COCIR
Brussels, Belgium

RoHS exemption 31a

Assessment of reuse of parts containing phthalates life cycle assessment

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1 BACKGROUND

The EU RoHS Directive (2011/65/EU) will restrict the four phthalate substances:

Bis (ethylhexyl)-phthalate	DEHP,
Dibutyl phthalate	DBP,
Di-isobutyl phthalate	DiBP, and;
Benzyl butyl phthalate	BBP,

in medical devices and in-vitro diagnostic (IVD) medical devices from the 21st July 2021. The medical sector frequently recovers parts from used medical equipment for reuse to repair other equipment and for refurbishment of used medical equipment. COCIR is requesting that RoHS exemption 31a be extended to include these four phthalates to allow reuse of parts that contain these substances.

COCIR has prepared an exemption request for DEHP, DBP, DiBP and BBP in recovered parts for reuse as spare parts for repair and refurbishment of medical devices and IVD medical devices and this request includes a life cycle assessment (LCA) to justify this exemption request. COCIR has asked RINA to provide a third party assessment of the LCA.

2 ASSESSMENT OF COCIR LCA

COCIR has used two quantitative comparative LCAs to justify its exemption request, one using the LCA carried out by Gabriel I Zlamparet *et. al* specifically for MRI and X-ray scanners and a second using the methodology developed for the European Commission for ecodesign preparatory studies by VHK. COCIR also assess qualitative life cycle impacts for the two scenarios of:

- **Scenario 1**: With the requested exemption granted in full;
- **Scenario 2**: Without this exemption.

Each of two quantitative and the qualitative LCAs are assessed below.

2.1 LCA BY ZAMPARET FOR MRI AND X-RAY SCANNERS

This LCA compares refurbishment of two types of medical device with construction of new but otherwise identical devices using all new parts comparing the two above scenarios.

2.1.1 Choice of medical equipment

MRI and X-ray systems are examples of commonly refurbished medical devices and so are good examples to illustrate the differences in overall impacts from the two scenarios.

MRI and X-ray systems were selected, according to the LCA's author, because MRI has a very high refurbishment potential, i.e. most parts can be reused whereas X-ray systems had the lowest potential of the types of equipment that were considered.

LCAs of these two therefore give the two extremes of differences between the two scenarios and so all other types of medical devices that are refurbished will lie somewhere between the two. As the LCA results for both MRI and X-ray systems were that all environmental and health impacts were lower for refurbishment than for use of new parts, it must be concluded that this will be the result for all types of medical device.

2.1.2 Method used

Commercial LCA software[1] was used to calculate 17 health and environmental impacts. The raw data used for the calculations was the measured quantities of materials, energy, wastes, etc. that was obtained by medical device manufacturers who refurbish large numbers of MRI and X-ray systems. The LCA included all stages of

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[1] Type not specified in publication

refurbishment including packaging, transportation, disassembly, decontamination, cleaning, parts testing, replacement or refurbishment, painting, software upgrades, reassembly and system testing followed by repackaging and delivery to users.

2.1.3 LCA assessment

It is clear that all relevant phases of the refurbishment or new build process have been considered and although the LCA software used was not specified, the comparative LCA does appear to accurately reflect the differences in overall impacts. In fact, as all health and environmental impacts from refurbishment are so much smaller than those for new systems (all <40% of new system impacts), even if the accuracy of data were limited, which does not in these examples appear to be the case, the conclusions would be the same.

The LCA includes mainly environmental impacts, but importantly includes human toxicity. Also, climate change can have both environmental and human impacts. Particulate matter can also have negative human health impacts. The choice of impacts is therefore reasonable so that the overall human and environmental impacts can be compared for the two scenarios.

As all impacts from refurbishment were determined to be much smaller than for new systems, it is clear that the overall impacts from refurbishment are less negative than from new systems built with new parts. These results should not be surprising as refurbishment and reuse of parts will nearly always use less raw materials, produce less waste and consume less energy than construction of a new part and disposal of the old part.

2.2 LCA USING EC ECODESIGN METHODOLOGY

A significant difficulty for COCIR with providing a comparative LCA, especially one based on ISO 14040, ISO 14044, PCF, CBA, etc. as recommended in the Commission's guidance on exemption requests is that the composition of used recovered parts is not known. Overall, COCIR's members reuse many thousands of different parts each having a different materials composition and energy "footprint". Also, as they were made before it was necessary to know if any of the four phthalates are present, this information was not determined when the parts are made and now it is impossible to obtain this data.

The VHK ecodesign methodology is used for preparatory studies as it is easy to use and enables the health and environmental impacts of different types of energy-using products, principally electrical equipment, to be compared. COCIR has therefore used this approach to compare reuse of parts with building new parts as medical devices are types of electrical equipment. COCIR focused on printed circuit boards as these are commonly refurbished for reuse, not only in refurbishment of equipment, but these are often used as spare parts for repair of medical devices. COCIR report that 2,000 tonnes of parts per year are recovered for reuse and a large proportion of these are likely to be PCBs.

This comparative LCA considers the two scenarios as follows:

2.2.1 Reuse of recovered parts

COCIR has assumed that as these parts already exist, there would be no impacts from mining and refining raw materials or from production of parts. Also, the impacts from disposal of these parts at end of life will be the same, whether this is without being reused or after being reused, the only difference is the date when this occurs. COCIR therefore concludes that part reuse has no human health or environmental impact.

2.2.2 Building new parts

COCIR has used the VHK methodology to calculate human health and environmental impacts. This is obviously much larger than zero (COCIR's assumption for reuse of parts) and is provided to illustrate the size of the human health and environmental benefits arising from reuse.

2.2.3 LCA assessment

This comparative LCA for reuse of parts as spare parts for the repair of medical devices complements the previous LCA for refurbishment of medical devices. Choosing PCBs for this LCA is reasonable as large quantities of PCBs are reused and the mining, refining and production phases of these parts are the most significant, as shown by the VHK methodology.

The assumption that there is zero impact from reuse of parts is not exactly correct. These parts are removed from medical devices that are returned to the manufacturer for either refurbishment or disposal. Therefore the impacts from returning the equipment are identical irrespective of whether parts are recovered or not.

Most types of medical device are large and so are disassembled irrespective of whether this is for collection of parts or disposal and so again, there is no difference in impacts.

Recovered parts that are intended for reuse may need to be tested, cleaned and repackaged. This would not occur if they were disposed of and so these are the only additional impacts from reuse. In fact, packaging and testing may not be additional as these would usually also be required for new parts. Environmental and health impacts from cleaning used parts will be extremely small in comparison with the manufacture of replacement new parts and so ignoring this very minor impact will not change the very clear result that reuse is preferable to new replacement.

2.3 QUALITATIVE LCA

Life cycle assessments generally compare the quantitative impacts of two alternative scenarios, however negative impacts can result from one scenario that is avoided by the other.

COCIR has described these potential impacts but is not able to provide quantitative comparative data as, in practice, this is not possible. The negative impacts are:

- Delays in treatment when a medical device fails and a new part has to be built because refurbished parts cannot be used.
- Implications of a hospital not being able to buy lower priced refurbished medical devices. Refurbished medical devices can be as little as half the price of new, but they can provide the diagnostic capability that the hospital requires. All EU hospitals have limited budgets. If, for example, a hospital's annual budget is €2 million and the price of a new MRI is €2 million, but a five year old refurbished MRI is €1 million, the implications are:
    - If they buy a new MRI, they cannot buy any other equipment in this year. This new MRI will perform the same diagnoses as a refurbished MRI so there is negative impact from not being able to buy €1 million worth of other equipment. In the longer term, this MRI will last longer and have a high resale value if the hospital wants to replace it, but there is a delay in buying other equipment that the hospital needs.
    - If they can buy the refurbished MRI, they can also by €1 million of other equipment. This additional new equipment will improve the hospital's ability to diagnose and treat its patients.
    - The hospital may decide to delay buying an MRI. If this were to be a replacement, then the old MRI will become less reliable as it ages. If it were to fail and so not be available, patients could not be treated, with potentially serious implications.

A question arises, why would a hospital not want to buy new equipment, especially in the more affluent EU States?

Most refurbished medical devices are sold in the more affluent EU countries such as Germany and this is because, even in these states, the hospital's budgets are limited and hospital staff want to buy a lot more medical equipment than is possible from the annual budget. Refurbished equipment of 3-5 years old will often have similar capability to new equipment and so will be suitable for most of the hospital's needs. Medical staff may want a new MRI if this gives superior capability and this is needed by the hospital, but sometimes a compromise 3 year old machine is preferable to continuing to use a 10 year machine.

2.3.1 LCA assessment

COCIR explain that it is not possible to quantify these impacts and this is reasonable.

Attempts have been made in the past to place a value on human life or the costs of ill health (e.g. from exposure to pollutants), but these figures are very variable. In any event, it is not possible to determine how many people would die or to calculate the additional cost of treatment that might be caused by delays in obtaining spare parts or from the non-availability of refurbished equipment. The health of EU citizens and their medical treatment are affected by very many parameters (as discussed by COCIR) so that this type of calculation is impossible to carry out. In conclusion, however, it is clear from COCIR's arguments that the health of EU patients could be negatively impacted if this exemption were not granted.

3 CONCLUSIONS

COCIR has used three methods to justify this exemption using two quantitative and one qualitative LCA. Each shows that the overall health, environmental and safety impacts of reuse of recovered parts is significantly less than the overall impacts from disposal of usable parts and making new replacement parts. The very wide variety of types of parts and their uncertain composition has prevented the use of formal LCA calculations (e.g. by using commercial LCA software), but the difference between the two scenarios is so large that the results are clear.

4 ABOUT RINA CONSULTING

RINA is a global corporation that provides engineering and consultancy services, as well as testing, inspection and certification. RINA provide a wide range of traditional and innovative services to critical industry sectors, including Oil & Gas, Power, Renewables, Space & Defence, Transport & Infrastructure sectors.

RINA is the result of the integration of a number of internationally respected companies including RINA Services, D'Appolonia, Centro Sviluppo Materiali, G.E.T., Logmarin Advisors, OST Energy, Polaris, SC Sembenelli Consulting, Seatech, and ERA Technology Ltd ("Edif ERA").

Through the acquisition of ERA Technology Ltd, RINA has accumulated over 12 years of consultancy experience on the RoHS Directive including:

- ERA carried out the first exemption review study for the European Commission in 2004;
- ERA carried out a study for the Commission into whether it was possible to include categories 8 and 9 in the scope of RoHS in 2006;
- ERA and BIO Intelligence Service carried out a scope review of the RoHS directive in 2012 for the European Commission.

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