COCIR contribution to stakeholder consultation on options for the review of Directive 2002/95/EC on RoHS

Released version

INTRODUCTION

COCIR, the European Committee representing the Radiology, Electromedical and Healthcare IT Industry welcomes the present consultation and is committed to cooperating with the European Commission on the inclusion of medical equipment in the scope of a revised RoHS Directive. We welcome the opportunity to provide our input into this latest stakeholder consultation and to comment on the different policy options proposed by the Commission for a revised RoHS Directive.

Our detailed response to the policy options proposed by the European Commission are contained hereafter structured in the same way as the consultation document and also in the Joint Statement attached.

COCIR COMMENTS ON GENERAL PRINCIPLES (in line with ORGALIME)

The surroundings of the RoHS directive today differ significantly from the legislative environment situation at the time of adopting the directives. In particular, other legislative initiatives that impact the RoHS directive have in the meantime been finally approved by EU regulators, notably the regulation 1907/2006 on the registration, evaluation and authorisation of chemicals (REACH) and directive 2005/32/EC establishing a framework for the setting of eco-design requirements for energy using products (EuP). Also, the Commission has meanwhile tabled its proposal for the Marketing of Goods (COM(2007)37 and 53), which is currently negotiated between European regulators.

In the light of Better Regulation and Simplification, COCIR underlines that the RoHS review should be the transition path of merging RoHS into the newly established REACH regulation and in this context be used as the opportunity to streamline RoHS to the maximum extent possible, towards consistency with REACH and EuP. This would mean that we support that any future NEW restriction of hazardous substances not covered by RoHS today should be carried out under REACH, while we support that the existing RoHS directive would continue to apply with its existing scope.

- For the existing RoHS directive, however, we propose to improve its workability, for example in the areas of the scope, the exemptions mechanism or stakeholder consultation, and especially to foster a fully harmonized transposition of the directive in EU member states.

- Proper market surveillance and enforcement are in our view of major relevance to the effectiveness of the directive.

- If other EC legislation applying on EEE, proposes to have restrictions of the use of specific substances, as it could arise under the implementation process to Directive 2005/32/EC (EuP), we consider that the specific restriction legislation should be adopted under REACH, too. Therefore, when considering introducing new restrictions in EEE, the subsequent restriction legislation should in our view be done under REACH taking into account the EuP directive and its implementation process.

I. PRODUCT GROUPS TO BE INCLUDED [ART. 6 OF RoHS] CATEGORIES 8 and 9

Question I.1: Continue excluding one or both categories altogether

Answer: COCIR would accept inclusion of category 8 products provided that adequate exemptions based on documented evidence are granted.
It should be noted that the actual volume of Medical equipment makes up a very small proportion of the overall electrical appliance industry and the tonnage of the RoHS banned substances is also low. The volume is less than 0.25% of the total 12 million tonnes of EEE sold annually in Europe.

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

Answer: COCIR supports encouraging eco-design with the following comments:
Since 1994, the Medical Device Industry has always strongly supported life cycle thinking and the environmental design objectives behind the RoHS, WEEE and EuP Directives. There are many ways that companies are dealing with these environmental issues and indeed the industry sector has voluntarily contributed to the development of the new **International Standard IEC 60601-1-9 published in July 2007: (title: Environmentally Conscious Design of Medical Electrical Equipment).** For more information on this standard as well as examples on how eco-design is used on medical devices, please refer to the attached Joint Statement "Chapter 4 Medical Device Industry strongly supports environmental design".

Finally many medical technological solutions require the use of hazardous substances, whether to improve the performance or reliability of devices, or provide effective patient protection. COCIR requests that the use of hazardous substances in medical devices be permitted provided that their use can be justified after a risk benefit analysis.

Note: It should be noted that WEEE Directive already has a requirement relating to eco–design in Article 4 Product Design (related to domestic products only) and Article 7 Recovery point 4.

Question I.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)

Answer: COCIR does not support this option for the following reasons:

- It will be difficult within this time scale to confirm the reliability performance required for all medical devices, potentially forcing the removal of products from the market due to the increased/unknown risk associated with replacement of component parts.

- COCIR recommends the following timelines:
  1. 2014: for MD's with the exclusion of the MD's as below in (2 and 3),
  2. 2016: for IVD's
  3. To be considered on case by case: AIMD's and MD's with life supporting applications (such as external pacemakers, defibrillators, perfusion systems etc.)

  Reasons substantiating these proposed timelines are explained in the attached Joint Statement "Chapter 9 Proposed timescales ...".

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

Answer: COCIR supports this option provided that the assessment from a life cycle perspective demonstrates its environmental benefit and relevant exemptions are considered**:**

- Lead and cadmium for specific electrical inter-connections
- Lead for radiation shielding
- Lead for high mass applications (e.g.: phantoms and counterweights)
- Lead for thermal management
- Lead, cadmium, hexavalent chromium and mercury used for sensing and detection
- Lead in piezoelectric crystals for diagnostic ultrasound transducers
- Plating finishes on lead less devices, e.g.: BGAs, CSPs, WLCSP, QFN
- Lead oxide containing glass used in X-Ray tubes (as vacuum adhesives)
- Lead in solders in portable emergency defibrillators, active implantable medical devices, MRI radio frequency coils and IVD optocouplers
- Lead in alloys to improve material properties in specific applications
- Lead for radiation shielding in radioactivity measurement and detection equipment
- Lead, mercury and cadmium in sensors, detectors and electrodes used in Category 8 and 9 equipment

In addition, it is recommended the European Commission considers input **from Notified Bodies** on whether the field data available is sufficient to ensure the safety and performance requirements in the relevant Directive can be satisfied. If the Notified Bodies' opinion is that the field data available is not sufficient to confirm reliability in safety critical applications, then the European Commission should not impose substance restrictions until such time as adequate field data does become available. Therefore, dates for imposing any substance restrictions on category 8 should take this into account.

Need for specific exemptions are explained in the attached Joint Statement Chapter 10.

Question I.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)

Answer: COCIR generally supports this option, however, further exemptions will be necessary and appropriate time lines considered (refer also to answer to Question I.3).
COCIR is supportive of a specific science based risk management process for the exemptions of the RoHS scope.

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

Answer: COCIR generally supports this option; however, according to the results of a previous study on lead free solders (EPA), we believe the environmental impact of lead free solders in medical devices should be assessed before deciding for exemptions or inclusions. We feel that such an assessment will confirm the need for specific exemptions for "lead in solders" in medical devices.

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

Answer: Not applicable to COCIR.

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

Answer: COCIR supports this option for reasons given in the Joint Statement attached (Chapter 9) covering MDs, IVDs and AIMDs as well as in the attached arguments from EDMA on IVDs.

II. SUBSTANCES COVERED [ARTICLE 6 OF ROHS]

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

Answer: COCIR supports this option as REACH already applies to Medical Devices.
This option would be consistent and coherent with EU legislation and increase legal certainty for companies. As far as hazardous substances not covered by RoHS directive today are concerned, we take the view that the RoHS directive should no longer be applied, i.e.: it should be "phased out" and any new restrictions of hazardous substances not included under RoHS today should be carried out under the newly adopted REACH regulation.

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

Answer: COCIR does not support this option for reasons given above.

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

Answer: COCIR does not support this option for reasons given above.

Question II.4: Add new substances for all EEE without exemptions at a deferred date

Answer: COCIR does not support this option for reasons given above.

Question II.5: Add new justified substances under RoHS only if substitutes already available and fully investigated

Answer: COCIR does not support this option for reasons given above.

Question II.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

Answer: COCIR does not support this option for reasons given above.
It is the duty of the manufacturer, under "Duty of Care of Waste" and WEEE Directive Article 10 Information for users, to make available information on any hazardous substance in their equipment which maybe present at end of life of the equipment.

Question II.7: Not add any new substances but introduce labelling requirements (for example certain phthalates for certain Medical Devices)

Answer: COCIR does not support this option for reasons given above.
Labelling for phthalates is already in the new MDD (2007/47/EEC), so it should be excluded from the revised RoHS.

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

Answer: COCIR supports this option as long as it does not hamper innovation.

III. TECHNICAL CHANGES TO THE SCOPE OF THE DIRECTIVE

Question III.1: Separate WEEE from RoHS scope

Answer: COCIR supports this option.

There is confusion between the two directives and their application to Medical Devices:
- WEEE concerns end of life and waste management and the responsibilities of both manufacturers and end users,
- RoHS focuses on design of equipment and the banning the use of certain substances which can be dangerous if present in landfills. The design is the responsibility of the manufacturer, plus the duty of informing the final user of the benefits of the design including compliance to legislation, environmental good practice etc.

Question III.2: Include explicitly spare parts & components

Answer: COCIR does not support this option.
Spare parts for use with medical devices placed on the market before the entry into force of RoHs should be specifically excluded from RoHS in order to maintain devices in working order.

Further emphasizing the service parts issue with “Not having the ability to service non RoHS compliant product designs could leave equipment unusable, which could increase the overall waste."

Question III.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)

Answer: COCIR supports this option. However this WEEE clause is causing confusion and, if adopted, is going to create much more confusion and so there is a need to define it with enough accuracy.

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

Answer: COCIR supports this option.

Question III.5: Clarify status of consumables

Answer: COCIR is of the opinion that consumables, not including electrical/electronic components, should be excluded from the RoHS.

The arguments are as follows:
- Consumables will often be supplied ‘with the equipment’ and the end user installs the consumable before use. This should not come under RoHS
- Many consumables have no electrical components so why should they be considered as part of RoHS?
- Only consumables in the product when placed on the market that have electrical/electronic components should be covered by RoHS

- Consumables are also included in WEEE if present in equipment at end of life.
- The scope of RoHS is electrical equipment. Consumables must be excluded, otherwise the scope expands exponentially, and conflicts with other directives.
- All "non-electrical" consumables will be captured under REACH.

Question III.6: Assess the need for including explicitly fixed installations

Answer: COCIR has no specific comment.
This does not impact the European Medical Device Industry.

Question III.7: Assess the need for maintaining a general exemption for LSIT (large-scale stationary industrial tools)

Answer: COCIR has no specific comment.
This does not impact the European Medical Device Industry.

Question III.8: Extend scope to cover all EEE

Answer: COCIR has no specific comment.

Question III.9: Add more specialized product categories in an indicative annex

Answer: COCIR does not support this option.
The annex 1B list is not particularly helpful as it does contain some medical procedures not medical equipment. It also has a final 'catch all' – other appliances for detecting, preventing, monitoring, treating, alleviating illness, injury or disability.

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

Answer: COCIR supports this option.

Per the Medical Device Directive, this is crucial, since only those parts which have been already validated can be used for repair and refurbishment of the device. Not allowing the use of those validated parts, although non-RoHS compliant parts and components would prevent the refurbishing of the devices for subsequent use.
This would have a detrimental effect on the environment and contravene the RoHS objectives. Allowing refurbishment of medical devices is crucial for the following reasons:

- Use the equipment during its entire product life (e.g. an imaging equipment could have a product life up to 20 years) without endangering the patient as long as refurbishment is done per documented procedures,
- Provide access to newer technology at an affordable price (lower price than compared to a new product) valid for hospitals having a limited budget. This would also allow to reduce the total cost of healthcare in countries and their overall budget,
- Reduce amount of waste equipment in a limited period of time,
- Consistent with recycling economy and overall objectives on environment,
- Minimize the use of natural resources.

IV. DEFINITIONS

Question IV.1: Insert new definition for "placing on the market"

Answer: COCIR supports this option by referring directly to the Blue Book.(Guidance for the New Approach Directive).

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

Answer: COCIR is supporting this option as long as those definitions do not contradict the MD Directives.

Question IV.3: Insert definition for "fixed installations"

Answer: COCIR does not support this option. There is already a definition given in the EMC Directive (2004/108/EC) Refer to Orgalime's Guidance Paper: Understanding the scope of the WEEE Directive (2002/96/EC).

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

Answer: COCIR does not support this option for category 8. We believe this is not necessary as further descriptive definitions could lead to more confusion and potential reclassification of products.

Question IV.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)

Answer: COCIR does not support this option. Instead of an indicative list, which can never be complete, clear criteria are needed to provide legal certainty. Indicative lists risk further fragmentation in the internal market.

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

Answer: COCIR believes that the definition of "homogeneous material" provided in the FAQ document should be used as a starting point for a legally binding definition, but it will require clarification in view of practicability.

Question IV.7: Insert definition for "spare parts"

Answer: COCIR supports this option by referring directly to the official guidance to the EMC Directive (also suggested by the ERA report, p. 45):
"Spare part" means a sub-assembly or component used in a medical device or system and which is not in itself a medical device with an intrinsic function intended for the final user and which may also be supplied for replacement of existing components of a medical device."

Amendments to Article 2.3:
Article 2.3 of the RoHS Directive excludes spare parts for the repair or refurbishment of equipment placed on the market before 1 July 2006. The EC has stated in its FAQ that this extends to spare parts

for upgrading equipment because one of the aims of the WEEE and RoHS Directives is to extend the life of products for as long as possible and to avoid waste.

If Medical Devices are included in the scope of the RoHS Directive then Article 2.3 will need to be amended to reflect that the date from which Category 8 products will be required to comply is different to the date of 1 July 2006 for Categories 1 to 7 and 10.

The wording of Article also needs to be changed to take account of temporary exemptions.

This is illustrated by the temporary exemption for lead in solders. Under this exemption, a server put onto the market in 2008 may use lead solders. Common industry practice is to manufacture spare parts (e.g. circuit boards) at the same time as the original equipment and using the same materials, particularly as some components may not be available several years later. However, if this exemption were to end in 2011, for example, and the server subsequently develops a fault, it could not legally be repaired with the (leaded) spare part made in 2008 because the current Article 2.3 only allows the use of spare parts for the repair of equipment put onto the market before 1 July 2006.

Design of Spare Parts:
Re-design of spare parts to comply with RoHS directive, while the unit itself is not compliant has implications on design verification and validation of the product to ensure it remains safe and meets its clinical performance. Hence, the exclusion of the spare parts must continue for at-least 15 years (average product life) from the inclusion of the medical devices in the RoHS directive.

V. FACILITATING IMPLEMENTATION

Va Enforcement of the RoHS Directive

Question Va.1: Introduce market surveillance mechanisms

Answer: COCIR is in favour of a common approach as long as it remains consistent with the provisions included in the Medical Device Directives.

Question Va.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)

Answer: COCIR does not support this option: RoHS should not be shifted into a New Approach directive at this stage.

Question Va.3: Introduce marking to demonstrate RoHS compliance

Answer: COCIR does not support this option. Too many different and overlapping labelling requirements are confusing for consumers.

We are already using the CE mark on our products which is part of the conformity process. We consider that no additional marking is necessary.

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

Answer: COCIR does not support this option.
It is the obligation of the manufacturer to pull non compliant products from the market. Common procedures should not be necessary.

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

Answer: COCIR supports the use of international standards. However, material databases and material declaration formats would impose too heavy administrative burden for companies, especially SMEs.

Question Va6: Insert obligation for MS to collect and make available data

Answer: COCIR considers MSs should respond to this option considering their available resources

Other comment: It would be helpful to institute regular 'review projects' to analyse both the true cost of compliance to RoHS Directive and the resulting environmental benefits from the reduction of certain substances.

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

Answer: COCIR does not support this option.
The RoHS directive already includes a review obligation of granted exemptions at least every four years after the item has been added to the RoHS annex.

Question Va.8: Introduce stakeholder forum

Answer: COCIR supports this option.
It would increase transparency and facilitate information gathering while at the same time foster consistency with EuP Directive.

Question Va.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))

Answer: COCIR does not support this option. It risks creating an additional, inefficient and diverted administrative burden.
In addition, Medical Devices already have CE Marking and labelling providing company details.

Vb. Mechanism for exemptions

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

Answer: COCIR does not support this option since companies have made significant investments to comply with the RoHS directive. Reducing the scope at this moment in time would hamper the implementation process and penalize the EEE industry for its proactive work.
The current system of granting exemption is too long and re-formatting should be considered to respond in time to customer needs. It is very important to have an exemption process for critical medical equipments.

Question Vb.2: Remove additional requirement for stakeholder consultation (art.5.2 of RoHS)

Answer: COCIR does not support this option. The stakeholder mechanism shall be improved (see option Va.8), however neither be reduced nor removed.

Question Vb.3: Exemptions to be granted only for new technologies or only for new equipment

Answer: COCIR does not support this option. Product legislation should ensure that same requirements apply for same products. However, it should not lead to discrimination between competing technologies. Regulators have confirmed the principle of technology neutrality in the EuP directive.

It is important that the exemption should be firmly based on the benefits to society of the equipment and this should apply to existing and future equipment.

Question Vb.4: Industry and not public authorities to assume the burden of proof and cost

Answer: COCIR does not support this option. Article 7 (2) of the RoHS Directive referring to Article 18 of Directive explicitly describes the duty of the Commission to thoroughly evaluate exemption requests according to the Comitology procedure. Relevant information need to be provided and assessed in a neutral manner and should not be biased by applicants interests.

Question Vb.5: Manufacturers to provide substitution plan when requesting exemptions

Answer: COCIR does not support this option. At the time there are often no 'equivalent' substitutions, thus there is no substitution plan yet.

However all exemptions are under review and it is possible substitutions can be introduced at some later stage.

Question Vb.6: Establish standard format for providing info on requested exemptions

Answer: COCIR supports this option since it would better structure the way of making exemption requests and thereby enhance transparency.

Question Vb.7: Introduce cost/broader sustainability criteria for granting exemptions

Answer: COCIR supports this option since sustainability requires the integration of economic, environmental and social aspects.

Question Vb.8: Introduce other criteria for granting exemptions

Answer: COCIR supports this option.

Question Vb.9: Exemption requests to be submitted directly to the TAC

Answer: COCIR does not support this option.

Technical analysis, impact and risk assessments shall be carried out by the responsible technical expert bodies. We would, however, support an improved link between the TAC and the stakeholder(s) requesting an exemption, such as proposed in option Va.8, which we support as we are not sure the TAC member would always have the necessary knowledge and experience to present the case for an exemption in an area as specialised as the Medical Device Industry.

We would suggest in addition the following exemption mechanism/process:

- Take any measure to harmonize transpositions in member states,
- Introduce a deadline to apply for the Commission (and TAC) to decide on an exemption request. No response within the time period should mean that the exemption is granted (may be on a reviewed timeframe).

CONCLUSIONS

COCIR would like to thank the European Commission for the opportunity to contribute as an industry to this consultation. We trust that the European Commission will give due consideration to our input, and we look forward to further dialoguing and discussing while going forward on these important matters.

General information about COCIR:

Founded as a non-profit trade association in 1959, COCIR represents the radiological, electromedical and healthcare IT industry in Europe. As such, our members play a driving role in developing the future of healthcare both in Europe and worldwide. COCIR is committed to supporting its members and communicating with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens. COCIR also works with various organisations promoting harmonised international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users. We encourage the use of advanced technology to support healthcare delivery worldwide. COCIR's key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

COCIR Company Members:

Agfa-Healthcare, Canon Europe, Carestream Health, Elekta, FujiFilm, GE Healthcare, Hitachi Medical Systems Europe, IBA Ion Beam Applications, IBM, ICW, Intel, iSoft, Philips Healthcare, Quovadx, Siemens Healthcare, Toshiba Medical Systems Europe

COCIR National Associations Members:

AGORIA (Belgium), AssoBiomedica (Italy), SNITEM (France), ZVEI (Germany), Spectaris (Germany), HHT (Netherlands), FENIN (Spain), Swedish MedTech (Sweden), FiHTA (Finland), AXREM (UK), TipGorDer (Turkey).