

Questionnaire 1 (Clarification) Exemption 11 of RoHS Annex IV

Wording of the requested exemption:

Lead and its alloys as a superconductor and thermal conductor in MRI

Requested validity: 7 years

1. Acronyms and Definitions

MRI magnetic resonance imaging

NMR nuclear magnetic resonance

2. 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.

COCIR has 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 21 August 2020 latest.

3. Questions

1. Clarification of the exemption scope:
 - a. You request the renewal of the exemption with a slightly different wording (“Lead and its alloys ...” while the current exemption reads “Lead in alloys ...”. While the current wording excludes the use of pure lead, your proposal would include this.
Is there any necessity to use pure lead as super- and/or thermal conductor in MRI devices? If yes, please explain this situation in detail, including why the use of pure lead is now required differently from the past years.

When medical devices were included in scope of RoHS, MRI manufacturers requested an exemption for superconducting MRI bonds. At that time, all MRI manufacturers used Woods Metal which is an alloy containing both lead and cadmium and this was granted as exemption 12. MRI manufacturers have since been able to eliminate the use of cadmium by use of various substitutes which are lead-based. As exemption 11 is for lead in alloys as a superconductor, MRI manufacturers have assumed that exemption 11 is a more suitable exemption for this application, although 12 would also be applicable. When COCIR submitted the exemption 11 renewal request, we had been informed that one MRI manufacturers used lead metal whereas all others use lead alloys such as lead-bismuth. We

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

have investigated further and have determined that all MRI manufacturers use lead alloys and none use pure lead metal.

- b. Exemption 11 indicates thermal conductivity as one criterion defining the scope of exemption 11. The aspect of thermal conductivity is not explained in your request, and we understand that exemption 29 covers the applications requiring lead as a thermal conductor if that exemption is renewed. Lead alloys used as thermal conductors could then be excluded from the scope of exemption 11. Is this correct?

When exemption 11 was originally requested and granted, it covered lead as a superconductor and as a thermal conductor of MRI. Exemption 29 was requested and granted more recently and has a scope of *“superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems”*. This list of uses does not include thermal bonding in MRI and as such thermal conductivity needs to be maintained within exemption 11. Inside MRI are cryo-coolers which maintains a bath of liquid helium, which is very cold. Having a very low temperature adjacent to warmer components creates a steep temperature gradient that imposes stresses on the equipment due to differing thermal expansion and contraction of materials. MRI manufacturers use lead as a thermal conductor to equilibrate the temperature inside the MRI to minimize these stresses.

- c. We welcome your considerations as to eliminate and avoid overlapping exemption scopes. In this sense, we think that excluding the applications in the scope of exemption 26 and 27 from the scope of this exemption would also advance these efforts (see below proposed wording). Do you see any technical issues with this approach?

Yes, this seems to be acceptable

- d. In the recent review of exemption 12 (c.f. Gensch et al. (2020 b) the applicant and COCIR had agreed to exclude NMR devices from exemption 12 and include it into exemption 11. We assume that COCIR still agrees to this change and, further on assuming that lead is only required in alloys, propose the following wording for the renewed exemption:

Lead in alloys as a superconductor in MRI and NMR excluding uses of lead alloys in the scope of exemptions 26 and 27.

Do you agree to the above wording?

Yes, this seems to be acceptable

2. You describe spot welding as a potential technique to eliminate the use of lead, and about approaches to overcome the low critical current of the welded bonds. Could you please let us know more about this technique and the achieved progress, including a roadmap for the further research?

This has been investigated as a possible alternative bonding method for niobium alloy superconducting wires in a copper support matrix. To date, this research has not been successful as the researchers found that thin layers of oxides



and residual copper form at the bond interface creating electrical resistance. In this bonding method, copper first has to be dissolved in acid then the exposed niobium alloy must be de-oxidised using hydrofluoric acid (to dissolve niobium oxide) before welding can be carried out. Unfortunately, exposed niobium metal alloy re-oxidises as soon as the hydrofluoric acid is washed off and the surface dried and this oxide remains in the spot welded bonds creating electrical resistance. Niobium oxide is exceptionally inert and is resistant to most chemicals. Niobium metal oxidises immediately when exposed to even low concentrations of oxygen. Oxford University has investigated other substitutes but all gave bonds with electrical resistance. Many potential alternatives to lead and its alloys have been investigated with none being suitable for MRI superconductor bonding and so it is difficult to predict when a more suitable substitute will be discovered. Our answer to question 7 (B) of our exemption 11 renewal request provides a roadmap for substitution.

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.

4. References

Gensch et al. 2020 b: Study to assess one (1) request for renewal of exemption 12 of Annex IV to Directive 2011/65/EU (Pack 19). Final Report Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation, Carl-Otto Gensch, Moch, Katja, Öko-Institut e. V. und Dr. Deubzer, Otmar, Fraunhofer IZM, https://circabc.europa.eu/sd/a/b464981f-1173-4ade-a056-c219ef3bbba4/RoHS_Pack19_final_report_20200615.pdf.