Consultation Questionnaire Exemption 31a of RoHS Annex IV

Current wording of the exemption:

Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.

Expires on 21 July 2021 for categegory 8 and 9 equipment other than in-vitro diagnostics and industrial monitoring and control instruments.

# 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 has 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 re-quested to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation.[[3]](#footnote-4)

COCIR requested the renewal of the exemption for seven years with the same wording and scope like the current exemption (see above)2

*Lead, cadmium, hexavalent chromium, and deca-brominated diphenyl ethers (deca-BDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.*

Expires on:

1. (a)21 July 2028 for the use in medical devices other than in vitro diagnostic medical devices;
2. (b)21 July 2030 for the use in vitro diagnostic medical devices

The applicant summarizes the request as follows:

*“Medical devices are frequently refurbished by the original manufacturer for reuse after they have been used by first users. Many refurbished medical devices are sold in the EU as EU hospitals have limited budgets and refurbished equipment provides the capability that they need and the lower prices allows hospitals to buy additional medical equipment and therefore offer a better healthcare to patients. Refurbishment uses recovered spare parts (which have also been refurbished themselves) as using new parts is not an option because they are no longer produced. Recovered and refurbished parts are also reused as spare parts for repair and maintenance of the installed base in the EU. Reuse of only some parts is permitted by RoHS without exemption 31a so that without this exemption, reused parts cannot be used in the EU as it is not possible to know if the part is covered by an exclusion or not.*

*Reuse of parts is always preferable to disposal as waste and manufacture of a replacement part. The overall health and environmental impact of reuse is shown, using life cycle assessments, to be significantly smaller than the overall impacts from disposal of parts as waste and manufacture of a replacement parts. There are also qualitative human health impacts, if limitations occur for the refurbishment market. Delays in hospitals being not able to afford new replacement equipment mean that old less reliable equipment has to be used for a longer time, or delays to treatment would be caused, if bigger upgrades (including making new replacement parts) would need to be performed, because adequate spare parts are not available.”*

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 requested the renewal of exemption 31a of RoHS Annex IV with the above-cited wording.
	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.
2. 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 MRI 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).
3. Is there any other information which you would like 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_31a-IV_COCIR_Renewal-Request.pdf> [↑](#footnote-ref-3)
3. Clarification questionnaire available at <https://rohs.biois.eu/Ex_31a-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)