

COCIR CONTRIBUTION TO THE CONSULTATION ON THE EVALUATION OF DIRECTIVE 2011/65/EU

COCIR, the European Association representing the radiological, radiotherapy, healthcare IT and electromedical industry, would like to thank the European Commission for the chance to provide a contribution for the evaluation process of the RoHS Directive. Medical imaging devices have been included in the Directive scope in 2014, despite being significantly different in their purpose from other EEE equipment. Our devices have a significant impact in improving healthcare, through early detection, screening, prevention and treatment. We therefore welcome the upcoming Commission's proposal of a Europe's Beating Cancer Plan and we look forward to contributing to it.

Since being included in the scope of the RoHS, our companies have collected enough experience to provide data to help assessing the efficacy and effectiveness of the Directive.

After 7 years from the first proposal of inclusion of medical devices, COCIR decided to look back to evaluate the real costs and impacts entailed by RoHS for the medical imaging sector, and the real benefits in terms of reduction of the use of hazardous substances compared to the impact for patient in terms of receiving the latest available healthcare technology. COCIR also decided to look forward to 2021 to estimate costs and benefits of the introduction of 4 phthalates to the list of banned substances.

Particular care has been given to assess the impact of the Directive on innovation. The medical imaging devices sector in Europe invests 7 to 8% of annual revenues in research and development, one of the highest investment rates in R&D for an industrial sector in Europe. In fact, COCIR member companies have production facilities in Germany, The Netherlands, France, Italy, Ireland, Spain and UK..

Innovation is aimed at the development of new equipment and systems that improve survival rates and give earlier diagnosis of diseases. Hindering the innovation ability of this sector means reducing the effectiveness of the healthcare systems for European citizens and also non-EU ones, as medical devices are designed for and sold on the global market.

All the data briefly presented in this paper are detailed in the COCIR study "RoHS directive and medical imaging devices (2006-2021): lessons learned and a closer look on benefits and impacts".

EFFICACY AND EFFICIENCY OF THE ROHS DIRECTIVE APPLIED TO THE MEDICAL IMAGING SECTOR

To evaluate the efficiency of the Directive, it is important to evaluate and possibly quantify the benefits and the impacts.

- **Efficacy:** a Directive is effective if its goals are met (it solves the problem) completely or partially
- **Efficiency:** a Directive is efficient if the goals are met (the problem is solved) with the minimum use of resources
- **Proportionate:** a Directive is proportionate if the benefits achieved by the Directive outweighs the negative impacts on economy, society, human health or the environment.

1. Benefits of the Directive

COCIR estimated that only 2,4% of the RoHS substances have been removed as a result of including medical imaging devices in scope, while 97,6% of the used ones is actually covered by exemptions, as no alternatives are available. The reason for this is that the majority of RoHS substances was already phased out before 2014 by other EEE industries

which are already in scope since 2006 (or by their component suppliers). With the medical imaging sector being a low-lot but high-tech sector, the power to ask for specific designs is very limited by nature and therefore the medical imaging sector takes the EEE components which are available on the market rather than developing their own. EEE component suppliers on the other hand do not specifically design parts for the medical device sector (the Medical Imaging Sector does only represent about 1% of the whole EEE sector). In 2021, the percentage of substitution would reach 13% in a reasonable scenario, where all the increase will be represented by substitution of lead in counterweights (however lead for counterweights has only a limited impact on the environment as most stems from recycled lead and no WEEE-treating facility would throw away solid blocks of lead).

RoHS substance	Amount used pre-RoHS (kg)	Removed by RoHS I (or REACH) (kg)	Quantity removed due to inclusion of category 8 in scope of RoHS 2 (kg)	Percentage removed due to inclusion of category 8 in scope of RoHS 2
Lead	1,119,546	2,955	26,591	2.4%
Cadmium	6,986	56	0	0%
Mercury	11	1	0	0%
CrVI	0.04	0.03	0	0%
PBDE* ¹	10,000	10,000	0	0%
PBB	Not used	n.a.	n.a.	n.a.
TOTAL	1,136,543	13,012	26,591	2.4%

Regarding benefits for human health and environment following the introduction of medical imaging devices into RoHS, no benefits could be identified:

- Medical imaging devices are safe for patients, due to the strict requirements of the MDD Directive and now the MDR Regulation.
- Medical imaging devices are reusable (and reused), highly recyclable and contain many tonnes of valuable materials (steel, copper, aluminium, pure lead, etc.). The limited reduction in RoHS substances did not bring any improvement to the already high recycling rates or separation of waste streams.
- RoHS did not bring any benefit to patients in terms innovation, as the few available alternatives have replaced the banned substances with equal performances at best.

2. Impact of the Directive

Cost and resources

COCIR estimated the cost for companies for compliance to substitute the small amount mentioned above. The cost, while expressed in millions of euros, is mostly represented by human resources, such as engineers, technicians and researchers. This is a very important aspect as it explains why RoHS is impacting innovation.

COCIR also identified a strong impact on circular economy activities such as refurbishment. The market of refurbished equipment has registered a downwards trend of around 30% in less than one year from the entry into force of RoHS obligations in July 2014

¹ 100% of PBDE used in medical devices in 2006 had been replaced by substitutes even before medical imaging devices entered into scope of RoHS

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	
Compliance	15	55	95	115	75							355	
Supply chain	5	5	5	5	5	5	5	5	5	5	5	5	60
Refurbishment					40	40	40	40	40	40	40	40	320
Substituting exemptions						7	7	7	7				28
New substances									24	24	24	24	96
Exemptions for phthalates							2	2	3	3			10
Total/y	20	60	100	120	120	45	54	54	79	79	69	69	869

Cost expressed in millions of €, distributed over the period 2010/2021 for the medical imaging sector represented by COCIR.

Innovation

RoHS is having a clear negative impact on innovation. A serious problem caused by RoHS is the uncertainty for investments in R&D, due to the short duration of exemptions. While exemptions are granted for a maximum validity of 7 years, this is not compatible with the highly sophisticated and complex R&D programs in the medical imaging sector that may have a design cycle of up to 10 years. With the medical imaging sector moving more and more into a Circular Economy, the number of shared parts across platforms is increasing, which means that not only future parts need to be made compliant, but also parts which had been designed decades ago.

At the same time the time required by the EC to grant a new exemption request has grown significantly since 2006, from 18 months to more than 3 years. This is clearly not compatible with the innovation pace in the medical device industry, and results in an even higher investment risk at the detriment of patient's health.

COCIR RECOMMENDATIONS

The following suggested solutions would contribute significantly to improve RoHS in terms of having pragmatic approach for a specific sector like medical imaging that has a fundamental relevance for human health. In addition, in terms of waste, we propose recommendations to align RoHS with the concept of circularity, by giving more prominence to reuse and refurbishment.

1. Exemptions Maximum Validity

The exemption process of RoHS is suited for electric and electronics products with short design cycles, short production period and relatively short life. On the contrary, medical imaging devices have highly complex design cycles (5-7 years), long production periods and very long life (from 10 to 20 years).

The actual maximum validity of RoHS exemptions (7 years for category 8) is not compatible with the design cycle. It creates uncertainty and companies are required to renew exemptions too often. The maximum validity of an exemption should be determined for each application based on its own merits. We believe that exemptions for medical devices (Annex IV) should range between 10 and 15 years, depending on each device.

For the general exemptions (Annex III) the validity period for Category 8 equipment should be at least 5 years longer than for the other categories accounting for the long design

cycles. Alternatively, the transition period for Category 8 equipment could be extended accordingly.

For certain critical applications, such as detectors for x-rays, a RoHS restriction has only drawbacks and therefore should not be considered as an appropriate tool. Companies' research efforts must focus on finding new better detector technologies and materials, to increase image quality and reduce the radiation dose to patients.

Companies must have the freedom to research any kind of material and any kind of technology in order to bring such vital benefits to the market and healthcare. Any delay caused by RoHS should not be acceptable.

As suggested by the final report of the EC consultant in 2006 (ERA), certain medical technologies should be permanently exempted by the RoHS Directive. If during the search for improved technologies a safer alternative is discovered that can ensure significant benefits to patients, then and only then, a RoHS restriction would be justified.

COCIR Recommendation

The maximum validity of an Annex III and IV exemptions should not be set at 7 years, but it should be determined for each application based on its own merits. Certain critical applications providing vital benefits to patients should be permanently exempted.

2. Exemptions Grace period

The grace period foreseen in case an exemption renewal is not granted, must be consistent with the design cycle. If an exemption request for renewal is not accepted, RoHS only allows for a short grace period. Considering the time needed for substitution or redesign plus the regulatory approval time for the medical imaging device sector, 18 months is not enough and would lead to critical medical devices to be prevented to be purchased by hospitals. The duration of the grace period should be set in such a way to allow companies to go through the substitution/redesign process that certain applications for Category 8 equipment could easily require up to 5 years.

COCIR Recommendation

The grace period for medical imaging devices in case an exemption renewal is not accepted should be compatible with the redesign cycle and substitution time for medical imaging devices

3. Existing products need to be excluded

New RoHS restrictions impact current designs. Medical device models are designed and priced according to an expected production life. The time a model is expected to be on the market and the market penetration over time are very important and critical elements of market strategy. The sales of the model also provide the cash flow to design and innovate new generations.

- A) When a hazardous substance is restricted, existing designs on sale become "obsolete" and unless they can be redesigned in a technical and economical feasible manner, they have to be discontinued. This is especially relevant for products for which the end of production is scheduled around one or two years after the restrictions come into force. This does have a negative effect on human health because Due to a shorter period of selling, the profit goes down which is resulting in less budget for R&D and innovation
- B) Due to products getting obsolete ahead of time, hospitals and doctors need to decide for products with higher costs and/or lower patient benefit (as the successor model covering the gap can usually not be made available in time).

Existing design models must be allowed to be placed on the market until the natural expiration of the model.

COCIR Recommendation

Ensure RoHS new substance restrictions do not affect existing designs to ensure they can be placed on the market until the natural expiration of their production life, by granting sufficient transition period.

4. Reuse of Recovered Parts

Reuse has been established by the European Union, well before the Circular Economy package, as the best environmental practice to avoid the environmental impacts associated with consumption and to move towards a circular economy model.

Several studies by the EC confirm that reuse/repair or life extension is always the preferred option compared to the manufacturing a new product to replace an old one. We also understand that reuse/repair will be prominent in the second Circular Economy Action plan of the upcoming Commission

Therefore, COCIR believes that reuse should be a guiding principle of the RoHS Directive to be included in the legal text and not a temporary solution in short lived exemptions.

COCIR Recommendation

Exemption 31a allowing the reuse of recovered parts should not be an exemption subject to renewals, but part of the legal text.

5. Exemptions requirements

Companies experienced that sometimes the cost of substitution can be dis-proportionate compared to the benefits. The cost/benefit ratio of the use of hazardous chemicals is not considered in RoHS but it should be. Certain applications are using few grams of hazardous substances per year (e.g. 200g/y lead in bearing of x-ray tubes) in medical devices which are used in the order of millions of tons per year in other sectors (e.g. car batteries). Substituting few grams of lead would require years of research and resources for an environmental benefit so low it cannot be even quantified, diverting such resources from the development of better technologies.

COCIR Recommendation

Exemptions should not only be granted based on environment, health or reliability reasons, but should also be granted based on the cost/benefit ratio when moderate quantities are involved.

STUDIES SUPPORTING COCIR RECOMMENDATIONS

EC Studies

Many studies had been launched by the EC to assess the impact of RoHS provisions on different industrial sectors, including medical devices:

1. “Measures to be implemented and additional impact assessment with regard to scope changes, pursuant to the new RoHS Directive” (BIOS IS, August 2012).
2. “Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment” (Oeko Institute, March 2013)
3. “Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance restrictions in Electrical and Electronic Equipment (RoHS Directive)” (Oeko Institute, September 2014)
4. “Study for the analysis of impacts from RoHS 2 on non-road mobile machinery without an on-board power source, on windows and doors with electric functions, and on the refurbishment of medical devices” (Oeko Institute, March 2015)
5. EC/JRC publication (2018) “*Best environmental management practices: Electrical and electronic equipment manufacturing sector*” chapter on refurbishment of medical devices:
<https://ec.europa.eu/jrc/en/research-topic/best-environmental-management-practice>
6. EC study in the context of job creation under the circular economy context (2017). “*Regulatory barriers for the Circular Economy: Lessons from ten case studies*”.
https://ec.europa.eu/growth/content/regulatory-barriers-circular-economy-lessons-ten-case-studies-1_en

COCIR studies and material

1. Brochure on environmental sustainability of refurbishment (2015)
http://globalditta.org/fileadmin/user_upload/press_releases/2015/14021.dit_-_refurbishment-brochure-15-06-15.pdf
2. COCIR study on the impacts and benefits of RoHS (February 2016): “*RoHS Directive and medical imaging devices (2006-2021): lessons learned and a closer look on benefits and impacts*”