JBCE answer to Questionnaire 1 (Clarification)

Exemption 5 of RoHS Annex IV

29th August, 2020

As an applicant, JBCE would like to answer the questions dated on 15th August.

Please kindly find our answers in the attached.

If you have any further questions, please do not hesitate to contact to us.

We are looking forward to continued contribution during the consultation phase of evaluation.

Yours sincerely,

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ABOUT JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organisation representing the interests of over 85 multinational companies of Japanese parentage active in Europe.

Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, railway, textiles and glass products.

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Questionnaire 1 (Clarification) Exemption 5 of RoHS Annex IV

Wording of the Requested Exemption:

Lead in shielding and in collimators used for ionising radiation

Requested validity: *7 years*

1. Acronyms and Definitions

EoL	end of life
Pb	lead
W	tungsten

2. 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.

COCIR, JBCE and TMC submitted a request for the renewal of the above-mentioned exemption, which has been subject to a first review. As a result we have identified that there is some information missing. Against this background the questions below are intended to clarify some aspects concerning the request at hand.

We ask you to kindly answer the below questions until 29 August 2020 latest.

3. Questions

1. You added collimators to the exemption. Why would they require an exemption now and not already in 2014?

   The ERA final report points out that "One function of lead in CP (capillary plate) is shielding for ionizing radiation and so, if exemption numbered 5in Table 71 is accepted, this exemption (3 in Table 71) is unnecessary on this basis."

   CP has a collimation application. So, based on the ERA report, we can see that the function of Pb in collimators is intrinsically the same as that in lead shielding. Therefore, we don't have an intention of newly adding a collimation application to Exemption no. 5 lead shielding.

   ERA final report: https://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

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

2. The table on page 12 of your exemption request shows the required thicknesses of steel and concrete at different energy radiations.

   a. The units of radiation energy should probably be keV, not kV?

      The correct unit is "keV" because it describes the energy of radiation.

   b. It seems that steel and concrete both become more efficient with increasing energy of the radiation. Could steel and concrete not be appropriate as shieldings for the high radations used in radiotherapy?

      The mass absorption coefficient depends on substance (atomic number) and X-ray energy, meaning higher X-ray energy reduce the difference between substances. So, the thickness can be a dominant parameter when the X-ray tube voltage is increasing and the mass absorption coefficient is decreasing. As you mentioned, the shielding efficiency among lead, steel, and concrete could be equaling in case of high energy radiation.

      Radioactivation could occur if the element in the shielding material is affected by strong irradiation. In fact, there was a case where Tungsten was radioactivated and had a cooling time of three years. Lead, however, cannot be radioactivated.

   c. Could you add W to this table, or do you have data showing a comparison of required thicknesses for Pb and W?

      We don't have the appropriate information. (We would like to leave the answer to COCIR.)

3. You argue that the larger thickness of most other than materials than lead consumes too much of precious space, which is plausible. You mention that W would require less space and thus may allow building smaller X-ray and similar devices, enable smaller rooms for examinations, etc. (assuming that manufacturers would design their devices in future to use the space saving potential).

   a. Why is the additional space requirement a problem, but the less space-consuming aspect not an advantage in newly designed devices? We are aware that W might not allow forming all shapes, but we assume that there are a lot of simple shieldings in most devices also.

      The less space-consuming aspect is an important requirement even for newly designed devices.

      Replacement with W is limited to simple shapes. In addition, in order to realize the replacement, it is necessary to carefully consider from various viewpoints.

   b. Heavier weights of less effective shieldings are a plausible argument as well. The higher shieling efficiency of W may, however, at least partially compensate the higher weights?

      In some cases, the weight can be reduced. However, it is necessary to carefully consider from various viewpoints.

4. You state that "Medical device manufacturers aim to minimise the amount of lead used to reduce weight and so the total quantity may have decreased since 2006." How was this possible, since certain energies of radiation require certain thicknesses of materials to provide the necessary protection, and the number of devices may even have increased in the past years?

   IEC 60601-1-9 requires for medical device manufacturers to design in an environmentally friendly manner including less resource use.

5. You argue that "It is very common for X-ray imaging equipment, PET and SPECT to be returned to manufacturers by users. These are refurbished for reuse if possible otherwise parts are removed for reuse. Damaged and unusable parts are recycled. Therefore most equipment is collected within a closed loop system." We assume that most hospitals in richer countries prefer buying new equipment with cutting edge technologies rather than older ones. Used equipment thus may be sold – or donated - to lower income countries, including developing countries. In many of these countries infrastructure and organization for sound recycling is lower quality than in the EU or missing.

   a. Do you have figures for sales or donations of used equipment outside the EU, in particular to lower income countries?

      We would like to leave answer to COCIR.

   b. Do the manufacturers maintain their producer responsibility and take care of the sound treatment at EoL when devices are sold outside the EU to such countries?

      We would like to leave answer to COCIR.

   c. Do you have experiences how the end of life of such devices would look like in those countries, in particular the treatment at end of life?

      We would like to leave answer to COCIR.

   d. You say that lead parts from medical devices are not treated in the extremely dirty circumstances like lead acid batteries. Besides the acids, why should lead sheets not be molten in the same plants like those which treat lead-acid batteries and probably other lead scrap as well?

      We would like to leave answer to COCIR.

6. Could you please let us know the source of the data in table 2 of your exemption request?

   Philip Nuss, Matthew J. Eckelman, Life Cycle Assessment of Metals: A Scientific Synthesis, July 7, 2014.

7. You mention that W is used as shielding material in some applications.

   a. Which ones besides the pin hole collimators?

      1)Shielding material for product entrance/exit of X-ray inspection equipment, which inspects unpackaged foods moving on a conveyor

If the lead used for shielding is accidentally mixed in the food, there is a risk of causing a serious health hazard to consumers. Therefore, in order to prevent this accident, lead-free materials are used for the shielding parts at product entrance/exit where there is a risk of contamination. Examples of non-lead materials include stainless steel (fig1) or tungsten (fig2).

fig1

fig2

b. What are the reasons why W is used in these cases?

1)Shielding material for product entrance/exit of X-ray inspection equipment, which inspects unpackaged foods moving on a conveyor

-vs Lead : Since oral toxicity is low, the risk of accidental contamination with food can be reduced.

-vs Stainless Steel : In the case of stainless steel, it is used as a tunnel guard that keeps a distance from the X-ray source, so that the device becomes long. In the case of tungsten, since it is used as a curtain using Metal-polymer composites, the device can be made shorter.

In these cases, shielding of non-lead materials has already been used, so expanding the use of tungsten does not necessarily contribute to reducing lead usage.

8. You state that W might have toxic effects, while such effects are well known for Pb, also including the mining phase, and including people living near such mines.[2] You present LCA data showing that the human toxicity of W is by far higher than for Pb. Were non-energy-related effects like emissions of Pb and W from mining and recycling, etc. taken into account in the LCA as well? Which ones?

   We don't have the appropriate information. (We would like to leave the answer to COCIR.)

9. Lead from informal, highly contaminating recycling of lead acid batteries may enter the market also in the EU, the more as metal markets are global, not mainly local. How would this impact the result?

   We don't have the appropriate information. (We would like to leave the answer to COCIR.)

[2] C.f. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2992867/, https://academic.oup.com/mutage/article/20/3/187/1060128 as examples

10. Why are 11.7 kg of lead compared to 15.4 kg of W? Based on your statements about the physics of shielding less W should be required than Pb. Possibly, the core is that less thickness/volume of W would be needed, but the higher density still results in a higher mass? If so, please illustrate this with a calculation.

    We don't have the appropriate information. (We would like to leave the answer to COCIR.)

11. Given the high price of W and the fact that it is or would be used in compact form rather than in tiny portions distributed over the product like e.g. lead in solders, how realistic is it to assume that in practice only 35 to 40 % of W are recycled? Wouldn't it be plausible to assume that such metal parts – W as well as Pb – are separated possibly even manually before further treatment, also taking into account that medical devices contain steel and other metals in larger parts which may be dismantled rather than shredded and thus be partially diluted over the shredding fractions. It is difficult to imagine that recyclers in the EU and other developed countries would forego this business. The price of W is around 13 times higher than that of Pb, and around six times higher[3] than that of copper, and recyclers already separate larger copper parts. In developing countries, even informal recyclers are normally informed about the prices of materials, since smart phones allow access to market information. It might therefore be reasonable to assume that close to 100 % of W undergo a final treatment in a smelter, taking into account also that almost all medical devices are collected and not ending up on landfills untreated.

    The price of W is indeed much higher than that of Pb, so it would definitely be economically beneficial to recyclers. But as we do not have full knowledge of the W recycling scheme, we can only assume that it would be very hard for W recyclers to achieve 100 % recycling capacity anytime soon because as of 2016, the recycling rate of W was only 15 % in Japan according to the report of the Japan Oil, Gas and Metals National Corporation (JOGMEC).

    Japan Oil, Gas and Metals National Corporation (JOGMEC), "12. Tungsten (W)," in Mineral Sources Material Flow, 1 March 2018.

    http://mric.jogmec.go.jp/wp-content/uploads/2018/03/material_flow2017.pdf

12. You state that "An application of the net scrap approach to W might have a positive impact on the results". You indicate that 35 – 40 % of W are recycled globally, compared to around 55 % of lead. Why didn't you apply the net scrap approach to W as well?

    We don't have the appropriate information. (We would like to leave the answer to COCIR.)

13. How would the result change if the above aspects concerning the functional unit (15.4 kg of W, if applcicable), the net scrap approach, impacts from other burdens than energy consumption (if applicable), higher recycling at EoL for W (close to 100 % like for lead) were taken into account?

    We don't have the appropriate information. (We would like to leave the answer to COCIR.)

[3] Price of copper: ~ 5,400 Euro pro tonne (https://www.gold.de/kurse/kupferpreis/); Tungsten: ~ 30,000 Euro per tonne

Please note that answers to these questions will 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.