

**THE REVIEW OF DIRECTIVE 2002/95/EC  
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL  
AND ELECTRONIC EQUIPMENT  
INVITATION FOR COMMENTS ON POLICY OPTIONS AND FOR INFORMATION SUPPLY**

## **THE DIRECTIVE**

Directive 2002/95/EC aims to approximate the laws of the Member States as regards the restriction of the use of hazardous substances in electrical and electronic equipment and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment. National laws or administrative measures can have a direct impact on the establishment and functioning of the internal market. Moreover Community-wide rules limiting the presence of hazardous substances in products and in production processes can benefit environment and health; restricting the use of these hazardous substances is likely to enhance the possibilities and economic profitability of recycling of waste from electrical and electronic equipment (WEEE) and decrease the negative health impact on workers in recycling plants.

## **INTRODUCTION: THE REVIEW**

The RoHS Directive is also among the EU legal acts identified as presenting a simplification potential in the Commission Communication<sup>1</sup> of 25 October 2005 "A strategy for the simplification of the regulatory environment". The objective of the simplification exercise is to contribute to a European regulatory framework of the highest standards of law making 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 in achieving its goals. Reduction of administrative burden from existing EU legislation is an important political objective and the Commission is committed to assist in avoiding unnecessary burdens while preserving the level of environmental protection.

Article 6 of the RoHS Directive calls on the Commission to review the measures provided for in the Directive taking into account, as necessary, 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.

The review of the RoHS Directive will be based on the experience of the application of the Directive, the developments in science and technology, environmental requirements and the functioning of the internal market and will assess the environmental, social and economic impacts in an integrated manner.

It aims at increasing the environmental benefit, removing the implementation and enforcement problems encountered to date and making the Directive cost effective.

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<sup>1</sup> [http://europa.eu.int/comm/enterprise/regulation/better\\_regulation/simplification.htm](http://europa.eu.int/comm/enterprise/regulation/better_regulation/simplification.htm)

The examination of the issues started in 2006 and will continue during 2008; a study on possible inclusion of categories 8&9 has been completed and further studies launched by the Commission services are ongoing.

**The Commission intends to present the review in 2008.**

**Neither the fact that the review process is being launched, nor the content of the present document should be interpreted as a political or legal signal that the Commission intends to take a given action.**

## **STAKEHOLDER INVOLVEMENT IN THE REVIEW**

The success of the RoHS review depends largely on the participation of the stakeholders who are involved in the implementation of the Directive and have the information and experience which must be taken into account.

Updated information on foreseen structured consultations and on the progress of the review in general will be available in:

[http://ec.europa.eu/comm/environment/waste/weee\\_index.htm](http://ec.europa.eu/comm/environment/waste/weee_index.htm)

## **REQUEST FOR COMMENTS AND INFORMATION SUPPLY ON THE POLICY OPTIONS**

In Spring 2007 the Commission services identified certain topics for the review and launched a consultation process to encourage and allow stakeholders to provide their input.

In general stakeholders commented on the topics suggested in the consultation document without fundamentally criticising the topics' selection; some but not completely new, additional topics were proposed which could in most cases be considered as more detailed subdivisions of a main topic. This points 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 policy options.

These options are presented below for each topic highlighting pros and cons; stakeholders are invited to express their opinion on the outlined options, on the possibility of combining options with a view to achieving the objectives of the review and on ranking of options within each topic; they are also invited to propose additional options that the review should consider.

The Commission services will base their analysis of issues and selection of options for amendment on factual evidence; it is therefore of paramount importance that any opinion is supported by **detailed evidence that you currently hold that facilitates the assessment of the economic, social and environmental impacts of the policy options**. In particular, we would like to receive **studies and evaluations** which will allow us to analyse the full costs and benefits of potential changes in the operation of the Directive.

Note that we will be using relevant data which has already been provided as part of the WEEE Review, particularly information already received from stakeholders and contained in the summary document contained on this web-page.

[http://forum.europa.eu.int/Public/irc/env/weee\\_2008/home](http://forum.europa.eu.int/Public/irc/env/weee_2008/home)

Please note that the information you provided may be shared with other stakeholders, in particular the contractors carrying out studies related to the RoHS review for the Commission services, unless you indicate that they should be considered confidential. Information provided in confidence (clearly indicated "CONFIDENTIAL") will not be made available to other parties.

**Addresses for submission of information:**

Please send information electronically to

[ENV-ROHS-DIRECTIVE-REVIEW@ec.europa.eu](mailto:ENV-ROHS-DIRECTIVE-REVIEW@ec.europa.eu)

Please send any paper copies of information which you do not hold electronically to:

European Commission  
Rue de la Loi 200  
1049 Brussels - BELGIUM

**We would like to receive the information by February 13<sup>th</sup>, 2008 after which the Review will move on to the next stage of its work.**

Options for the RoHS review

**NB : HS = hazardous substances, MS = Member States**

*Policy options which are likely to entail major changes are marked in bold; in some cases where detailed evidence and data are particularly required – beyond the above mentioned general need - this is explicitly indicated*

**I. PRODUCT GROUPS TO BE INCLUDED [ARTICLE 6 OF ROHS]**

**(page and table numbers refer to the ERA report:**

[http://ec.europa.eu/environment/waste/weee/pdf/era\\_study\\_final\\_report.pdf](http://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf) )

1. Continue excluding one or both categories altogether

Avoidance of possible additional costs and burdens for manufacturers and for national and EU administrations; avoidance of possible confusion, especially in case exemptions would be granted; more flexibility for manufacturers to move towards reducing toxicity of their products at their own pace;

*Loss of opportunity to enhance environmental objective of the Directive (degree of environmental improvement depending on the category(ies) remaining out of scope; no encouragement for innovation and reduced toxicity, in spite of fierce international*

competition in this area; risk of fragmentation of the market if national legislation aims to fill this non-harmonised sector.

2. Continue excluding one or both categories altogether and encourage eco-design

Eco-design would provide more flexibility to manufacturers for introducing overall environmental improvements;

*There is no guarantee that voluntary efforts (for example based on standards) will deliver the same results as legislation or that reduction of toxicity will receive the necessary attention in the context of eco-design by the manufacturer, even if its is undertaken; the existing EU framework Directive for eco-design (EuP) would, in principle, not cover several categories of medical devices and monitoring and control instruments which are sold in small quantities but may be very relevant for their HS content.*

- 3. Include them both from the beginning (probably around 2012 taking into account time necessary for co-decision and accomplishing transposition of revised RoHS in all MS)**

Clear timetable for all medical devices and monitoring and control instruments, avoiding confusion for manufacturers and authorities; from the early years of WEEE/RoHS preparations until 2012, manufacturers will have had almost 15 years for preparing themselves;

*Time may not be sufficient, especially for complex and high tech products with critical applications; cost and other social implications may be quite heavy, especially for applications requiring high reliability and products with long life cycles.*

4. Include both categories but with a deferred deadline (e.g. 2014)

Once the legal certainty that these products will be included is established, such a solution would provide more space to manufacturers; it would also be in line with the original approach whereby the ban became valid some years after the entry into force of the Directive;

*For many Cat.8&9 products, such a postponement does not seem necessary (the manufacturers themselves consider 2012 a reasonable deadline); the environmental effect of the Directive would be weakened and some uncertainty prolonged.*

5. Include both from the beginning with the exemptions proposed by ERA (tables 71&72: depending on the adoption date, table 72 exemptions may be redundant)

Cat.8&9 would be included in RoHS without technical or reliability problems; any impacts on cost would not affect the availability of related services (in particular in the health sector);

*Environmental effect of inclusion would be reduced (if exemptions account for a large % of the overall quantity of the restricted substances used in Cat.8&9); risk of confusion related to the enforcement and monitoring of the exemptions and related*

*additional requests; such an option would entail considerable technical work in the Regulatory Committee (TAC).*

6. Include both with exemptions (tables 71&72) and deferred deadlines and general exemption for lead in solders (p.230&246-248)

Cat.8&9 would be included in RoHS at the lowest possible, if any, cost or requested effort by the producers and without any impacts whatsoever on reliability or availability of products or services;

*Environmental impact of inclusion would be greatly reduced (see also table 11); almost complete absence of motivation for reducing toxicity of products; given the ongoing efforts (pressure on environmental issues internationally, substitution push for other EEE due to RoHS) this amounts to a "business as usual" scenario. In particular a permanent exclusion for sensors (p.247) does not seem justified and would give the wrong signal to manufacturers.*

7. Differentiate between consumer/industrial equipment for cat.9 (maximum deadline for industrial equipment: 2018)

Allow room for more complex and critical equipment, while not substantially reducing the environmental benefit of the Directive; allow smooth adaptation of the sector without loss in quality of services, innovation potential and competitiveness; use of existing international standard may contribute to differentiation;

*It is not clear which products would fall under this category, possibly leading to new "grey areas" in the RoHS scope; standard definition would include consumer products; both a comprehensive definition and a list of products may be necessary.*

8. Differentiate for In Vitro Diagnostics (IVD) (2016) and Active Implanted Medical Devices (AIMD) (permanent exclusion or exemption until 2020) (p.230)

Smooth transition into RoHS compliance for these product categories, while maintaining fully the demanded critical reliability (in particular for AIMD), product quality and innovation and decreasing "cost per test" for IVD;

*The environmental benefit of the Directive would be impaired, although the HS quantities involved (in particular for AIMD) are low. A more detailed differentiation within IVD would be necessary since some IVD products could be compliant much earlier. Such a differentiated approach might give the wrong signal to industry and not provide the necessary motivation for innovation (RoHS-like legislation is spreading around the world and is likely to include these products) and adaptation (how long can AIMD manufacturers rely on the availability of components with lead-solders?).*

## II. SUBSTANCES COVERED [ARTICLE 6 OF ROHS]

***A study to investigate possible policy options for fulfilling the requirements of Article 4(3) and 6 (§3 and 4) of RoHS was launched by DG ENV in October 2007; this study will consider all available relevant information and its results are expected for May 2008; the below indicated preliminary options are in line with the ones the study will examine and the present consultation can contribute by providing an early and informed feedback***

1. Not add any new justified substances under RoHS and deal with them under REACH

Simpler and faster procedure for adopting the revised RoHS; reduced risk for confusion (the "RoHS substances" should be widely known by now by interested stakeholders, any remaining HS will be tackled by REACH). REACH provides mechanisms to assess the risk due to dangerous substances including those used in EEE. In case of risk evidence at use or waste level, REACH authorisation or restriction will then apply to manage the risks on an appropriate way;

*If evidence points to a different direction, doing nothing could be interpreted as disregarding the legislator's mandate (Article 6 of RoHS); missing the opportunity for minimising risks for health and the environment much earlier than it would have been possible with REACH. Authorisation under REACH will only apply to European producers of EEE.*

2. Add new substances but only for certain categories of EEE in the scope of RoHS

Extension, albeit limited (by the reduction of product categories covered), of the environmental and health benefit of the Directive; avoiding the administrative burden associated with managing exemption requests and monitoring implementation of exemptions;

*Leaving unexploited potential for further increasing the environmental benefit of the Directive; some sectors may feel disadvantaged, especially if there is competition in use between included/excluded products; possible need for a review clause (like is the case now with cat.8&9 products), creating room for uncertainty and speculation.*

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

Extension, albeit limited (by the exemptions), of the environmental and health benefit of the Directive; smooth transition into the "extended" ban; continuation of a transparent approach already known to manufacturers and other stakeholders;

*Complaints about length and complexity of exemptions' process have been submitted; possible uncertainty as to approval and the time horizon for validity of the exemptions; it must be checked what the exemptions represent in terms of % of the overall quantity of the HS used in EEE; the time horizon should be compared with REACH, probably on a case by case basis.*

#### **4. Add new substances for all EEE without exemptions at a deferred date**

Extending as much as possible the environmental benefit of the Directive and giving a clear signal to manufacturers; avoidance of confusion; faster and simpler procedure for adopting the revised RoHS;

*Postponement could be as long as the time needed for the HS substitution in the most critical applications; the time horizon should be compared with REACH, probably on a case by case basis.*

5. Add new justified substances under RoHs only if substitutes already available and fully investigated

Easier adoption process; transition into the "extended" ban in the smoothest possible way for manufacturers and with certainty that substitution will not incur excessive costs to society or have overall adverse environmental consequences. Any new substance ban must be based on sound scientific evidence with due consideration of the availability and adequacy of substitutes. Any decision leading to the inclusion of a new substance in RoHs should be based on an evaluation and risk assessment process. A reasonable time period to phase out existing uses of a targeted substance is required

*List of substances added may be too short, hence reduced environmental benefit; inclusion of a new hazardous substance in RoHS, even with exemptions and postponements, spurs efforts and research into the availability and characteristics of possible substitutes, which would otherwise not take place; a requirement for full investigation of substitutes might prolong the process if the necessary data are not already available to a large extent.*

6. Link inclusion of substances at a given deadline (e.g 2014) with the results of a report on the efficiency of waste (WEEE) management for removing HS from the waste stream

A purely risk based approach, hoping that all stakeholders will behave responsibly and the benefits of the WEEE Directive will be reaped in their entirety; manufacturers retain full flexibility in their product design, while being aware that certain HS have been identified as possible candidates for RoHS;

*It is not possible to foresee or identify the pathways of dissemination of a HS in the waste stream if separate collection and state of the art treatment of WEEE do not take place sufficiently. Experience has shown that it is very hard to collect comprehensive and reliable data (see latest UNU report for WEEE review), which would be necessary if the risk for particularly harmful HS were to be properly managed. Such an option is not expected to deliver the necessary environmental benefit, if not combined with other actions; could be appropriate as one among other indicators/milestones in a review process (see also option Va 7).*

- 7. Not add any new substances but introduce labelling requirements (for example certain phthalates for certain Medical Devices)**

Faster and easier adoption process, since such a "light" requirement would necessitate less investigation and would be most probably more readily accepted. Lower cost and easier transition (increased design flexibility) for manufacturers; could be examined in connexion with the risk that the specific use of the given HS presents;

*Lower environmental benefit, since the HS would still be present in the waste; possible confusion between the HS "for labelling" and HS "for restriction".*

8. Not add any new substances but introduce obligation for easy removability of parts containing HS

Faster and easier adoption process; could be even adopted as a "horizontal" implementing measure under the EuP Directive; a link could be created with the treatment requirements (Annex II) of the WEEE Directive; low cost for manufacturers, could become part of their more general eco-design strategy;

*A solid and complete WEEE separate collection/recycling/treatment of hazardous waste chain should be in place, which is far from being the case now in the 27 MS (or, for that matter, in developing countries where, unfortunately, large quantities of WEEE end up). It is very doubtful whether such an option alone would suffice for ensuring a high level of environmental protection.*

### **III. TECHNICAL CHANGES TO THE SCOPE OF THE DIRECTIVE**

1. Separate WEEE from RoHS scope

Completeness and autonomy of the text increases legal security and transparency; RoHS is based on Article 95 hence aims at harmonisation of requirements, including on what the scope comprises; this will be clearer if RoHS has its own scope, independent from the WEEE Directive; a commonly defined but not identical scope for two Directives regulating product design and waste management respectively has created interpretation problems; such a separation would reduce the administrative burden for administrations and manufacturers;

*For many EEE categories both WEEE and RoHS apply and manufacturers can implement them jointly; stakeholders accustomed to "twin" character of two Directives.*

2. Include explicitly spare parts&components

Expected increase of the environmental benefit of the Directive (taking however into account that all parts and components integrated in finished products must be RoHS-compliant already); it would remove the uncertainties as to whether some equipment should be considered "part/component" or "final product"; it would spread clearly and equally the burden of compliance throughout the supply chain; it would facilitate information supply and compliance for final product manufacturers;

*It could entail additional cost and administrative burden for some parts' manufacturers (which are mostly SMEs), which should be investigated; this cost should not be too big, given that, already now, all parts and components integrated in finished products must be RoHS-compliant; care must be taken so that the provisions can be effectively enforced for all parts&components placed in the EU market.*

3. 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)

Such an addition would clarify the scope of RoHS It is in line with the Guidance document prepared by the Commission services in cooperation with the Member States;

*No apparent disadvantages; in coherence with the Guidance document it should however be clarified that the exclusion refers only to equipment that is specifically designed to be installed in equipment that does not fall within the scope of RoHS (for example airplanes, boats and other means of transport) and that "dual use" products are not exempted on the grounds that they may also be integrated in another type of equipment that does not fall within the scope of RoHS.*

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

It would further clarify the scope of RoHS and remove ambiguity; it is in line with the Guidance document.

*No apparent disadvantages; in coherence with the Guidance document it should be clarified that the exclusion does not, however, apply to products which are not intended for specifically military purposes (dual use products).*

5. Clarify status of consumables

Questions have been raised as to whether for example ink cartridges fall within the scope of RoHS; it might be helpful to clarify that consumables do not fall under the scope of RoHS, unless they are part of the product when it is placed on the market;

*No apparent disadvantage; it is clear that any general requirements on consumables flowing from other pieces of EU legislation (e.g. REACH) will apply also when the consumables are used in EEE.*

## **6. Assess the need for including explicitly fixed installations**

A further clarification of the scope in this respect might be helpful;

*It should remain clear and non-controversial that the inclusion in RoHS of each "finished product" is not affected by its being part of a fixed installation. It has proven very difficult to find a generally acceptable definition for avoiding abusive interpretations.*

## **7. Assess the need for maintaining a general exemption for LSIT (large-scale stationary industrial tools)**

An inclusive approach would enhance clarity and transparency (see also option below). Maintaining the general exemption risks to prolong uncertainty and diverging interpretations. HS should be substituted whenever possible; it may be a wrong signal to prolong the exclusion of equipment from RoHS

requirements, if similar (in terms of composition or use) equipment is subject to substance restrictions;

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

#### **8. Extend scope to cover all EEE**

It would enhance the environmental effect of the Directive in the medium term; it would remove any uncertainty as to which equipment falls under the scope; any additional time needed for collecting data to evaluate the impacts would be offset by avoiding the discussion of what each product category in the annex comprises and which product categories should go in the annex;

*For some EEE categories, the costs may be disproportionate to the expected environmental benefit (especially if there are ongoing voluntary eco-design initiatives and efficient take back and treatment channels). In some cases, reliability may be critical to health and safety aspects of products. Concerning military equipment, political and strategic security aspects need to be carefully taken into account.*

**Detailed evidence, studies and evaluations that facilitate the assessment of the economic, social and environmental impacts of this policy option would be particularly welcome**

#### **9. Add more specialized product categories in an indicative annex**

Extending the indicative annex for the scope (see annex IB of the WEEE Directive) would improve clarity

*This will not be a definitive solution to the problem since such an annex could not be exhaustive; the benefit of increased clarity would be restricted to the named product categories and it is doubtful whether it would justify the discussions needed*

#### **10. "Repair as produced" principle : exclude parts for repairing and for the reuse of products lawfully placed on the market**

It would enhance legal clarity and security; it would be beneficial for the environment since it contributes to extending life time and avoiding untimely disposal of equipment; it would be a wider application of a principle already established in the Directive (Article 2.3 of RoHS);

*There are no apparent disadvantages on the condition that a careful formulation of the legal text and adequate enforcement practices prevent any abusive generalisation of use of non-compliant parts and components.*

## **IV. DEFINITIONS**

1. Insert new definition for "placing on the market"

Diverging interpretations of this concept may lead to market fragmentation according to some industry stakeholders; defining it would remove ambiguity and it is also an opportunity to contribute to increased coherence with other pieces of Community product legislation ("Marketing of products" package, presented by the Commission COM(2007)37 and 53) . Such a clarification could lead to substantial economic benefits (reduction of administrative burden for administrations and producers);

*No apparent disadvantages.*

2. Insert new definitions for the economic operators (such as manufacturer, distributor, importer)

This would enhance clarity, facilitate implementation and increase coherence with other Community product legislation (see above);

*No apparent disadvantages.*

3. Insert definition for "fixed installations"

It will provide legal clarity, in coherence with the Guidance document prepared by Commission services in cooperation with the Member States. The Guidance text is based on the updated EMC Directive Guidance document was and already widely discussed in this context;

*No apparent disadvantages.*

4. Add descriptive definitions for each product category (specifically proposed for cat.8&9 by ERA study)

It would increase clarity as to which products are included in the scope;

*Could be too time consuming since in many cases there are no generally accepted definitions; it is doubtful whether definitions alone would solve the problem, indicative products (see option III.9) might also be necessary; it is not sure whether such an effort is justified by the current "grey area" products which are few, in view of the overall scope of RoHS. It risks to undermine the efforts made to date to clarify the status of 'grey area' products.*

5. Include a comitology procedure to update the list of illustrative examples thereby clarifying the status of 'grey area' products (see Art 19 of the Packaging and Packaging Waste Directive)

It will enhance the legal clarity of the Directive and ease its implementation;

*No clear disadvantages. The TAC has already been discussing at length these issues and no substantial workload will be added.*

6. Insert definition for "homogeneous material" and the MCVs of the Commission decision

Adoption of a definition and of the MCVs would enhance clarity and legal certainty and facilitate implementation; it seems that manufacturers already use the definition of the Guidance Document. It would also support the standardisation process (standards currently under preparation are based on the non-binding definition of the Guidance Document). Any remaining detailed technical problems could be further explored probably in the appropriate technical bodies (e.g. standardisation);

*It seems that it would not be sufficient to just transpose the widely accepted definition of the WEEE/RoHS Guidance Document; some stakeholders raise doubts as to the suitability of this definition for enforcing the ban on Chromium VI+ and there might exist similar or more acute problems with other HS, possibly to be added in the scope of RoHS.*

#### 7. Insert definition for "spare parts"

Should be seen in conjunction with options III.2 and III(10) which could be supported by a definition, whichever the outcome (include parts or not). It would increase legal certainty and attribution of responsibilities across the supply chain; text available in other pieces of EU legislation, which could be adapted for the needs of RoHS;

*No apparent disadvantages.*

## V. FACILITATING IMPLEMENTATION

### Va Enforcement of the RoHS Directive

#### 1. Introduce market surveillance mechanisms

Effective market surveillance mechanisms at national level would greatly enhance the environmental benefit of RoHS by minimising the number of non-compliant products; a major disincentive for free riding, it would contribute to a level playing field for producers. Market surveillance is about to be introduced horizontally through the the "Marketing of products" package which applies to RoHS; it may be useful or necessary to develop more detailed arrangements for RoHS. An Informal Enforcement Bodies Network already exists;

*It would create some additional administrative burden and costs for authorities and possibly also for non-compliant producers, especially in the transition phase, but additional cost would be reduced given that some work in this direction has already been done (informal network exists).*

**Detailed evidence, studies and evaluations that facilitate the assessment of the economic, social and environmental impacts of this policy option would be particularly welcome**

#### 2. Include conformity assessment (CA) procedures (sub options: self declaration or third party verification) (suggested also in the "Enforcement Guide", prepared by the informal network, see above)

It would enhance clarity for manufacturers (who apparently now face problems as to how to demonstrate compliance) and authorities who have no guidance in the Directive as to what should be requested by manufacturers. It would preserve the internal market (some MS 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). It would be beneficial for the environment because much less non-compliant products would circulate. Same procedures and forms could be applied, as already required by other New Approach Directives (e.g. safety, electromagnetic compatibility) under which fall already most of the "RoHS-products". It would foster coherence of EU legislation on products;

*Probably some additional costs for some manufacturers (compliance certification is already required by China); costs for manufacturers would be higher in case of 3<sup>rd</sup> party verification (from an external laboratory).*

**Detailed evidence, studies and evaluations that facilitate the assessment of the economic, social and environmental impacts of this policy option would be particularly welcome**

3. Introduce marking to demonstrate RoHS compliance

An easy way for giving the product presumption of conformity; CE marking could be chosen, which is widely recognisable. As an alternative, a dedicated, visible RoHS marking could also be beneficial for giving presumption of conformity and increasing among manufacturers awareness about need to comply. Voluntary marking could also be considered;

*If CE marking is retained, possible confusion because CE marking covers all New Approach Directives and may not prove specific enough for RoHS. Risk of confusion from proliferation of not necessarily easily recognisable marks on a products, taking also into account that in particular, EEE are subject to mandatory labelling under the WEEE Directive); this confusion would be greater if the marking is voluntary (in which case also the environmental benefit would be reduced). Depending on the retained option (CE or other marking, voluntary or obligatory) some additional cost for industry would be entailed.*

4. Introduce common procedures for withdrawing non-compliant products from the market and for administrative cooperation

It would enhance the environmental benefit of RoHS by removal of non-compliant products (it would seem that such a removal is still not possible in all MS); it would reduce administrative costs for both the authorities (no 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); increase of coherence of Community product legislation, such procedures are already used in other areas (see also COM(2007)37 and 53); has been recognised as one effective means for promoting implementation of EU legislation ((see also recent Communication

from the Commission on implementation COM(2007)502fin); possibility to use existing notification systems, such as RAPEX ;

*Some administrative burden for establishing and following the procedure of notification to the producer, invitation to bring in compliance, notification to COM services etc..and further handling; additional burden would be rather low due to the existence of and work carried out by the informal network (see above, option 1).*

5. Use of (international) standards; elaboration of material data bases and material declaration formats

Stakeholders have advocated the use of standards in several instances of implementation of the RoHS Directive, for example for identification and measurement of the restricted substances, for labelling and for communicating across the supply chain; standards can provide a flexible, expedient and cost-effective way to industry for complying with the legal requirements; international standards can promote world trade; their use or reference to them can shorten and facilitate the decision-making process, ridding it of unnecessary and long technical discussions; 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;

*If stakeholders are reluctant, standardisation process can be very long International standards may not be in line with the political priorities of the EU, but EU harmonised standards could provide this reassurance. Effort will be required by stakeholders and administrations to develop the standards (in particular for harmonised standards); such technical tasks should not be attributed to the legislator or administrations; instead of burdening the decision-making process and making implementation of legislation subject to availability of standards, the affected stakeholders could take the initiative and start standardisation activities for making RoHS implementation easier.*

**6. Insert obligation for MS to collect and make available data**

Enlarge the information basis, necessary for any monitoring or improvement of implementation and review proposals; has been recognised as an effective means for promoting implementation of EU legislation ((see also recent Communication from the Commission on implementation COM(2007)502fin); increase of transparency;

*It requires additional administrative effort from industry and public administrations at MS and Commission level; The effort could be greatly reduced through an efficient use of the SEIS (Shared Environmental Information System) that may be sufficient to deliver the objective without any additional explicit requirements to business and MS.*

7. Insert review clause with or without progress criteria/indicators

Review clauses have become standard practice in proposing/reviewing legislation and can contribute to achieving the Directive's objectives in a flexible way, as endorsed by the Commission in its Communication for a Action Plan on 'Simplifying

and improving the regulatory environment' - COM(2002) 278 final; such a review clause could (to be seen in relationship with options under II and III) identify product categories or substances to be examined by a given date (approach similar to current Article 6) or include other measurable indicators for assessing the environmental, economic and internal market impact of the Directive (see also option II 6);

*The expected review benefits should be weighed against some uncertainty because of "open" legislation. Identification of "candidate" products or substances may create some uncertainty and confusion; it may be difficult to find generally acceptable, quantified and easily measurable indicators to measure the environmental, economic and internal market impact of the Directive.*

## **8. Introduce stakeholder forum**

It positively replies to some stakeholders calls for increasing the transparency of the decision-making process during implementation (*inter alia*, with regard to granting and withdrawing exemptions); in some cases it may provide an efficient and quick way of collecting information and views from different sources thereby speeding up the decision making process; it is used in other instances of Community legislation (e.g. EuP Directive);

*It represents an additional step in decision-making that would probably slow down the process considerably (already many stakeholders find the exemptions' process very time consuming). Sufficient provisions and safeguards for stakeholder information and intervention are provided in the current RoHS.*

9. Introduce implementation-related provisions already existing in WEEE, such as EEE producer traceability requirements (Art. 11(2)), producer register (Art.12(1)), information for users and treatment facilities (Art.10&11(1))

Would facilitate identification of the producer, separate collection of WEEE and removal of HS during treatment, with obvious positive impacts on monitoring (reducing administrative cost) and the environmental effect; minimal, if any, additional cost for industry (this requirement is already imposed by WEEE and for many sectors similar requirements are foreseen by other pieces of EU legislation); would be necessary, if option III.1 is retained;

*No apparent disadvantages; some additional costs for products which would not fall under WEEE or any other EU legislation with similar requirements.*

## **Vb. Mechanism for exemptions**

1. No more exemptions, but reduce scope of the Directive (in terms of EEE or HS covered).

Avoidance of exemptions granting procedure which, is claimed to be too long by some stakeholders and required administrative effort from authorities and manufacturers; increased clarity about the scope and facilitation of market surveillance (no need for designers to consult changing lists of exemptions, products within the scope must be "free" of the restricted substances);

*Possibly long controversies would be sparked about which product categories would be excluded; excluding one of the existing categories would nullify ongoing compliance efforts by manufacturers and undermine the legislators' credibility; there is no data or information available to validate such a hypothesis the exclusion of product categories will most probably reduce the environmental benefit of the Directive.*

## 2. Remove additional requirement for stakeholder consultation (art.5.2 of RoHS)

It would speed up the exemption process and reduce administrative burden. Consultation of stakeholders may be instead mandated to the consultant in charge of assessing the exemption requests. (according to current practice);

*Some stakeholders might perceive a loss of transparency.*

## 3. Exemptions to be granted only for new technologies or only for new equipment

It would speed up the exemption process and reduce administrative burden by pre-empting abuses of the process (unreasonable requests, same request submitted several times, requests for applications which exist long enough for substitutes to be in place); it 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. Limited impact on the environment;

*It might be difficult to define which product or technology/application is "new" or "innovative" (the exemption could be limited to recently patented processes, technologies and products and would be only temporary).*

**Detailed evidence, studies and evaluations that facilitate the assessment of the economic, social and environmental impacts of this policy option would be particularly welcome**

## 4. Industry and not public authorities to assume the burden of proof and cost

Approximately 70% of the submitted requests were rejected by the decision-making process, while provoking costs, wasting effort and causing delays in the treatment of the remaining justified 30%; these costs should be "internalized" and borne by those who will benefit from the derogation of the law; this would contribute to better quality of the exemption process in terms of speed and information supply;

*Probably some increase of cost for industry but this could be minimised with better organisation and coordination and the introduction of appropriate feedback mechanisms in the exemption mechanism; could burden the decision-making process. Exemptions could be seen not only derogation to the law but also as an essential part of its implementation to the benefit of consumers, producers and the environment; introducing merely some limitations to the possibility of resubmitting rejected proposal could tackle the problem.*

**Detailed evidence, studies and evaluations that facilitate the assessment of the economic, social and environmental impacts of this policy option would be particularly welcome**

5. Manufacturers to provide substitution plan when requesting exemptions

It would enhance the environmental effect of the Directive and increase certainty by clearly signalling that exemptions should only be seen as a temporary measure, the objective being substitution; it would encourage stakeholders to establish clear roadmaps towards this substitution. Similar requirements exist under REACH, integrating them in RoHS would increase coherence and equal treatment and should not incur any additional costs in the medium term;

*There might be some technical and scientific uncertainty as to when substitution can actually take place. It would impose additional burden on industry, to the extent that similar requirements are not already foreseen by REACH.*

6. Establish standard format for providing info on requested exemptions

Would be helpful for simplifying and speeding up the decision-making process in the Regulatory Committee (TAC), which has welcomed the principle in the past. A mandate to elaborate such a standard format could be given by the Directive to the Regulatory Committee;

*No apparent disadvantage.*

7. Introduce cost/broader sustainability criteria for granting exemptions

Sustainability requires the integration of economic, environmental and social aspects. Choices based only on the minimisation of environmental impact lead to sub-optimal choices when the economic and social costs are not matched by environmental benefits (that include the benefits for workers and society); for example, in some cases solutions which would have a rather restricted environmental impact (such as extending a deadline by some months) may well have heavy financial implications in terms of investments or products to be withdrawn from or not allowed to be placed in the market;

*Final product cost being influenced by a host of varying parameters and given the difficulty to extract information, it can prove hard to distinguish the real contribution of substitution to any cost increase; the considerations of cost should be comprehensive (include benefits for manufacturers from reduced hazards in the work place and from reduction of hazardous waste benefits from the free movement of EEE in the internal market, as well as costs to the society as a whole). The sustainability of the potential substitutes should also be considered.*

8. Introduce other criteria for granting exemptions

Article 5(1)(b) lists a set of criteria for granting exemptions. However, the first criterion of the "impracticability" of substitution has proved difficult to apply in some cases. The set of criteria could be extended to reflect for example : the availability and "maturity" of alternative technologies (including Intellectual Property Right issues); sufficient testing on the ground data, especially for sensitive applications; quantity of substances involved; innovative character of

the application; socio-economic aspects; control of HS through WEEE management;

*Risk of overburdening the decision-making, if selected criteria are too technical.*

#### 9. Exemption requests to be submitted directly to the TAC

In conjunction with above option 4, the necessary material will be made available from the applicant to the MS technical experts (if necessary, a presentation from /discussion with the applicant in TAC could also be envisaged) , so that no additional study is necessary; this would lead to reduction of administrative costs for both Commission services and national administrations, acceleration and increase of transparency (through reduction of the necessary procedural steps). Considering the recommendation from the TAC, the Commission would then adopt the Decision based on the Comitology procedure;

*Risk of disproportionate attention and time consumption of the TAC for the exemptions, to the detriment of other implementation issues of RoHS.*

## THE REVIEW PROCESS

### THE DIFFERENT STEPS IN THE REVIEW PROCESS AND TIMING

#### *Initial information gathering and ongoing studies*

The review will be based on the best and widest possible available information. Therefore the Commission services will be seeking information on a range of issues, from the stakeholders which have specific knowledge (public and private sector statistics, information on operations, costs, and benefits, scientific and technical information).

The Commission will also use information provided by a range of new research studies.

The studies directly relevant for the RoHS review are mentioned below.

Apart from these studies - to which stakeholders are encouraged to actively provide input and participate - there will be additional opportunities for stakeholders to provide valuable information for the review process.

1. A comprehensive study in relationship to the inclusion of medical devices monitoring and control instruments has been carried out:

[http://ec.europa.eu/environment/waste/pdf/era\\_study\\_final\\_report.pdf](http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf)

2. In the context of the WEEE Directive review, two studies have been executed:

[http://ec.europa.eu/environment/waste/pdf/weee\\_review.pdf](http://ec.europa.eu/environment/waste/pdf/weee_review.pdf)

which are relevant for the RoHS review as well, in particular with regard to the scope, the definitions, the EE quantities and composition (content in hazardous substances and materials, including those not regulated by RoHS) as well as the structure of the EE markets and development of cost/prices.

3. An additional study, managed by the Directorate General Enterprise and Industry of the Commission, focusing on innovation and competition aspects of the WEEE and RoHS review is underway.

4. A study on hazardous substances in electrical and electronic equipment, not regulated by the ROHS Directive has been launched in October 2007:

[http://ec.europa.eu/environment/waste/weee/events\\_en.htm](http://ec.europa.eu/environment/waste/weee/events_en.htm)

#### *Additional data gathering and possible additional studies*

Depending on the information received and the progress of the ongoing studies, the Commission services will decide whether additional studies need to be launched for supporting the review.

When considering options for changes, the Commission services are very likely to require additional specific factual information and contact stakeholders to request assistance at a later stage.

**The information gathering exercise should to a large extent be finalised by early 2008.**

#### *Impact Assessment*

The proposal for review will be based on a systematic assessment of potential impacts of policy options. The Impact Assessment (IA) will examine costs and benefits of different policy options for revision of the Directive, drawing on previously gathered information, and their comparative (dis)advantages. An Impact Assessment document will be produced, which will accompany the proposal for revision. It should be noted that IA is an aid to political decision-making, not a substitute for it.

General information on impact assessment can be found:

[http://ec.europa.eu/governance/impact/docs/SEC2005\\_791\\_IA\\_guidelines\\_main.pdf](http://ec.europa.eu/governance/impact/docs/SEC2005_791_IA_guidelines_main.pdf)

More information on the impact assessment will be made available at [http://ec.europa.eu/comm/environment/waste/weee\\_index.htm](http://ec.europa.eu/comm/environment/waste/weee_index.htm).

#### *Proposal & legislative procedure*

As explained above, the RoHS review will be guided by current Article 6 of the Directive and the Commission's commitment to simplification.

The Commission, following analysis of the available information and options, and taking into account the experience of the application of the Directive, will submit, if appropriate, proposals for revision of the relevant provisions of the Directive to the European Parliament and Council.

**A legislative proposal, if appropriate, may be presented in 2008.**

The proposal will follow the co-decision procedure if modifications to the articles of the Directive are concerned. More information on the co-decision

procedure and detailed information on the development and the content of the dossier can respectively be found at [http://ec.europa.eu/comm/codecision/index\\_en.htm](http://ec.europa.eu/comm/codecision/index_en.htm) and <http://ec.europa.eu/prelex/apcnet.cfm?CL=en>.