Consultation Questionnaire Exemption 11 of RoHS Annex IV

Current wording of the exemption:

Lead in alloys as a superconductor and thermal conductor in MRI

Expires in July 2021 for cat. 8 and 9 equipment other than in-vitro diagnostic devices and monitoring and control instruments in industry

# Acronyms and Definitions

# Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[[1]](#footnote-2) 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 submitted a request[[2]](#footnote-3) for the continuation of the above-mentioned exemption. The request has been subject to a first completeness and plausibility check. The applicant has been asked to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation.[[3]](#footnote-4)

SUMMARY OF THE EXEMPTION REQUEST

The applicant requests the renewal of the above exemption2 with a slightly different wording and scope (c.f. below question 1) for the maximum 7 years:

*Lead in shielding and in collimators used for ionising radiation*

According to the applicant*2*,”*Lead and its alloys are used to make superconducting and thermal bonds to superconducting electromagnet coils of medical Magnetic Resonance Imaging (MRI) scanners. Superconducting materials must be used to achieve the very powerful magnetic fields needed to obtain clear MRI images. The bonding material that contains lead must be a superconductor as otherwise, the large current used to generate the powerful magnetic field would cause enough heat to raise the electromagnet coil’s temperature above the superconducting critical temperature; rapid heating would occur and the MRI would not function. Very few metals suitable for making bonds are superconductors at the temperature required for the magnet coils to be a superconductor and only lead and certain of its alloys meet all of the essential requirements which include an ability to be formed into a reliable bond.*

*This exemption needs to be renewed for the foreseeable future to allow new MRI to be sold in the EU as no substitute materials or designs exist with proven reliability for decades at low temperatures.*

*MRI manufacturers have assumed that exemption 11 is the applicable exemption for superconducting and thermal bonds made with lead or lead alloys in MRI. However, lead as a thermal conductor (used in cyrocoolers, cold heads, i.e. cryorefridgeration components) has been assumed to be covered by exemption 29 so does not also need to be included in exemption 11. COCIR has learned that some manufacturers, especially NMR manufacturers, rely on exemption 12 for lead in superconducting bonds to superconducting electromagnet coils used in both MRI and NMR. Only one of these exemptions would appear to be needed to cover superconducting and thermal bonds as described in this renewal request.”*

The stakeholder consultation is part of the review process for the request at hand. The objective of this consultation and the review process is to collect and to evaluate information and evidence according to the criteria listed in Art. 5(1)(a) of Directive 2011/65/EU.[[4]](#footnote-5)

To contribute to this stakeholder consultation, please answer the questions below by December 2nd, 2020.

# Questions

1. The applicant has agreed (c.f. clarification questionnaire3) to renew the exemption with the following wording for seven years, provided the renewal is in line with Art. 5(1)(a):

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

* 1. Please let us know whether you support or disagree with the wording, scope and re-quested duration of the exemption. To support your views, please provide detailed technical argumentation / evidence in line with the criteria4 in Art. 5(1)(a).
	2. If applicable, please suggest an alternative wording and duration and explain your proposal.
1. Please provide information concerning possible substitutes or elimination possibilities at pre sent or in the future so that the requested exemption could be restricted or revoked.
	1. Please explain substitution and elimination possibilities and for which part of the ap-plications in the scope of the requested exemption they are relevant.
	2. Please provide information as to research to find alternatives that do not rely on the exemption under review (substitution or elimination), and which may cover part or all of the applications in the scope of the exemption request.
	3. Please provide a roadmap of such on-going substitution/elimination and research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.
2. Do you know of other manufacturers producing devices of comparable features and performance like the ones in the scope of this exemption request that do not depend on RoHS-restricted substances, or use smaller amounts of these substances compared to the applications in the scope of this requested exemption?
3. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, if you have information on socioeconomic aspects, please provide details in respect of the following:
	1. What are the volumes of EEE in the scope of the requested exemptions which are placed on the market per year?
	2. What are the volumes of additional waste to be generated should the requested ex-emption not be renewed or not be renewed for the requested duration?
	3. What are estimated impacts on employment in total, in the EU and outside the EU, should the requested exemption not be renewed or be renewed for less than the re-quested time period? Please detail the main sectors in which possible impacts are expected – manufacturers of equipment in the scope of the exemption, suppliers, re-tail, users of medical devices, etc.
	4. Please estimate additional costs associated should the requested exemption not be renewed, and how this is divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers).
4. Is there any other information you wish to provide?

Please note that answers to these questions can be published in the stakeholder consultation, which is 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.

Please do not forget to provide your contact details (Name, Organisation, e-mail and phone number) so that the project team can contact you in case there are questions concerning your contribution.

1. It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017 [↑](#footnote-ref-2)
2. Exemption request available at <https://rohs.biois.eu/Ex_11-IV_COCIR_Renewal-Request.pdf> [↑](#footnote-ref-3)
3. Clarification questionnaire available at <https://rohs.biois.eu/Ex_11-IV_COCIR_Questionnaire-1_Clarification_Answers.pdf> [↑](#footnote-ref-4)
4. Directive 2011/65/EU (RoHS) available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT> [↑](#footnote-ref-5)