europa.eu/environment/waste/pdf/weee_review.pdf

Furthermore, the relevant information from the preparatory studies carried out under the Eco-design framework Directive (EuP) has been considered where relevant.

- *Stakeholder consultations*

Two structured stakeholder consultations have been launched via the EUROPA website, one inviting comments on topics and for information supply for the RoHS Directive review in March-May 2007 and a second for receiving feedback and information on proposed policy options during winter 2007 (December – February 2008).

Apart from this there were regular contacts with industry (in particular the industry associations for medical devices, control and monitoring instruments) and NGOs. The Member States representatives were frequently updated during the meetings of the Regulatory Committee and at informal meetings. Technical workshops with stakeholders were held, for providing input during critical stages of the above mentioned studies (for example in July 2007 and May 2008).

The responses to the consultations covered a large stakeholder and geographical spectrum and there were considerable variations in the extent and quality of the contributions.

Industry stakeholders focused on the need of streamlined and harmonised implementation (in particular with regard to scope and demonstration of compliance) and speeding up the exemptions mechanism. NGOs called for enhancing the environmental and health benefits of the Directive.

The preselection of topics' by the Commission services was not fundamentally criticised; few additional topics were proposed which could in most cases be considered as more detailed subdivisions of a main topic. This pointed to a comprehensive coverage of the possible topics for review in the first consultation document and therefore the Commission services used it as a basis for developing the detailed policy options.

In the second consultation the options were presented for each topic highlighting pros and cons; stakeholders were invited to express their opinion on the outlined options, on the possibility of combining options, on ranking of options within each topic and to propose additional options. They were explicitly asked to provide studies and evaluations which would allow to analyse the full costs and benefits of any changes in the Directive.

In most cases little new factual information was provided. However, stakeholders responded extensively, in many cases on each individual option, thus giving a clear idea as to the opinions on the individual options and on the future orientations of RoHS in general.

Some went as far as suggesting phasing out of RoHS and entrusting the hazardous substances management in REACH, but the vast majority of stakeholders did not share this view. In general stakeholders submitted constructive ideas for clarifying concepts and reducing uncertainties.

The standards applicable to public consultations in terms of duration, transparency, acknowledgement of receipt and feedback have been respected. Stakeholders have been pro-actively notified about launching of the consultations, given the possibility to view all relevant non-confidential contributions and informed about the outcome through publication of a summary of the comments.

Contributions and summary of stakeholder comments are available at http://ec.europa.eu/environment/waste/weee/events_rohs2_en.htm.

A common feature of both consultations and studies launched by the Commission services was the difficult access to quantitative data. Possible reasons[11] include the inability of stakeholders to provide data and information and the fact that the Directive is quite young (entry into force of the ban in July 2006, enforcement activities started in 2007) as well as the absence of formalized compliance/reporting mechanisms. Another important aspect is that some information on cost of compliance activities (for example technical modifications of products, materials' use, internal organisation) are considered by some companies as too commercially sensitive to be shared in a stakeholder consultation or a study of the Commission services.

Comments from the Impact Assessment Board

A draft of this Impact Assessment was examined by the Impact Assessment Board and discussed during its meeting of 2 July 2008, after which comments were formulated by the Board, complementing its preliminary remarks prior to the meeting. In essence the Board recommended clarifications and improvements of the IA text on five main areas:

- The development of the baseline scenario (what will happen if no action is taken)
- Clarification of the relationship and interaction of RoHS with other major policies of the EU on chemicals (REACH) and environmental performance of products (EuP)
- Need to support the analysis of options and final recommendations with additional quantitative data and quantified arguments
- Upgrading of the assessment of the administrative burden
- More consistent presentation of the views of stakeholders, in particular with regard to the more sensitive options, such as the recommended inclusion of medical devices, control and monitoring instruments (categories 8&9), the adaptation of the list of banned substances and of spare parts.

Further to these comments, a baseline scenario was outlined, information on the environmental benefits of including categories 8&9 in RoHS and a new annex giving quantitative information on cost impacts and methodological approach and assumptions were added; in particular this annex addresses the estimation of the administrative burden from the current RoHS Directive and its expected reduction if the recommended options are adopted during the RoHS review. As appropriate, key information was inserted also in the analysis of options and the executive summary.

[11] Following two rounds of structured and targeted information collection activities response was received from 36 companies in total, out of which 20 tried to give a more comprehensive image of the costs involved (Arcadis report, p.87-98); after two rounds of consultation on the use of other HS in EEE, Ökoinstitut observes that "…the manufacturers/supplier provided only very limited information on concentrations or quantity ranges of hazardous substances in electrical and electronic components. Therefore, it will be difficult to estimate the relevance of EEE for the total consumption of the substances…"

The relationship with REACH and RoHS was further explained, including in the analysis of options, as well as some further elements from the broader context (ECJ ruling on DecaBDE), necessary for better understanding of options and recommendations. Stakeholders' views were more amply presented in the introduction and some individual key options.

2. PROBLEM DEFINITION

2.1. Problems requiring action

EEE contains numerous substances that can harm human health and the environment (Annex I) if the equipment is designed inappropriately or treated inappropriately during its use or when discarded. These risks keep growing as rapidly growing consumption of EEE in the EU and globally would increase the amounts of hazardous substances (HS) that, unless managed properly, can end up in the environment and humans[12]. Sound management of waste from EEE (WEEE) reduces release of HS into the environment and Community legislation to this effect is in place. However, even in the EU less than one third of WEEE arisings are treated according to this specific legislation much of the rest being illegally dumped or shipped outside the EU, with severe environmental and health impacts.

The RoHS Directive therefore aims at reducing the future risk of the most harmful HS release from EEE at source by reducing the use of these substances. It thus complements other measures such as separate waste collection and treatment, while ensuring the free movement of EEE on the Community market. The RoHS Directive therefore is a building block within a set of Community legislation to reduce the risk of environmental and health impacts due to the release of HS.

The Directive has been in force for less than two years. During this time it has already reduced the use of HS in EEE and thereby the risk of exposure significantly (Annex I). Within this time neither the drivers mentioned above nor the rationale for reducing the use of HS in EEE outside the scope of the legislation have changed. Although it was necessary for the calculations to use a hypothetical scenario whereby all EEE would be replaced by RoHS compliant equipment[13], one has to take into account that the environmental benefit from the RoHS substance ban enacted in 2006 will be felt for many years to come, considering that for some EEE it can take years or even decades before they reach the end of life stage.

In addition, experience with the first years of implementation has indicated technical, legal and administrative problems that result in unintentionally high efforts or costs for market actors and administrations in complying with the Directive. Most recently, the Electra report[14]

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12 About 70% of heavy metals (mercury and cadmium) in US landfills come from electronic waste. Consumer electronics make up 40% of the lead in landfills, Environmental Impact Assessment review 25 (2005), p.444. Although some benefits from RoHS in terms of decrease of human toxicity potential and ecotoxicity have been identified (Arcadis study, p. II) it is not possible due to the complexity and uncertainties involved to evaluate fully the avoided exposure and direct environmental and health impacts attributable to RoHS

13 Arcadis report, p.69

14 "Electra" is a joint initiative by the EU's electrical and electronic engineering industry and the European Commission; in a report issued in June 2008, general recommendations on several EU policy acts, including RoHS, are formulated : "…RoHS transpositions are quite divergent in different member states. Some member states, for instance, reject the New Approach understanding in the context of the putting products on the community market. Other countries, Austria, Italy included the «Homogeneous

recommends harmonisation of the RoHS scope and of its application, including use of EU horizontal product related legislation, where applicable.

Alleviating these problems would enable faster, more comprehensive and more cost-efficient achievement of the environmental and market objectives .

- *Implementation-related problems*

The following shortcomings have been identified[15]:

– Continued environmental harm from products which are in practice treated as outside the Directive's scope due to uncertainty about whether those products fall within the RoHS scope[16];

– Insufficient approximation of Member States' (MS) laws with regard to authorities' views as to when an EEE is considered to have been placed on the market, resulting in uncertainty whether it is considered to fall under the scope of RoHS ban (entering in force on 1 July 2006) or not;

– Unintended and unnecessary legal counselling and personnel costs for economic operators who need to track potentially diverging transpositions of the RoHS Directive and associated legislation (e.g. Commission decisions on exemptions);

– Operators placing EEE in the markets of different Member States have to demonstrate product compliance (for example, what means "lead- or cadmium-free"?) in different ways as some Member States have specified differing methodologies. This creates additional administrative costs for operators trading in more than one Member State. Other Member States have not specified any methodology on how to demonstrate compliance which leads to delay and additional personnel costs;

– Perceived shortcomings in the exemptions procedure, which are addressed in detail below in relationship to adaptation to technical/scientific progress;

– Uncertainty about the status of "spare parts"; although there is no information on the quantities of non-compliant parts which are placed in the market by manufacturers and whether they are used exclusively for the EEE (placed in the market before 01/07/2006) for which they are destined according to the current RoHS text, it would seem that certain types of equipment are considered by some stakeholders as "part/component" and not "final product" which, in their view, can be the only type of equipment falling under RoHS.

- *Enforcement-related problems*

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material» definition in national laws (but for Italy, there is a divergence from European Commission F.A.Q. document of 24 May 2005). Germany and Italy included MCVs (maximum concentration values) into transposition laws. Proposals for improvement: The scope of RoHS should be fully harmonised. As a matter of better regulation, the European Commission should continue to put pressure on national governments to ensure a harmonised application of the directive…"

15 See ARCADIS study, part 5.2.2.3, p.103-104 and industry contributions to the stakeholder consultations: http://ec.europa.eu/environment/waste/weee/events_rohs2_en.htm

16 See ARCADIS study, p.133

First market surveillance activities have revealed a potentially high (up to 44% in one MS) proportion of non-compliant EEE on the market which increases the risk of future environmental harm. This could indicate need for possible further measures for enforcing the national laws implementing the RoHS Directive and some ineffectiveness of proportionate and dissuasive penalties.

Costs and effectiveness of the enforcement action that Member States do take would improve and synergies created by better communication through the internal market. Unequal treatment of EEE on the internal market[17] and resulting additional, unnecessary administrative costs[18] as Member States have taken divergent approaches with respect to national enforcement.

The recently adopted Regulation concerning market surveillance[19] ("Marketing of Products Package") will apply also to RoHS, however this is not likely to be clear to economic operators, and may not be immediately clear to many enforcement authorities, so some confusion and difference in implementation across the Member States is predicted to continue.

- *Problems related to perceived inconsistency with other Community legislation or technical/ scientific progress.*

Since the development of the RoHS Directive several major new pieces of Community legislation have been adopted with objectives and scopes related to those of the RoHS Directive but the legal and practical consequences of these relations are not always sufficiently clear for operators. There are perceptions of inconsistencies between RoHS and other pieces of EU legislation, leading to unnecessary legal counselling costs and possibly to unintentional infringements of legislation.

Beyond the HS already regulated by RoHS, many other substances that are used in EEE present similar hazards to health and environment (Annex II). These have been investigated in the course of the present review, at the request of the European Parliament and Council, to establish if further substances should be included in the RoHS substance ban.

Certain categories of EEE outside the scope of RoHS contain hazardous substances with the related human and environmental risks. In the course of the present review, at the request of the European Parliament and Council stated in the text of the Directive, the Commission has investigated if the scope should be widened, in particular to medical equipment and measuring instruments.

Certain applications of the banned HS in EEE cannot be avoided as substituting them is either scientifically or technically impracticable or would lead to more negative impacts than the

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[17] Martin et al. In "The EU restriction of Hazardous substances Directive: Problems arising from Implementation Differences between Member States and Proposed Solutions", (RECIEL 16(2) 2007, Blackwell Publishing Ltd) present the results of telephone interviews conducted with 21 Member State RoHS enforcement officials and come across, inter alia, different interpretations of the phrase "put on the market", different expectations on evidence for RoHS compliance to be supplied by manufacturers different penalties for non-compliance and varying levels of fines as well as different preferences of RoHS enforcement officials towards market surveillance.

[18] "Collecting and reviewing information" accounted for 49% of administrative burden, according to ARCADIS study, part 5.2.2.3, p.104

[19] Decision 768/2008/EC and Regulation (EC) 765/2008, OJEU L218, 13.08.2008

present situation. It is therefore necessary to exempt such applications from the legal ban. However, the RoHS process for granting exemptions has proven too cumbersome and too lengthy to keep pace with innovation, in particular for products with lead to market times which can be in some cases even shorter than the exemption procedure. Producers therefore experience delays in being allowed to put equipment on the market and administrators face legal uncertainty when trying to assess the compliance of such equipment. Especially for products with short innovation cycles this can lead to significant economic losses.

2.2. Underlying drivers of the problems

- *Implementation-related problems*

Implementation-related problems (notably difficulties in deciding whether certain products fall within the scope of RoHS and diverging views among Member States authorities as to when putting on the market of an EEE is deemed to take place) are driven by a lack of clear, agreed scope of RoHS and by a lack of clarity in legal provisions and definitions. A lack of precision in the RoHS Directive is contributing to this.

- Enforcement-related problems

Enforcement-related problems (notably too many non-compliant products and unequal treatment of EEE in the internal market) reflect disparities in MS' approaches and the political priority, resources and organisation given to product compliance. Disparities, in turn, are partly due to differing perceptions by Member States of what constitute effective mechanisms for reporting, assessing product compliance and carrying out market surveillance.

- Coherence/consistency-related problems

Problems arising from mis-perceptions of the inter-relation between legislation are largely due to uncertainty about the relation of RoHS and newer policies and legislation such as REACH and EuP. The problem is driven by the need of market players to ensure compliance with different pieces of closely related legislation while trying to minimize additional burden and efforts without reference to authoritative and user-friendly explanations or cross-references.

Restrictions in scope are related to incomplete knowledge at the time the RoHS Directive was created, whilst technical and scientific progress has now provided more information. This has caused the exclusion of other product categories that could have enhanced the benefits of the Directive.

Inconclusive and incomplete scientific and socio-economic information is also the main driver behind problems related to adapting the list of banned substances.

Finally, the complexity of the scientific work needed and necessity for extensive stakeholder consultation for deciding on whether exemptions from the substance ban are justified is driving the lengthiness and of administrative and procedures for granting or withdrawing exemptions. Furthermore, an under-representation of socio-economic considerations in the process can cause market disadvantages for producers that are refused exemptions as a result of insufficient cost-benefit assessments.

2.3. Who is affected, in what ways, and to what extent?

– Companies that place EEE on the EU market, such as manufacturers (who have to adapt the design of their products, need legal certainty as to whether their product falls under the scope of RoHS and want to benefit from its free movement in the internal market) and importers/distributors/distant sales operators who can be held responsible for compliance of the EEE they place on the market;

– Enforcement officials in Member States administrations who need clear rules and efficient tools for assessing product compliance and carrying out market surveillance;

– Suppliers of parts and components, including in 3rd countries, because they need to adapt their products to the requirements of their client;

– Producers of the HS;

– Recyclers and other waste treatment facilities operators, because the complexity and cost of the WEEE treatment depends to a certain extent on its composition and in particular its content of HS;

– Users of EEE, workers in EEE production and WEEE recycling and treatment facilities (in the EU and particularly overseas), because of potential exposure to HS;

– The civil society at large because of the negative environmental and health impacts from the release of HS; design changes can affect product price, availability of products and functions.

2.4. How would the problem evolve, if no action is taken

- *Risks for environment and health from exposure to Hazardous Substances in EEE and already regulated by RoHS*

There are various factors which will influence this exposure over time, making forecasts about future overall levels of exposure in the EU and in third countries difficult:

The weight of WEEE produced in the EU is increasing, from an estimated 8,3 to 9,1 million tonnes per year in 2005 to 12,3 million tonnes by 2020. This tendency is further exacerbated for some products with short innovation cycles, in particular in the information and communication technologies and the consumer electronics sectors.

On the other hand the phasing out of the use of substances, enacted in 2006, as well as of the exemptions granted will contribute to a reduction of exposure for the next 5 to 10 years at least. Indeed, one needs to take into account the life time of EEE which is quite diverse and can be even longer that 20 years for some specialised products. This means that there can be a considerable time span from product design and end of life of the product meaning that the environmental benefits will be reaped gradually, taking also into account the recommended differentiated enforcement dates and the proposed exemptions, which are to be phased out when substitutes become available.

In particular with regard to third countries, where severe environmental and health problems have been observed due to unsafe handling of WEEE, the actual exposure will depend on

many factors including the efficient checking of illegal WEEE shipments, the improvement of facilities and strengthening of environmental legislation and enforcement in these countries as well as on the raw materials' prices which, if high, can, in some cases, be an incentive for illegal shipments and low cost/below standard treatment.

Concerning the percentage of non-compliant products placed on the market, first market surveillance campaigns show that in some cases (one MS); it can be as high as 44%. Due also to the rather short time since the entry into force of the ban (July 2006) there is not much information from market surveillance activities; 10 MS have reported inspection campaigns; these campaigns covered various numbers of EEE products and companies (below 100), involved various degrees of requests for compliance documentation&testing and resulted in warnings or even (very few) withdrawals of products; the results of most of these campaigns have not been published or are not even available.. The scarcity of data does not allow us to have an overview of the % of the EEE placed in the Community market which are not fully RoHS compliant or an idea about the evolution of this percentage since the last data were provided.

However, this percentage is expected to drop with increasing knowledge of the Directive and more systematic checking at national level with the appliaction of the recently adopted related Regulation (in the context of the "Marketing of products package"). Obviously the actual improvement will depend on the extent of the market surveillance activities that national authorities will deploy and the efforts that manufacturers will undertake to improve and demonstrate compliance; but no drivers for a change in these trends are currently observed.

Looking at the problem caused in particular by medical devices and control and monitoring instruments, although it is claimed that many of these products due to their specialized use are not disposed of in an uncontrolled way at their end of life, studies[20] show that only 50% (medical devices) to 65% (control and monitoring instruments) are being separately collected. On the reasonable assumption that a large proportion of those products not collected separately are not being treated and recycled according to high environmental standards, this means that there is a risk that a large proportion of the HS they would contain will be released in the environment. This is predicted to lead to environmental harm, as reflected by toxicity indicators such as human toxicity potential, freshwater aquatic, freshwater sedimental and terrestrial ecotoxicity potentials.

It seems highly unlikely that the content of the substances in these products will be affected in the short to medium term (e.g up to 2016) by either REACH or EuP given that most of these substances are already regulated for many uses and there is no indication that they can constitute a priority under REACH. Many of these products (for example computer tomography scanners or x-ray electron microscopes) do not meet the EuP threshold of 200 000 units sold per year; such complex and specialised products due to their size can also be assumed to represent a higher % in the overall WEEE tonnage than their sold numbers would make believe[21]; the fact that they normally do not have energy consumption as their overriding environmental impact brings them further down the priority list of EuP at this stage.

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[20] UNU study, final report August 2007 carried out to support the WEEE review

[21] On the basis of the ERA report, p.51 it can be estimated that they could amount to more than 20 000 tonnes out of the total of almost 27 000 tonnes estimated by industry (COCIR and EDMA)

These categories of products account for approximately 1% of all EEE sold annually in EU and for 0,2 – 0,3% of WEEE by weight. The quantities of HS contained in them are much lower compared with other applications (for example lead or cadmium in batteries) and in total would amount to approximately 1400, 2,2, 0,03 and 0,8 tonnes of lead, cadmium, mercury and hexavalent chromium respectively. They contain also approximately 10 tons of deca-BDE[22].

Industry claims that lead-free soldering is anyway increasingly used (mainly in preparation for an expected introduction of these products into the scope of RoHS) with estimates that current use of lead for solders in category 8 products amounts to roughly 0,08% of the overall lead use in EU[23] with predictions that this on-going substitution would reduce the consumption of lead in future by up to 90%. However, if these products are not included now in RoHS it is highly likely that the momentum for substitution and related voluntary initiatives (such as use of an eco-design standard) developed with the perspective of legislation may subside. Some re-introduction of lead solder over time would also be expected.

- *Unnecessary Costs*

If no action is taken, divergent implementations of the RoHS Directive at national level will persist, preventing EEE manufacturers to make best use of a well functioning internal market. Uncertainty among manufacturers about legal requirements for demonstrating RoHS-compliance and about enforcement methodologies in the 27 Member States will persist, maintaining or increasing administrative burden and legal uncertainty.

The Impact Assessment of the Marketing of Products Package[24] indicates that product conformity assessment related costs can be on the average up to 1-2% of unit production cost (less for large scale production) for complying with related requirements in the area of harmonised EU legislation affecting EEE, e.g. on safety.

The RoHS Directive currently does not foresee explicit reporting obligations for Member States or for information supply requirements by manufacturers in RoHS and in most cases Member States have not introduced such legal obligations at national level either for manufacturers. This makes an estimation of the current costs for manufacturers resulting from potentially divergent expectations of MS authorities for compliance demonstration and their development impossible; they might now be less or more that the abovementioned rate of 1-2%

If RoHS is not amended, several of the provisions of the "Marketing of Products Package" will apply automatically, but this is not likely to be clear to economic operators, and may not be immediately clear to many enforcement authorities; the result could be costs higher than 1-2% which would be the maximum expected rate if harmonised conformity assessment requirements are introduced in RoHS.confusion and difference in implementation across the

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22 The figures provided in the ERA report, p.71 come from various sources and it is not clear whether they refer to yearly quantities placed on the market or to the HS contained in category 8&9 present in the EU market at a given moment. Industry (COCIR contribution to the stakeholder consultation) estimates that the amounts (tonnes) of lead, cadmium hexavalent cromium and mercury contained in medical devices put on the EU market each year are respectively 1148,/1,7/0,008 and 0,012

23 EDMA contribution to the stakeholder consultation

24 P.58

Member States. The future annual cost for RoHS compliance is estimated at 0,04% of turnover (minimum 165 million €, maximum 23000 million €, see Annex V) and is estimated to decrease over time because EEE manufacturers and their suppliers become more familiar with RoHS. However, it might turn out to be higher if the unnecessary costs from lack of clarity and divergent Member State practices are not addressed, in particular if more rigorous and wide-spread conformity assessment and market surveillance activities take place.

The number of exemption requests is expected to decrease for the EEE already covered by RoHS due to the maturity of the increasing availability of field data for substitutes which would promote their reliability and availability; it cannot however be excluded that some exemptions will still be needed for innovative applications for which their intrinsic properties make the banned substances suitable; as far as costs are concerned, they could further fall, due to familiarisation of manufacturers with the procedure, further possible improvements through guidance documents or standard formats and also due to the decreasing number of requests.

2.5. The EU right to act

This is a review of existing Community legislation, put in place to tackle problems arising with both products and waste. Moreover, Council and the European Parliament have explicitly called on the Commission in Articles 4(3) and 6 of the RoHS Directive to review the measures provided for in the Directive, taking into account, as necessary, the precautionary principle and new scientific evidence, in particular with regard to the inclusion of two additional categories of equipment in the scope (categories 8&9: medical devices and monitoring and control instruments) and the adaptation of the list of restricted substances.

This review is a part of work to developing a **better regulatory environment in the EU,** respecting the principles of subsidiarity and proportionality. Simplification intends to make legislation at both Community and national level less burdensome, easier to apply and thereby more effective. The Commission is committed to reduce unnecessary burdens while preserving the level of environmental protection.

3. OBJECTIVES

3.1. Objectives

The **general objective** is to achieve the objectives of the RoHS Directive more effectively and efficiently, thus optimizing benefits for the society as a whole in return for the legislative, administrative and economic efforts required, thereby to contribute to a better regulatory environment that is simple, understandable, effective and enforceable, thus advancing sustainable development and environmental protection while helping businesses to maintain its competitiveness and ability to grow and create jobs.

The **specific objectives** are to:

– Bring clarity to the users about the requirements of the Directive and simplify its operation;

– Cut unnecessary costs for relevant business;

– Minimize the numbers of non-compliant products by improving the enforcement of the Directive.

This leads to **three operational objectives** defined as follows:

(1) A clearer Directive that is simpler in its operation and is clearly coherent with other pieces of EU legislation:

   (a) A harmonized RoHS scope in all Member States with clarity on products included in the "grey" areas (e.g. "part of another equipment") and clarity on important terminology, e.g. "put on the market";

   (b) Definitions that are easier to interpret (for example in line with Community product legislation).

   (c) Clarity for users on the relationship to other legislation

(2) Improved enforcement of the Directive at national level:

   (a) Minimized number of non-compliant products by improved effectiveness of enforcement;

   (b) Increased legal certainty for operators across the internal market.

(3) A Directive that is adapted to technical and scientific progress :

   (a) Faster mechanism for granting exemptions;

   (b) A product scope adapted to technical and scientific progress;

   (c) Restrictions on use of HS in EEE where justified by scientific facts and the precautionary principle;

3.2. Consistency of these objectives with other EU policies

In the course of implementation questions have been raised with regard to coherence and complementarity between the WEEE and RoHS Directives and with other Community policy and legislation introduced since their adoption. These include notably the Lisbon and Sustainable Development Strategies (including simplification/better regulation), the “Energy and Climate” Package, the 6th Environment Action Programme and the Community Strategies on natural resources and waste management, other Community Strategies (IPP, the marketing of products, lead markets), REACH (regarding the use of substances), the EuP Directive (regarding the design of EEE) and other legislation related to EEE and its waste management.

Synergies between the RoHS Directive and REACH and the EuP Directive are particularly relevant.

REACH focuses on the chemical substances while RoHS is product legislation dealing only with hazardous substances in EEE. The complementarity consists in that, if a substance that is subject to authorisation under REACH is restricted under RoHS, such application will be exempted from the REACH requirements; it explains why RoHS and the subsequently adopted REACH were meant to coexist and ensures that any conflict between REACH and RoHS is avoided.

EuP addresses toxicity as one among all significant environmental aspects of a product and during the first phase of implementation focuses on energy efficiency; it was not meant to examine the use of individual hazardous substances nor can preparatory studies for implementing measures dwell on the feasibility (technical/economic) of their substitution with the necessary degree of detail. EuP contains an explicit reference to RoHS, ensuring that any conflict is avoided; if the EuP preparatory studies reveal the need for measures on a hazardous substance, this will be done under RoHS (as recently the case for mercury in lamps).The assessment in Annex IV shows that the RoHS Directive is complementary and coherent in its substance with other relevant Community legislation. Nevertheless, some scope for better clarifying these relations and modernizing terminology in line with newer policy exists. Options for doing this are also discussed in this impact assessment.

4. DESCRIPTION OF POLICY OPTIONS

Options are grouped in relation to the objectives described in section 3. To focus the analysis on the most important possibilities, other options which the Commission had considered at an earlier stage but found unsuitable are given in Annex III.

4.1. Options to clarify and simplify the Directive

The below mentioned options 4.1.2- 4.1.5 are not mutually exclusive but complementary in serving objective 1.

4.1.1. Make no changes to scope or definitions

4.1.2. Create an independent scope for RoHS

To date, RoHS refers to the WEEE Directive for its scope; this option consists in providing to RoHS an independent, harmonised scope; in addition, through this option the current WEEE annex with indicative examples is transformed to a binding one and can be amended through Committee procedure.

As an option in the review of the WEEE Directive it is considered to remove the annexes defining the scope from the WEEE Directive; the WEEE Directive would refer for its scope to the RoHS Directive.

4.1.3. Clarification on spare parts

(a) Explicit inclusion of spare parts

RoHS does not define "spare parts"; an option for increased clarity and legal security would be to include them explicitly in RoHS

(b) "Repair as produced principle"

This option would modify the legal text of RoHS so that it is explicitly allowed that EEE using a banned substance in an application exempted from the ban when placed on the market, would be able to be repaired and reused with parts using the banned substance in this application even after the expiry of the exemption.

4.1.4. Clarification on excluded equipment

The WEEE Directive excludes explicitly some types of equipment; although the Commission services and stakeholders consider that these exclusions apply for RoHS as well, it is not written in the RoHS legal text; this option consists in explicitly excluding military equipment and equipment which is part of another equipment in the definition of the RoHS scope. Specifically to:

(d) Insert in RoHS clause similar to WEEE Art 2.1 (excluding equipment which is part of another type of equipment that does not fall within the scope);

(e) Insert in RoHS clause similar to WEEE Art 2.3 (excluding equipment which is intended for specifically military purposes).

4.1.5. Adding/modifying definitions

This option would be to insert several definitions into the text of RoHS. These would be definitions relevant for RoHS from the recently adopted "Marketing of Products Package"; definitions for medical devices and industrial control and monitoring equipment; definition for "homogeneous material" from the Guidance Document of the Commission services[25].

4.2. Options to improve enforcement

The options 4.2.2–4.2.3 are not mutually exclusive but complementary in serving objective 2.

4.2.1. Make no changes: not add provisions aiming at better enforcement

4.2.2. Strengthen mechanisms to remove non-compliant products from the market

This option consists in inserting provisions from the "Marketing of Products Package" establishing obligations for Member States to carry out market surveillance activities with regard to products' compliance with RoHS, to exchange information on enforcement activities and cooperate with other Member States and the Commission for spotting non-compliant products. The "Marketing of Products Package" provides a consistent legal framework including harmonised definitions, obligations for the economic operators and safeguard mechanisms intended to apply across sectoral EU product legislation.

4.2.3. Harmonize methods for demonstrating compliance

The below options a) and b) are mutually exclusive

(a) Include conformity assessment procedures: use of standards, self declaration and CE marking

Insert the obligation for producers to carry out internal design control for compliance of their products with RoHS and affix the CE marking before placing them in the market and give the possibility to use EU harmonised standards

[25] http://ec.europa.eu/environment/waste/weee/pdf/faq_weee.pdf.

(b) Include conformity assessment procedures: use of standards, external verification and CE marking

Insert the obligation for producers to have verification of compliance of their products with RoHS by a third party carried out and affix the CE marking before placing them in the market and give the possibility to use EU harmonised standards.

4.3. Options to adapt the Directive to technical and scientific progress

4.3.1. Exemptions

4.3.1.1. Make no changes to the exemption mechanism

4.3.1.2. Remove the exemption mechanism from the Directive.

The ban of the substances would be total (no possibility for exemptions) but this ban would only apply to those products which do not create a need for exemptions.

4.3.1.3. Maintain the exemptions procedure with changes in the criteria for granting and withdrawing exemptions

(a) introduce requirement for analysis of substitutes

Insertion of obligation for manufacturers requesting an exemption to submit their analysis for possibilities of substitution of the banned substance in the application and, if possible, a substitution plan. A similar provision exists in the REACH regulation (Article (62)(4)(e)); detailed rules will be set out in the standard format to be produced by the Commission.

(b) introduce broader criteria for granting exemptions

These would be availability or reliability of substitutes. If availability or reliability of substitutes is not ensured, an exemption should be granted, so as to avoid negative socioeconomic effects, such as steep price increases and withdrawal of products. The Regulatory Committee will assess to which extent these criteria are met.

(c) introduce standard format and validity period

Creation, through Committee procedure, of a standard format for exemption requests; by default, an exemption expires after 4 years, unless a renewed request is accepted.

4.3.2. Adapt product coverage to technical and scientific progress

4.3.2.1. Remove all products from scope of RoHS – repeal RoHS

Scientific and technical progress may facilitate voluntary substitution of the HS regulated by RoHS and hence help achieving the objectives of RoHS in a more cost-effective way. This option would involve the effective repeal of RoHS and the use of voluntary commitments or standards and existing EU legislation (Ecodesign Framework Directive, REACH) to try to achieve the objectives.

4.3.2.2. Make no changes, not include Categories 8 and 9.

Medical devices and 'control and monitoring' instruments (Categories 8 and 9) were included in the WEEE Directive but excluded from the RoHS Directive because a longer adaptation period was needed for these products the high reliability of some of which is critical.

Council and Parliament (in Article 6 of the Directive) required the Commission to consider their inclusion. This option would leave the coverage of RoHS unchanged, Categories 8, 9 would remain out of the scope of RoHS.

4.3.2.3. Include all of Categories 8 and 9 with specific exemptions:

(a) from 2012

(b) from 2014

(c) delayed inclusion of cat.9 industrial equipment (2015)

(d) delayed inclusion of certain medical devices (IVD : 2016, AIMD : 2020)

This option consists in including both categories in the scope of RoHS and granting exemptions for certain applications of the banned substances. The sub-options differ in the deadlines and the treatment of some sub-categories of products.

a) Inclusion of products falling within categories 8 and 9 from 2012. 2012 is a realistic date for the legislative proposal to pass through the legislative process and be implemented by MS.

b) same as a) but with longer period for adaptation granted.

c) Can be combined with any of a) or b); independent from 3d): granting longer adaptation period to industrial monitoring and control instruments by submitting them to RoHS in 2015.

d) deferred enforcement date for in vitro diagnostic devices (IVD:2016) and for active implanted medical devices (AIMD : 2020); Can be combined with any of a) or b); independent from c).

4.3.3. Substances covered [Article 6 of RoHS]

Besides the already regulated substances under RoHS, EEE contain other HS. Article 6 of RoHS asks the Commission to adapt the list of regulated substances on the basis of scientific facts and taking the precautionary principle into account.

4.3.3.1. Make no changes to the list of substances regulated by RoHS

4.3.3.2. Remove substances from the list of banned substances under RoHS

The only substance for which updated information justifies examining whether it should be removed from the scope of RoHS is DecaBDE, which belongs to the group of PBDEs; this option would consist in releasing DecaBDE from the ban[26].

4.3.3.3. Add new substances for all EEE, in the scope of RoHS but with exempted applications

In line with the abovementioned requirements of Article 6 the results of a study of the Commission services and other available information, this option consists in extending the list of substances banned by RoHS by adding certain HS.

5. ANALYSIS OF IMPACTS

As mentioned before, it proved difficult to obtain all the necessary information in order to comprehensively address all the impacts of the policy options. This applies to an even greater extent to the social impacts.

However, during the stakeholder consultations and the preparatory studies two broad kinds of impacts of social nature were identified:

Health: In particular related to the health of workers in WEEE recycling plants; these were referred to earlier as well, in connection with low standard recycling facilities overseas. Similar concerns for plants in the EU have been raised during the stakeholder meetings by non-profit organisations involved in WEEE recycling. The recommended options for the inclusion of medical devices (section 6) are such that any negative impacts on healthcare are avoided. Finally all the environmental benefits of the review would be likely have a small positive impact on health as well, due to the reduction of the exposure to HS.

Employment: Although economic operators and administrations had to mobilise human resources for complying with RoHS, the preparatory studies did not reveal any substantial impact on employment[27]. There seems however to emerge a positive impact on the quality of skills of scientists and engineers involved in the practical implementation of HS substitution.

These are general observations, and the remainder of this section deals with *specific* benefits and costs for each option.

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[26] On 1 April 2008, the European Court of Justice annulled the DecaBDE exemption granted through a Commission Decision from 2005. The Court ruled that the risk assessment report does not examine the possibility of substituting DecaBDE or the negative effects that substitution could have. Furthermore, since the updated risk assessment report is from 2002, the Court concluded that the decision was not based on technical or scientific progress. The Court thus ruled that the conditions for granting exemptions were not complied with and annulled the exemption for DecaBDE while maintaining its effects until 30 June 2008.

[27] Arcadis study, p.109: in most cases apparently a reallocation of staff took place but no job creation

5.1. Options to clarify and simplify the Directive

5.1.1. Make no changes to scope and definitions

Benefits:

- No additional effort for stakeholders to get familiar with and implement modified provisions, hence no additional administrative burden and cost in the short term.

Costs:

- The interpretation difficulties outlined in section 2 will persist or increase because of the increasing variety of EEE and distribution outlets, as well as further differentiation of implementation in MS. This would create an administrative burden probably higher than the one avoided by not introducing new provisions for scope and definitions.

- Informal clarification and coordination initiatives by Member States authorities and the Commission services are not legally binding. Continued legal uncertainty would lead to continuing economic risks for manufacturers.

5.1.2. Create an independent scope for RoHS

Benefits:

- RoHS regulates product (EEE) design and therefore is based on Article 95 of the Treaty to harmonise requirements.. To date, RoHS scope is defined in the WEEE Directive which is based on Article 175, which gives Member States much more leeway than Article 95 for adding products in the scope.

- With an autonomous RoHS Directive scope under Article 95 manufacturers can be confident that enforcement authorities in the various Member States will not define the scope of RoHS differently. This will reduce administrative burden, legal uncertainty and related economic risks for manufacturers.

- Currently in the WEEE Directive there is a binding Annex (IA) mentioning the broad EEE categories falling under the RoHS scope and an additional annex (IB) indicating specific EEE falling under these broad categories. The Regulatory Committee and the informal network of Member States enforcement authorities have already been discussing at length the "grey area" products and have developed considerable expertise[28]. Making Annex IB binding would clarify the scope and therefore reduce administrative burden and would be compatible with the legal basis of RoHS (Article 95 of the Treaty, harmonisation).

- Environmental and health protection will remain at least at the same level, since this option does not foresee removal of any product from the scope of RoHS.

Costs:

[28] SeveralMember Statesmeet informally at regular intervals in the context of an "Enforcement Network"; this group has produced a "Manual of Decision" aiming to assistMember Statesauthorities in deciding whether an EEE falls within the RoHS scope or not; it has also produced a "RoHS Enforcement Guidance Document" for assisting industry in demonstrating andMember Statesin checking compliance of EEE with the RoHS Directive

- For many EEE categories both WEEE and RoHS will still apply. Manufacturers and other stakeholders will have to implement them jointly and there is a close link between the two Directives (for example the treatment requirements of WEEE must take into account RoHS); separating the scope will not relieve stakeholders from having in mind both Directives and some confusion might be created in the early phases of implementation of the revised RoHS Directive; however, these costs will be eliminated if RoHS defines the WEEE scope (an option examined under the WEEE review).

- The adaptation of the annexes by the Regulatory committee might in some cases be longer than an informal conclusion as to whether a specific EEE falls under the scope, but, given that such discussions are taking place already, additional burden from formalizing them in the Regulatory Committee is unlikely.

5.1.3. Clarification on spare parts

(a) Explicit inclusion of spare parts

Benefits:

- Currently, parts contained in EEE implicitly have to be compliant because the EEE as a whole must comply; non-compliant spare parts may be used for EEE placed on the market before 1 July 2006. Clarifying in the legal text that also parts which are placed on the market independently from the equipment in which they will be incorporated are in the scope of RoHS would further clarify the scope and hence include legal certainty and reduce economic risks, for example from different Member States' interpretation: certain types of equipment are considered by some stakeholders as "part/component" and not "final product" which, in their view, can be the only type of equipment falling under RoHS; such diverging interpretations will cease with the proposed clarification. NGOs are in favour of such a clarification.

- RoHS allows the use of non-compliant parts in certain cases, and an option to extend this derogation will be considered (“repair as produced principle”, see below) but there is no information as to how the existing provision is being enforced by MS, which quantities of non-compliant parts are placed in the market by manufacturers and whether they are used exclusively for the EEE (placed in the market before 1 July 2006) for which they are destined; an explicit provision in the text that parts are included will provide the necessary legal clarity basis for Member States and manufacturers to deploy the necessary resources for fulfilling their obligations.

- Including explicitly spare parts will shift some of the responsibility for compliance to part manufacturers and would contribute to spreading clearly and more equally the burden and cost of compliance throughout the supply chain. It would facilitate information supply and compliance for final product manufacturers, who would benefit from a reduction of the administrative cost.

- The environmental benefit of the clarification of this scope is uncertain, though positive: the Commission does not have data on the number of non-compliant parts currently put on the market, though it can be expected that the majority of parts used for equipment placed on the market after 1 July 2006, being replicas of components integrated in finished products, will be RoHS-compliant already.

Costs:

- The practical implementation cost for parts' manufacturers should not be significant, given that, already now, all parts and components integrated in new finished products must be RoHS-compliant.

- The majority of industry stakeholders are against inserting a definition for "spare parts" and see additional administrative burden if spare parts are made subject to all the obligations of RoHS; however this cost will be minimized if parts are subject to the substance ban but not to the other obligations of the revised RoHS (e.g. conformity assessment and CE marking).

(b) "Repair as produced principle"

This concept is implemented also in the End of Life Vehicles Directive for spare parts that cannot be redesigned without HS.

Benefits:

- Allowing the use of non-compliant spare parts for EEE placed on the market while an exemption was valid would be beneficial for the environment since it contributes to extending life time and avoiding untimely disposal of equipment.

- It would bring legal certainty for manufacturers with regard to servicing EEE after an exemption expires and security for end users that they will not have to replace prematurely the EEE because of lack of spare parts. This is particularly important for high cost and long life time EEE as, for example, some medical equipment or other equipment for non-household use, such as some IT or control and monitoring equipment.

Costs:

- Market surveillance authorities in Member States and EEE manufacturers must deploy the necessary resources for ensuring that such a provision does not lead to an abusive generalisation and that the term "part" is used properly (some industry stakeholders consider whole EEE destined to replace defective products under manufacturers' guarantee as "part", which should benefit from such an exemption); it is however not clear that this effort will cost more than the fulfilment of the current obligations under RoHS, which allows in exceptional cases the use of non-compliant spare parts.

5.1.4. Clarification on excluded equipment

(a) Insert in RoHS clause similar to WEEE Art 2.1 (excluding equipment which is part of another type of equipment that does not fall within the scope);

(b) Insert in RoHS clause similar to WEEE Art 2.3 (excluding equipment which is intended for specifically military purposes).

Benefits:

- The Guidance document prepared by the Commission services in cooperation with Member States is known and to a large extent already used by Member States and manufacturers; transposing its interpretation in the RoHS legal text will increase legal

certainty about the scope and hence reduce administrative burden, particularly by reducing differences in interpretation between Member States in future.

- Environmental and health protection will remain at least at the same level, since this option does not foresee removal of any product from the scope of RoHS

Costs:

- No apparent disadvantages or costs since it would reflect in the legal text what is already current practice.

5.1.5. Adding/modifying definitions

Benefits:

- Industry stakeholders have pointed out at various occasions since the entry into force of RoHS that diverging interpretations of some concepts ("placing on the market") leads to market fragmentation ; defining them would remove ambiguity, enhance the free movement of EEE in the internal market[29] lead to more harmonised interpretation and hence increase legal certainty and reduce economic risks because firms can have the same strategy across the EU

- Given that tracking the different Member States' transpositions of RoHS requires a lot of legal counselling and staff working time substantial economic benefits (reduction of administrative burden for administrations and producers[30]) can be achieved

- In the case of medical devices, adopting the definitions of other relevant EU legislation would create legal certainty;

- As a postponement of the enforcement date is proposed for industrial control and monitoring instruments, clarification of what is “industrial” would increase clarity and reduce administrative burden for the implementation of this postponed enforcement.

- Inserting the definition for "homogeneous material" of the Guidance Document (already largely used by stakeholders) in the legal text would strengthen the legal basis for EEE manufacturers in demonstrating compliance and for Member States during testing in the course of market surveillance activities; it will also boost ongoing standardisation processes, which tend to be quicker and more efficient when they are intended to support the implementation of legal requirements.

Costs:

- Inconvenience and need for adaptation in the case where differing interpretations have been given to various definitions and implementation was based on them; this is not expected to be significant because many stakeholders already apply the definitions of relevant Guidance documents.

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29 Martin et A1, p.225

30 Arcadis report, Martin et Al

- Some stakeholders raise doubts as to the suitability of the available definition for "homogeneous material" for enforcing the ban (for example for measuring content of hexavalent chromium; it is also claimed that small parts should be considered as "homogeneous material"); if a different definition for "homogeneous material" than the one of the Guidance Document would be adopted in the Directive, the inconvenience and need for adaptation on such a highly technical issue would give rise to uncertainty and possible increase of administrative burden for authorities and manufacturers.

5.2. Options to improve enforcement

5.2.1. Make no changes: not add provisions aiming at better implementation and enforcement

Benefits:

- Continuation of flexibility for Member States' administrations in the way they implement and enforce RoHS and for EEE manufactures to check and demonstrate RoHS compliance in the ways they deem appropriate.

Costs:

- Similarly to the "business as usual" scenario for scope and definitions, adding no new provisions facilitating implementation will lead to a continuation of the implementation problems identified in section 2 and to continued and increased administrative burden and problems in the free movement of EEE to the extent that not sufficiently coordinated and coherent national market surveillance activities will be deployed.

5.2.2. Strengthen mechanisms to remove non-compliant products from the market

Benefits:

- There is currently no provision in RoHS on how Member State check compliance of EEE placed on the market. An explicit provision would mobilise and coordinate efficient market surveillance activities. This is considered also by producers[31] a major step to protect compliant companies from unfair competition of non-compliant products‘: although it is difficult to estimate the share of non-compliant products on the market first market surveillance campaigns for RoHS show that up to 44% of EEE were found in a Member States not to be fully compliant; the loss of industry due to non-compliant products have been estimated to range between 4-25%[32] of the annual turnover.

- Adopting relevant provisions of the "Marketing of products" package will reduce cost for administrations (through clarification of obligations, facilitation of internal arrangements, sharing of resources among Member States authorities and allowing these authorities to simultaneously control product compliance with requirements from several Community legal acts) and increase coherence and predictability for EEE economic operators (such as manufacturers, distributors, importers).

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31 This is also one of the conclusions of the Arcadis report, p.144

32 Information from the impact assessment on the Marketing of Products package: figures are taken from the SME panel and the enterprise questionnaire and reflect the general tendency; they do not refer to RoHS but to other EU harmonisation legislation for EEE (e.g. on safety)

- Effective market surveillance mechanisms at national level and harmonised approach for removal of non-compliant products would greatly enhance the environmental benefit of RoHS by minimising the number of non-compliant products on the market. Current Member States' checks revealed that up to 44% of EEE checked were not fully compliant.

- Structured cooperation between market surveillance authorities would reduce administrative costs for both the authorities (for example enhanced information sharing would avoid the need for repeating investigations on a product done in another MS, in particular regarding expensive testing) and the manufacturers (no need to submit the same file in various administrations).

- Information availability and exchange would be significantly enhanced by structured and harmonised market surveillance [33]

- The provisions on market surveillance are part of the recently adopted Regulation ("Marketing of Products Package") which means that they would apply even if not inserted in RoHS; however, their explicit inclusion will facilitate understanding and promote legal certainty of the RoHS legal text both for manufacturers and enforcement authorities

Costs:

- In the first implementation phases such measures could create some additional costs for authorities (for example through designating or setting up market surveillance authorities), but this would vary depending on current implementation practices of individual MS; Moreover, given that some work in this direction has already been done (informal network exists), additional cost for authorities should be reasonable[34].

- Administrative burden (especially in the first phases and if they have not already taken measures for ensuring compliance) also for producers, who will have to make available documents to Member States authorities and dedicate time for meetings and replies to questions. However, such inaction by now would be violation of their existing obligations. If "due diligence" is already in place by the manufacturer, additional effort should be minimal.

- Since, as explained above, the horizontal EU provisions for market surveillance would apply to RoHS as well, inserting them in RoHS does not create any additional cost

5.2.3. Harmonize methods for demonstrating compliance

(a) Include conformity assessment procedures: use of standards, self declaration and CE marking

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33 Market surveillance in FIN yielded important information on the content of hazardous substances in EEE,

34 On this point the Impact assessment carried out for the "Marketing of Products" package observes that the costs for supporting the various types of coordination and cooperation activities foreseen in this context by the Community budget is estimated at 1 200 000 € per year. The additional costs for public authorities can hardly be quantified but surveys among market surveillance authorities show that only 21 % expect significant additional costs whilst 60 % of respondents expect an overall reduction of costs due to cost savings by more targeted controls enabled by, inter alia, improved information flows

(b) Include conformity assessment procedures: use of standards, external verification and CE marking

Benefits:

- RoHS has currently no provision on how manufacturers should demonstrate compliance and this means that they either will face diverging requirements or they cannot be sure that the method they will choose for ensuring compliance will be accepted by different MS. Inserting such a provision would enhance clarity for manufacturers (for which this omission can be an important source of administrative burden[35]) and for authorities. Although significant work has been accomplished by their informal network, its recommendations cannot be legally binding. Establishing provisions for conformity assessment (CA) in RoHS would therefore increase legal certainty and reduce administrative costs for manufacturers and authorities alike.

- Harmonisation of CA procedures would be beneficial for the internal market (some Member States already introduce on an individual basis CA procedures or envisage to do so, and if they diverge, this might create problems in the movement of goods) and fair competition (including through harmonisation of requirements on documentation for compliance and declaration of conformity).

- A structured, uniform CA procedure facilitates the manufacturers' efforts to achieve compliance and Member States' task to verify compliance thus overall reducing the number of non-compliant products placed in the market and increasing the environmental benefit.

- CE marking provides already presumption of conformity with other EU legislation (e.g. on safety) for almost all EEE covered by RoHS; if it is extended to RoHS it will give manufacturers a cost efficient and recognisable means to demonstrate compliance

- In option 2.3 (a) : The "Marketing of Products" package introduces CA procedures that would allow manufacturers to demonstrate compliance with RoHS and a number of other Directives in one single document (Declaration of Conformity).

- Standards for identification and measurement of the restricted substances, for labelling and for communicating across the supply chain facilitate demonstration of product compliance and enforcement activities and can promote world trade; data bases have proved particularly useful in other sectors (automotive), may contribute to maximum availability of information at low, or no, cost and could be valuable for SMEs.

- In option 2.3 (b): External verification from a neutral body could increase credibility of the CA and the checks would prompt greater compliance action by producers currently not aware that they are non-compliant. It would therefore probably lead to an increase in substitution of the banned HS compared to self declaration. Otherwise the benefits would be the same, as described above.

Costs:

[35] Martin et Al, p. 226-227

- Certification of compliance with requirements similar to RoHS is already required in major markets (China). However, introducing such requirements for the EU market via RoHS will incur additional costs for some manufacturers.

- The costs for putting in place adequate mechanisms for demonstrating compliance would be higher for those manufacturers who still have no such mechanisms for the existing RoHS; however, such inaction would mean that those manufacturers do not ensure compliance with their obligations under the existing RoHS. Those who do ensure compliance will have minimal or zero additional costs since they will be able to use procedures and documents that they already use due to other EU legal requirements on EEE (e.g. on safety)

- In the case of 3rd party verification (from an external accredited organisation such as a notified body) such costs would be higher and they could vary substantially depending on the verifying organisation. The 'normal' cost 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 similar to that for third party assessment of other products[36]. Binding 3rd party certification has not been considered cost-efficient in several other areas (such as safety of electrical equipment or machinery).

- The standardisation process can be long. Effort will be required by stakeholders and administrations to develop the harmonised standards. If such standards take too long to prepare and the Directive depends on their existence, the Directive's implementation would be delayed. Although international standards can promote world trade and should be preferred, when possible, it is only EU harmonised standards that can be expected to be in line with the political priorities of the EU.

5.3. Options to adapt the Directive to technical and scientific progress

5.3.1. Exemptions

NB: This Impact Assessment does not refer to the content of the Annexes with exemptions accompanying the legal proposal; Annex II is currently under separate technical review in accordance with Article (5)(1)(c) of RoHS; the draft proposal for the review of RoHS will therefore include as Annex II the current annex of RoHS, as amended by the successive Commission decisions.

In Annex III are included the specific exemptions for the new categories of products (medical devices and control and monitoring instruments), which preparatory studies have shown to be justified.

The Impact Assessment examines options for reducing the administrative burden from the current procedure for granting exemptions.

5.3.1.1. Make no changes to the exemption mechanism

Benefits

[36] Information from the Impact Assessment supporting the Marketing of Products package

- The few stakeholders who have used the existing mechanism have staff who are used to the existing mechanism and no adaptation effort to a new mechanism would be needed

Costs

- The problems and needs outlined in section 2 will persist or increase due to the increasing variety and innovative functions of EEE; this will create administrative burden probably higher than the one to be avoided if no changes are introduced to the exemption process.

5.3.1.2. Remove the exemption mechanism from the Directive

Benefits:

- Avoidance of the exemptions granting procedure and the associated required administrative effort from authorities and manufacturers; increased clarity about the scope of RoHS for manufacturers (product designers would no longer need to consult changing lists of exemptions) and facilitation of market surveillance (products within the scope must be "free" of the restricted substances, no exemptions to be taken into account).

- It is estimated that manufacturers' costs for exemption procedures make up about 1% of total costs related to RoHS[37], which would be the avoided cost if the exemption mechanism was removed. Although it is difficult to make forecasts on the number of future exemption requests, there will be some, not least because of the development of new products; it is expected however that the streamlining of the exemption procedure proposed in this review will reduce drastically the number of unjustified requests.

Costs:

- There is no data or information available to determine which product categories can remain under RoHS without any exemptions whatsoever, but these are very few. It has not been possible to demonstrate for any of the EEE categories currently covered that the implementation cost is disproportionate to the environmental benefit and thus justify its exclusion from RoHS. This means that excluding all the EEE product categories which need exemptions so that for the ones remaining in RoHS the whole exemption mechanism would be redundant, will most probably reduce substantially the environmental benefit of the Directive.

- Adopting this option in relation to any product group would nullify past and ongoing compliance efforts by manufacturers.

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[37] Arcadis report, p.110. This estimation is based on a small sample of only 10 companies which gave quantitative information on costs or time spent in relation to exemption requests; companies indicated costs ranging from 1000€ to 2000000€, spread over several years. The Commission services estimate that a figure of 3000-4000€ (based on a daily rate of 800€) for preparing, sending and following up (discussions with the consultant appointed by the Commission, further follow up) of a well prepared application is closer to reality; this figure could be even lower, taking into account that exemptions affecting several producers are requested in a joint effort. Concerning distribution of costs across EEE sectors, although the electrical & electronic components that contain the hazardous substances (and for which exemptions are requested) are used in almost all kinds of EEE categories, it is reasonable to expect that most applications will come from sectors with high innovation rates, like the ICT and consumer products sectors; this is confirmed by direct communications with industry representatives.

5.3.1.3. Maintain the exemptions procedure with changes in the criteria for granting and withdrawing exemptions and in the procedure for granting exemptions

(a) Introduce requirement for analysis of substitutes;

(b) Introduce broader criteria for granting exemptions;

(c) Introduce standard format and validity period.

Benefits:

- Poorly substantiated and unjustified requests have negative impact on the speed of the exemption process: approximately 70% of the submitted requests to date were rejected while provoking costs, wasting effort and causing delays in the treatment of the remaining justified 30%. A requirement for more comprehensive information from the applicants reflected, if possible, in a substitution plan would filter out unsubstantiated requests. As a result, it would free resources for processing of the other requests, improving the quality and speed of the process and thereby reduce administrative burden for Member States' administrations, Commission services and manufacturers, in particular those who submit justified and well substantiated requests, which will be accepted much more quickly than in the past.

- Currently RoHS accepts as reasons for granting an exemption technical or scientific impracticability of substitution and the demonstration that substitution would bring more environmental/health disadvantages than the banned substance. Taking into account in addition the availability and reliability of substitutes avoids negative socioeconomic effects, such as steep price increases or distortion of competition, withdrawal of products or deterioration of quality of products or services (for example medical equipment and health care services).

- A standard format would reduce administrative burden for manufacturers given that it makes it easier for them to know what to submit in the request for exemptions; design of a request for exemption is reported to account for >50% of the burden related to the exemption procedure.

Costs:

- In cases of technical, scientific or economic uncertainty as to when substitution can actually take place, detailed substitution plans may prove hard to draw up and a legal requirement to produce them would be too burdensome, if it is not flexible enough to take this into account; this is why the substitution plans will not be systematically required .

- The costs for analysing alternatives to HS range from 4300€ to 57000€[38], depending on the available data on the HS to be substituted, the specific application, and the depth of analysis required for the substitution plan. Integrating a requirement for analysing substitutes in RoHS should not incur any significant additional costs in the medium term, because economic operators will have to get acquainted with the REACH procedures and

[38] http://ec.europa.eu/enterprise/reach/docs/reach/REACH_TAC_summary_report_final_19122006.pdf table 1, p.18

establish mechanisms internally and for cooperation (e.g. on sharing of data) with each other for fulfilling those at a reduced cost.

- It may prove hard to collect data to adequately support claims of lack of reliability or availability of substitutes for requesting an exemption which would lead to increase of administrative burden for manufacturers (submitting the exemption applications) and Commission services and Member States authorities (who have to evaluate them in the Regulatory Committee).

5.3.2. Adapt product coverage to technical and scientific progress

5.3.2.1. Remove all products from scope of ROHS – repeal ROHS

Benefits:

- Manufacturers would avoid some ongoing costs of RoHS. Where manufacturers have already complied with RoHS and products have been redesigned, the future yearly costs are relatively small: estimated at 0.04% of turnover[39]. This would be the maximum cost avoided, but the costs actually avoided will depend on the extent to which industry switches back to using the HS

- If industry makes voluntary agreements not to return to those substances, repealing RoHS might help reach the policy objectives in a more cost-effective way; (for example, the medical industry has already created an eco-design standard), however administrative costs from implementing any voluntary agreements and reporting under those agreements is likely to be similarly, or perhaps more, burdensome for manufacturers compared to the ongoing administrative costs from RoHS.

- The upfront costs incurred by industry for RoHS compliance (understanding and implementing the legislation, capital expenditure and operating costs for making the necessary changes in the production process) would not be saved by repeal. Although most manufacturers have not calculated the cost, industry (for products currently included in RoHS) estimates it would vary from 1-4% of turnover[40]. More recent surveys give an average overall cost related to RoHS of 1,9% of turnover (past cost and one-off future costs).

- Yearly administrative costs (in particular verification of compliance) make up approximately 67% of total costs, while the share of technical costs amounts to 33% (expected to drop to 12% in the future). The most important administrative cost is compliance verification, which is an ongoing expense. There are few data and many uncertainties about actual cost impact of RoHS but; assuming the total number of EU companies affected by RoHS to 87,000, we come up with an extremely large range of 165 to 23000 million €, corresponding to 0.042 to 5% of the total turnover of EU companies affected by RoHS.

- Repeal would remove the administrative costs from RoHS implementation for national administrations (staff training, awareness raising, market surveillance involving purchase

[39] Arcadis report, p.101; the sample of companies is small (30 companies) but category 8&9 products are well represented

[40] ERA report, p.30, 150

of analytical instruments and of products on the shelf for checking product compliance, additional staff expenses). Ireland reported monitoring costs of 10 000 € in 2007[41].

Costs:

- As there is no guarantee that voluntary efforts will deliver the same results as legislation (for example there is no information on how the abovementioned eco-design standard for medical devices is applied and to which reductions of use of HS it has led), the worst potential environmental impact of this option would be the return to use of HS in EEE and subsequent increase of environmental exposure.

- Manufacturers might start using again the banned substances, for cost reasons. Researchers[42] conclude that lead-free soldering creates additional costs for EEE producers. If return to the banned substances takes place in a large scale, the exposure to HS from EEE will most probably increase substantially, if there is no clear increase in WEEE separate collection and state-of-the art recycling.

- The actual extent of this environmental harm depends on the return to use of HS. As an illustration, the Arcadis study reports, for selected products not covering the whole scope of RoHS, that thousands of tonnes of heavy metals and hazardous flame retardants have been avoided from being used in EEE (see Annex I).

- For estimating the net environmental cost (expressed in tonnes of HS avoided from being used in EEE) one would have furthermore to consider that the volumes of EEE have risen (and continue to rise) significantly but also that some uses of these substances could be restricted by REACH in the future. Yet, neither EuP Directive nor REACH would provide the same level of protection from HS in EEE.

- Substances that are relevant for RoHS (used in some cases in low or very low amounts, large share of imported products) may not be a priority for REACH, which does not aim to meet the RoHS objectives. Authorisation under REACH captures incorporation of substances into articles only if this is done inside the EU, thus potentially reducing protection from imported products. Should restrictions on whole groups of substances used in EEE (e.g. PBBs or PBDEs) be deemed necessary, they can be made more easily via RoHS. Given the potentially different priorities and the inevitably limited working capacity of the authorities involved in REACH implementation and enforcement, RoHS offers a quicker way for taking the necessary measures in relation to the protection of health and the environment from the hazardous substances contained in EEE.

- EuP either cannot ensure the same level of protection: it works through implementing measures and a great number of those would be needed if one wanted to cover the EEE currently covered by RoHS. EuP has a quantitative threshold (200 000 units of the product placed in the market yearly) for triggering implementing measures; this would leave, among others, many medical devices out of the reach of implementing measures.

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41 Arcadis report, p.17

42 Explorative study into the Sustainable Use and substitution of soldering metals in Electronics, O.Deubzer, PhD Thesis, p. 178 – 180; the total additional ownership cost for lead free soldering worldwide amounts to approximately 3 billion €; material cost amounting to approximately to 1,34 and opportunity cost to 1,9 bn € respectively.

- Repealing RoHS would also be likely to have negative impacts on the internal market and competitiveness of business due to risk of unilateral restrictions by Member States and damage to increased recycling[43]

- Repealing RoHS would furthermore have far reaching impacts on research to undertake efforts for substituting HS in new and existing applications as well as on orientations of the research community to support such efforts (possible loss of jobs for highly qualified scientists/technicians). This increases the costs of any future removal of HS both in the EU and globally

- Stakeholders have known RoHS for the past years as the stand-alone legal instrument regulating HS in EEE; this includes industry, which after long efforts is increasingly understanding and complying with RoHS requirements. Merging RoHS with other instruments would most likely lead to inefficiency concerning the achievement of the pursued aims and uncertainty, if not confusion among stakeholders[44].

5.3.2.2. Make no changes, not include categories 8 and 9.

Benefits:

- Continued flexibility for manufacturers to move towards reducing toxicity of their products at their own pace; categories 8&9 comprise certain complex products, the functional characteristics of which are diverse and technically demanding; moreover, due to their sensitive character, some of them are already subject to customer qualification and legal certification requirements. Relieving them from a possible additional RoHS-burden would allow the industry to use fully its scarce specialized human resources for developing innovative products.

Costs:

- Discriminatory treatment: many pro-active manufacturers have already substituted the RoHS substances in many of their products, anticipating the forthcoming inclusion (Article 6 of RoHS); some would stop substitution efforts if it were announced that these categories would not be included and many manufacturers would prefer inclusion (with sufficient time to make changes) for avoiding unfair competition from free riders[45].

- Risk of fragmentation of the market:: it can not be excluded that some Member States may follow the example of Norway and introduce more stringent requirements on the use of substances at national level; this can be avoided by introducing categories 8&9 in RoHS.

5.3.2.3. Include all of Categories 8 and 9 with specific exemptions:

NB: The ERA report as well as stakeholders contributions have stated that it is not technically feasible to include all of Categories 8 and 9 in the scope of RoHS without exemptions for specific applications of the banned substances.

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43 Arcadis report p.130

44 Arcadis report, part 5.2.1, p.97 : "…most companies have completed the changes required and are not requesting revisions…"

45 ERA report, p.234

The elements provided by the ERA report on:

– The suitability of existing exemptions in the Annex of the RoHS Directive

– The need for additional exemptions, specific to category 8&9 products

have been considered and updated by some of the other research activities carried out on behalf of the Commission services for supporting the review of RoHS and discussed in detail with the concerned industry.

The result of this work is not further discussed in this Impact Assessment but reflected in the annex to the proposed Directive.

(a) From 2012

Benefits:

- Environmental benefit: Although use of some HS in categories 8&9 such as mercury has already been reduced due to other legislation[46], they still contain several tonnes of the heavy metals banned under RoHS (>1400 tonnes of lead, approximately 2,2 tonnes of cadmium[47]) which, by improper waste management may be released to the environment (only 49,7% of waste medical devices and 65,2% of waste control and monitoring instruments are separately collected[48]). Including these categories will further amplify the knock-on effects in the supply chain (accelerated phasing out of non-RoHS compliant parts) and will facilitate implementation for the existing EEE categories. With this option, the environmental benefit is reaped at the earliest possible stage since manufacturers, even if they have alternative compliant products already from 2007, will not withdraw non-compliant products unless there is legislative pressure[49]. NGOs favour an early inclusion of categories 8&9 in RoHS, considering that phasing out of the HS is taking place to a large extent already (for some HS such as mercury also under the pressure of legislation outside the EU) and, given the anticipated inclusion by manufacturers, many products are already RoHS compliant.

- The table below indicates the expected environmental benefits (expressed as reduction of the HS present in cat 8&9 products) of the various options, as described in the 2nd consultation (December 2007 – February 2008) document of the Commission services; Business as usual (option 5.3.2.2) is compared (in the graph, the business as usual is set equal to 1), inter alia, to option 5.3.2.3 (a) and (b) (options 3 and 2B of the graph respectively)[50]. Option 2 of the graph does not foresee any exemptions and was considered impracticable at this stage (see Annex III) but gives the medium to long term environmental benefit, taking into account that exemptions are provided on a temporary basis and are to be repealed as soon as substitutes are available.

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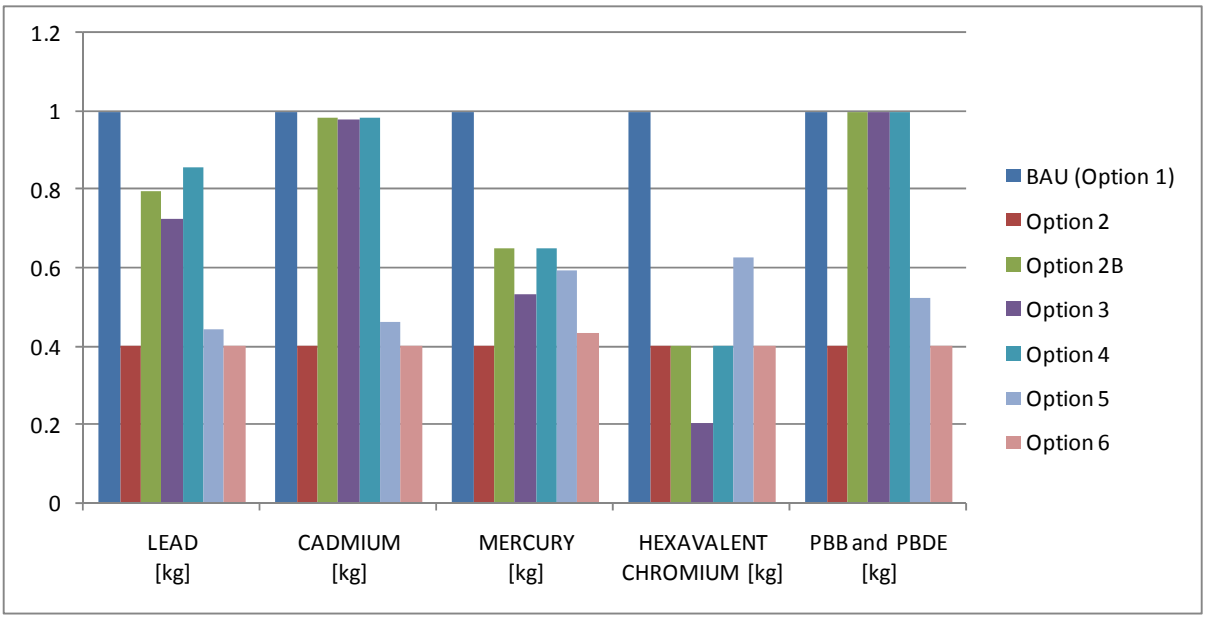
46 For example in the US, or recently in the EU Directive 2007/51/EC of the European Parliament and of the Council of 25 September 2007 amending Council Directive 76/769/EEC relating to restrictions on the marketing of certain measuring devices containing mercury

47 ERA report, p.68, 235

48 UNU Final report on the review of the WEEE Directive, August 2007, p.iv

49 ERA report, p.237

50 BIO intelligence study; this graph does not take into account the cancellation of the DecaBDE exemption, which would mean zero DecaBDE for all options, including BAU



- Further analysis, to take into account impact of waste management methods on the possible release of HS to the environment reveals that even in the most optimistic scenario (90% recycling) inclusion fo categories 8&9 in the scope would result in improvements of at least 50% for all 4 toxicity indicators used[51]; if current reported recycling rates (57%) are taken as basis, the medium to long term reduction would be up to 70% compared to BAU.

- RoHS helped companies for a better preparation for export markets, improved the knowledge of EEE composition and the supply chain management, as well as the global skill levels and the process control within companies resulting in some cases in monetary gains[52]; if categories 8&9 are included these benefits will accrue also to companies in these sectors, in particular those which have not taken any measures to reduce product toxicity yet and to "SMEs – EEE manufacturers" which will benefit from wider data availability and to "SMEs – components manufacturers" which will benefit from even greater harmonisation of the requirements of their customers in the EEE sector

Costs:

- The cost of compliance for categories 8&9 could be as high as 7 – 10% of turnover due to the additional test and approval costs. In the case of modifying an existing complex product, as some products in categories 8&9 are, the cost to make it RoHS compliant can be up to 20% although in most cases it will be less, in the order of 1-10%[53]. In spite of intensive efforts it has not been possible to obtain reliable and comprehensive data, the margin of uncertainty remaining high (indicative overall compliance costs for categories 8&9 are estimated in the range of 400 to 1600million€)[54]

- If some specific medical devices (in vitro diagnostics or active implanted medical devices) or industrial control and monitoring instruments are included already in 2012, a potentially

51 BIO intelligence study; the indicators used were human toxicity potential, freshwater aquatic, freshwater sedimental and terrestrial ecotoxicity potentials

52 Arcadis report, p.130

53 The figures are from the ERA report, p.237 and 150 respectively

54 BIO intelligence study

high number of products will have to be withdrawn from the market because of technical impossibility of substitution. In their recent submissions specialised industry stakeholders support in principle the inclusion of categories 8&9 in RoHS but consider that doing so as of 2012 will lead to unacceptably high costs and withdrawal of certain products from the market due to the impossibility of RoHS compliance (losses of sales revenue estimated in the order of magnitude of billions of €)[55]

- Possible negative impacts on health care : the cost increase would be passed on to users increasing the price of e.g. sophisticated medical equipment and thus making advanced health care services less affordable to some patients' categories. The later the inclusion of certain types of products, the less is the likely impact on users, because this would allow manufacturers to fit substitution with existing resources and product development cycles; if the date of inclusion is earlier than 2012, average prices of some medical equipment could rise by 5%[56] thus possibly resulting in negative effects on healthcare provision but this is unlikely to happen if inclusion takes place on 2012, which is considered a date by which the most complex medical equipment could be compliant[57]. Note that the equipment costs are usually only a small proportion of health care costs, with the majority being the staff , medication and infrastructure costs.

- Possible uncertainty and costs, associated with the exemption procedure; although costs incurred by the exemption procedure make up only 1% of the total cost related to RoHS, some stakeholders associate administrative burden to the perceived as lengthy exemption process and the related uncertainty. More exemptions (probably more than 10) will be needed for 2012 in comparison to a later entry into force.

(b) From 2014

Benefits:

- The environmental benefit of this option would be as previously, but delayed by two years

Costs:

- According to estimates provided by manufacturers (ERA, p.149) most category 8&9 products could be compliant already in 2012, taking into account the most complex products without negative economic impact; including them in 2014 would unnecessarily delay the environmental effect of the Directive. In recent position papers specialised industry stakeholders indicate 2014 as the preferred date for medical equipment except IVD and AIMD.

- Due to the long life cycles, relatively (compared to consumer products) small numbers sold, longer research, redesign, validation and testing periods, the compliance cost per product and its dependence on the enforcement date for categories 8&9 is higher. Choosing 2014 as implementation date would present a reduced risk for cost increase compared to the previous option, because increase of prices and removal of products from the market are due mainly to the limitation of resources and lack of profitability for marketing new, compliant products so quickly. This is illustrated by the expectances for degree of products'

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55 Direct confidential submissions to the Commission services

56 ERA report, p.236-237

57 ERA report, p.149

compliance: a group of category 9 products manufacturers estimates that on the average <3% of products will be non-compliant if entry into force is 2018, while this range (depending on product type) would be 10-30% for 2015 and 30-40% for 2012. Household instruments would comply by 95% already in 2012, while for some industrial equipment; this % for 2012 could be as low as 52%[58].

(c) Delayed inclusion of cat.9 industrial equipment (2015)

Benefits:

- Due account is taken of higher technical complexity and need for reliability for industrial monitoring and control instruments. The entry into force will take place with minimal technical and other (e.g. withdrawal of products, loss of jobs) complications, effects on quality of services, innovation potential and competitiveness because it is possible to bring by this date the majority of industrial category 9 equipment in compliance within the normal marketing cycles of companies.

Costs:

- Possible uncertainty and grey areas through the introduction of yet another distinction ("industrial" vs. "household" products) leading to an increase of administrative burden; the use of an existing international standard was proposed for clarifying the differentiation but this solution does not enjoy a universal support, even within industry. Such uncertainty will be reduced by the proposed insertion of a new definition for industrial control and monitoring equipment.

- Producers of Category 9 products estimate that the cost (loss of sales because of impossibility to comply and hence withdrawal from the market) would be 439, 246,3 and 49,3 million € for enforcement dates 2012, 2015 and 2018 respectively. They consider 2018 as an appropriate date for the inclusion of industrial products, to be properly defined in the revised RoHS.

- The environmental benefit of the Directive will be delayed but it is not expected to be significant for this 3-year period, although Category 9 equipment not used in households accounts for almost 75 % of the total[59].

(d) Delayed inclusion of certain medical devices (IVD: 2016, AIMD: 2020)

Benefits:

- Until the proposed deferred enforcement date of 2016 (2020) manufacturers will have sufficient time to bring these product categories into RoHS compliance without jeopardising product diversity or reliability. Such an addition will contribute to the overall environmental benefit from including Category 8 products (for example, estimates for lead used in solders in IVD and AIMD are 6000 and 800 tonnes respectively, out of the 66 000 tonnes used in category 8 equipment[60].

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58 Direct submissions of industry to the Commission services

59 UNU Final report on the review of the WEEE Directive, August 2007, information from Spain and Hungary, % of weight

60 ERA report, p.66

- As for the previous option, proposing an earlier enforcement date for this type of equipment could lead to a too high % of withdrawal of products from the EU market, because manufacturers would not have the necessary time for redesigning and testing products. Forcing a too early enforcement date would increase the overall compliance cost also because untimely withdrawal of products and this would lead to increases in cost for the health services (for example "cost per test" for IVD).

Costs:

- The environmental benefit of the Directive would be delayed, although the HS quantities involved (in particular for AIMD) are low.

- Some IVD products could be compliant much earlier without additional cost or health risks; given that a more detailed differentiation has not been possible on the basis of the available information, the proposed postponed enforcement date benefits also products which do not need it.

- Specialized industry stakeholders agree to 2016 as an appropriate date for including IVD but consider that AIMD, due to their critical character should be excluded for the foreseeable future from RoHS, 2020 is suggested as the earliest possible date for the review of such an exclusion.

- Such a differentiated approach might give the wrong signal to industry and not provide the necessary motivation for substituting HS; if such substitution efforts are not undertaken in time, adaptation will be more difficult later, given the possibility of RoHS-like legislation spreading around the world and the decreasing availability of non-compliant parts (how long can AIMD manufacturers rely on the availability of components with lead-solders?).

5.3.3. Substances covered [article 6 of RoHS]

Besides the already regulated substances under RoHS, EEE contain other HS. Article 6 of RoHS asks the Commission to adapt the list of regulated substances on the basis of scientific facts and taking the precautionary principle into account.

5.3.3.1. Make no changes to the list of substances regulated by RoHS

Benefits

- If no new HS would be banned under RoHS, this would leave more room for flexibility in further reducing toxicity of their products with voluntary instruments (such as standards, lists of substances of concern) stimulated by market demand for more environmentally friendly products; this would lead to an economic benefit because the redesign for reducing toxicity would be integrated in the normal product redesign cycles and no additional cost would be generated.

- For many of the substances that could be handled by RoHS, more information will become available in the forthcoming years due to the notification and registration requirements of REACH; this will facilitate decision making on appropriate risk management measures, including restrictions under REACH for the HS satisfying the REACH criteria For industry, wider information availability throughout the supply chain will reduce cost for

implementing voluntary initiatives or regulatory risk management measures, if and when they are decided.

- No additional effort required for getting acquainted with requirements for new HS in RoHS and possible related exemptions.

Costs:

- While the main benefits of this option are economic, the potential costs are mainly of environmental nature and pertain to potential damage to human health and the environment from the continued use of HS. The extent of these costs will depend on the future use of these HS in EEE.

5.3.3.2. Remove substances from the list of banned substances under RoHS

The only banned substance for which available information justifies examining whether it should be removed from the scope of RoHS is DecaBDE.

Benefits:

- In view of the remaining uncertainties, there are studies ongoing to investigate toxicity of DecaBDE and its degradation to other, already banned PBDEs such as octa-BDE and penta-BDE. Removing DecaBDE from the list of banned substances would give more time to EEE manufacturers to prepare for a possible later substitution.

- Removing DecaBDE from the ban would give more time to assess the relevance and concrete achievements of an ongoing industry initiative for checking DecaBDE emissions as regards EEE. It would give more weight to voluntary initiatives for phasing out the use of DecaBDE.

- DecaBDE manufacturers claim that the ECJ ruling only referred to procedural aspects and does not put in doubt the scientific and technical basis for exempting DecaBDE; in order to overcome the procedural hurdle, DecaBDE should be removed altogether from the list of banned substances, otherwise there would be unacceptable costs due to a forced substitution and increased fire risks for consumers.

Costs:

- Environmental: studies show that out of 22000 tonnes of DecaBDE used in certain EEE, 179 tonnes volatilise into ambient air during service life; in view of the current uncertainties about toxicity and degradation to toxic products in the environment this could cause considerable environmental and health costs in the future;

- Discriminatory treatment : many pro-active manufacturers (including large electronic manufacturers) have already replaced DecaBDE in many or all of their products by substitutes. At least some of the substitutes may have minimal potential adverse environmental and human health effects[61]. Repealing a substitution obligation which is apparently economically feasible and technically possible by safer substitutes would create

[61] ECB study, January 2007, on the assessment of Deca-BDE substitutes by the Commission

legal uncertainty and would discourage economic operators from further voluntary substitution efforts;

- In view of the recent ruling of the ECJ annulling the Commission Decision which allowed further use of DecaBDE, proposing to remove DecaBDE from the list of banned substances would create confusion among stakeholders

- Repealing the ban is very likely to have negative impacts on the internal market and competitiveness of business due to risk of unilateral restrictions by MS; a Member State has already notified to the Commission its intention to ban DecaBDE in other applications; the environmental protection agency of another Member State has clearly indicated its intention to implement immediately the ECJ ruling[62]

5.3.3.3. Add new substances for all EEE, in the scope of RoHS but with exempted applications

Benefits:

- Preparatory studies have indeed revealed the presence of other HS which potentially may need to be managed properly. Possible environmental and health concerns could be anticipated at an early stage (see Annex II). The quantities used in EEE for some of these HS are quite large (tonnes/year in the EU: TBBPA: 40 000, DEHP:29 000), while some of these HS are not chemically bound additives which may leak to the environment during use[63].

- Environmental and health benefits from addressing additional HS through RoHS could be achieved using the necessary mechanisms for ensuring and checking compliance that should be in place already. Some of the substances identified as possible candidates for RoHS have been under investigation for a long time as to their environmental and health impacts or have even been proposed for restrictions or other measures at national or EU level (e.g. TBBPA, phthalates). Restricting them under RoHS would ensure equal treatment in the internal market. The ban could be implemented with the necessary room for unavoidable uses via the exemption mechanism which could become more flexible and efficient (see options outlined above). NGOs claim that the documented health and environmental impacts of substances such as all brominated flame retardants, phthalates, PVC and beryllium justify their inclusion in RoHS in the near future.

Costs:

- The risks from the use of substitutes of the substances in certain applications are not sufficiently known. This is for example the case for the possible substitutes of TBBPA and HBCDD and, to a certain extent, of phthalates. The potential environmental cost from substitution is therefore uncertain. For some of the investigated substances the small quantities contained in EEE would result in disproportionately high burden for business and consumers.

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62 http://www.umweltbundesamt.de/uba-info-presse/2008/pd08-050.htm

63 Ökoinstitut report

- Too little information is available about cost: even in cases where the substitutes or the necessary design changes (for example use instead of PVC other polymers which need less or no plasticizers such as phthalates) are available and safe, these can be more expensive and there is a risk that imposing restrictions through RoHS would create, for certain categories of EEE, economic cost for manufacturers and increase considerably product price to the end user. The overwhelming majority of industry stakeholders is against the idea of adding new substances under RoHS and propose that the REACH mechanisms are used instead for addressing any risks that might be identified; in particular manufacturers of the chemicals used in EEE insist that it is not justified to add substances in view of the scarcity of information on environmental risks and financial consequences from the generalized use of substitutes.

- Four out of the five HS identified for further analysis for possible inclusion in RoHS at a later stage have already been identified as possible candidates for characterisation as substances of very high concern under REACH; imposing at this stage a restriction through RoHS would create confusion among stakeholders

6. COMPARING THE OPTIONS

6.1. Options to clarify and simplify the Directive

The table below gives a summary of the overall impact of each option, based on the analysis of costs and benefits in section 5. It also makes recommendations for selecting options

Option (numbers refer to section 4)	**Overall Impact** (based on analysis in section 5)	**Recommended Selection**
4.1.1. Make no changes to scope and definitions	Existing problems for business and authorities will continue or even increase.	Reject
4.1.2. Create an independent scope for RoHS	Reduction of administrative burden. Harmonised scope improves implementation of Directive.	Accept
4.1.3. Clarification of Spare Parts a) Explicit inclusion of spare parts b) "Repair as produced principle"	a) Explicit inclusion of spare parts improves clarity. Distributes responsibility for compliance more evenly b) Allows extended life-time of EE products due to availability of suitable spare parts	Accept a) and b)
4.1.4. Clarification of excluded equipment a) Insert in RoHS clause similar to WEEE Art 2.1 (excluding equipment which is part of another type of equipment that does not fall within the scope) b) Insert in RoHS clause similar to WEEE Art 2.3 (excluding equipment which is intended for specifically military purposes)	a) & b) Benefits for Member States and manufactures due to improved legal certainty	Accept

4.1.5. Adding modifying definitions	Adds to harmonisation of definitions and legal clarity. Reduces administrative costs.	Accept

Options 4.1.2, 4.1.4 and 4.1.5 were widely supported by stakeholders. Most industry stakeholders opposed the introduction of a definition of spare parts and possible associated administrative burden. The recommended option consists therefore in subjecting the parts explicitly to the substance ban but not to the other requirements of the revised RoHS Directive. As far as the definition of "homogeneous material is concerned, the Commission services believe that it is useful to introduce in the Directive the one provided in the Guidance document, for reasons of legal certainty.

Summary: Options 4.1.2- 4.1.5 are recommended, resulting in:

Creation of binding, independent lists of products defining the scope for the RoHS Directive

Exclusion only of spare parts needed for repairing EEE lawfully placed in the market

Exclusion of military equipment and of EEE which are parts of other products falling outside the scope of RoHS

Adapting definitions to the "Marketing of products package" and adding definitions on category 8&9 products, and for "homogeneous material"

6.2. Options to improve enforcement

The table below gives a summary of the overall impact of each option, based on the analysis of costs and benefits in section 5. It also makes recommendations for selecting options

Option (numbers refer to section 4)	**Overall Impact** (based on analysis in section 5)	**Recommended Selection**
4.2.1. Make no changes: not add provisions aiming at better implementation and enforcement	Problems with free movement of EE in internal market continue. Continued administrative burden for both Member States and business.	Reject
4.2.2. Strengthen mechanisms to remove non-compliant products from the market	Reduction of non compliant products on market, resulting in reduced environmental hazards. Increased synergies with other EU product legislation, resulting in reduced administrative burden for Member States authorities and manufacturers. Promotes fair competition.	Accept

4.2.3. Harmonize methods for demonstrating compliance a) Include conformity assessment procedures: use of standards, self declaration and CE marking b) Include conformity assessment procedures: use of standards, external verification and CE marking	a) increased legal certainty and reduced administrative costs for Member States and manufactures; standardisation can facilitate demonstration of conformity and enforcement b) leads to disproportionate costs, in particular for SMEs, and is not justified by the risk	Accept a) Reject b)

Promotion of harmonised implementation and enforcement of the Directive are major goals of the RoHS review. It is also an important concern of stakeholders, in particular economic operators. The Commission services estimate that such harmonisation will be promoted if RoHS includes provisions for market surveillance, EEE conformity assessment by manufacturers and for presumption of conformity of products manufactured in accordance with EU harmonised standards.

Such provisions will also contribute to the achievement of the environmental objectives, reduce risks for distortion of competition among manufacturers and facilitate free movement of EEE in the internal market.

The Commission services also consider that the abovementioned new provisions should be coherent with other EU product legislation, in particular the recently adopted "Marketing of Products Package" because not doing anything and let potentially diverging compliance verification and checking practices proliferate will result in increase of administrative burden for both national administrations and businesses.

Summary: Options 4.2.2 and 4.2.3 a) are recommended, for introducing all necessary provisions on the basis of the "Marketing of products package" concerning :

- national market surveillance activities
- mechanisms for assessing the conformity of the product prior to its placing on the market based on the self declaration by the producer
- presumption of conformity of the product on the basis of harmonised standards and CE marking

6.3. Options to adapt the Directive to technical and scientific progress

6.3.1. Exemptions

The table below gives a summary of the overall impact of each option, based on the analysis of costs and benefits in section 5. It also makes recommendations for selecting options

Option (numbers refer to section 4)	**Overall Impact** (based on analysis in section 5)	**Recommended Selection**
4.3.1.1. Make no changes to the exemption mechanism	Problems with length and administrative costs of exemption procedure continued	Reject
4.3.1.2. Remove the exemption mechanism from the Directive.	Could hinder adaptation to scientific and technical progress. Reduced environmental benefit.	Reject
4.3.1.3. Maintain the exemptions procedure with changes in the criteria for granting and withdrawing exemptions and in the procedure for granting exemptions (a) introduce requirement for analysis of substitutes (b) introduce broader criteria for granting exemptions (c) introduce standard format and validity period	a) & b) Faster and more transparent procedure for granting exemptions. Encourages substitution efforts. b) avoids negative effects such as price increases, or withdrawal of certain products from the market c) Faster exemption procedure and increased legal certainty	Accept a), b) and c)

The Commission services estimate that abolishing the exemption mechanism would deprive the Directive of the necessary flexibility for cases where substitution is not possible immediately and for adapting it to technical and scientific progress; moreover, were this to be done at the expense of a reduced scope, an additional disadvantage would be a reduction of the environmental benefit.

At the same time the Commission acknowledges the comments in favour of reducing the administrative burden for both Member States and producers, for speeding up the process and further increasing its transparency and legal certainty, in line with requirements of the chemicals' legislation and for taking into account broader criteria than the ones currently included in the Directive for granting exemptions.

While the standardisation of the format enjoyed a unanimous support, industry stakeholders were against the substitution plan because it would increase the administrative burden while those mostly concerned with enhancing the environmental effect of RoHS resisted the insertion of additional criteria because they would be too difficult to evaluate and prolong rather than speed up the exemption process.

The Commission services believe however that coherence with REACH, which has very similar provisions concerning substitution plans, will also ensure synergies for economic operators, thus reducing substantially any additional cost from and facilitating the implementation of the related requirements in RoHS; furthermore refusing exemptions even when substitutes are not reliable and available may have negative environmental, economic and social impacts.

The general time limitation for exemptions increases legal certainty and has been explicitly supported by many Member States during informal meetings and in the Regulatory Committee.

Option **4.3.1.3 is recommended**:

- Applicants submit an analysis of substitutes together with their request for exempting an application of the banned substance
- If availability or reliability of substitutes is not ensured, an exemption should be granted
- A standard format for requesting an exemption should be established (by the regulatory Committee)
- Granted exemptions have a maximum validity period of 4 years but can be renewed

6.3.2. Adapt product coverage to technical and scientific progress

The table below gives a summary of the overall impact of each option, based on the analysis of costs and benefits in section 5. It also makes recommendations for selecting options

Option (numbers refer to section 4)	**Overall Impact** (based on analysis in section 5)	**Recommended Selection**
4.3.2.1. Remove all products from scope of ROHS – repeal ROHS	Damage to environment due to increased exposure to HS. Hinders recycling. Fragmentation of internal market	Reject
4.3.2.2. Make no changes, not include categories 8 and 9.	Would penalise manufacturers and discourage substitution efforts. Fragmentation of internal market.	Reject

4.3.2.3. Include all of Categories 8 and 9 with specific exemptions: (a) from 2012 (b) from 2014 (c) delayed inclusion of cat.9 industrial equipment (2015) (d) delayed inclusion of certain medical devices (IVD : 2016, AIMD : 2020)	a), c) & d): Environmental benefit from reduction of HS. Level playing field for manufacturers. b)Unnecessary delay for implementation of regulation and associated environmental impacts. c) & d) postponement for these specific sub-categories are justified.	Accept a), c) & d) Reject b)

The Commission services estimate that including Categories 8&9 would reduce environmental impacts from the presence of HS in these products. Equivalent environmental benefits would not be achieved by REACH, which focuses on substances rather than products and has its own prioritisation criteria, the EuP Directive which does not focus on toxicity of products and which has quantitative thresholds excluding in practice many products of Categories 8&9 from its scope or by voluntary industry actions such as standards, the content and implementation of which do not necessarily reflect the policy objectives. Furthermore a continued exclusion would have negative economic repercussions.

Maintaining Categories 8&9 out of scope would possibly avoid certain additional costs to some manufacturers but would be detrimental to those who already invested in substitution and in the medium and long run could be economically unfavourable to everybody, depriving the EU industry from the competitive advantage stemming from a better product and process control and adequate preparation for facing environmental, including reduced toxicity, requirements worldwide.

While the available data do not allow a fully quantified comparison of the benefits and costs of bringing these products in the scope at the various possible enforcement dates, taking into account that it is technically feasible to achieve the expected environmental benefit without excessive costs already in 2012, the Commission considers this as the most appropriate option for bringing in the scope medical devices and non- industrial control and monitoring instruments.

At the same time and taking into account the specificities of some of Category 8 and 9 products[64] (safety critical, long lifecycles, long product development not least because of diverse and technically demanding functional characteristics) as well as scientific and technical development with regard to substitution of the substances in certain applications, it is considered necessary that some exemptions are granted[65] and that the enforcement dates are staged in such a way for some product categories so that negative social impacts (reduced availability of products due to forced withdrawal of products impossible to be made

64 ERA report, p. 27

65 ERA report, p.242 – 245,

compliant, limitation of access to high quality health care due to disproportionate increase of medical devices' price) are avoided.

Summary: The **recommended options are the inclusion of, with the exemptions of the Annex to the Directive proposal:**

medical devices and non- industrial control and monitoring instruments from 2012

industrial control and monitoring instruments from 2015

in vitro diagnostics (IVD) from 2016

active implanted medical devices (AIMD) from 2020

6.3.3. Substances covered [article 6 of RoHS]

The table below gives a summary of the overall impact of each option, based on the analysis of costs and benefits in section 5. It also makes recommendations for selecting options

Option (numbers refer to section 4)	**Overall Impact** (based on analysis in section 5)	**Recommended Selection**
4.3.3.1. Make no changes to the list of substances regulated by RoHS	Manufactures will have greater flexibility. Lack of sufficient scientific and market information to justify changing the list	Accept
4.3.3.2. Remove substances from the list of banned substances under RoHS	DecaBDE only substance concerned. Potential environmental and health risks. Substitutes exist.	Reject
4.3.3.3. Add new substances for all EEE, in the scope of RoHS but with exempted applications	Lack of sufficient scientific and market information to justify adding new substances	Reject

Considering the available evidence (Ökoinstitut report, stakeholder consultations in connection with this report, bilateral contacts with industry and other stakeholders) the Commission services conclude that:

- Beyond the HS already regulated by RoHS, EEE contains other HS and it is necessary to manage the risks emanating from their use in EEE.
- There seem to be substitutes in many applications of these HS in EEE but they are either insufficiently investigated as to their potential environmental and health impacts, or too expensive to apply in all EEE covered by the RoHS scope, or both.

For the abovementioned reasons the Commission services do not consider appropriate that new HS are added to the scope of RoHS but will continue to monitor the evolution of knowledge on HS in EEE not regulated by RoHS and their possible substitutes and, if necessary, propose to add HS in the scope at the occasion of the next review of the Directive.

Concerning DecaBDE, the Commission services consider that the remaining uncertainties about its toxicity and degradation to other banned products, as well as the commercial availability of substitutes justify maintaining the ban on this substance.

No new hazardous substances added to the scope of RoHS at this stage

6.4. Overall benefits and costs from the recommended options

- There is little experience of actual **compliance costs in industry;** for products currently included in RoHS, estimates are it would vary from 1-4% of turnover. More recent surveys give an average overall cost related to RoHS of 1,9% of turnover (past cost and one-off future costs).

In the case of medical devices and control and monitoring instruments some of which are produced in low numbers or have critical applications and hence increased testing and reliability requirements, approximate yearly compliance cost is estimated to 400-1600 million €; it is even claimed that cost of RoHS compliance for some complex products could be as high as 7-10% of turnover (new product) or 1-10% (modification of existing product). A large part of this cost is attributable to the long development, testing and approval cycles of the more complex products. This is why a **staged introduction** for these products is proposed allowing the compliance conversion to take place in the framework of existing resources and product development cycles.

The RoHS Directive does not foresee explicit reporting obligations for Member States or for information supply requirements by manufacturers in RoHS and in most cases Member States have not introduced such legal obligations at national level either for manufacturers. The process for granting exemptions is considered lengthy for products with short innovation cycles; harmonising the requirements for the contents of the application and clarifying the period of validity of exemptions will **speed up the process**, increase legal security and reduce administrative burden for both authorities and the applicants.

The introduction of harmonised requirements for scope, definitions, assessment of product conformity and market surveillance which are in line with other product-related EU legal requirements will **increase legal certainty** and thus **reduce the administrative burden.**

Initial implementation of these revisions could create **additional administrative burden** for Member States and producers dependent on the Member State's current level of preparation for proper enforcement and on the adequacy of measures taken by producers for ensuring product compliance.

The Commission services estimate that overall net benefits, albeit modest, will ensue. Moreover, the recommended options will have an important cumulative effect in clarifying the Directive and harmonising its implementation and enforcement with a positive contribution to better regulation.

Environmental benefits are likely to be significant: several tonnes of the heavy metals banned under RoHS (>1400 tonnes of lead, approximately 2,2 tonnes of cadmium) are used in medical devices and control and monitoring instruments, which account for 0,2-03% of waste from electrical and electronic equipment by weigh; these substances by improper waste management may be released to the environment (only 49,7% of waste medical devices and 65,2% of waste control and monitoring instruments are separately collected); restricting the use of these substances through RoHS will in the medium to long term eliminate their presence in the products and in the waste thereof; further analysis shows that even in scenarios assuming much higher recycling rates there is some environmental benefit from including these categories of equipment in the scope of RoHS.

Taking into account that current Member States' checks revealed that up to 44% of EEE checked were not fully compliant, effective market surveillance mechanisms at national level and enhanced cooperation among Member State authorities for removal of non-compliant products are expected to increase considerably the environmental benefit of RoHS by minimising the number of non-compliant products on the market.

Concerning the adaptation of list of hazardous substances regulated by RoHS, the preparatory studies identified candidate substances, but given the lack of sufficient information on substitutes, which does not allow a clear view on whether they are environmentally safer or, in cases where environmentally safer alternatives do exist, whether replacement costs are proportionate to environmental benefits, **it is not considered feasible to propose new hazardous substances in the scope of RoHS.**

7. MONITORING AND EVALUATION

7.1. Core indicators of progress towards meeting the objectives

The core indicators for progress towards meeting the objectives set for this policy initiative are the following:

(1) Reduction of the level of the HS regulated by RoHS in the EEE falling under its present scope

(2) Reduction of the level of the HS regulated by RoHS in medical devices, control and monitoring instruments.

(3) Overall extent, effects and efficiency of the measures taken by Member States to implement RoHS (for example via number of product checks carried out, % of compliant products, trends in reducing number of non-compliant products)

(4) Extent to which unnecessary administrative burdens are cut at EU and Member States levels to be evaluated via:

  (a) number of substantiated complaints from economic operators about non-harmonized interpretation or enforcement of RoHS by Member States leading to avoidable cost

  (b) reduction of cost for conformity assessment for economic operators,

(c) reduction of enforcement cost for authorities through improved administrative cooperation

(5) Stimulation of R&D efforts for substituting HS in EEE to be assessed by number of EU patents obtained in relationship to substituting HS in EEE

(6) Extent to which the RoHS review contributes to the reduction of environmental burdens and health problems worldwide, for example through contributing to the promotion of less toxic and more environmentally friendly EEE, including through the adoption of legislation restricting the use of HS in EEE in other parts of the world or of voluntary instruments (such as lists of HS, voluntary phase out of non-regulated substances by individual companies, data bases, information and training of the supply chain on avoidance of HS in EEE)

(7) Reduction on number of voluntary marks for RoHS-compliance

(8) Promotion of use of harmonised standards for presumption of conformity, to be evaluated on the basis of adoption of harmonised standards related to RoHS implementation and of decrease in time needed to agree harmonised standards

(9) Improvement of the exemption mechanism to be evaluated on the basis of:

- Decrease in the time needed for granting an exemption
- Decrease in the number of exemption requests
- Decrease in the number of unsuccessful exemption requests

7.2. Broad outline for possible monitoring and evaluation arrangements

Taking into account the severe difficulties for collecting quantitatively and qualitatively meaningful data for carrying out the review (see section 1) it is suggested that the Regulatory Committee determines in close cooperation with stakeholders specific data needs and collection processes to monitor the progress made using the core indicators mentioned above. The details on the frequency and means of this reporting process will be left to the decision of the Committee.

ANNEX I

The environmental benefits of RoHS

The reduction of quantities of the HS banned by RoHS contained in EEE are used as a straightforward and easily understandable indicator of its environmental benefit. Theoretically in order to calculate it, one would need to compare the HS quantities in EEE placed on the market before and after RoHS enforcement.

However, the following should be considered:

(1) There is little information about the HS quantities used in EEE before RoHS and it is not possible to elaborate a realistic scenario on what the situation would have been today (2008) if RoHS had never existed.

(2) Even today there are uncertainties about the quantities of the banned substances in EEE: manufacturers point out that it is very difficult to know exactly the product composition in particular when it incorporates thousands of components from a long supply chain stretching around the world.

(3) There are uncertainties about the quantities of EEE placed in the EU market, a necessary piece of information if one is to calculate the overall HS quantities.

(4) It is not always easy to determine to which extent the reduction of the HS in EEE can be attributed to RoHS or is due to other factors as well, such as technology changes or consumer preferences, or indeed other EU legal acts.

The Arcadis study ("Study on RoHS and WEEE Directives", No30CE-0095296/00-09, March 2008) carried out for the Commission services (Directorate General Enterprise and Industry) in preparation of the RoHS review calculated (approximations) the quantities of the banned substances avoided being present in EEE due to RoHS : 130605 tonnes of lead, 6251 tonnes of cadmium, 760 tonnes of hexavalent chromium, 31 tonnes of mercury and 18468 tonnes of Octa-BDE.

TV sets are an illustrative example; Pre-RoHS TVs contained (ranges of substances, in grams): Lead : 2131-5473, cadmium : 125, DecaBDE : 452-1597, Octa-BDE:301-904. After RoHS the quantities are : Lead : 472-562, cadmium : 7-13, Octa-BDE : 0, Deca-BDE: 452-1597 (when DecaBDE ban enters into force this will also be zero).

By multiplying these figures with the average 35 million TVsets sold yearly in EU 25 one can calculate the absolute quantities of the substances.

It has to be added that for lead a lot of the reduction is due not to RoHS but to technological change from cathode ray tubes to flat screens; taking this into account, it is estimated that the minimum amounts of lead in TVs avoided thanks to RoHS are in the order of 67 000 tons per year

On the above basis, and taking into account the separate collection rates from the UNU study supporting the WEEE review, they also calculated the quantities of the banned substances avoided being disposed of and potentially released into the environment: 89800 tonnes of

lead, 4300 tonnes of cadmium, 537 tonnes of hexavalent chromium, 22 tonnes of mercury and 12600 tonnes of Octa-BDE.

Key assumptions were the following:

- Out of the whole scope of RoHS, only the following products are considered: Refrigerators, PCs ,Laptops, Printers, Copiers, Cell phones, TV sets, Watch/clocks, Fluorescent (double end) lamps, lawn mowers + gardening equipment.

- Video games and handheld video games, Dispenser for hot and cold beverages.

- Minimum benefit scenario i.e. minimum concentration of the HS in EEE before RoHS and minimum concentration after RoHS for the items with exemption and for the items without exemption after RoHS the presumed concentrations are based on the maximum allowable values :0.1 % by weight for Pb, Hg, Deca-BDE; 0.01 % for Cd and of 0 % for Cr(VI) and Octa-BDE.

- Technology changes or changes in the demand of product type after the implementation of RoHS are mostly not taken into account in the determination of the quantities and the further calculations, because there was often no detailed information. Only for PCs and TV sets the technology change from a cathode ray tube before RoHS to a flat screen after RoHS was included.

- Reduction in Deca-BDE presence and emissions is put to zero, based on the assumption that its use is allowed but from 30.06.2008 this will no longer be the case. It is estimated that approximately 22 000 tonnes of Deca-BDE are used yearly in the selected products.

The overall environmental effects of lead substitution in solders have been largely discussed. Besides the positive environmental effects of substitution, it can also have negative environmental effects, in particular energy consumption. However, there seems to be no consensus yet on energy consumption of Pb-free soldering versus Pb soldering. 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 yet.

RoHS has generated additional environmental benefits as well which are probably even more uncertain to assess quantitatively but are nonetheless concrete and real:

– stimulation of compliance throughout the supply chain affecting also EEE outside the RoHS scope (knock on effect).

– greater awareness about product composition and toxicity leading to better control of HS, including those not regulated by RoHS.

– similar legislation worldwide and hence increase of the market pressure for reducing EEE toxicity, beyond the elimination of the regulated substances.

– reduction of quantities of hazardous waste at the EEE production plants.

– reduction of health and safety risks stemming from the use of these substances in production plants.

– reduction of environmental and health impacts during service life: Brominated flame retardants tend to volatilise from products during service life; thanks to RoHS the release of 150 tonnes of octa-BDE in the environment during use of EEE has been avoided (the quantities have been estimated per product/year; over the total lifetime of a product and for the number of products in the EU 25). With the entry into force of the ban, 179 tonnes of Deca-BDE should be added.

ANNEX II

Additional hazardous substances used in electrical and electronic equipment

The Commission services had a study carried out to determine which other HS are present in EEE, in which quantities, how their risks are managed and what could/should be done under RoHS (taking in particular REACH into account) if anything, to further reduce these risks.

The contractor carried out an extensive consultation (overall duration three and a half months) with stakeholders, in particular industry, to determine nature and quantities of HS used in EEE other than those regulated by RoHS.

On the basis of the terms of reference, the contractor applied the following criteria to be used for the selection of HS to be further investigated:

– Substances meting the criteria for classification as dangerous according to Directive 67/548.

– Substances meeting the criteria for classification as substances of very high concern (SVHC) in accordance with REACH.

– Substances which have been found as contaminants in humans and biota.

– Substances which can form HS during the collection and treatment of EEE.

Based on these criteria and after extensive stakeholder consultations, the contractor (Öko-Institut) established the following **list of (groups of) substances**, for further assessment with regard to possible future inclusion in the RoHS substance ban:

Tetrabromo bisphenol A (TBBP-A)

Hexabromocyclododecane (HBCDD)

Bis (2-ethylhexyl) phthalate (DEHP)

Butylbenzylphthalate (BBP)

Dibutylphthalate (DBP)

Medium-chained chlorinated paraffins (MCCP) (Alkanes, C14-17, chloro)

Short-chained chlorinated paraffins (SCCP) (Alkanes, C10-13, chloro)

Nonylphenol ethoxylates

Halogenated organic compounds

These preliminary findings as well as the need for additional risk management measures under the RoHS Directive for these substances in light of (on-going or finalized) Risk Assessments were discussed in a **stakeholder workshop** on 6 May 2008. The outcome of the stakeholder workshop can be summarized as follows:

Stakeholders contested the relevance of certain hazardous substance for EEE, due to the reported low quantities.

Stakeholders felt that 'halogenated organic compounds' is too broad a description (many substances included) to be used as a basis for restrictions under the RoHS Directive.

Concerning the substitutes -- although some information is available and it is settled that they do not present some of the hazards (such as, persistence, bioaccumulation or toxicity for the halogen-free flame retardants) of the hazardous substances currently in use -- stakeholders were of the opinion that the scientific information would not be sufficient to establish with certainty that substitutes would be safer for environment and health than the candidate hazardous substances of the list above.

Some stakeholders pointed out that phthalates, used in EEE mainly as plasticizers in PVC, may also be released out of the material into the environment during the life time of EEE. In this case for many EEE applications safer alternative substances or design solutions (use of polymers other than PVC which do not need phthalates as plasticizers) seem to exist but stakeholders stated that they would not be fit for all EEE or would be too expensive.

Taking into account the stakeholder comments, only the first five items of the above list were retained for more in-depth investigation.

In spite of some additional data collected after the workshop, the study concludes that further investigation of technical suitability, (eco-) toxicological and environmental endpoints of substitutes is necessary; limited information exists on environmental (e.g. energy use, toxicity, impact on waste stream), social (occupational health and consumer safety) impacts caused by substitution, on which costs will arise through a possible restriction of the proposed candidate substances in the supply chain both for industry and consumers or the competitiveness of industry on the internal and external market. Further impacts may arise from administrative burden (i.e. information and verification activities). The available information has not been specific enough to quantify the impacts mentioned above within the study.

The available data therefore do not allow to decide that for any of the abovementioned candidate substances a ban under RoHS would bring more important environmental, economic or social benefits than the respective costs it is likely to incur, therefore it is not proposed to include any new hazardous substance in the scope of RoHS.

ANNEX III

Options discarded at an early stage

During the stakeholder consultations several other options, not analysed in section 5 were considered but rejected at an early stage. These are summarised below:

Options to clarify and simplify the Directive

Some options for additional definitions, such as for "fixed installations", "consumables" or analytical description of the various product categories (including for example the "large scale industrial tools") have not been retained. Elaborating new definitions in these cases, some of which are highly controversial, could prove too time consuming; it is doubtful whether definitions alone would solve the problem, moreover, the current "grey area" products are rather few, in view of the overall scope of RoHS. It would be preferable not to undermine the efforts made to date for clarifying the status of 'grey area' products but rather encourage efforts by stakeholders, in particular enforcement authorities in MS, to settle any remaining or emerging cases; this will be facilitated by the possibility to amend one of the annexes by Comitology, as proposed in the present review. Available information does not justify either the inclusion of electricity generating equipment as a new product category in the scope of RoHS.

Options to improve enforcement

New marking has been almost unanimously rejected by stakeholders and does not seem indeed to bring enough benefits to counterbalance the visible drawbacks, such as risk of confusion from proliferation of not necessarily easily recognisable marks (taking also into account that EEE are subject to mandatory labelling under the WEEE Directive); this confusion would be greater if the marking is voluntary (in this case also the environmental benefit would be reduced). Furthermore, any additional marking (voluntary or obligatory) would entail some additional cost for industry.

Some stakeholders supported the creation of a stakeholder forum; this would represent an additional step in decision-making that would probably slow down the process considerably (already many stakeholders find the exemptions' process very time consuming). The added value would be limited, if any, since sufficient provisions and safeguards for stakeholder information and intervention are provided in the current RoHS.

Options to adapt the Directive to technical and scientific progress

- **Exemptions**

Other options examined but rejected at an early stage included removing explicit legal requirements for stakeholder consultation and integrating this consultation in the technical work leading to positive or negative recommendations for each exemption request or submitting directly such requests to the Regulatory Committee; they were not retained, in spite of the apparent gains in expediency, because of the possible loss of transparency and the massive rejection by stakeholders.

Granting exemptions only for new technologies or only for new equipment would probably pre-empt abuses of the process (unreasonable requests, same request submitted several times,

requests for applications which exist long enough for substitutes to be in place) and would leave room for innovation by allowing use of the HS in new applications and technologies whilst not considerably damaging the overall environmental benefit of the Directive. However, stakeholders in their vast majority are of the opinion that it would be too difficult to define which product or technology/application is "new" or "innovative". The Commission considers that the risk of confusion and uncertainty is too high for such an option to be retained.

- **Adapt product coverage to technical and scientific progress**

Including category 8&9 products without exemptions soon (e.g. 2012) would have been impracticable while postponing the entry into force (e.g. until 2018) so that all these products may be included without a need for exemptions would mean an unnecessary postponement for the vast majority of products which are already compliant or close to substitution of the HS in question.

Extending the scope of RoHS to cover all EEE would have certainly been a far reaching amendment and did get support from several stakeholders (NGOs and MS). Realizing it, would enhance the environmental effect of the Directive in the medium term and remove any uncertainty as to which equipment falls under the scope. However, the creation of the necessary negative list with exempted equipment (military equipment, aerospace applications, transport equipment, large stationary equipment) might lead to prolonged discussions; most importantly, the investigation of the full impacts of such an option cannot take place within the time schedule of the present review. Other options for clarification of the scope (related to fixed installations and large scale industrial tools) were mooted but, given the almost diametrically opposed views of stakeholders and the lack of sufficient data for evaluating them, it was decided to discard them.

- **Substances covered [Article 6 of RoHS]**

Options of managing risks alternative to restrictions of use have been considered: waste management of EEE (thus reducing the release of HS in the environment); easy removability of parts containing HS (thus facilitating WEEE recycling and reducing release of substances during the end of life phase). Stakeholders considered them at most as part of the solution; labelling is almost unanimously rejected, since it is deemed likely to bring confusion. Rejected were also the options aiming at simplification (choosing the time of entry into force of the ban in such a way that no exemptions are needed) because the availability of substitutes would not be necessarily ensured.

ANNEX IV

Relations of the WEEE and RoHS Directives and coherence with other Community Policies or Legislation

The WEEE and RoHS Directives are closely linked and complement each other: the RoHS Directive prohibits the use of certain hazardous substances in electrical and electronic equipment and thus facilitates the treatment of this equipment when it becomes waste.

Coherence with general Community strategies

The objectives of both Directives are in line with relevant Community strategies, including the Lisbon Strategy, the Sustainable Development Strategy, the Energy and Climate Package, the 6th Environmental Action Programme and its mid-term review, Integrated Product Policy, the Thematic Strategies on the sustainable use of natural resources and on waste prevention and recycling, the 'Marketing of Products' package and the Commission's recent lead market initiative.

> The review of the Directives is foreseen in the Commission's simplification programme, with implements the Community Lisbon Programme[66]. It will contribute to eliminating unnecessary barriers and burdens facing European business and society, in line with the "growth and jobs" strategy of the EU.

Both Directives contribute to the reducing CO2 emissions through energy savings from recycled materials and thus contribute to European climate reduction targets agreed in Kyoto[67].

> The substance ban, design requirements and waste management approach of the RoHS and WEEE Directives contribute to the objective of Thematic Strategy on the Sustainable Use of Natural Resources[68] which calls for lowering the overall environmental impact of resource use in a growing economy. The RoHS Directive takes account of this by allowing exemptions from the substance ban where "substitution is technically or scientifically impracticable or where the negative environmental health and/or consumer safety impacts caused by substation are likely to outweigh the environment, health and/or consumer safety benefits thereof"[69] and by requiring regular reviews of the substance bans in the light of scientific evidence[70]. The WEEE Directive responds to this by reducing the environmental and health impacts per unit of material used without restricting the use itself or limiting quantities.

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66 The objective of the simplification exercise is to contribute to a European regulatory framework of the highest standards in respect of the principle of subsidiary and proportionality. Simplification intends to make legislation less burdensome, easier to apply and thereby more effective in achieving its goals. Following on these principles, a regulatory action should not be beyond what is necessary to achieve the policy objectives pursued, needs to be cost-efficient, and should take the lightest form of regulation called for.

67 Prognos study, May 2008, http://www.prognos.com/Singleview.306+M5c828d79ff6.0.html.

68 http://europa.eu.int/comm/environment/natres/index.htm

69 RoHS Article 5

70 RoHS Article6?

The WEEE and RoHS Directives also contribute to the objectives of the Thematic Strategy on Waste Prevention and Recycling[71] which calls for less waste being generated in terms of toxicity ("qualitative waste prevention") and weight ("quantitative prevention"), and for an optimization of recycling in view of overall environmental and health benefits. The substance ban of the RoHS Directive responds in particular to the call for "qualitative prevention". The WEEE Directive responds to the aim of optimized re-use, recycling, and other recovery at a high level of environmental and health protection, giving planning security to economic actors through binding collection targets and harmonized standards for waste treatment.

In line with the Integrated Product Policy approach[72], the RoHS Directive introduces life-cycle considerations as an essential criterion for granting exemptions.[73] The WEEE Directive seeks to improve the environmental performance of all operators involved in the life-cycle of electrical and electronic equipment, e.g. distributors and consumers and treatment operators.

WEEE and RoHS contribute to the objectives established by the 6th Environmental Action Programme[74] and its mid-term review[75], which call, *inter alia*, for a significant reduction in the quantity of waste going to disposal and the volumes of hazardous waste produced while avoiding an increase of emissions to air, water. Moreover, the RoHS Directive explicitly refers to the Sixth Environment Action Programme with respect to future decisions on the prohibition of additional hazardous substances under the RoHS Directive.[76]

Ensuring consistency with the "Marketing of Products" Package[77] is particularly important in the context of the RoHS review. This legislative package aims to simplify and improve existing internal market legislation on goods, by providing a clear and consistent legal framework which will at the same time guarantee safe products on the market. In the case of RoHS, harmonised definitions and obligations for the economic operators could lead to substantial economic benefits (reduction of administrative burden for administrations and producers) and more efficient and coordinated enforcement at Community level.

The WEEE Directive is one of the policy instruments mentioned in the Lead Market initiative [78] to foster recycling markets, help more and better recycling yielding environmental and economic gains.

Coherence with EU legislation on product design and waste management

The provisions of the Directives are coherent with the requirements of other pieces of EU legislation on product design and waste management as explained below.

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71 http://europa.eu.int/comm/environment/waste/strategy.htm

72 Reference IPP

73 Exemptions from the substance ban are allowed where "substitution is technically or scientifically impracticable or where the negative environmental health and/or consumer safety impacts caused by substation are likely to outweigh the environment, health and/or consumer safety benefits thereof.

74 Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme OJ L 242, 10.9.2002, p. 1–15.

75 COM(2007) 225 final.

76 Article 4(3) of RoHS.

77 Add reference when published. June?

78 COM (2007)860 final

RoHS and REACH

REACH[79] aims to create an EU-wide system for the management of chemicals and their safe use, by *inter alia* requiring manufacturers and importers to gather information on the properties of chemical substances, which will allow their safe handling, and to register the information in a central database run by the European Chemicals Agency (ECHA). RoHS, on the other hand aims to contribute to the protection of human health and the environmentally sound recovery and disposal of WEEE and to eliminate the disparities between the national laws of the Member States. To this end, it restricts the use of certain hazardous substances in electrical and electronic equipment put on the Community market. Since the objectives and approaches of both pieces of legislation differ, one cannot be replaced by the other but they complement each other.

REACH confirms the importance of managing chemical releases related to waste treatment, which forms the core of RoHS, by requiring information on all stages of a substance's lifecycle to be provided for in the chemical safety report. It is based on the demonstrated risk of a substances resulting from its use, while RoHS is founded on a preventive approach, based on the hazard profile of the substances (as opposed to only demonstrated risk from their use), similarly with the recent Commission proposal for the revision of the toys' Directive. Currently, should a substance that is subject to authorisation under REACH be restricted under the RoHS Directive for use in EEE, such application will be exempted from the REACH authorisation requirements.

However, since REACH is subsequent to RoHS, and much wider and elaborate in scope, certain provisions of RoHS could be clarified or further elaborated upon in the light of REACH. For example, it could be clarified how the link to REACH should be if further hazardous substances would be restricted under Article 4(3) of RoHS[80] . Using the REACH model, it could be clarified in the RoHS Directive that producers requesting exemptions under RoHS should be required to provide relevant information on the available substitutes and their characteristics and, if possible, a substitution plan. Likewise, by June 2012, the Commission will carry out a review of the scope of REACH with a view to identify overlaps with other Community legislation that may exist and propose an amendment of the scope of REACH if appropriate.

RoHS, WEEE and the EuP Directive

The "EuP" Directive (2005/32/EC)[81] establishes a framework for the setting of ecodesign requirements for energy-using products.

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79 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, OJ L 396 of 30 December 2006.

80 While RoHS simply states that further prohibitions can be decided based on available scientific evidence, and the substitution of those substances by more environment-friendly alternatives which ensure at least the same level of protection for consumers, without providing any definition of these criteria, REACH provides for a detailed risks identification for substances and their substitutes.

81 OJ L 191, 22.7.2005, p.29.

On the basis of the EuP Directive, the Commission could set specific eco-design requirements for EEE which may also be covered by the WEEE and RoHS Directives.

However, the EuP Directive aims at improving the overall environmental performance of selected groups of EEE, while considering economic feasibility. Reducing toxicity of the product, e.g. by avoiding hazardous substances could be considered but restricting the use of substances is not an aim of the Directive. EuP was not meant to substitute specific legislation (otherwise REACH would contain a reference to it, as far as EuP products are concerned) but to ensure that sectoral/specific legislation is applied in a coherent and efficient way, for the benefit of the environment and the internal market.

To the contrary, the RoHS Directive aims primarily at avoiding the banned substances for all EEE within its scope. Exemptions are only possible if substitution is technically or scientifically impracticable or where the negative impacts of substitution outweigh the positive ones As regards the hazardous substances the RoHS Directive therefore provides a more direct protection of the environment and human health. RoHS may not result in a negative impact on the overall environmental performance; it has direct (in the exemption process) and indirect (to chemicals policy, REACH) references to the life cycle environmental effects of substitution which need to be overall positive.

There is a need to avoid ambiguity for those EEE potentially covered by all three Directives. With regard to substances banned by the RoHS Directive, ambiguity is avoided because the EuP Directive applies without prejudice to the RoHS Directive. With regard to the WEEE Directive ambiguity could arise as concerns the general requirement of the WEEE Directive for Member States to encourage design for recycling (Article 4 of the WEEE Directive). However, since this is a general requirement, it should be seen as addition to any specific design requirements developed under EuP.

RoHS, WEEE and specific EU waste management legislation

The WEEE and RoHS Directives apply without prejudice to Community legislation on safety and health requirements protecting all actors in contact with WEEE as well as specific Community waste management legislation, such as the Battery Directive[82] and the End-of Life Vehicles Directive[83].

The Commission has clarified the links between these pieces of legislation in several guidance documents. For example, with respect to restrictions on the use of hazardous substances, batteries are covered by the provisions of the Batteries Directive[84]; not by the RoHS Directive. Batteries are only covered by the requirements of the WEEE Directive where they are still included in EEE at the moment of discarding. EEE is covered by the End-of Life Vehicles Directive where specifically designed to be used in vehicles, otherwise they are covered by the WEEE and RoHS Directives.

WEEE and general EU waste management legislation

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82 Recital 10 and Article 2 (2). It also required the 'old' Battery Directive to be revised in light of the WEEE Directive, recital 11.

83 ELV reference

84 OJ L 266, 26.9.2006, p.1

The WEEE Directive is coherent with general EU waste management legislation, such as the Waste Framework Directive,[85] the Landfill[86] and Incineration[87] Directives. It refers back to the general definitions set out in these Directives, for instance regarding the definition of waste and general waste management operations such as recovery and disposal[88] and to the general provisions of the Waste Shipment Regulation.[89]

85 OJ L 114, 27.4.2006, p.9
86 OJ L 182, 16.7.1999, p.1
87 OJ L 332, 28.12.2000, p.91
88 See Article 3 of the WEEE Directive.
89 See Article 6 of the WEEE Directive.

GLOSSARY

AIMD Active Implanted Medical Devices

CA Conformity assesment

DecaBDE DecaBromo- diphenylether

EEE Electrical and electronic equipment

EE Electrical and Electronic

EuP Directive on the Eco-Design of Energy Using Products

RoHS Restrictction of Hazardous substances

IVD in vitro dignostics

HS Hazardous Substances

HBCDD Hexabromocyclododecane

MS Member States

PBDEs Polybrominated diphenylethers

PVC Polyvinyl Chloride

REACH: Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemical substances

TBBPA Tetrabromobisphenol-A

WEEE Directive on Waste electronic and Electrical Equipment

DEHP : Bis(2-ethylhexylphthalate)

NGO : Non Government Organisation

ECJ European court of Justice

Annex V

Assessment of the reduction of administrative burden

In order to evaluate the overall cost of compliance to RoHS as a first step for calculating the expected reduction of administrative burden from the recommended options in the review, several information sources were used (see also p.11) in particular :

- The ERA report
- The Arcadis Study
- The study made by the US-based Consumer Electronics Association (CEA) on the economic impacts of RoHS on the electronics industry
- UK Regulatory Impact Assessment on the transposition of RoHS Directive
- The "BIO Intelligence contract"

In the context of **the Arcadis study** extensive consultation took place to identify and calculate RoHS compliance costs; only 36 companies responded to the 1st and 2nd round of questionnaires. Most of them were large companies and in order to partly overcome the lack of SMEs (only 3) the results of 4 case studies from another project (GreenRose) were added, making up a total sample of 40 companies. The majority of respondents were EEE manufacturers/assemblers, two companies manufacture components as their sole activity.

The quality of the responses was diverse. Some companies only gave qualitative information. The interpretation of the data was often complicated by the fact that the provided figures in many cases were incoherent. Moreover, only a limited number of companies have provided turnover or employment figures.

The total costs include the so-called "compliance costs" (getting acquainted with the Directive's requirements; provision of training and information to the different actors in the chain; cost of collecting, organising and reviewing information (e.g. material declarations); costs related to exemption procedures; costs related to organisational implications causing monetary losses) and the "technical costs of phase-out of RoHS substances" (capital and operating expenditure for the substitution, research and development to find, test and employ substitutes to replace the restricted substances. Compliance costs (apart from the last item on monetary losses) correspond broadly to what is defined as "administrative burden" in the impact assessment guidelines[90]; given however the absence of detailed information on each of the items of "compliance costs" it is considered that this approximation does not influence the conclusions.

[90] 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.

On the basis of these data and assumptions, Arcadis calculated the past and future one-off compliance costs. Compliance costs make up 67% of total costs; the share of technical costs amounts to 33%. Within the future yearly costs to stay RoHS compliant, the share of technical costs drops to 12%, whereas compliance costs reach a level of 88% of total costs. Future yearly costs amount to a maximum of € 4.7 million, with an average of € 1.3 million and a weighted average of € 2.8 million.

The most important compliance cost consists of compliance verification, which is an ongoing expense. When taking into account all compliance costs made in the past, almost half of it is dedicated to collecting and reviewing information activities. 41% of compliance costs is dedicated to training and information activities. 8% is dedicated to organisational implications causing monetary losses and 2% relates to exemption procedures. When only looking at the yearly recurring costs expected in the future, the share of costs dedicated to compliance verification increases from 49% to 68%. The share of compliance costs dedicated to training and information activities falls from 41% to 26%.

The "BIO Intelligence contract" summarised the available information and presented data from additional sources, such as EUROSTAT and dedicated Commission studies for the engineering industry.

The aim was to assess the administrative costs generated by the implementation of the RoHS Directive and their expected reduction thanks to the review.

Given that administrative costs in available studies are rather expressed in €/company or % of turnover, the total administrative costs due to the RoHS Directive were estimated starting from the number of companies affected by RoHS and their turnover in the EU.

The table below summarises the data found on administrative costs:

Summary of available estimates of administrative costs

Source	Past costs and one-off future administrative costs	Future yearly administrative costs
Arcadis 2008	€5,900,000/ company 0.184% of turnover	€265,500/company 0.042% of turnover
CEA 2008	€286,000/ company	€97,000/company

It is clear from the differences observed in the above table that these figures must be taken with extreme care. If we apply them to an estimate of 15,000 (figure from statistics on engineering industry) to 87,000 (Eurostat) EU companies affected by RoHS, we obtain the following figures (rounded), on the basis of an estimated overall turnover of approximately 392 billion€ (Eurostat, EU 27, 2004) :

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 2008	89,000 – 513,000 (on the basis of cost /company) 721 (on the basis of % of turnover)	4,000 – 23,000(on the basis of cost /company) 165 (on the basis of % of turnover)
CEA 2008	4,000 – 25,000	1,400 – 8,000

If we focus on future yearly costs, assume 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 2008], we come up with an extremely large range of **165 to 23,000 million euros**, corresponding to 0.042 to 5% of the total turnover of EU companies affected by RoHS.

However, 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 international companies, whereas the percentage of 0.042% of turnover is not representative either, since basically, administrative costs are proportionally higher for SMEs than for large companies. So neither 165 nor 25,000 million€ can be considered accurate, because either under- or overestimated.

It therefore appears not feasible to assess the total future RoHS-related administrative costs for European companies, as data available is not consistent enough.

In a further attempt to obtain more precise information regarding the impact on the administrative burden for a group of specific options (identified as options which could decrease the administrative burden of RoHS for companies), a short questionnaire was sent by BIO to some major industry associations but too few responses to allow any meaningful quantitative conclusions were received.

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.

Given the scarcity and lack coherence of data, **other sources** were also used in an attempt to get the best possible estimation of cost of compliance to the current RoHS and the impact of the recommended options; in particular the ERA report provided some input for medical devices and control and monitoring instruments; it states that for some complex products sold in small quantities cost might be as high as 7-10% of turnover, but this as well is based on estimates of an unspecified number of manufacturers (p.150). Assuming costs in the order of 1-4% of the turnover, BIO intelligence estimated the yearly compliance costs to 400-1600million€ for categories 8&9. Date of entry into scope seems to be the main concern of manufacturers and to have an important impact, although difficult to quantify. In a late submission, the medical industry claims, based on a sample of few companies, millions of losses (confidential figures) if 2012 instead of 2014 is chosen as an enforcement date. For industrial test and measurement instruments, manufacturers claim that the estimated cost (loss of sales because of products which cannot be made RoHS compliant, even if exemptions are granted) would be 439, 246,3 and 49,3 million€ for enforcement dates 2012, 2015 and 2018 respectively. For comparison purposes, the total sales revenue for a sub-group (test instrument categories only) is 1520 million € for the EU. It should be stressed however that these figures have not been subject to any third party assessment, nor is it possible to weigh them against the expected increased environmental benefit of early enforcement date, which is very hard to calculate.

In the Impact Assessment of the "Marketing of products package" some cost elements are given which, although general and pertaining to other regulated aspects of products such as safety and, to a certain extent, to products not covered by RoHS, do give an idea of the order

of magnitude of estimated cost from conformity assessment procedures (1-2% of overall unit production cost; for third party verification, cost could be as low as 500€, but would normally range from 2500 – 3500€) and market surveillance (industry estimates that non-compliant products cost them 4-25% of their annual turnover; increase of cost by 5-10% for administrations). Again it has to be stressed that the actual costs will depend on the degree of current preparation and compliance with RoHS and that subjecting RoHS explicitly to the same requirements and procedures as for other regulated aspects will create synergies and reduce costs (declaration of conformity covering many regulated aspects, facilitation of market surveillance).

Finally, concerning the substitution plan, the Impact Assessment of REACH was used and the figures given in the analysis of options above are extracted from the below table

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

The possible administrative costs could be estimated on the basis of the above table, but these would of course vary considerably depending on what the actual substitution plan would look like and the substance/process in question.

Use of the standard cost model

Full calculation of administrative costs using the core equation of the cost model presented in the IA guidelines Annex 10[91] was not possible due to absence of reliable and comprehensive data. An attempt was made to use it for two items which are considered most relevant and liable for quantification that is to say demonstration of compliance and the exemptions procedure.

Concerning the exemptions procedure, the Commission services, estimate that 3000-4000€ (based on a daily rate of 800€) for preparing, sending and following up (discussions with the consultant appointed by the Commission, further follow up) of a well prepared application is a realistic figure. The Commission services have received approximately 140 exemption requests during the last 5 years, i.e. on the average 28 requests per year meaning a yearly cost to applicants of 84 – 112 000€. Several of the requests were submitted or followed up by industry associations, meaning that the cost has not been borne by one single company but spread among several. Even if we multiply the man/hours spent by factor 10, still the amount would be negligible, compared to overall turnover of the EEE industry in EU, despite uncertainties and approximations.

[91] Administrative costs should be assessed on the basis of the average cost of the required action (Price) multiplied by the total number of actions performed per year (Quantity). The average cost per action will be generally estimated by multiplying a tariff (based on average labour cost per hour including prorated overheads) and the time required per action. Where appropriate, other types of costs such as equipment or supplies' costs will be taken into account. The quantity will be calculated as the frequency of required actions multiplied by the number of entities concerned.

The RoHS Directive does not foresee explicit reporting obligations for Member States or for information supply requirements by manufacturers in RoHS and in most cases Member States have not introduced such legal obligations at national level either for manufacturers. In this respect, a strict interpretation of the "administrative cost" definition could lead us to the conclusion that RoHS does not create any administrative burden for manufacturers, as far demonstration of compliance is concerned.

Costs for testing may be significant but, as explained, in the majority of cases testing is not required; in most cases testing costs should be considered as cost for technical compliance, hence outside the definition of administrative burden. The "RoHS enforcement Guidance Document" produced by the informal network of national authorities, although not binding, is largely used by manufacturers. Testing of a single component may cost up to 530€ but full product tests according to international standards (ISO17025) that closely follow the guidelines of the informal network are available at 630€. However, the focus of manufacturers' effort as confirmed by direct communications with manufacturers and the Arcadis report (p.104) is on "collecting and reviewing information" primarily from their suppliers so as to make sure that the purchased parts are RoHS compliant.

In the absence of more detailed information on the actual cost for producing RoHS compliance documentation, the Commission services base their estimation on the relationship of cost of exemption request/collecting and reviewing information, which the Arcadis report estimated to 1/6. This would mean that, on the assumption that the annual cost for exemption request is 4000€ (see above) the annual cost for compliance documentation would be 24 000€. Applying the 87,000 figure for the total number of EU companies affected by RoHS (see above), the result is approximately 2100 million€ for the EU.

Conclusion

The analysis in Annex V shows that there are few data and many uncertainties for the calculation of the administrative burden incurred from RoHS, which seems to be low (or even negligible, if the administrative cost definition is strictly interpreted).

It is therefore difficult to calculate the reduction of administrative cost that the recommended options will result in, but it is expected to be modest, albeit positive (for the reasons explained in the analysis of the individual recommended options). Nevertheless, the recommended options will have an important cumulative effect in clarifying the Directive and harmonising its implementation and enforcement with a positive contribution to better regulation.