Questionnaire 3 Exemption 5 of RoHS Annex IV

Acronyms and Definitions

ITIA	International Tungsten Industry Association
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 19 March 2021 latest.

2. Questions

1) According to the ITIA, neither pure tungsten nor tungsten composite (with PA6) would be the material of choice for counterweights, but tungsten heavy alloys. According to ITIA, neither complex shape nor recycling would be a problem for that material. Additionally, there are companies, which 3D-print tungsten to achieve individual and complex shapes for medical equipment.
   What is your opinion on that? Do your mentioned limitations on space and shape requirements still apply for that material?

   We suppose you refer to ionising radiation shielding in this question rather than to counterweights (which is exemption 13). We did not receive anything from ITIA and we have not seen any contribution posted during the public consultation with details about the possibility to use tungsten alloys for such applications. If you have received such details and technical information, we would be happy to check and understand if it is applicable for medical devices. Most of the times claims of “available alternatives” prove to be for applications in other sectors with pretty serious constraints that makes them unfit for medical devices.

   In any case, we would like to reiterate that our dossier focuses on the higher environmental impact of tungsten not on the technical unfeasibility of using tungsten.

   The same goes for applications of 3D printed tungsten.

   Tungsten alloys have a lower density (e.g. 18.5g/cc with 97%W) than tungsten (19.3g/cc) and so thicker sections of these alloys would be needed to achieve the same shielding performance.

2) Tungsten heavy alloys are manufactured with powder metallurgical process and CNC milling and are recyclable to new shieldings. How would this material change the LCA results compared to lead?

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

Could you provide some additional information about heavy alloys being "recyclable to counterweights"? Do you mean that heavy alloys, used for other applications, can be recycled to produce counterweights? Without additional details on the "recycling" process it is not possible to estimate the impact on LCA results.

In terms of processing, the LCA considers for Tungsten (sintered) the manufacturing process of Grinding and Sintering based on Continuous Burning Ceramic process, resulting in a 2% loss as a best case. Tungsten heavy alloys manufactured by powder metallurgical process and CNC milling is not likely to be dissimilar to this. It is worthwhile noting that even if the alternative processing resulted in a lower loss, this has been considered for tungsten composites which considered <1% loss, which still demonstrated a higher overall health, safety and environmental impact. We also believe that as tungsten heavy alloys are typically 95 – 97% tungsten, the LCA will still be applicable.

Our LCA did consider a scenario where tungsten metal is recycled (but as sintered powder and as composite). The results are given on page 37 of the LCA report, which states (for recycling) "*in the case of Tungsten (sintered) the difference would be higher (GWP of Tungsten sintered approx. 252kg CO_2eq.)".* The LCA concludes that the energy for recycling tungsten composites would be similar to lead, if this were technically feasible - which it is not. The GWP for lead at 13 kg CO_2eq is much lower than of sintered tungsten that is recycled at 252kg CO_2eq. This large difference is likely to be due to the very hard nature of tungsten metal and its alloys which requires the consumption of considerable energy to grind these materials and also energy for sintering shapes at high temperature (typically at >1000°C).

Following additional information from COCIR members we have further information to share in relation to Questionnaire 2, Question 7 which poses the following:

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.

As tungsten is rarely used for most medical applications, the generation of radioisotopes during the lifetime in hospitals is not known. It is known that radiation from radiotherapy equipment does create long lived radioisotopes from tungsten, but not with lead. Linear accelerator activation of radioisotopes has been studied using underground gamma spectrometric analyses[2] that measures the isotopes created in a Tungsten collimator leaf from a radiotherapy system that uses photon beams of 4MV – 15MV. Although these energies are a factor of 10 or more greater than the energies in PET and SPECT photons, with significantly higher dose / exposure rates, it indicates that this exposure to radiotherapy photons can be a problem over typical exposure lifetimes. Lower energy levels were not tested or speculated upon, however, PET and SPECT photons may have the potential to create Tungsten radioisotopes and this would need to be investigated.

Given that the exposure intensity of CT collimator parts is significantly higher due to it's proximity to and the activity of the source material, albeit at lower energies than PET and some SPECT photons, there is also potential for creation of tungsten radioisotopes and this question also needs to be considered for other applications.

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.

[2] https://arxiv.org/ftp/arxiv/papers/1805/1805.10846.pdf