Cleeve Road, Leatherhead
Surrey, KT22 7SA, UK
T: +44 (0) 1372 367350

Your Ref:

Our Project Ref:

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Riccardo Corridori
COCIR
Bvd A. Reyers 80,
1030 Brussels

Direct Dial: +44 (0) 1372 367221
Paul.goodman@edifera.com

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ROHS DIRECTIVE AND MEDICAL IMAGING DEVICES (2006-2021)

LESSONS LEARNED AND A CLOSER LOOK ON BENEFITS AND IMPACTS

- ONLY FOR COCIR INTERNAL USE -

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TABLE OF CONTENTS

1. EXECUTIVE SUMMARY

The European Commission in 2006 reviewed the RoHS Directive to evaluate the inclusion of additional product groups including medical devices. Two studies were launched in 2006 and 2008 to evaluate the feasibility and the impacts of the proposal. Despite that both studies showed very limited benefits and high costs for medical devices, the EU institutions supported their inclusion, and in 2011 RoHS 2 was published in the Official Journal of the European Union.

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. COCIR also decided to look forward to 2021 to estimate costs and benefits of the recently published amendment to Annex II of RoHS, introducing 4 phthalates to the list of banned substances.

The results of the evaluation of the reduction of the use of RoHS substances are presented in Chapter 4. It is estimated that only 2,4% of the RoHS substances have been removed as a result of including medical devices in scope, while 97,6% is actually covered by exemptions, as no alternatives are available. In 2021, the percentage of substitution would reach 13% in the most optimistic scenario.

Chapter 5 looks closely at the 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.
- Medical imaging devices are reusable (and reused), highly recyclable and contain many tonnes of valuable materials (steel, copper, aluminium, pure lead, etc.). The insignificant 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 from innovation, as the few available alternatives have replaced the banned substances with equal performances at best.

Chapter 6 and 8 provides estimations of the costs and impacts sustained by companies to comply with RoHS by 2014 and of future costs until 2021. A dedicated section deals with the impact on the market of refurbished equipment, which has lost 30% of its share in less than one year from the entry into force of RoHS obligations in July 2014.

RoHS is having a clear negative impact on innovation in the medical sector, which means new life-saving technologies are not being developed as resources have to be diverted for ensuring RoHS compliance. Chapter 7 provides a complete overview of the negative effect of RoHS on innovation both from a quantitative and a qualitative perspective.

In Chapter 9, costs and benefits are compared. Costs of 380 million euros by 2014 and 890 by 2021 are estimated for a reduction in the content of hazardous substances of 13% at best. The additional reduction from 2.4% to 13% is mainly due to the substitution of lead in counterweights. Medical device manufacturers need to comply with EN60601-1-9[1] which encourages substitution of hazardous substances and so this may have happened anyway without RoHS. It has to be noted that resources would be better used in research and development of innovative medical imaging technologies.

The study concludes with 7 recommendations to the European Institutions to amend RoHS to reduce the burden on medical devices manufacturers by removing unnecessary requirements and allowing resources to be used where it really matters. Some recommendations are addressed to the removal of legal barriers to the

[1] Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design

implementation of circular economy business models which would benefit manufactures, the healthcare system and the environment as well.

2. BACKGROUND

The original RoHS Directive was reviewed by the Commission in 2005 – 2006 and one of the changes that was considered was the inclusion in scope of medical devices (category 8) and monitoring and control instruments (category 9). ERA was awarded the contract to answer the question: "Is it possible to include categories 8 and 9?". They concluded that there were no technical reasons to exclude, as long as manufacturers had sufficient time and exemptions for certain applications (e.g. lead for radiation shielding). An impact assessment was also carried out by the Commission which showed that costs were far larger than the benefits, but despite this result, categories 8 and 9 of equipment were included in scope from 2014.

Since 2006, medical device manufacturers have gained experience of the effect of being in scope of RoHS. Several issues that have an impact on the long term provision of healthcare to the public have been discovered that outweigh the benefits of inclusion in the scope of RoHS. This report discusses these issues and suggests future options for minimising the negative impact on future healthcare.

3. THE MEDICAL IMAGING DEVICE SECTOR IN EUROPE

The medical imaging devices sector in Europe represented by COCIR is a small sector of highly technological products, including companies with around 28 billion total turnover. The sector 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.

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.

4. EFFECT OF INCLUSION OF MEDICAL IMAGING DEVICES IN SCOPE OF ROHS

4.1. Reduction in use of RoHS restricted substances

The 2006 ERA study made an estimate of the quantity of the RoHS substances used in medical devices and so at that time it was assumed that the potential benefit of RoHS would be a reduction in this amount except the substances that cannot be replaced as no substitutes exist or were likely to be developed in the future. This data was estimated by medical device manufacturers based on their knowledge at that time and this now appears to have been an under-estimate due to uses that companies were unaware of at that time (it was often difficult to obtain data on RoHS substances from suppliers). Sales have changed since 2006 which of course complicates the calculations of RoHS substance reductions. COCIR has since made more detailed calculations based on the known reductions in use and the amounts still in use that are covered by exemptions. REACH has also had an impact as it has discouraged the use of hexavalent chromium chemicals as well as by restricting cadmium and some of the PBDE flame retardants.
The data is as follows:

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*[2]	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%**

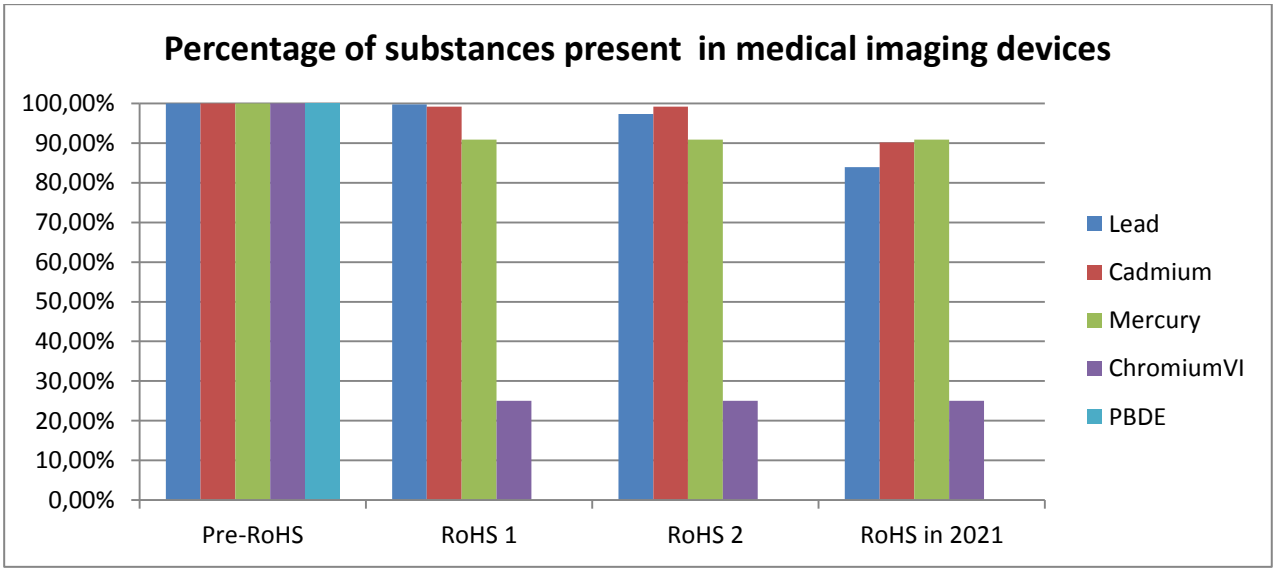
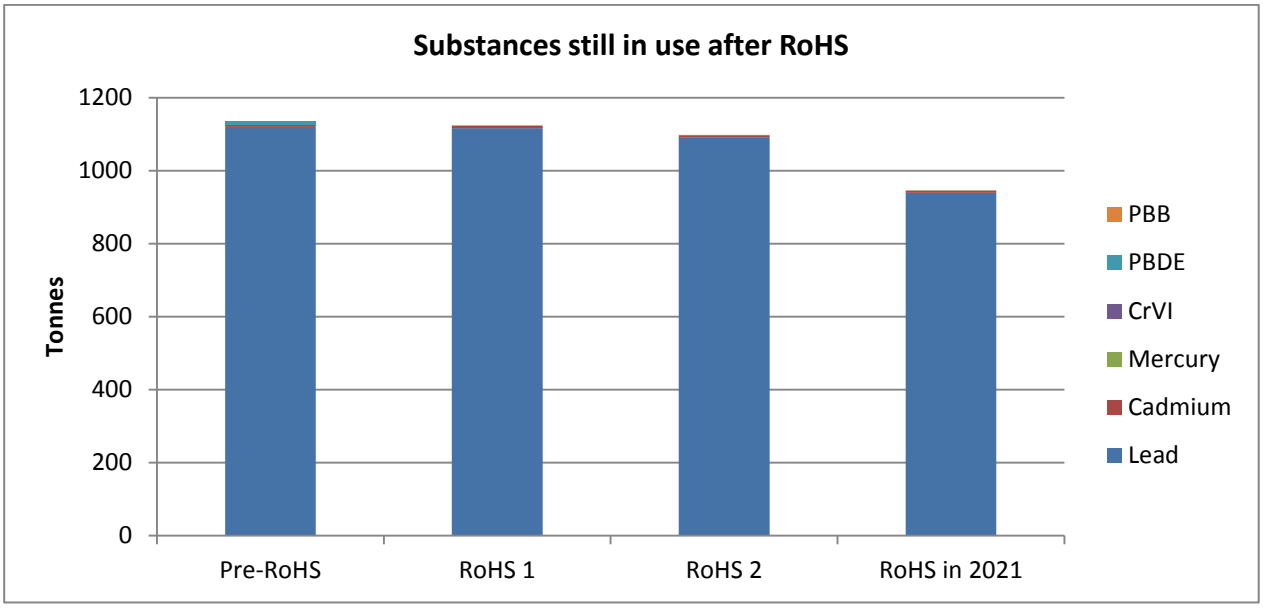


Fig 1: *graphical representation of content of RoHS 6 substances in medical imaging devices before and after RoHS I and RoHS II.*

[2] *100% of PBDE used in medical devices in 2006 had been replaced by substitutes even before medical imaging devices entered into scope of RoHS*



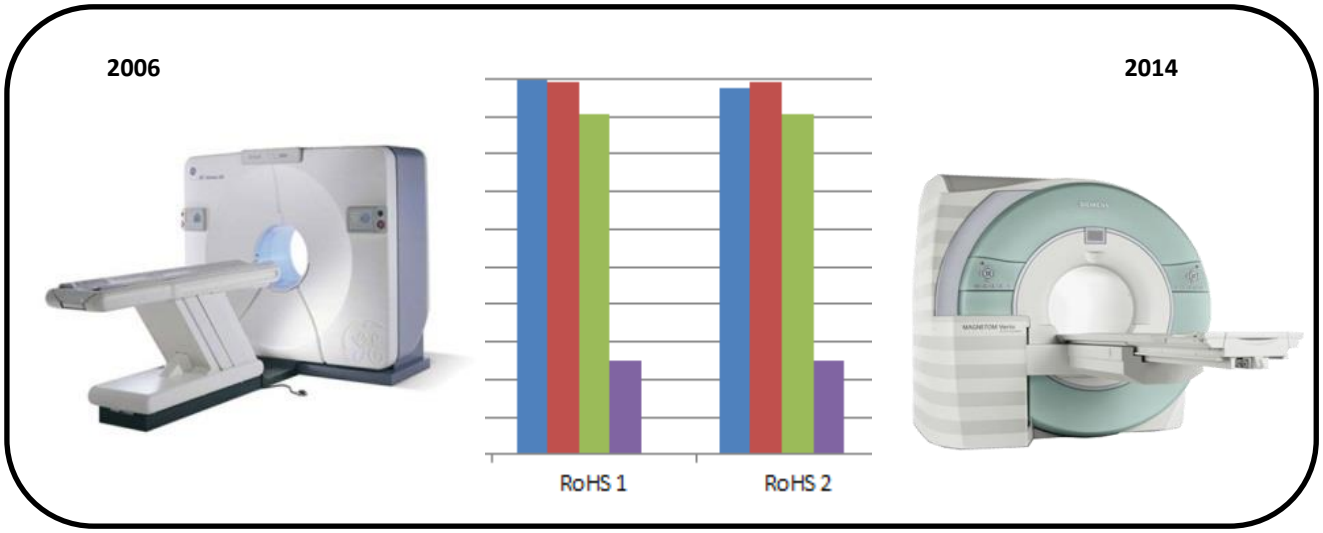


Fig 2: *Difference between medical devices before and after RoHS II. Only lead is slightly affected by RoHS II (same color code of Fig 1).*

Lead – Lead is by far the largest amount of a RoHS substance used in medical devices accounting for 98.5% of all RoHS substances used in 2006. Despite a very significant effort to reduce the use of lead, a reduction of only 2.37% has been possible because most uses (shielding and counterweights) have no substitutes and so require exemptions. It is likely that further reductions will be possible as alternatives are found for exempt uses, but the benefits from R&D into substitution will diminish over time as it is probable that no alternatives will be found for many uses.

Cadmium – Most cadmium is needed in advanced detectors for imaging equipment and so the reduction in use due to RoHS has been very small. Cadmium used as a pigment, stabiliser, in coatings and brazing alloys is also banned by REACH, and this ban predates RoHS. As a result, RoHS has had only a minimal impact on cadmium used in medical equipment.

Mercury – Mercury is a very uncommon element in medical devices with an estimated 11 kg only being used in 2006. Most of this was used in specialty detectors for which an exemption has been granted because of technical reasons. Mercury use by the electronics industry had already significantly decreased before 2006 as a

result of US legislation, so the inclusion of medical devices in scope of RoHS had only a minimal impact on mercury usage.

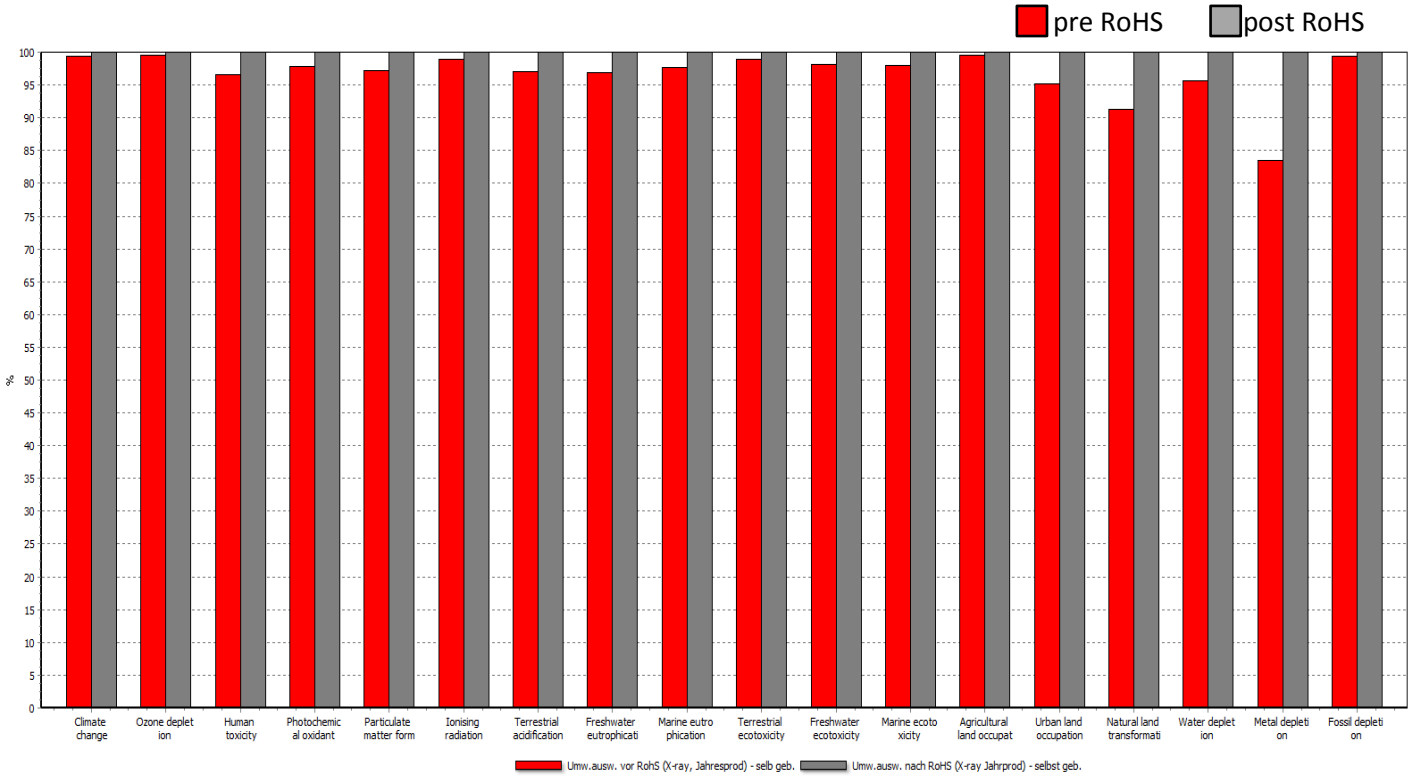
Hexavalent chromium – Only a very small amount was used in 2006. It is used mainly as passivation coatings which are very thin. These are produced from soluble hexavalent chromium compounds, all of which are now regulated by the REACH Regulation which will require authorisation for use in the EU. If medical devices had not been included in scope since 2014, it is likely that the small reduction in use would have occurred anyway due to REACH.

PBDE – In 2006, medical equipment manufacturers had no knowledge of the amount of PBDE that was used in their equipment and so ERA made an estimate based on previous research that estimated the total amount used in all types of electrical equipment and the proportion of this that was medical equipment. Of course, RoHS had an impact on PBDE usage in all types of electrical equipment in 2006 because of the demand for RoHS compliant flame retarded plastics without PBDE. This meant that the availability of PBDE flame retarded plastics would have very significantly declined and this would have affected the usage in medical devices, although to an unknown extent. Although the table above shows that 100% of PBDE used in medical devices in 2006 has since been replaced by substitutes, this may to a large extent have occurred even if medical devices had not been included in the scope of RoHS. Most of the reduction in use therefore could be due to market forces and was not a benefit of inclusion of category 8 in scope.

4.2. LCA Analysis

An LCA analysis has been performed by a medical equipment manufacturer comparing environmental impacts for MRI, CT and X-ray devices before and after RoHS. The analysis is based on the lead content (which is the most used substance in medical imaging devices) and the environmental impact was calculated for the annual production of the devices mentioned above.

For simplicity the analysis was performed only on the material use and not the whole life cycle (e.g. no transports/no production processes /no use phase/ no EoL regarded). As medical devices in the EU are taken back by manufacturers and properly recycled, the end of life phase was not considered relevant.



Selection of datasets: focus on ecoinvent datasets. If no ecoinvent datasets available the composition has been taken from Idemat and recreated with ecoinvent datasets.

4.3. Reduction of substances up to 2021

The 7 year validity period of the exemptions now in Annex IV will end in 2021 for imaging equipment. While for some, alternatives are expected to be available, for other exemptions manufacturers are sure this will not be the case. Table 1 shows the predicted reduction in RoHS substances by 2021.

Table 1: Estimated reduction in content of RoHS substances by 2021

2021	Lead (kg)	Cd (kg)	CrVI (kg)	Hg(kg)	PBDE (kg)	Total	Reduction %
Reduction	**150,068**	**630**	**0**	**10**	**0**	**150,698**	
Still in use	939,932	6,300	0	0	0	946,232	**13.7%**

This result shows that in more than 10 years (2011-2021) RoHS will only achieve, in the best case scenario, a reduction of 13.7% of the content of hazardous substances in medical imaging devices (the reduction in lead use is all related to counterweights).

5. POTENTIAL BENEFITS FROM REDUCTION IN ROHS SUBSTANCE USE

Determining benefits from reduced use of RoHS substances is very complex. Although RoHS substances are classified as hazardous, they only pose a risk and cause harm if not used safely in a controlled way; risk being from a combination of hazard and extent of exposure compared with the levels that cause harm. Moreover any benefits could be negated by the impact of substitutes, which are often not benign and some may not be less harmful[3].

5.1. Benefits for human health

Medical imaging devices are safe for users and patients as they are heavily regulated by the Medial Device Directive. Medical imaging equipment does not use the 6 restricted chemicals (and the recently added 4 phthalates) in ways that may give rise to exposure to humans in the use phase; therefore RoHS does not improve safety of medical devices.

5.2. Benefits for environment and recycling

European Union: as the use phase of medical devices is heavily regulated by the MDD to ensure safety for patients and users, the manufacturing processes and end of life disposal/recycling are the only life phases where exposure to humans or environment could potentially occur.

According to the medical devices industry, recycling is already the common practice to treat category 8 products, at the end of life. The European healthcare industry states that over 90% of the medical imaging devices are collected, reused or recycled and thus do not end up in the environment [COCIR et al. 2007]. The remaining up to 10% is disposed of safely in strict compliance with EU waste legislation. This was confirmed by the United Nation University, [UNU 2007] which also states that most of the B2B appliances are already collected and treated outside the consumer oriented compliance schemes. Medical imaging devices contain valuable parts and materials and thus companies favour direct take-back of their old appliances.

In the EU, manufacturing and recycling are strictly regulated (e.g. by the Industrial Emissions Directive and worker safety legislation), so that no harm to should be caused to workers or the environment. Uncontrollable risk for such activities in the EEE sector has become extremely uncommon because of this legislation.

As shown in chapter 4 of this study, RoHS managed to remove 2.4% of the hazardous substances in medical imaging devices by 2014, therefore there is virtually no difference between the impacts of manufacturing or recycling of RoHS or non-RoHS medical devices.

[3] *Especially relatively new substances where full health and environmental hazard and risk assessments have not yet been completed so that unrecognised hazards have yet to be discovered.*

Lead is the most commonly used substance in medical devices for radiation shielding and in counterweights (both covered by exemptions). As this is relatively pure lead, this is easily recycled by melting and this does not cause lead emissions to air and the lead can be and is reused. Cadmium and Chromium VI are not emitted to air during regulated EU recycling processes and PBDE in the plastic fraction is completely removed and destroyed during incineration processes that comply with EU legal obligations.

Outside of the EU

Medical imaging devices are bulky (several tonnes) and highly valuable in terms of metals at the point that they have a positive value for recycling (an MRI can be valued at more than 500 euro) making therefore illegal export very unlikely as transport costs are high, due to the large weight, whereas EU recycling is profitable.

Any measures to encourage reuse in the EU of refurbished medical equipment will mean that these devices reach end of life in the EU and not in countries where EU waste legislation does not apply. Refurbishment issues are discussed in section 6.4.

Regulation and control of recycling in non-EU countries should be the responsibility of the governments of these countries. Therefore it is difficult to quantify the benefits for non-EU countries from the inclusion of medical devices in the scope of RoHS as:

a. the quantity of waste of medical equipment is only about 1% of all EU generated WEEE (and medical imaging constitutes a small fraction of this)
b. waste imaging equipment tends to be large, heavy and has a high value due its metal content, so most is recycled in the EU and there is no evidence any is illegally exported
c. due to necessary exemptions, RoHS substances still have to be used (2.4% difference between RoHS and non-RoHS devices).

Furthermore, in countries where dangerous processes are used, today most of the feedstock is waste from equipment that has been owned and used by local people and is not subject to EU legislation. Furthermore, as it has not yet been technically possible to replace all of the RoHS substances in electrical equipment, all types of WEEE will contain in particular RoHS exempt substances for many more years, and so the only effective way to prevent harm is to stop using unsafe recycling processes, even if this is the more difficult political option.

5.3. Benefits for innovation

Experience has shown that RoHS has not contributed to innovation in medical devices. Research and development for compliance with RoHS aimed at finding alternative substances or alternative designs to substitutes for RoHS substances has so far only replaced 2.4% of the RoHS substances. This has been proved to provide, at best, the same medical treatment and diagnosis performances as the original designs with the restricted substances. No new technological advancement has been promoted by RoHS. In fact, on the contrary, it has limited innovation, as detailed in Chapter 7.

6. IMPACTS OF ROHS ON THE MEDICAL IMAGING SECTOR

6.1. Impacts of RoHS estimated in 2007

In 2007, BIO IS performed a study commissioned by DG Environment: **"Study to support the impact assessment of the RoHS review"**[4]

According to the study, the financial impact for the medical device sector (imaging+IVD+everything else) was estimated between 330 million € and 1,320 million € (1 to 4% of the total turnover).

The medical imaging device market accounts only for a small share of the total turnover, at around 3 billion euros/year (COCIR data). Therefore the estimated impact for the imaging equipment market of COCIR's members, according to BIO IS (1 to 4%) would have been between 35 mil € (min) and 141 mil € (Max) per year.

[4] *http://ec.europa.eu/environment/waste/weee/pdf/ia_report.pdf*

6.2. Impact on business

The impact of RoHS on the medical sector was estimated in 2006. At that time manufacturers of medical imaging devices had little or no experience with RoHS. Building on experience of other sectors, ERA and COCIR have estimated the figures in the table below.
In 2014 manufacturers have been able to provide COCIR with detailed reports on costs sustained to ensure RoHS compliance. The figures are probably underestimated due to the difficulty in segregating the costs due to RoHS from the cost of development of new products.

RoHS COST CENTERS	COST (Mil €)
Supply chain management	19.6
Regulatory	4.3
Workload Full Time Equivalent (FTE)	164.2
Non Recurring Engineering (NRE), materials, testing	99.92
Additional/unexpected	3.4
IT infrastructure	4.3
Scrapping of parts	48.5
Request for Exemptions	36.4
TOTAL	**381.2**

However, as with all manufacturers, finance for investment is not unlimited and so if additional costs are incurred, such as due to compliance with legislation, this inevitably reduces the money available for research and development. The extent that RoHS affects R&D is discussed later in Chapter 7.

6.2.1. Supply chain management costs

This includes contacting suppliers, training suppliers, setting up and running a tool for managing supplier declarations of RoHS data (e.g. BOMCheck), targeted RoHS analysis, RoHS audit of suppliers to determine trustworthiness and activities associated with producing technical files for products. COCIR estimates that, on average for the imaging sector, this is about 19.6 million €, which is higher than the cost percentage estimated by earlier studies[5]. This may be due to the complexity of the supply chain which for some manufacturers can count up to 11,000 suppliers in 5 to 7 tiers.

6.2.2. IT Infrastructure

Manufacturers had to deal with the information on RoHS compliance about hundreds of thousands of components and subassemblies. This huge effort required the modification of IT infrastructures (e.g. SAP) or the creation of new ones.
Additional efforts have been spent for the management of warehouses and production processes where RoHS compliant components are stored together with non-RoHS compliant ones for manufacturing, servicing, repairing or refurbishing other medical devices.

6.2.3. Scrapping of parts

Despite the best efforts of manufacturers to eliminate/deplete stocks of non-compliant parts before July 2014, a significant amount of parts and components has had to be scrapped as it was not possible to use them before the RoHS deadline. Those parts and components therefore contributed to create unnecessary waste and new parts had to be produced with production of additional waste and consume resources and energy.

6.2.4. Requesting exemptions

In addition to the above costs, manufacturers incurred costs associated with requesting exemptions. The main costs are in terms of employees' time and typically each exemption requires 5 man-days per employee and 2 or

[5] *For example, by the Consumer Electronics Association (CEA), which estimated 0.1% from survey of its members.*

3 employees per business unit of a company. Larger manufacturers may have up to 10 business units. Exemptions are required by many companies so we have assumed that 10 companies have been involved in the development of exemption requests dossiers on average, although in practice there will be considerably more for some and fewer for some other.
Time required for each exemption: 10 companies x 2.5 people x 5 days x 10 business units = 1,250 man-days.
COCIR has estimated that the cost of the types of employee who would be involved with exemptions (senior engineers and compliance managers) has an average employment cost of €100 per hour so the total cost per exemption would be (assuming an 8 hour day):

1250 x 8 x 100 = €1,000,000

There have also been costs for COCIR, who coordinated the activities and submitted the requests to the EC, and employed external consultants to assist with data and evidence collection and drafting of the exemption request.
RoHS Annex IV includes about 28 exemptions that are applicable to medical imaging equipment that are likely to need to be renewed (excludes those associated with image intensifiers that are not expected to need renewal and exemptions primarily for category 9 applications). Therefore, the cost to manufacturers in terms of employee could be estimated **€28 million**. Most of these employees are the same as those who would otherwise be working on new product development. Exemptions for medical devices have a validity period of 7 years and so the annual cost would be on average €4 million per year. This is in addition to the considerable costs incurred for R&D into substitutes that need to be expended even if none can be found that prove to be suitable.

6.3. Impact of researching substitutes for renewing existing exemptions

It is very difficult if not impossible to estimate costs for the on-going activities to research alternatives to the exemptions expiring around 2021, both in Annex III and Annex IV.
Considering that around 30 exemptions are involved, and that activities would range from development, designing and prototyping of numerous alternatives, to testing and eventually submitting exemption renewals, it is reasonable to assume that a cost for companies at least comparable to the cost sustained so far for the existing exemptions (28 million €) may be involved.

6.4. Impact on refurbishment

The market for refurbished medical devices is a small one but it has great potential for development and to provide a workable solution to healthcare sustainability in the framework of circular economy. In 2012 it accounted for 480 million euros, 124 of which was spent in the EU (26%). Hospitals in the EU often want to buy refurbished medical devices, either to have a diagnosis technology that was not previously available or to replace an old device. However, all hospital's budgets are very limited and they often cannot afford to buy new equipment, whereas refurbished ones are more affordable and can provide the diagnosis capability that they require. If fewer refurbished devices are available because of RoHS, this would prevent hospitals replacing old equipment and / or from having additional diagnosis capability and both would be harmful to the healthcare that hospitals are able to provide. The impact on patients is longer waiting times (if fewer older equipment are available that are less reliable) and later diagnosis with associated health risks if older technology has to be used.

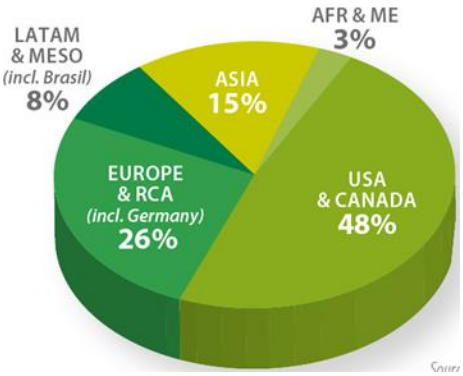


Fig 3: *Market for refurbished MDs. Source: MITA and COCIR market data*

The market for medical devices is global. With free movement, some equipment originally placed on markets outside the EU will be refurbished for use in the EU. As from July 2014 this has not been possible anymore for non-RoHS devices, therefore only devices originally used in the EU are refurbished for reuse in the EU. This is

reducing the supply to a level that is smaller than current demand which is preventing some EU hospitals from buying refurbished equipment (as their new equipment budgets will be fixed). This will have a knock-on impact on healthcare in the EU.

Between 2010 and 2011 COCIR submitted to the European Commission data regarding the possible impact of RoHS on the market of refurbished medical imaging equipment. Starting from 2012 the EC launched a series of studies which confirmed RoHS could negatively reduce the refurbishment business by a staggering 30%:

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)*

6.4.1. Impact on the refurbishment business

The data on the market for refurbished equipment collected by the COCIR Market Statistic Group (SHARE) are now confirming the decrease in sales due to less availability of medical devices to be refurbished.

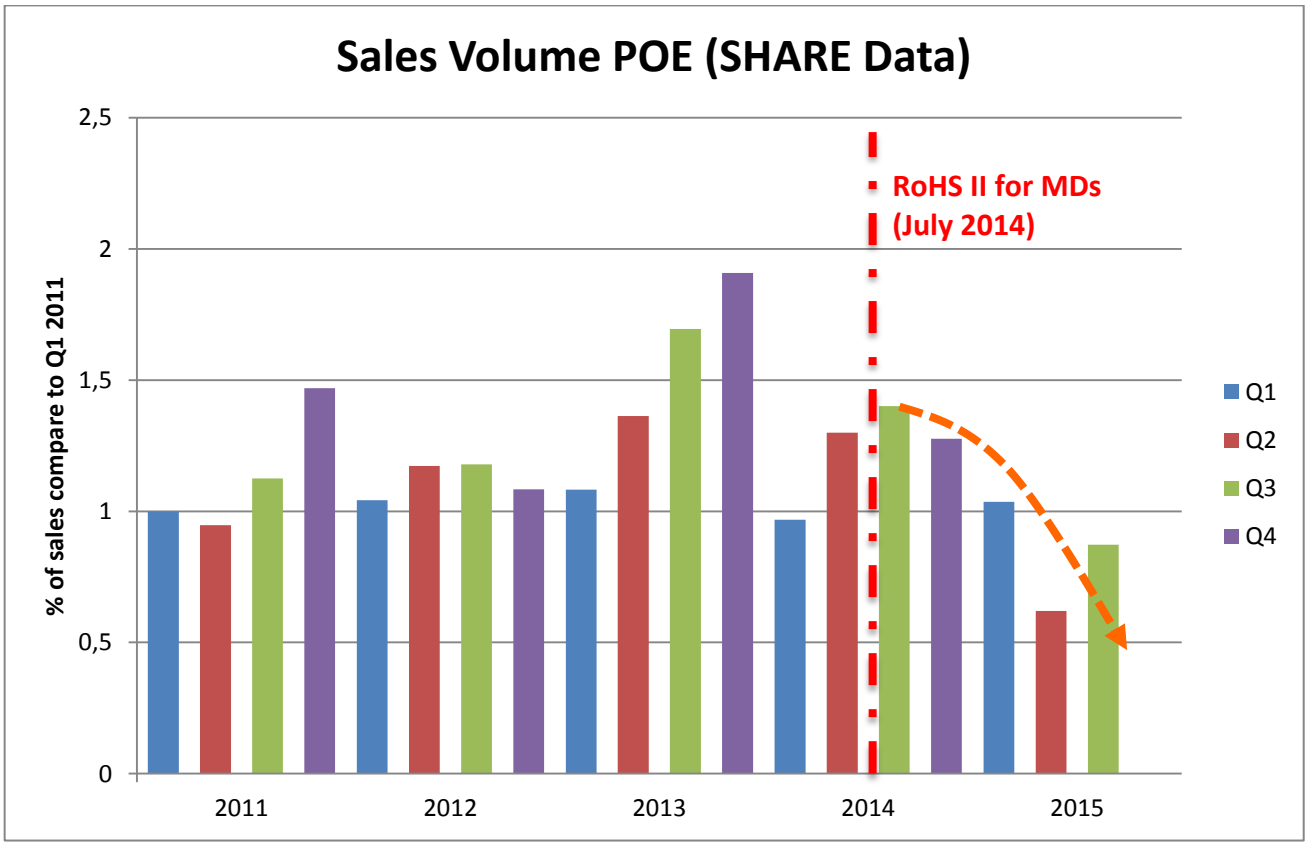


Fig 4: *Sales data for refurbished medical imaging equipment as percentage of Q1 2011.*

There may be many different factors behind the decrease in sales, not RoHS alone, but it has to be noticed that:

- the decrease in sales volume is not due to a decrease or increase in prices
- the availability of used medical devices eligible for refurbishment to be sold in Europe is lower than before RoHS
- The decreasing trend started just a few months after July 2014 and is unprecedented in EU.

All eligible devices imported into EU, despite compliance with EU relevant legislation (except RoHS), have to be exported after refurbishment just because they contain some RoHS substances which are not covered by exemptions (2.4% of difference with RoHS compliant devices).
According to the data on 2nd quarter of 2015, the impact on the sector may be estimated in a reduction of around 30% on the yearly total sales volume, corresponding to around 40 million euros per year.

COCIR also considers that the value of lost parts and components which will be scrapped due to the barrier created by the future ban of phthalates to the import of used equipment for refurbishment **can be estimated in more than 300 million euros in the years after 2021.** As this study only considers impact up to 2021, this figure is not taken into consideration. Nonetheless it shows that the impact of RoHS has far reaching consequences.

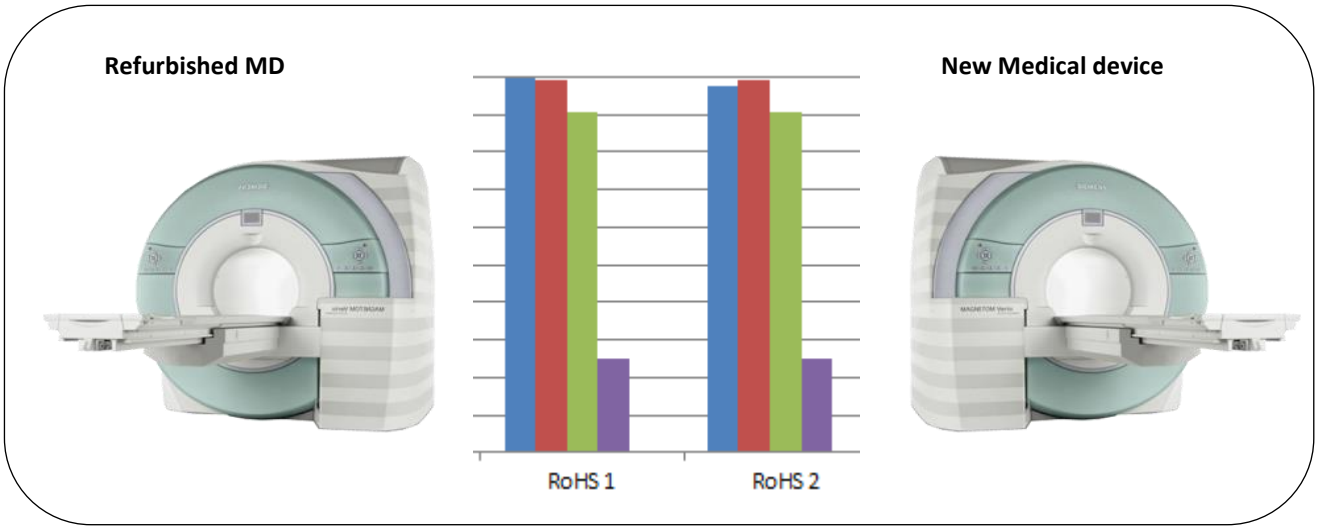


Fig 5: *Difference between a refurbished non-RoHS device and a new RoHS-compliant device (same color code of fig 1)*

6.4.2. Impact on healthcare: age profile of installed base

As already illustrated by the numerous studies performed by the European Commission, refurbished medical devices have been shown to play a role in the sustainability of healthcare systems in the EU. The long economic crisis, the austerity and cuts to EU MSs spending in healthcare are drastically worsening the age profile of the installed base of imaging medical devices.

Medical imaging device life can range from 5 to 15 years but as technology ages; it becomes less suited to, and often incapable of performing at the levels demanded by healthcare professional, not to mention that new equipment can have improved diagnostic and imaging performances. A bad age profile is indicative of non-optimal healthcare service to the population. Refurbishment can upgrade functionality and capacity of medical imaging equipment as well as improving reliability and so give the equipment a longer life as well as providing the performance that healthcare professionals require.

The COCIR "Age Profile 2014 & Density[6]" published in 2014 provides an alarming overview on the ageing of the installed base in the EU. The figures demonstrate that in many countries the installed base is the oldest it has ever been and this comes at a time when healthcare systems need to adjust to increased demand.

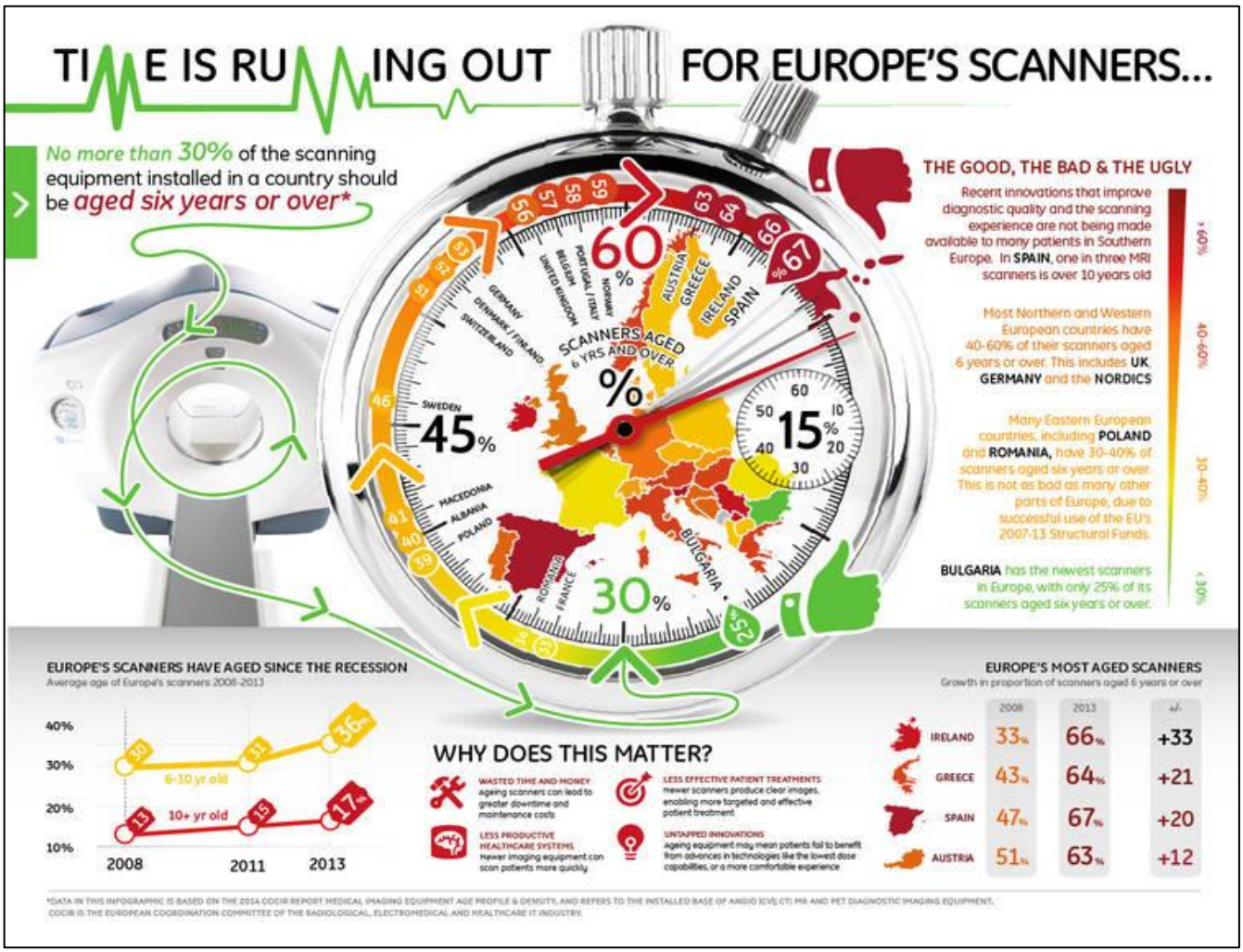


Fig 6: *Infographic from the COCIR "Age Profile 2014 & Density"*

6.4.3. Impact on environment

Reuse is a fundamental principle of ecological thinking in a recycling economy by preventing equipment to become waste (and is encouraged by the RoHS and WEEE directives). Refurbishment is a form of reuse which extends the service life and ensures safety and performance. Refurbishment:

- Saves energy: by avoiding the production of new equipment, refurbishment contributes to save energy. DITTA[7] estimates that around 30 MWh can be saved for each tonne of refurbished medical devices.
- Saves CO2: by saving energy used in the production of new equipment, reducing the mining of raw materials and decreasing associated industrial production processes.
- Prevents waste generation: DITTA estimates that in 2012 around 16,400 tons of used medical devices have been prevented from becoming waste, instead being shipped world-wide for refurbishment and repair. Europe and Unites States account for most of the refurbishment activities worldwide.
- Saves resources and raw materials: medical devices make use of many scarce raw materials thanks to their unique properties - this includes beryllium and other rare earth metals. Refurbishment saves these resources and helps to ensure their supply.

[6] http://cocir.org/uploads/media/14008_COC_Age_Profile_web_01.pdf
[7] http://globalditta.org/

Fig 7 below shows the results of a Life Cycle Analysis assessment on the manufacturing of a MRI. This compares the impacts of a new device (RED) and those of a refurbished one, which includes 800 km transport (GREY).

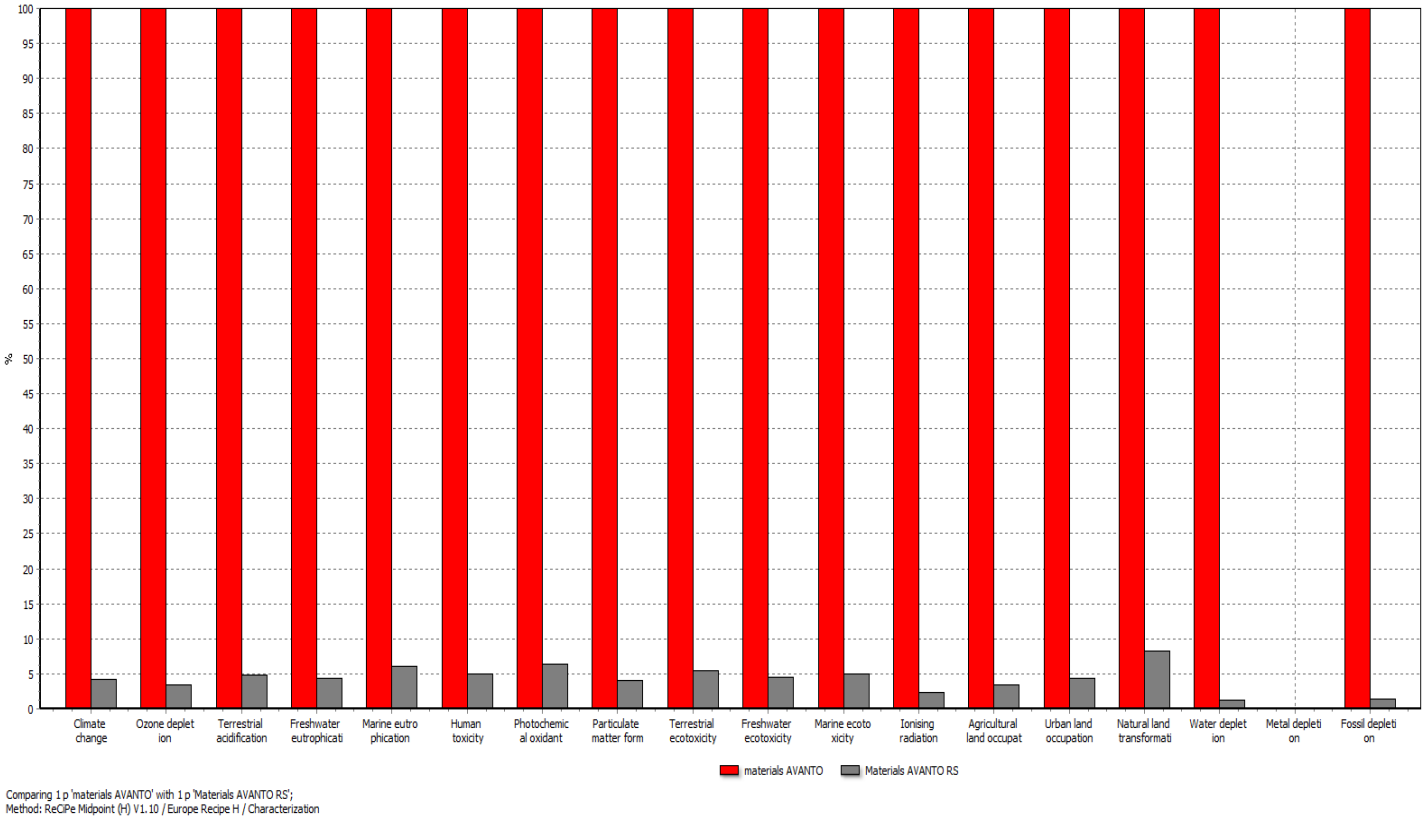


Fig 7: *LCA comparison between a new MRI equipment (**RED**) and a refurbished one (**GREY**)*

6.4.4. Additional point for consideration:

When medical devices are refurbished, the performance may also be upgraded. The resulting equipment's performance is suitable for many medical diagnoses and treatments and so allows hospitals to purchase more equipment within their limited budgets. New state of the art equipment may have features and performance that is not possible with refurbished equipment, but this will not always be required. Hospitals need to balance their budgetary limitations against having sufficient suitable equipment and being able to carry out the procedures that they are required and able to do.

6.5. Potential cost benefits from reduction in RoHS substances

The reduction in the use of hazardous substances did not bring any cost benefit for manufacturers of medical devices:

- RoHS components are not cheaper than non-RoHS ones.
- The presence of hazardous substances was never a source of risk for hospital workers and patients, so RoHS has no impact in the use phase. There is no evidence that a reduction of 2.4% (see above) brings any economic benefits in the production phase in term of less safety measures being required. There is however evidence that some substitutes have a more negative impact in the production phase[8].
- Disposal cost at end of life has not been reduced:
  - **Lead**: occurs in printed circuit boards where the recycling process is to smelt the material to recover metals. The presence of lead has no effect on this process because smelters treat a variety of materials including

[8] *Results from USA EPA LCA on solders. This showed no overall difference between lead and lead-free solders, but if the production phase impacts are considered, lead appears to have a smaller impact than lead-free solders that contain silver.*

mining concentrates and so their processes need to be able to recover any lead present. Therefore avoiding lead has no effect on treatment costs. The main uses in imaging medical equipment is as radiation shielding which at end of life gives a waste material (pure lead) that is easy and safe to recycle for reuse. All possible alternatives shielding materials, if they could be used (this is usually not possible which is why the exemption is needed) are much more difficult and therefore expensive to recycle.

- **Cadmium**: relatively small amounts are used in medical devices and all require exemptions.
- **Mercury**: not used, except in lamps.
- **Hexavalent chromium**: when this is used on steel, the very small amount of chromium is transferred into the recycled steel and does not affect the recycling process in any way. This is also used on aluminium and as with steel, the aluminium recycling process is unaffected by the extremely small quantity present.
- **PBDE and PBB**: most plastics in electrical equipment waste have no value and so are combined with metal recycling streams and are pyrolised. This has to be carried out at a high temperature irrespective of whether PBB or PBDE are present because all plastics emit toxic by-products (polycyclic aromatic hydrocarbons) if burned at too low temperatures. Therefore the presence of these substances has no effect on recycling costs or the process used.
- **Phthalates**: as with PBDE, most plastics are pyrolised at end of life due to the value of the metals content and this is especially the case with cables. Burning plastics requires a high temperature, as explained above, but the presence of phthalates is not hazardous as these will decompose to carbon dioxide and water. Insulation can be stripped from cables, but the market for recycled plasticised materials is quite small and when phthalates are banned users will be discouraged from using this material due to the relatively high chemical analysis costs (to ensure that they meet the 0.1% limit) and so the demand for it will become even smaller.

6.6. Impacts of the addition of phthalates to RoHS

Estimating the impact of the recently published ban on 4 phthalates under RoHS is extremely challenging as companies are still in the process of getting information from their suppliers about the use of such substances and looking at possible already available alternatives. Based on the experience gathered with RoHS and the 2014 COCIR, EDMA and Eucomed study[9] on the impact of the ban of phthalates, COCIR assumes it is reasonable to believe the process would costs around 80 million euros in the period 2018/2021.

It is likely that exemptions for specific applications will be needed as already highlighted by the COCIR, EDMA and Eucomed study. Moreover significant costs are expected for the scrapping of parts and for additional restrictions to the market of refurbished medical devices.

RoHS PHTHALATE RESTRICTION COST CENTERS UNTIL 2021	COST (Mil €)
Supply chain management **Regulatory** **Workload Full Time Equivalent (FTE)** **Non Recurring Engineering (NRE), materials, testing** **Additional/unexpected** **IT infrastructure**	80
Scrapping of parts	6.4
Request for Exemptions	10
TOTAL	**96**

6.7. Summing up the impacts

The impact to the medical imaging device sector can be roughly estimated in 381 million euros up to 2014 (see section 6.2). Compliance activities started in 2008/2009 but did not reach full regime until the publication of the RoHS Directive in 2011. In fact, in the normal course of business, companies cannot allocate important

[9] http://cocir.org/fileadmin/5.5_Policies_Environment/RoHS/REG0122001_COCIR_Add_RoHS_Subs_Report_final.pdf

budgets on the basis of the intention of legislators, but only when a legislative proposal is actually approved and published.

Therefore companies in the medical imaging sector incurred an annual cost of around 120 million euros per year in the period 2011/2014 which correspond to 4% on sales volume in 2014.
The reduction to the refurbishment market has already cost around 42 million € per year and may impact annually the sector in the future (unless RoHS is revised). This total does not include healthcare costs that might be incurred from a lack of refurbished equipment in the EU as this is very difficult to estimate.

	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**

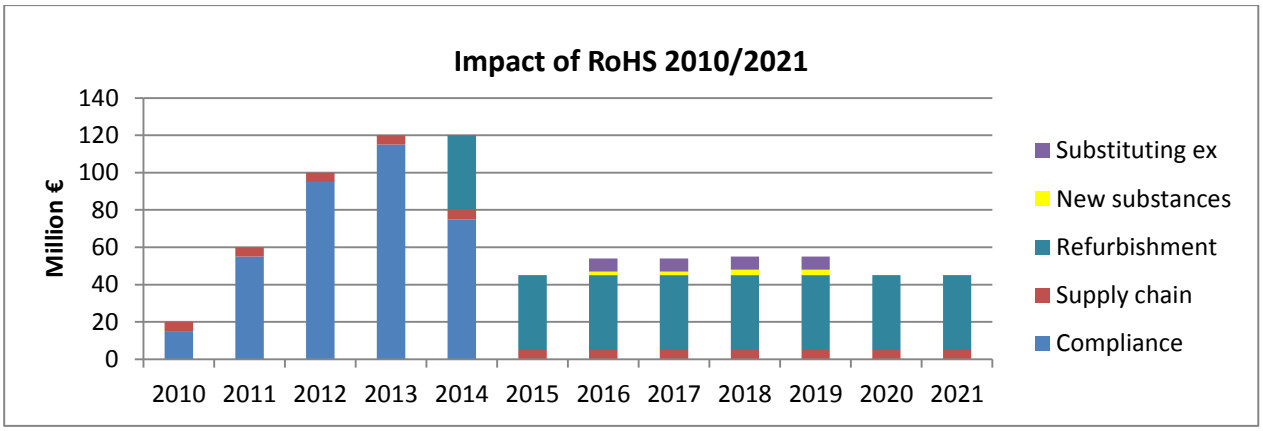


Fig. 8: Annual costs from the RoHS directive

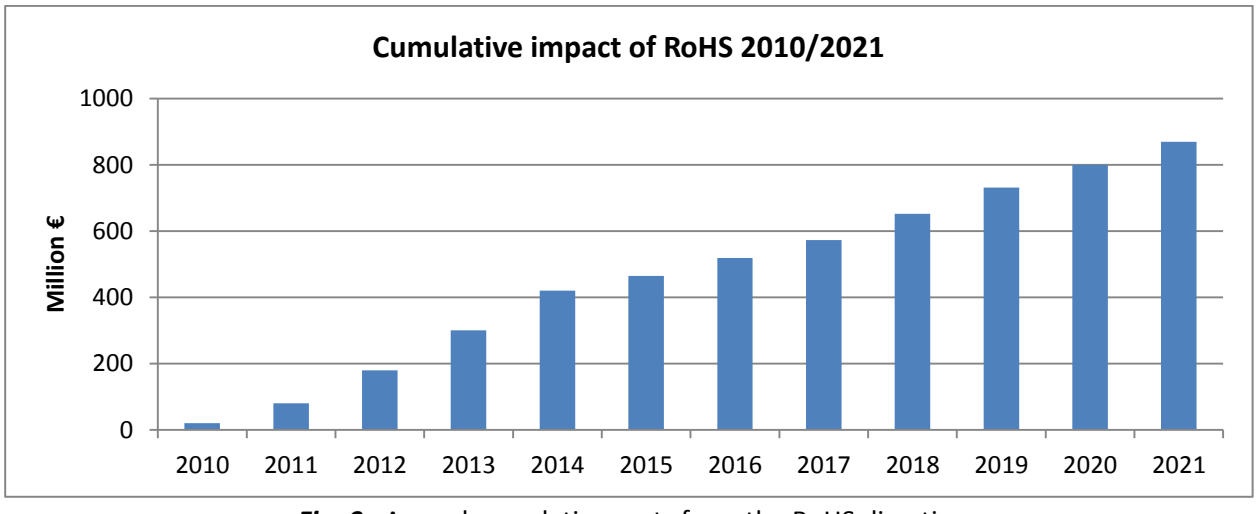


Fig. 9: Annual cumulative costs from the RoHS directive

7. IMPACT ON INNOVATION

7.1. Cost for compliance impacts innovation

All manufacturers have a hierarchy for expenditure:

1. Factory worker safety
2. Product compliance
3. Maintenance of factories and infrastructure and
4. New product development

The first 3 points are critical obligations and therefore no reduction in expenditure can be accepted. The more companies have to spend on compliance, the less is available for new product development.
COCIR has determined that companies in the medical imaging sector invest 7 – 8% of annual sales volume on new product development which corresponds roughly to 1.2 billion € per year.
The following table shows the impact of RoHS using the data from figure 8 above, on available resources and investments for innovation.

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	
Total/y (mil€)	20	60	100	120	120	45	54	54	79	79	69	69	**869**
Impact on innovation	2%	5%	8%	10%	10%	4%	5%	5%	7%	7%	6%	6%	

The RoHS Directive costs (estimated above) have reduced the availability of resources for investment in innovation from 2010 to 2014 and the effect will not stop even after 2021 due to the need to search for substitutes for exempted applications and to replace additionally restricted substances.

7.2. Substance restrictions impose limitations on the development of innovative new medical devices

Innovation in the medical devices sector needs some particular consideration compared to all other EEE categories in scope of RoHS. When limitations on the development of innovative new products occur with Category 8 products this could mean that **potentially life-saving inventions would not be developed**.

Innovations in Category 8 are intended to give better and earlier diagnosis, more effective and successful treatment and completely new treatments. For instance:

- New semiconductor X-ray detector arrays based on cadmium telluride have been introduced in the last few years. These allow up to a ten-fold reduction in X-ray dose — clearly a health benefit to the patient and a reduction in risk to healthcare professionals. Also, the images obtained with these detectors are clearer so that earlier diagnosis is possible which improves survival and recovery rates.
- Another example of a beneficial innovation is MRI scanners, which rely on superconducting connections made from lead/cadmium alloys; this technology, and its associated healthcare benefits would not have been developed if these metals were excluded from research.

It is impossible to predict future discoveries, but there is no reason to assume that the discoveries that rely on hazardous substances will never occur - indeed, the above examples indicate that precisely the opposite is likely.

7.3. New Technologies based on RoHS substances are lost forever

Companies in the medical imaging sector clearly will never choose to continue research of RoHS restricted substances in the future. Possible new technologies based on such substances could be lost forever. It is true that RoHS allows for exemptions but an expensive research program of 3/7 years cannot be funded on the hope that an exemption will be granted once the technology is available.

Moreover such technology would need to prove to be far superior to alternative existing ones for an exemption to be granted, and unfortunately this is mostly unknown until the end (or close to the end) of the research program.

The direction of funding for new developments will not even consider hazardous substances for which there is significant risk that they cannot be used over an extended period (e.g. at risk of being introduced in RoHS or REACH). However under some circumstances, physics or chemistry may dictate that lead, cadmium, mercury or other toxic materials would provide a significant technical advantage that could lead to new products which are beneficial to healthcare, safety or the environment and so these should not be prevented from being developed.

7.4. The exemption process is not suited for innovative sectors

Under the present system, where a product is within the scope of RoHS a new innovation requiring the use of a restricted substance could be used only if an exemption were to be granted. Manufacturers' experience with applying for exemptions is that this process takes at least two years.
Leading edge research is usually carried out by universities as short term contracts (1 — 3 years). The development of new technology takes place in a competitive (and often highly commercially sensitive) environment and it is not possible for researchers and companies to operate with this type of uncertainty or delay. Investment decisions require that acceptability or otherwise of the use of a restricted substance (where researchers suspect that no alternative will exist) in a particular application must be known before funds are committed. Even if an exemption already exists, the risk that it may be removed will also push the direction of research away from the use of restricted substances. **So if a RoHS substance is determined to be essential and no alternatives exist for a new innovative medical treatment, this line of research could be terminated.**

As it stands, manufacturers of medical devices are more and more forced to avoid the RoHS restricted substances even if they believe that no substitutes exist in their research and so innovations that would otherwise potentially greatly benefit citizens health would never be developed. Note that research carried out outside the EU will also be affected as RoHS-legislation in other countries tends to follow EU—RoHS.

8. IMPACT OF FUTURE ADDITIONAL ROHS SUBSTANCES AFTER 2021

Restriction of additional substances after 2021 will incur compliance costs, even if these are unlikely to be present in medical imaging devices, because the RoHS Directive requires manufacturers to comply using module A of Annex II of Regulation 768/2008/EC. Manufacturers need to:

- Determine if and where these substances are used
- Determine whether suppliers will replace substances in parts and components
- Determine the effect on reliability of substitution; reliability testing is usually needed
- Redesign part or devices and re-approval under the Medical Devices Directive and equivalent legislation in other jurisdictions may be required
- Carry out on-going supply chain management to ensure continued compliance

The cost already estimated in this study can be used as a sound basis to estimate future RoHS cost for the medical imaging sector.

9. COST/BENEFIT EVALUATION OF ROHS

The estimations provided in this study show that the extension of the RoHS Directive to medical imaging devices brought negligible benefits but high impacts to EU manufacturers.

The only result of RoHS that can be quantified is the removal 26,591 tonnes of lead (2.4% of the total) between 2009 and 2014 with an estimated cost for industry of 380 million €, without any apparent benefits for patients or the environment and diverting such resources from research and development of new medical technologies. The same result could have been achieved in a more efficient way by policymakers, ensuring at the same time competitiveness and better healthcare for EU citizens.

By 2021 RoHS will cost to medical device companies an additional 400 million € to remove substances which would be eliminated anyway by the inclusion of the other RoHS categories, and for renew existing exemptions for which alternatives are not available.

To this already worrying landscape the impact on one of the best circular economy model business (refurbishment) has to be added, as RoHS has permanently reduced this market by 30%, which has a knock-on effect on EU healthcare.

10. RECOMMENDATIONS

The findings of this study point to a need for reducing the impact caused by RoHS on the medical device sector by reducing the administrative and compliance costs for the future and removing all barriers to the full implementation of circular economy models. These recommendations would not however have a negative impact on the environment or human health.

RECOMMENDATION 1 - Exclusion of medical device from RoHS

Considering all the findings of this study, the option to exclude medical imaging devices in a future amendment of the RoHS Directive has to be seriously considered for the benefits it entails and the negligible negative impacts on the environment.

Such an option:

- Would maintain the reduction in RoHS substances achieved so far for the initial 6 substances and would not hinder the reduction for the new 4 phthalates (the reduction is anyway achieved automatically due to the inclusion of other RoHS categories and the impact of the REACH Regulation)
- Would save the burden for compliance and for submitting and renewing exemptions, allowing companies to focus their investments on innovation
- Would not affect in any way safety for patients and for the environment as:
  - There is virtually no difference between a RoHS and a non-RoHS compliant medical device
  - Medical devices are safe for patients whether they are RoHS compliant or not
  - RoHS substances do not leak in the environment during end of life treatment
  - Impact on refurbishment and reuse would be removed integrally allowing the realization of a full circular economy model

Recommendation 1

Considering the limited benefits and high impacts of RoHS so far and the even more limited benefits achievable in the future, medical imaging devices should be excluded from RoHS to reduce the impact on Companies and to free resources to be used in innovation of medical technologies.

RECOMMENDATION 2 - Exclusion of medical devices from future amendment of Annex II of RoHS

In case option one is not achievable for political reasons, it is at least recommended to add an exclusion from future additions to the list of restricted substances. As proven in this study, RoHS is going to have a continued impact on innovation of medical imaging devices due to the constant growth of Annex II. At the same time the already small marginal benefits of RoHS will be incrementally smaller in the future as additional substances will be removed from components and materials used in medical devices as most of these are also used in electrical equipment in the other RoHS categories, as has already been experienced with the original six substances and the four phthalates. The inclusion of medical imaging devices would not be justifiable on sound scientific cost/benefit analysis.

Recommendation 2

Considering the limited benefits and high impacts of RoHS so far and the even more limited benefits achievable in the future, medical imaging devices should be excluded a priori from any future amendment of RoHS Annex II.

RECOMMENDATION 3 – Impacts for medical imaging devices should be assessed separately from the other 10 categories in the future

This study makes it clear that medical imaging devices cannot be considered in the future together with the other 10 categories and that separate consideration is needed each time new restrictions are considered.

Just to make a practical example, the 2014 UBA dossiers evaluating the introduction in Annex II of RoHS of DEHP, DBB, DBP and DIBP concluded that insignificant costs were involved for industry: 11.6 million € over a total turnover of 411 billion € of the EU market of EEE (11 categories).
This is clearly not correct and the assessment completely ignored:

- The complexity of compliance of medical devices to the strict EU rules in terms of safety (Medical Devices Directive)
- The business model
- The very long product lifetimes
- The long development cycles

As shown in chapter 6.6, the impact of the recent ban of phthalates can be estimated in around 96 million euros, while the estimation by UBA in 2013/2014, if related to the market share of medical imaging would be 100 times lower (0,9 million €).

	Annual turnover (mil €)	UBA Estimated impact (mil €)	%	COCIR estimated Impact (mil €)	%
EEE market	411,000	11.6	0.003%		
Medical Imaging	3,000	**0.9**	0.003%	**96**	3.2%

This is a clear example that the considerations that may be used for most of the categories in Annex I of the RoHS Directive are not valid for medical imaging devices.

Recommendation 3

In order to come to reasonable estimates of environmental and socio-economic impacts on the medical imaging sector, a specific assessment should be performed in cooperation with the medical technology industry on any proposal to restrict substances in the medical imaging sector.

RECOMMENDATION 4 – Benefits of including medical devices should be assessed separately

This study shows that the inclusion of medical imaging devices into RoHS brought very limited benefits as most of the substitution would have occurred anyway in the same timeframe (due to no availability of non-RoHS compliant parts). The future RoHS restrictions of phthalates has also been proven to entail no benefits, as most of the application of phthalates, except the very few which will require exemptions, would be removed anyway by the application to other RoHS categories. Nonetheless compliance costs can be estimated in the order of hundreds of millions.

Recommendation 4

Benefits of applying restrictions to medical imaging devices should be assessed separately from other categories, in relation to the substitution rate that will occur anyway if future restrictions did not apply to category 8.

RECOMMENDATION 5 - Remove barriers to the implementation of a full circular economy model

Allow the use of recovered parts without restrictions

The principle of the reuse of recovered spare parts to repair or refurbish devices and to manufacture new ones has been already proven by many studies[10] as the best contribution to a circular economy and it is already integrated in the very heart of RoHS (article 4.5) for all categories until 2016. Unfortunately, article 4.5 has not been extended to medical devices when they have been included in RoHS. A new article 4.7 should be added to article 4 extending the concept of article 4.5 to the categories newly into the scope and in particular to medical imaging devices. Note that exemption 31 of Annex IV allows the use of recovered parts as spare parts, but does not allow their use to build new equipment.

Remove restrictions to the sourcing of used MDs

As the market of medical devices is global, and as EU is one of the main markets, but not the main source for used medical devices, it is necessary to remove RoHS restrictions which are making it impossible to import used CE marked medical devices to be refurbished and sold on the EU market.

This can be easily achieved by introducing exclusion for refurbished medical imaging devices in the text of RoHS article 4. Such exclusion will lower the impact on refurbishment activities and foster the growth of the sector.

If the intention of the European Union is to promote reuse and circular economy, unnecessary legal barriers have to be removed. Exemptions are not the right tool for this as these are for specific applications and cannot exemption types of equipment. Exemptions are temporary, they need to be submitted each time a new substance is added to RoHS and to be renewed periodically. This involves costs and legal uncertainty for companies, reducing the palatability of investments for improving circular economy related activities. Barriers should be removed by amending the text of RoHS.

Recommendation 5

Remove legal barriers to reuse and refurbishment by adding a new point to RoHS article 4, excluding reused parts and refurbished medical imaging devices from the scope.

[10] *http://bookshop.europa.eu/en/technical-support-for-environmental-footprinting-material-efficiency-in-product-policy-and-the-european-platform-on-lca-pbLBNA27512/*
http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/201410_RoHS_Ex_Pack5_Final_Report_final.pdf

RECOMMENDATION 6 – Time for substitution for medical devices needs to be considered with special attention

In the history of RoHS the time for substituting substances, i.e. the time between the publication of a RoHS amendment and the entry into force of the ban, has not been decided on the basis of a clear methodology, but on the basis of rough estimations as below:.

- In 2008 BIO IS assessed the impact on the medical device sector by asking Companies about an impact they could not forecast due to the lack of experience.
- In 2012 UBA assessed the impact of the ban of phthalates for all EEE without any specific consideration for the medical sector.
- In 2013 the EU Parliament proposed a ban of hundreds of substances from medical devices within just 3/5 years (as part of the recast negotiations).

In the future, the following elements have to be taken into account by the EC and Member States when discussing to subject medical devices to restrictions to the use of chemicals:

a) It has been already estimated that a minimum of 18 months is required to collect information on the use of a newly restricted substance from the supply chain (typically from 5,000 to 11,000 suppliers). 3 years are considered a reasonable period to make sure that all critical applications of the restricted substance have been detected.
b) The preparation of a dossier for submitting a request for an exemption can take up to 6 months. It depends on how accessible the evidence may be and how many different alternatives have been tested (and failed) by different actors.
c) The time required for the approval of an exemption is around 2 years and can be longer. Experience shows that in case of disagreement in the EC “Expert Group on Delegated Acts”, the process can take up to 3 years.
d) The regulatory approval of a new alternative can take from 6 months to one year. This has an impact on the time to market.

Companies in the medical imaging sector needs at least 4 years from the moment a new substance is restricted to the moment an exemption is published. This timescale does not include the time required to test alternatives to prove that they are not suitable or “available” is not considered. The process is illustrated in the following figure.

The COCIR, EDMA and Eucomed study on phthalates demonstrated that only for few critical applications of the restricted phthalates, substitution can successfully happen within 3 - 4 years and this is because alternatives are already known, tested and available for other sectors. In fact, this was due to these being classified as REACH SVHCs in October 2008 and replacement in some applications was made by about 2012. However, 5 years is the minimum time required to medical device manufacturers to file exemption requests for applications for which it is already well known alternatives are not available.

Recommendation 6

5 year is the minimum required time to ensure that medical device manufacturers are given enough time to identify applications, test alternatives and file exemption requests for newly banned substances.

RECOMMENDATION 7 - Extend lifetime of exemptions for Annex IV

Exemptions added to Annex IV of the RoHS Directive have a maximum validity time of 7 years. This may seem a long time, but it is not for the medical sector.

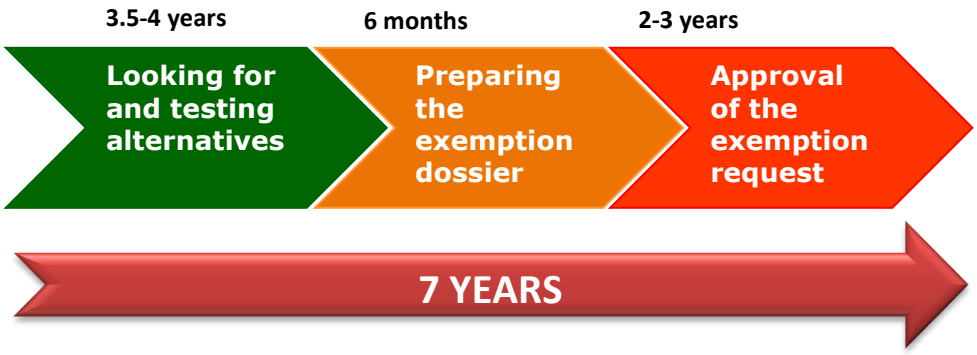
A few considerations, as for recommendation 6, are required:

a) The preparation of a dossier for submitting a request for an exemption can take up to 1 year. It depends on how accessible the evidence may be and how many different alternatives have been tested (and failed) by different actors.

b) The time required for the approval of an exemption is approximately 2 years. Experience shows that in case of disagreement in the EC "Expert Group on Delegated Acts", the process can take up to 3 years.

c) The expiration of an exemption creates a barrier to the use of recovered spare parts and to the placing on the EU market of refurbishment equipment the same way the introduction of a new substance in Annex II does. Exemptions should be valid for at least the "second" life of products after reuse.

d) In 2016, medical device manufacturers have been looking for substitutes since before 2011, at least 5 years and so for the exemptions where no alternatives have yet been found, it is clear that they will need many more years of research before alternatives might be found.



Companies are constantly burdened with the necessity to test alternatives and to file requests for renewal every 3 to 4 years. The expiry date of an exemption is unnecessary as exemptions can be withdrawn on the initiative of any actor (EC, Member State, Company).

Recommendation 7

The validity of exemptions should not be fixed to 7 years but should be determined by the consultant in charge of the technical evaluation on the basis of the collected scientific evidence. The evaluation should also take into account the reuse of spare parts and the impacts on the market for refurbished medical devices.

Report compiled by:	Checked and approved by:
Dr Paul Goodman	Dr Chris Robertson
Principal Regulatory Consultant	Head of Regulatory Compliance

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