Questionnaire 5 Exemption 5 of RoHS Annex IV

Acronyms and Definitions

COM	European Commission
ITIA	International Tungsten Industry Association
LCA	Life cycle assessment
Pb	Lead

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] 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 28 April 2021 latest.

2. Communication from the European Commission concerning ISO-conformity of LCA for exemption 5 and 13

We contacted the COM concerning the ISO conformity of LCAs in this exemption request as follow up of your answers to our previous questionnaire. The European Commission informed us that an LCA should fulfil the requirements of ISO 14040/14044 including a review by interested parties, in particular if the exemption request is justified by the overall environmental benefit. As you state in the answer to questionnaire 3 "*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*", this would apply. The information by the European Commission to us reads as follows:
"*In Article 5(1)(a) is mentioned as secondary criterion that the life-cycle thinking on the overall impacts of the exemption shall apply, when relevant. Additionally, the life cycle thinking shall be part of the application according to Annex V (d). Depending on the exemption request and their justification, these paragraphs might be differently applied case by case to applications. However, life cycle thinking is clearly part of the exemption evaluation.*
If the first two primary criteria of Article 5(1)(a) are not fulfilled and the application justification is based on the third criterion 'total negative impacts of a substitution outweigh the total benefits', the LCA is more relevant as the decision to grant an exemption is only depending on this criterion. That means, the minimum criteria of an LCA should be applied. On the other hand, the life cycle requirements for an exemption application, in which a substitution is proved as impracticable or non-reliable (first and second criteria), are less relevant in the evaluation.
Depending on this, the LCA requirements should be applied for exemption requests for ex. 5 and 13 of Annex IV.
Where an LCA is crucial for the decision, the submitted LCA studies should meet the minimum requirements in the norms EN ISO 14040 and EN ISO 14044. These standards provide the framework to conduct an LCA. These requirements are not prescriptive in detail and they provide sufficient options for their execution.
[…] the current RoHS Directive does not demand explicitly the full compliance with an ISO norm.

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

However, the Commission has announced in the Circular Economy Action Plan that companies shall substantiate their environmental claims using Product (…) Environmental Footprint (PEF) methods. PEF is a more prescriptive approach to standardize LCA in the EU. LCA and life cycling thinking have been become more and more part of other legislations. In our ongoing review of RoHS we will address also the requirements for LCA's and I already like to follow the respective standards, where necessary.
Regarding the question if LCA studies shall include a critical review according to EN ISO 14044 section 6.3 or not, I would like to follow that the critical review has to be carried out by interested parties."
At the current state, we would interpret your LCA as reviewed, but not as fully compliant with ISO 14040/14044 as no review by interested parties was carried out. If you have any additional information you would like to add to the LCA or the existing review, please do so. Otherwise, we kindly ask you to raise comments or questions you might have related to the COM's above decision directly to the COM.

COCIR has followed official EC guidance on preparation of LCAs to justify exemptions available from https://ec.europa.eu/environment/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en This was published in 2012 and has not changed due to EU policy. This specifies (page 11) "Third party verified documentation such as life cycle assessment according to ISO 14040, ISO 14044, PCF, CBA etc.". Thinkstep have fully complied with ISO 14040 and COCIR has obtained third party verification from RINA and so we believe that we have provided what was required at the time of our application to renew this exemption.

As already explained in our previous answer, we did not include the costly external panel critical review after consulting with the European Commission policy Officer in charge of RoHS at that time.

3. Questions

1) According to communication with the International Tungsten Industry Association (ITIA) some assumptions of the LCA are questioned. There is specifically the question if the LCA is applicable for the different material (tungsten heavy alloy). Can you refute these arguments and elaborate on your assumptions:

   a) "*Table 3 "Life Cycle Phase"; under "Extraction and refining process" it is stated in the table that "Each of the above steps creates wastes that must be disposed of. Some wastes contain hazardous by-products". Step 5: tungsten oxide is reduced to tungsten metal using hydrogen, the only "by product" is water vapour. Step 4: when APT is converted to WO3, a mixture of ammonia and hydrogen forms, which can either be catalytically transformed to nitrogen and water vapour or separated and reused in the previous steps, which is done in all the fully integrated APT production facilities. Step 3: either sodium chloride or sodium sulfate are formed as by-product, which even can be reused, such as sodium sulfate for the glass-, and detergent-industries. Step 2 and 1 are the hydrometallurgical refining steps comparable to the pyrometallurgical refining steps in case of lead and it is correct that associated by-products have to be disposed according to respective legislation. It is worth mentioning that also in China respective legislation for proper disposal exists since some years now and is strictly executed*."
   Are these assumptions questioned here used within the LCA you provide? If yes, can you refute these arguments and elaborate on your assumptions

Before dealing with "questioned assumptions" we would like to understand if ITIA also question the outcome of the study. It is well established that tungsten has a higher environmental impact than lead. Is ITIA arguing against this conclusion? Have they provided an estimation, based on the LCA data they have for sure about how much they think our results are off target?

Wastes that contain hazardous materials will mainly be generated from mining and refining of ores, both from tungsten and lead ores. The quantity of these wastes is dependent on the metal content of the ores. As lead typically occurs at higher concentrations in lead ores than tungsten in tungsten ores[2], tungsten mining will generate more waste (per tonne of metal) than lead mining. In addition, generation of power generates wastes. China still uses a very high proportion of fossil fuels to generate power and this creates fly ash waste that contains lead, cadmium, mercury and other hazardous substances. These metals are also emitted to air, even with the best controlled power generation processes. Therefore, the more energy needed, the larger the quantity of hazardous waste that is generated. All of these issues were taken into account in Thinkstep's LCAs.

It is true that China and many other countries have waste legislation. However, any hazardous waste poses a risk as waste disposal processes may not be 100% effective at preventing emissions and so it is preferable to minimise waste generation as far as possible.

b) "*Table 3 "Life Cycle Phase"; "Fabrication" it is stated that "Tungsten melts at 3422°C and so melting into shapes is extremely difficult and energy intensive": NOBODY melts tungsten to make any forms; this is not existing! The other two options described "hot-pressed metal powder and combined with polymers" exist, but the really (industrially) relevant tungsten material for production of counterweights is so called tungsten heavy alloy (as the author of the Request cites a paper #9, one typical such alloy with the trade name: Plansee/Densimet_D176 is described, containing 92.5wt% tungsten and the balance of nickel and iron; such a material has a density of 17.6g/cm3). In the ITIA Newsletter Dec 2015 the 3D printing of tungsten metal parts is featured, which could also produce appropriate shapes.*"
Can you refute these arguments regarding a different material choice? If not how would tungsten heavy metal would change the LCA comparison?

If tungsten heavy alloys were used instead of pure tungsten, COCIR believes that this is unlikely to have a significant effect on the results for tungsten as these alloys have a very high tungsten concentration.

We are also not sure why ITIA refers to 3D Printing as mentioned in a newsletter of 7 years ago. Is 3D printing of tungsten an established industrial practice or is it some kind of experimental technique, reported in 2015 in a newsletter?

c) "*Table 3 "Life Cycle Phase"; "End of life" A comparison of the global recycling rate of a certain element (material) makes no sense to evaluate (deduct) the situation for a specific application. Here more so, as this is an industrial product, no consumer good and no mass product. The vendor of such machinery can do exactly the same as is done with lead: take the machine back and either directly re-use the counterweight (if physically the same shape in the new machine) or have it recycled. Both pure tungsten metal (in this case the 3D-printed version; or a simple stack of tungsten metal sheet material screwed together) and tungsten heavy alloy can be recycled in multiple ways (in the special alloys/steel industry, in the powder metallurgical industry, through all kinds of processes such as direct recycling of the heavy alloy to produce heavy alloy parts again, or chemical recycling to further use the tungsten in any possible application – ie highest flexibility). The processes exist and are industrial standard, with respective facilities all over the world including Europe. Despite the fact that a tungsten polymer could also be recycled, one would probably not use it for this application for other reasons (ie the mentioned embrittlement of the organic phase by x-ray radiation).*"
The possibility of recycling and the assumed recycling rate were already part of the discussion. Can you elaborate and quantify how tungsten heavy alloy and the respective recycling procedures would change the results of the LCA comparison? Is the LCA applicable for the different material?

It is conceivable that a high proportion of tungsten could be recovered and recycled from end of life medical devices, but COCIR's members have no experience of this and so cannot determine

[2] Lead can occur at up to 70% according to https://www.azom.com/article.aspx?ArticleID=10878 whereas tungsten ores contain <1% tungsten, according to https://www.mindat.org/element/Tungsten (see section "important ores of tungsten".

whether this would occur in practice, they have experience only with lead which is recycled. We have stated in answers to earlier questions that the Thinkstep LCA included the scenario that 100% of tungsten metal is recycled and the result was that the overall global warming impact of tungsten is much larger than for lead.

2) In your answers to questionnaire 3 you state "*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.*"
According to ITIA, "*Tungsten heavy alloy, as it combines the high density and radiation shielding properties of tungsten with the ductility of nickel and iron (or copper), can be machined on any modern CNC milling machine and there would be absolutely no difficulty to produce a shape as shown in Figure 5. Furthermore, the density of an alloy such as Densimet D180 is considerably higher than that of lead (18.0g/cm3 compared to 11.3g/cm3), thus it may allow an even better suited construction of the C-Arm as compared to the "old fashioned" way with lead.*
Counterweights made from tungsten heavy alloys, ranging from counterweights in the watch industry of several grams up to individual part weighing as much as 1-2 tons, are industry standard, thus a complex shaped counterweight of 10-20kg is absolutely no problem to produce. Capable companies could be found both inside and outside Europe, the sourcing risk can be eliminated by this choice. The material is 100% recyclable!
SUMMARY: Tungsten heavy alloy (W/3%Ni/3%Fe or W/3%Ni/3%Cu) would be the obvious choice for production of such counterweights, there is no technical need to stick to lead for this purpose any longer. The tungsten-based material can be 100% recycled to either produce tungsten heavy alloy again or any other tungsten-based materials, if so desired. The supply risk can be eliminated by closed loop sourcing (ie recycling by the supplier)"
This refers specifically to counter weights, but there are also companies producing shieldings and collimators for medical applications according to their website with the same material and processes, e.g. https://www.wolfmet.com/applications/radiation-shielding-and-collimators/, https://www.plansee.com/en/products/components/radiation-generation-radiation-protection-and-beam-guidance/collimators-for-x-ray-detectors.html, https://www.dunlee.com/a-w/3d-metal-printing.html.
Could you explain what the technical constraints are or if they seem to fit for medical applications?

Our statement in questionnaire 3 referred to 3D printing, that does not seem a technique used by the company linked here above, therefore it is not possible for us to make any statement about suitability of this technique.

Technical constraints are listed in section 4 (C) of COCIR's exemption request. In addition, it must be possible to produce all of the complex shapes that are required including the grid shown in figure 4. As stated many times, while tungsten may be used to realize most of the shielding designs, it cannot replace all of them. Moreover, utilizing tungsten in medical devices would increase the overall negative environmental impacts.

Typically, if a new material were to become available, it can take at least 8 years to design, build test and obtain approval for one new design and significantly longer to change all of a manufacturer's products. However, the socio-economic impact described in section 8 (D) must also be taken into account as this would directly affect the health of EU citizens. Note also that leaded glass shielding is also used for some applications and there is no technical substitute available.

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.