COCIR
Brussels, Belgium

RoHS exemption 5 Annex IV

Assessment of comparative cycle assessment for lead and tungsten

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1 BACKGROUND

The EU RoHS Directive (2011/65/EU) restricts hazardous substances in electrical equipment including in medical devices. Medical devices have been in scope of the Directive since 22 July 2014 and so the restrictions have applied from this date except where they are permitted by exemptions. One of these exemptions, item 5 of RoHS Annex IV, allows the use of lead in shielding for ionising radiation. This exemption will expire 21 July 2021, unless it is renewed.

COCIR, the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries, is requesting that RoHS exemption 5 be renewed for another 7 years. This exemption request is justified by COCIR on the basis of both technical advantage, as well as the overall health, safety and environmental impact with the exemption are less negative than the overall impact without this exemption.

COCIR has prepared an exemption renewal request for exemption 5 including life cycle assessments (LCA) to justify this exemption request. COCIR has asked RINA to provide a third party assessment of these LCAs.

2 ASSESSMENT OF LCA PREPARED FOR COCIR BY THINKSTEP

COCIR has used a quantitative comparative LCA as evidence to demonstrate the justification of its renewal request for exemption 5 of Annex IV. The LCA compared lead with tungsten metal and with tungsten-polymer composites and was carried out by the independent consultancy Thinkstep.

Thinkstep reports that the LCA is compliant with ISO14044. This standard includes a list of considerations (section 4.2.3.1) which are briefly assessed here.

ISO14044 states that the following items shall be considered and clearly described:

- The product system to be studied; - in this case, a specified mass of radiation shielding used in a commercially available medical X-ray imaging system
- The functions of the product system or, in the case of comparative studies, the systems; - Shielding of X-radiation. Lead is used and COCIR's exemption renewal request explains why tungsten was selected for comparison
- The functional unit; - Defined as 11.3kg of lead
- The system boundary; - Only the shielding is considered as all other parts of the equipment are identical irrespective of the shielding material used.
- Allocation procedures; Input and output flows and data are defined by GaBi software with additional data from published sources
- LCA methodology and types of impacts; - Calculations using GaBi software and impacts calculated are defined
- Interpretation to be used; - Completeness check and sensitivity analysis, see discussion below
- Data requirements; - Most data used for lead and tungsten was already available to Thinkstep (see below). Additional data for tungsten composites was provided by COCIR using published sources.
- Assumptions; These are defined in Thinkstep's report and COCIR's exemption renewal request
- Value choices and optional elements; Amount of lead is the actual amount in a commercial product
- Limitations; Thinkstep defines these in its report, notably a limitation of data quality for ozone depletion.
- Data quality requirements; this should be as accurate as possible. Data for lead and tungsten life cycles obtained from previous studies (see below) and are described in Thinkstep's report
- Type of critical review, if any; - In this case, a simple comparison of impacts of lead and tungsten
- Type and format of the report required for the study. – Thinkstep's report is in the form of a slide-pack.

2.1 SUITABILITY OF COMPARISON OF TUNGSTEN WITH LEAD FOR THE LCA

Shielding materials are required to have a high atomic number and high density to be effective. Of the alternative elements to lead in the periodic table that are (a) not RoHS restricted and (b) have higher density and atomic number than lead (meaning that they are at least as effective shielding as lead), tungsten should have the smallest overall health, safety and environmental impact based on its global warming potential. Hence it is appropriate to compare lead with tungsten using a LCA.

Tungsten is suitable for comparison with lead because:

- It is sometimes used, as both metal and as composites, as radiation shielding in medical devices for technical reasons. Its use is also encouraged by the RoHS Directive's restrictions, as manufacturers are expected to replace RoHS restricted substances – of which lead is restricted, but tungsten is not, and
- Of all of the metals that have higher atomic number and higher density than lead, apart from RoHS restricted mercury, tungsten has the smallest environmental impact in terms of its global warming potential. As most impacts arise from mining, refining and production, as shown by Thinkstep's LCA results, it is reasonable to conclude that all other choices of metals that have a higher atomic number than lead would have an even larger more-negative overall impact than tungsten. Therefore, if tungsten is shown to be overall more negative than lead, then these other metals with higher global warming potential would also all be even more negative overall than lead.

2.2 DATA RELIABILITY AND COMPLETENESS

The accuracy of LCA is always dependent on the data used as well as whether suitable boundaries are used for the assessment; these are well defined and realistic with the underlying assumptions detailed. Thinkstep mainly used published data sources (described in slides 14 and 15 of Thinkstep's report) for lead and tungsten. Additional data was provided by COCIR, mainly from published sources (composition of composites, etc.). Most of the data used by Thinkstep will be expected to be reliable and should also be representative as it is obtained from sources that will have access to lead and tungsten mining, refining and production data. For example, most tungsten is sourced globally from China and Chinese mining and refining data is used. The data for tungsten raw materials is as recent as 2017, whereas the lead raw material data is seven years old (2011). However, lead production is a very mature industry and so 2011 data should be representative of 2017-2019 with only small changes globally[1]. The processes used for lead mining and refining as well as recycling have not changed during this period and the quantities have not changed significantly.

Medical devices that utilise exemption 5 are manufactured globally so data for lead and tungsten mining, refining and production for globally sourced materials has been appropriately utilised. The end-of-life of these products, however, is mainly in the EU for products placed on the EU market, although a proportion of medical devices will be refurbished for use outside of the EU. Thinkstep has assumed best and worst cases for end-of-life where lead is recycled or landfilled as well as tungsten being recycled or landfilled. Although tungsten composite recycling is not currently technically possible, this is assessed as a hypothetical option by Thinkstep.

The data on quantities of lead used for the LCA is taken from an example medical device provided by COCIR which formed the functional unit of this LCA. The amounts of tungsten metal and tungsten composites were calculated based on the shielding performance of these materials. As shielding design is not changed by substitution, it is reasonable to set the system boundary to include only the shielding material as all other parts of the equipment will not be affected by the choice of shielding material.

The LCA includes the majority of environmental inputs and outputs associated with shielding, w. the exceptions to this relating to the melting of tungsten metal at end-of-life and the cutting of tungsten metal during manufacture. The analysis may underestimate the impact of the melting of tungsten metal as additional impacts, such as cutting large pieces or the refining processes (e.g. to remove oxides), etc. have not have been taken into account. The hypothetical recycling of tungsten powder from composites excludes many other impacts such as polymer removal and impacts from incineration by-products, purification of powder, etc. and so probably also underestimates the overall impacts for this hypothetical option. The omission should not undermine the overall conclusions as it would only further support the conclusion of lead being of lower impact.

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[1] This is with the exception to ozone depleting substances emissions from EU energy generation which Thinkstep reports is old and probably out of date data.

Cutting of tungsten metal into the desired shape will require much more energy and tool wear than lead or composites, but this extra impact is included by Thinkstep in the LCA as "grinding and sintering based on continuous burning ceramic process." Production of tungsten parts will not be the same as ceramics due to the difficulty with grinding such a hard material and the very high sintering temperature, which may have been underestimated in the analysis

Elements of the analysis have been determined correctly to have minimal or no impact on the LCA which will not influence the results due to the similarities in the situations and the magnitude of the differences in the two scenarios;

- X-ray and other medical equipment will be manufactured with shielding parts, with the only difference being in the composition of the material. Lead, tungsten or composite sheet is commonly used and installed in medical devices using the same methods and fixing component;
- Once shielding parts are formed the installation process for the moulded parts is the same. It is therefore not necessary to include differences between parts used to attach shielding to medical devices; and
- There is no expected difference in the use phase as patients and hospital staff are not exposed to shielding materials.

Overall the arguments are transparent and consistently demonstrate that the health of EU patients would be negatively impacted if this exemption were not granted.

2.3 RESULTS OF LCA

Thinkstep use GaBi software for the LCA calculations, which is commercial software developed by Thinkstep and is widely used by other organisations for LCAs which is accepted to be reliable and accurate. It includes databases that are constantly updated as processes change and new data becomes available. Furthermore, the LCA was carried out by Thinkstep according to the International Organisation for Standardisation (ISO) LCA standards, the ISO 14040 series.

The LCA calculates 12 health and environmental impacts. These include the important impacts of global warming potential and human toxicity. These 12 impacts should be sufficient to compare two materials to determine whether one is superior to the other overall.

The LCA shows that for all but one impact, that of lead, the impacts are very significantly smaller than those from tungsten or tungsten composites. Even assuming that the accuracy of the analysis were poor, which does not appear to be the case here, the overall result - that lead has a less negative impact compared with tungsten - would not change if input data were changed by 10 or 20%. As discussed above, some impacts of tungsten may be underestimated, but this does not change the result that lead is overall less negative than tungsten.

Thinkstep points out correctly that the only impact where lead had a larger impact than tungsten is regarding ozone depleting substances and they explain that this is because the software uses old data for calculating this impact. As the EU is a signatory of the Montreal Protocol, emissions of ozone depleting substances from older EU nuclear power stations should now be negligible.

Thinkstep also considers several alternative end-of-life scenarios comparing landfill with recycling (i.e. a sensitivity analysis). Landfill for lead is not a realistic option for metal shielding as this has a significant value, is easy to remove and recycle. Therefore a very high proportion of lead will be recycled. It is less clear what proportion of tungsten metal will be recycled and so it would seem sensible for the LCA to utilise the data from the International Tungsten Industry Association that 35-40% of tungsten metal scrap is recycled. If this figure is used, lead will be significantly less negative overall than tungsten for 11 of the 12 impacts.

Overall, the LCA adequately demonstrated in a transparent and robust way that the impact of lead is smaller than that of tungsten. The environmental considerations of relevance have been captured by the study and the data used is adequately defined. The outcomes of the study are sufficiently robust to demonstrate that variations in the data utilised should not influence this conclusion and therefore is determined not to be sensitive.

2.4 INTERPRETATION OF LCA RESULTS AND EXEMPTION JUSTIFICATION

The requirement of Article 5c of RoHS is that the overall health, safety and environmental impacts of substitutes (tungsten) are more negative than the RoHS substance (lead). Safety is not considered by the Thinkstep LCA but there will be no differences in the safety of medical devices made with lead or tungsten as they will function identically. Workers who handle heavy pieces of lead or tungsten during production or at end-of-life will be identically affected as pieces will be of similar mass and have the same dimensions. Therefore when considering the overall health, safety and environmental impacts of lead compared with tungsten, safety impacts can be considered not to affect the analysis.

3 CONCLUSIONS

COCIR is requesting renewal of exemption 5 of Annex IV of the RoHS Directive. Although there are technical reasons for the use of lead, other heavy metals may be considered in some circumstances.

The LCA undertaken by Thinkstep demonstrates that the overall health and environmental impacts of lead are significantly less than those of alternative shielding materials. This conclusion is robust as a 10-20% change in input data would not affect this conclusion. The conclusion is also unchanged if different end-of-life options are considered. Safety is unaffected and is determined to be the same for both lead and alternative shielding materials.

4 ABOUT RINA CONSULTING

RINA is a global corporation that provides engineering and consultancy services, as well as testing, inspection and certification. RINA provides 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 14 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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