Consultation Questionnaire Exemption 29 of RoHS Annex IV

Current wording of the exemption:

Lead in alloys, as a 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, in medical devices (category 8) and/or in industrial monitoring and control instruments.

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 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 different wording and scope (c.f. below question 1) for the maximum 7 years:

According to the applicant*2, “Cryo-cooled cold probes are used in cryoablation therapy to generate local low temperatures in medical therapy to destroy abnormal or diseased tissue. The interface between the components of the cryo-cooled cold probe are joined together using lead-tin-silver solder. The solder wicks in between the components, joining them mechanically and thermally. The cryo-cooled cold probe functionality depends directly on its ability to cool (freeze) and heat (thaw) rapidly during a cryoablation procedure and so a high thermal conductivity of the solder is essential. In turn this is dependent upon the ability of the internal components including the cryostat (machined heat exchanger) to reach the desired temperatures rapidly and uniformly.*

*The lead alloy solder joints are required to be able to withstand a large amount of stress (mechanical, chock and temperature) while having suitable ductility. Due to the substrates the solder has to join (stainless steel, copper, and brass) and wick between the manufacturability of the joint is technically challenging.*

*Lead free solders of tin-silver and tin-copper have been trialled and deemed unsuitable, with current testing on tin-copper-silver solder being undertaken. Alternative technologies have been considered, including the use of brazing/welding, adhesives, mechanical bonds and additive manufacturing; all of which are unable to demonstrate the required technical performance required for cryo-cooled cold probes.”*

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 for 7 years:

*Lead in alloys as a thermal conductor in cryo-cooled cold probes in medical devices
(category 8)*

* 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 request available at <https://rohs.biois.eu/RoHS_V_Application_Form_29_COCIR.pdf> [↑](#footnote-ref-3)
3. Clarification questionnaire available at <https://rohs.biois.eu/Exe29-IV_COCIR_Questionnaire-1_Clarification.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)