

# Questionnaire 2 Exemption 13 of RoHS Annex IV

## Acronyms and Definitions

LCA Life cycle assessment

### 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 05 March 2021 latest.

### 2. Questions

- 1) Regarding your LCA: could you please specify the results for exemption 13 for the additional scenarios.

*It is not understood what is meant by this question, please could you elaborate?*

- 2) 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. According to JRC [2018], “the recycling of tungsten from EOL products at present provides about 42% of its total demand in the EU”.

Could you estimate which additional impact the “net scrap approach” would have?

*A high percentage of lead metal is recycled and so good data is available for the LCA. Some types of tungsten scrap are recycled (as stated in the JRC publication), 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.*

- 3) You write “Due to limited space near the x-ray tube and detector the shapes have been made to fit unique shapes to make use of all available space” and additionally “There is sufficient space for the surgeon now with lead counterweights so this would not be an advantage”.

Why can the possibility of tungsten occupying less volume in the same overall space not be used to design simpler shapes?

*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. Even with the of the volume consideration, parts even approaching the complexity of the example part provided in the previous clarification questions are unlikely to be able to be manufactured from tungsten metal.*

<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

Using tungsten would require a complete redesign of shielding in such a way to use shapes that could be easily manufactured. 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.

**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.**

### 3. References

- JRC 2018 Talens Peiro, L., Nuss, P., Mathieux, F. and Blengini, G., Towards Recycling Indicators based on EU flows and Raw Materials System Analysis data, EUR 29435 EN, Publications Office of the European Union, Luxembourg, 2018, ISBN 978-92-79-97247-8 (online), doi:10.2760/092885 (online), JRC112720