Questionnaire Exemption Request No. 12

Exemption for "*Leaded solder used to create stacked, area array electronics within ionizing radiation detectors used in CT and X-ray systems until 31 December 2019 and in spare parts for CT and X-ray systems placed on the EU market before 1 Jan 2020*"

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]

GE Healthcare (GE) has applied for an exemption of *"Leaded solder used to create stacked, area array electronics within ionizing radiation detectors used in CT and X-ray systems until 31 December 2019 and in spare parts for CT and X-ray systems placed on the EU market before 1 Jan 2020"*

The applicant puts forward the following main arguments.

- Summary of the exemption request
  A new digital X-ray detector architecture is being developed that will allow reducing patients' exposition to X-ray by approximately 20% to 25% to achieve equivalent image quality. This design requires the use of a solder alloy containing lead. The interconnects within these architectures require a lower temperature solder with superior wetting and reflow qualities that is compatible with the stacked assembly requirements and the only viable solution found has been eutectic Pb/Sn solder. Research has been carried out with a SAC solder but this gives unsatisfactory performance and no other lead–free solder fulfills all of the essential requirements. All alternative designs of digital silicon X-ray detectors require higher X-ray doses to the patient which have been shown to increase the risk of side-effects such as cancer.

For details, please check the applicant's exemption request at http://rohs.exemptions.oeko.info/index.php?id=154. 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).

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

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 you can download from here:

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 wording suggested by the applicant for this exemption would be **"*Leaded solder used to create stacked, area array electronics within ionizing radiation detectors used in CT and X-ray systems until 31 December 2019 and in spare parts for CT and X-ray systems placed on the EU market before 1 Jan 2020*"**
    a. Do you agree with the scope and timing of the exemption as proposed by the applicant? Please suggest an alternative wording and timing, and explain your proposal, if you do not agree with the proposed exemption wording.

2. 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:
    a. please provide detailed technical argumentation / evidence in line with the criteria in Art. 5 (1) (a) to support your statement incl. information concerning possible substitutes or developments that may enable substitution or elimination at present or in the future.
    b. please indicate 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.

3. GE applies for this exemption, but GE is not the only medical equipment manufacturer offering digital detectors for diagnostic systems based on X-ray. GE puts forward that the exemption would enable reducing the X-ray dosage for patients and maintaining image quality at the same time.
    a. Please provide information whether other medical equipment manufacturers depend on this exemption as well to achieve an equivalent performance with digital detector systems: lower dosage of X-ray at good image quality

b. If other manufacturers have designs that do not require the use of lead in the detectors, but achieve a similar performance, please provide arguments why the GE-solution requiring the requested exemption still might be justified.

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.