Questionnaire 2 Exemption 5 of RoHS Annex IV

Acronyms and Definitions

LCA	Life cycle assessment
Pb	Lead

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed1 by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

You submitted information to substantiate your request for the renewal of the above-mentioned exemption. This information was reviewed and as a result, we ask you to kindly answer the below questions for further clarification of your request until 02 March 2021 latest.

2. Questions

1) Although you point out your main argument regarding tungsten is LCA based, we would still like to clarify the purely technical aspects of your exemption request. You explain throughout your application that tungsten and other substitutes have technical disadvantages such as additional space requirements.

   Another such technical disadvantage is the use of X-ray shields mammography machines. The operator shield is transparent, to allow mammography technologist to have a protective X-ray barrier but observe the patient during their mammogram. Lead oxide is infused into glass to provide the shield, however if tungsten were to be used the required transparency would not be present.

   a) Therefore, we would repeat the question why is the additional space requirement a problem, but the less space-consuming aspect of tungsten not an advantage in newly designed devices?

      As indicated in the introduction of this questionnaire tungsten has not been considered an alternative by manufacturers for its intrinsic higher environmental impact (Companies use LCAs to assess alternative designs) and for the disadvantages posed by the material. In case of serious advantages companies may also switch, under certain conditions, to solutions with higher environmental impacts, but all of the advantages and disadvantages of the solution have to be considered.

      For the less dense alternatives (such as steel), thicker shielding would be needed. At best this will result in the medical devices having to be completely redesigned to accommodate this extra volume of shielding, and the overall dimensions of the equipment would be larger. This would take many years to undertake for each model. Also, space in many EU hospitals is limited and so larger size equipment may prevent some hospitals from being able to use larger sized equipment, due to rooms in which they are used being too small and elevators and doorways being too small for mobile equipment. Alternatively, manufactures could choose to maintain system volume and reduce the detector's active area, which may have

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

an impact on system performance including increased scan time and potentially higher doses to the patient.

If tungsten composites were to be used there is no difference in the dimensions compared to lead, so there is no difference.

If tungsten alloys were to be used, this would offer only a small advantage in terms of space which would not be significant, with the additional problem in achieving complicated shapes and concern raised over the limitations this might pose in imaging performance for applications such as SPECT collimators.

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b) You also mention that within re-design processes the amount of lead in shieldings is reduced by minimising the thickness to what really needed and new positioning of electronics. Why can these re-design processes not be used to make up for the additional weight and space requirements of tungsten (composite)?

Although using tungsten instead of lead, as explained in the dossier, is technically possible except for applications where tungsten may not be ideal, for reasons such as complex shapes are required. However, this does not account for the fact, as explained by the exemption renewal request, that using tungsten would significantly increase the environmental impact of Medical Devices, which has been assessed with LCA tools.

Moreover, the reduction in the quantity of lead has already been carried out over the last 10+ years. If less dense materials were to be used, they would need to be proportionally thicker than the current thickness used of lead requiring a complete redesign of equipment (many components and technologies are carried over in the next generation due to their functionalities, performances, reliability etc).

2) You mention that complicated shapes are difficult to achieve with tungsten, but it would work for more simple shape. Could you explain in more detail for which shapes tungsten would work?

The challenges to fabricating complex tungsten shapes is well acknowledged within industry with significant limitations on the shapes that can be achieved in comparison with other materials. The extent to which the complexity of shapes can meet the requirements was not prioritised as the overall environmental impact was determined to be more impactful than that of lead.

Tungsten is supplied as sheet and this can be cut into smaller pieces. Drilling holes is possible but difficult due to the hard and brittle nature of tungsten and it is not possible to make the grid shown in figure 4 of our request with tungsten.

Tungsten composites are also produced as sheet although cutting and drilling are easier than for metal and it can also be bent such as to conform to a cylindrical shape. However where fibres are used in the composites, there is the additional consideration for tungsten composites that is can only be processed in the fibre direction, and processing in different directions is not possible.

Complex shapes that need to be made by injection moulding are possible with lead as it has a low melting point, but this is impossible with tungsten metal as its melting point is higher than any possible mould materials. Tungsten composites are too hard to be moulded except into very simple shapes such as a cube or cylinder.

Due to leads low melting point and relatively high flow rate, it’s possible to cast or mould the material into complex shapes. It’s formability also lends itself to rolling, allowing the ability to make foils. Conversely, tungsten’s much higher melting point limits the size and complexity of the mould design. Tungsten co-polymers attempt to address this by using a polymer carrier to support a tungsten powder. This carrier is responsible for reducing the overall effectiveness of the material but does allow more complex geometry than one can obtain through tungsten casting. However, these materials are typically much more viscus than traditional plastics, some have compared the flow rate to that of concrete, which limits the minimum feature size and maximum part size.

3) You state that tungsten might have toxic effects, while such effects are well known for Pb, also including the mining phase, and including people living near such mines. You present LCA data showing that the human toxicity of tungsten is by far higher than for Pb. You point out which data are included for lead. Which aspects were included for tungsten?

   Life cycle data for mining, refining and manufacture of tungsten metal powder and sintered tungsten shapes using Chinese data from industry sources (that are available to ThinkStep) and also from published literature (note that most tungsten produced globally is from China) for the year 2017. This included all inputs and outputs from raw materials, from energy (electricity, etc.) generation and its emissions as well as from energy consumed in refining processes. In addition, energy impacts for grinding sintered tungsten and from composite injection moulding (to make simple shapes) was also obtained from published literature sources.

4) You state that the “net scrap approach” for tungsten was not applied due to limited available data as tungsten is not widely used as shielding in medical devices. However, a scenario for 100% recycling of tungsten is applied although also not available currently. The scenario levels out most of the environmental impact for tungsten composite and reduces the difference to lead significantly.
   Could you estimate which additional impact the “net scrap approach” would have?

   A high percentage of lead metal is recycled, so good data is available for the LCA. Some types of tungsten scrap are recycled, but only to manufacture steel and other alloys and it is not currently technically possible to recycle tungsten metal scrap to make new tungsten shielding or to recycle tungsten composites. As a result, there is no data available to calculate the impacts using the ‘net scrap approach’ for tungsten and so we are not able to provide an estimate.

5) You state recycling of composites (tungsten powder) “is not currently possible commercially”. Is it correct that these limitations are commercially and not technically? How would the situation change if larger amounts (and large amounts per recycled product) of tungsten composites would be available if used widely in medical equipment?

   COCIR members are not experts in recycling, but we can confirm that to the best of our knowledge, recycling of tungsten composites is technically not possible. It is known that in use, exposure to ionising radiation degrades the polymer matrix so that used composite becomes brittle and easily fractures so that it cannot be remoulded into new shapes. In theory, the composite could be heated to a high temperature to pyrolyse the polymer matrix but this would also oxidise the tungsten powder so that to be able to use it, it would probably need to go through the refining process again. COCIR has not found any publications to show that this is technically possible, even on a laboratory scale.

6) Lead has a low melting point. In case of fire, lead melts and causes various problems as could be observed during and after the fire in the Notre Dame cathedral in Paris with its lead roof, even though this might not be directly comparable to the situation of lead shieldings in hospitals. Would the use of a higher melting point shielding not provide more security in cases of fire compared to lead? Are any specific measures taken to prevent such damages?

   The melting point of shielding is not deemed a critical parameter for products which utilise this exemption. The rationale for this is that if such products were exposed to a fire at temperatures which would melt lead would likely result in the complete destruction of the equipment as a whole and therefore a higher melting point would not offer any benefit.

7) You mention that “high energy radiation generates radioisotopes from tungsten shielding” and “Used tungsten shielding from radiotherapy equipment is radioactive”. Could you explain in more detail for which applications or energy levels this is the case.

The energies used for X-ray imaging (40KV to 150KV) are usually not sufficient to generate radio-isotopes. PET and SPECT detects gamma radiation emitted from radioisotopes, that has higher energy level, but it is unknown how tungsten shielding would exactly react as the impurities may also be impacted by the radiation.

LINACS for radiotherapy uses energy levels that are likely to cause radioisotopes. Other radiotherapy equipment such a cobalt teletherapy (the most known is the Gamma Knife) use gamma rays from cobalt-60 sources. While the energy is theoretically sufficient to create radioisotopes, further details cannot be provided as tungsten has never been used to enclose the radioactive sources. Equipment for radioisotope production (used in PET/SPECT) like cyclotron can generate radio-isotopes.

While RT and radio pharma production applications are not in the scope of RoHS, forcing a switch to tungsten could also influence the availability of lead shielding for such sectors

Please note that answers to these questions may be published as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.

It would be helpful if you could kindly provide the information in formats that allow copying text, figures and tables to be included into the review report.