

Questionnaire Exemption Request No. 2013-3

Exemption for Lead in solders used in boards of heart-lung machines

Background

The Öko-Institut together with Fraunhofer IZM has been appointed within a framework contract for the evaluation of applications for granting, renewing or revoking an exemption to be included in or deleted from Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.¹

The Maquet Cardiopulmonary AG has applied for an exemption of²

Lead in solders of printed circuit boards in

- a) heart-lung machines, exemption to expire in December 2015*
- b) centrifugal pumps that can be used as components of heart-lung-machines and as stand-alone devices; exemption to expire in December 2017*

The applicant puts forward the following main arguments:

Lead-free soldering and the use of lead-free electrical and electronic components are state of the art. Many of these components used in the heart-lung-machine (HLM) are, however, not available as drop-in lead-free versions, and a redesign of the printed wiring boards is therefore required. Since the HLM are life-supporting medical equipment, the redesigned devices must be tested and approved according to Directive 93/42/EC, which together with the redesign work requires time beyond July 2014.

For details, please check the applicant's exemption request at:

<http://rohs.exemptions.oeko.info/index.php?id=183>.

¹ Contract is implemented through Framework Contract No. ENV.C.2/FRA/2011/0020 led by Eunomia

² To avoid confusion, the applicant updated its originally proposed exemption wording "Lead in solders used in boards of heart-lung machines" to include the centrifugal pump as well, which are part of the applicant's exemption request.

This exemption request has been subject to a first completeness and plausibility check. The applicant has been requested to answer additional questions and to provide additional information (c.f. link above).

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 (RoHS II), which can be found under:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT>.

If you would like to contribute to the stakeholder consultation, please answer the following questions:

Questions

1. The above wording was suggested by the applicant for this exemption.
 - a. Do you agree with the scope of the exemption? Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.
 - b. Please state whether you either support the applicant's request or whether you would like to provide argumentation against the applicant's request. In both cases provide detailed technical argumentation / evidence in line with the criteria in Art. 5 (1) (a) to support your statement.
2. Are centrifugal pumps as mentioned in the exemption request only used in heart-lung-machines (cat. 8), or possibly also in or as devices relevant for other categories of equipment according to Annex I of the RoHS Directive?
3. The applicant cannot provide any quantities of lead used in this application. Please quantify how much lead is used in the application for which the exemption is requested. Please quantify for the EU, if possible. Estimation is fine in case you do not have exact data. Please elaborate as to assumptions and calculations.
4. Please provide information concerning the time needed for redesign, requalification and approval of heart-lung-machines and centrifugal pumps. Please detail your statement with the various steps needed and the related timelines.

5. Please provide evidence if the negative environmental, health and/or consumer safety impacts caused by substitution are likely to outweigh the environmental, health and/or consumer safety benefits. If existing, please refer to relevant studies on negative impacts caused by substitution.

In case parts of your contribution are confidential, please clearly mark relevant text excerpts or provide your contribution in two versions (public /confidential).

Finally, please do not forget to provide **your contact details** (Name, Organisation, e-mail and phone number) so that Öko-Institut/Fraunhofer IZM can contact you in case there are questions concerning your contribution.