Consultation Questionnaire Exemption 17 of RoHS Annex IV

Current wording of the exemption:

Lead in solders of portable emergency defibrillators (category 8)

Expires on 21 July 2021 for cat. 8 and 9 devices 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)

According to the applicant2, “*Portable emergency defibrillators are used to save lives when people suffer from heart attacks. Patients whose hearts have stopped must be treated within 10 minutes for survival to be possible. Defibrillators must be very reliable as any defects could result in a fatality. There are many types of defibrillator sold in the EU that rely on exemption 17 and manufacturers have been working on substitution for many years, however substitution of lead is not straightforward. Usually redesign is necessary as older designs often include components that contain lead with no lead-free alternative available. Redesign introduces uncertainty over the reliability and usually it is preferable to develop new designs instead, as these can be designed for maximum reliability and also utilise the latest medical science on survival from heart attacks. An added complication is that the Medical Device Directive is being replaced by the Medical Device Regulation, which requires all medical devices sold in the EU to be submitted for re-approval by EU Notified Bodies. Defibrillator manufacturers have estimated that the current work on new models will be completed and approvals granted by the end of 2025, at which time the lead soldered models can be discontinued.*“

The applicant requests a renewal of this exemption until the end of 2025.

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 the above exemption with the same scope and wording until the end of 2025.
   1. Please let us know whether you support or disagree with the wording, scope and re-quested duration of the exemption. Please take into account that the applicant already had 9 years to replace the defibrillator models with new lead-free designs and check the applicant’s justification in the application form. To support your views, please provide detailed technical argumentation / evidence in line with the criteria4 in Art. 5(1)(a). Please take into account that the applicant already had 9 years to replace the defibrillator models with new lead-free designs and check the applicant’s justification
   2. If applicable, please suggest an alternative wording and duration and explain your proposal.
2. 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.
3. 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 exemption?
4. 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).
5. There are limitations to the types of use environments for some defibrillators. Some models have been designed for harsher use scenarios (e.g. in battlefield, commercial aircraft, marine environments and helicopters) whereas hospital versions of defibrillators are intended to sit on a stable cart. Is it possible to change in particular the current models for hospitals, public institutions and private applications faster than by the end of 2025?

**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_17-IV_COCIR_Renewal-Request.pdf> [↑](#footnote-ref-3)
3. Clarification questionnaire available at <https://rohs.biois.eu/Exe-17-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)