Consultation Questionnaire Exemption 26 of RoHS Annex IV

Current wording of the exemption:

Lead in the following applications that are used durably at a temperature below
 – 20 °C under normal operating and storage conditions:

(a) solders on printed circuit boards;

(b) termination coatings of electrical and electronic components and coatings of printed circuit boards;

(c) solders for connecting wires and cables;(d) solders connecting transducers and sensors. Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures
below – 150 °C.

Expires in June 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 and Lake Shore 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:

According to the applicants*2, COCIR submitted the application for category 8 medical imaging devices. Lake Shore supports the request but wants category 9 equipment to be included as well.
“Medical magnetic resonance imaging (MRI) scanners are large and very complex and utilise liquid helium cooled superconducting electromagnets. Associated with these magnets are wires, cables, sensors and control electronics some of which are at locations where the temperature is very low. Everything inside of the vacuum vessel of an MRI magnet during normal operation is at ~40K = -233 C (or less) and ~4.2K = -268.8C (or less). Everything at/on the outer vacuum vessel including service turret elements must withstand storage conditions to -25 C. During helium filling, ramping, quenching the service turret elements will experience temperatures below -150C as air is known to be liquefied in these conditions (Oxygen liquefies at -183C); the service turret and vent area is at cryogenic temperatures during such periodic operations or events. Manufacturers have built MRI circuits using tin/lead and lead-free solders and tested these at realistic use conditions of low temperature and vibration to compare the reliability with different solders. At low temperatures, the lead-free soldered circuits failed sooner than the tin/led circuits due to bond failure. It is not possible to determine whether tin pest failures will occur in the normal lifetime of an MRI because this failure mode cannot be accelerated and research has shown that this takes at least eight years to occur. MRI system once installed may be used for 15 – 25 years so published data on tin pest suggests that there may be a reliability concern with lead-free solders during this timescale, although this cannot be proven. However, the risk posed by tin pest is extremely high – if/when it occurs and impacts the entire magnet of the MRI system which would need to be replaced. The average cost of a single magnet replacement is >$250,000 which most EU hospitals can ill-afford. This exemption is justified as reliability of substitute solders is not ensured. MRI scanner designs are reviewed and modified by manufacturers to improve diagnostic capability and this may also reduce the amount of lead solders needed in some designs.*

*The latest magnet design of MRI uses only 7 litres of liquid helium instead of the usual ~1500 litres of liquid helium. This design includes control circuits that are at low temperature and suffer from vibration and so will continue to need this exemption. Examples of components with soldered lead connections are contactors that thermally disconnect the cold components after the magnet has been energized, as well as temperature and voltage sensors to monitor the condition of the magnet. This will be required until research can be carried out that determines whether any substitutes exist that will be reliable for up to 25 years lifetime.*

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 applicants ask for the renewal of the above exemption with the current wording and scope, but with different validity periods:

1. *Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions:*

*(a) solders on printed circuit boards;*

*(b) termination coatings of electrical and electronic components and coatings of printed circuit boards;*

*(c) solders for connecting wires and cables;*

*(d) solders connecting transducers and sensors.*

*Duration where applicable:*

* *Low helium content MRI (<10kg / scanner) Maximum validity period of at least 7 years*
* *Standard MRI: Until 30 June 2027*
1. *Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C.*

*Duration where applicable:*

* *• Categories 8 and 9 equipment: Maximum validity period of at least 7 years*
	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 applications 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 requests available at <https://rohs.biois.eu/Ex_26-IV_COCIR_Renewal-Request.pdf>, <https://rohs.biois.eu/Ex_26-IV_LakeShore_Renewal-Request.pdf> [↑](#footnote-ref-3)
3. Clarification questionnaire available at <https://rohs.biois.eu/Ex_26-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)