

# Questionnaire 3 Exemption 13 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 appointed<sup>1</sup> 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) In reference to the question 1 of Questionnaire 2: could you please specify the numeric LCA results for the comparison of lead and tungsten in counterweights (same weight for both materials) not only for baseline assumptions, but also for the additional scenarios on end-of-life?

The baseline scenario results are given in table 3 of our exemption renewal request. The additional scenarios for recycling of tungsten are given below (based on the data in slide 37 of the LCA results). Note that these are simple calculations based on the differences calculated for exemption 5 but with the different quantities used for exemption 13 as given in table 2.

Impact	Lead baseline	Tungsten composite baseline	Tungsten sintered baseline	Tungsten composite recycled (theoretical as not technically possible)	Tungsten metal sintered recycled
GWP kgCO <sub>2</sub> eq	13	344	524	16.1	185
Human toxicity potential kg DCB eq *	1.56	81.4	101.3	3.81	35.8

\* The values for human toxicity potential (for the recycling of tungsten option) were calculated as a proportion of baseline values, where the proportion is the ratio of the recycled value and the baseline value.

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

- 2) In reference to question 3 in Questionnaire 2, you write “Coupled with the higher environmental impact of tungsten, the solution has not been explored as for the majority of applications the use of stainless steel in new designs offers the same outcome without any technical difficulty and for a lower cost”.

Do we understand correctly that with redesign, counterweights from steel are possible? Could you specify in which specific applications steel can be used?

As explained in our exemption renewal request, where it has been technically possible, X-ray equipment counterweights have been replaced by steel (mild steel or stainless steel). Only in the applications specified in our request could steel not be used due to the space constraints that we explained. As steel has been used as counterweight in other X-ray applications, it is the most likely candidate to play the counterweight role in a differently designed c-arm and table geometry, if the space limitation issues could be overcome.

As outlined in the dossier, we expect it would take at least 8 years to find an alternative solution to lead counterweights in the applications detailed in the exemption renewal request. This information is to the best of our knowledge but has some uncertainty as an alternative solution may not exist.

- 3) 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 shapes 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 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 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 very serious constraints that makes them unfit for medical devices. The same goes for applications of 3D printed tungsten.

There is also the socio-economic issues explained in section 8D of our renewal request. The significantly higher cost of tungsten may prevent some EU hospitals from being able to buy the equipment that they need, which would have a negative impact on the health of EU citizens.

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

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.

Even if recycling were possible, the values shown in the above table in answer to Q1, show that these alloys, which are typically 95 – 97% tungsten, will have a more negative overall impact compared with lead.



**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.**