

Questionnaire Exemption Request No. 3

“Lead in solders used on detector and data acquisition unit printed circuit boards of PET/MRI scanners”

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.

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has applied for an exemption for “Lead in solders used on detector and data acquisition unit printed circuit boards of PET/MRI scanners”.

The applicant puts forward the following main arguments:

1. The applicant states that PET/MRI is a relatively new technique which uses an array of complex high component density printed circuit boards that will experience severe vibration for long periods in use. Research has shown that lead-free solders that have been investigated for vibration susceptibility are more vulnerable to early failure under severe vibration conditions than bonds made with tin/lead solder and so PET/MRI could fail prematurely if lead-free alloys were used.
2. According to the applicant, in most aspects, lead free solders showed inferior reliability and susceptibility to various conditions (malfunction due to vibration, thermal fatigue failure, tin whiskers etc.). It is further mentioned that acceleration factors for testing lead-free solders are not yet known because lead-free solders have not been used in this type of environment for sufficiently long periods. For this reason conclusions concerning the reliability of substitute solder are limited in respect to approving substitutes for use in medical devices.
3. The applicant mentions a life cycle impact analyses conducted by the US Environmental Protection Agency (EPA) concerning the alternatives SnPb solder and several lead-free solders. The analyses concluded that for the majority of environmental impacts, lead-free solders had greater negative impacts than the tin/lead solder they replace.
4. PET/MRI equipment is large, complex and contains valuable metals that can be recovered for re-use. The applicant states that this type of medical device will nearly

always be recycled by professional recyclers who recover metals with high yields and comply with national emission legislation.

5. According to the applicant, research into a lead-free soldered version, of the detector and of the PET/MRI's Data Acquisition Units' (DAU) Printed Circuit Boards (PCB), will be needed to ensure reliability of devices applying lead free solders. The applicant estimates that such research will require 8-9 years, including approval of equipment for use.

Reference to an exemption which might be related to the request for exemption at hand can be found under results previous evaluations

(http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_3/Request_3_4_Results_Previous_Monthly_Report_7_2006.pdf). The referenced exemption, referring to vibration conditions for "Lead in solders for transducers used in loudspeakers with sound pressure levels of 100 dB (A) and more for products that have to suffice the test requirements of the standard EN54-3" was reviewed and granted in 2006, set 2, request No 16. This exemption was reviewed again in 2009 and as there was no support for continuation throughout the stakeholder consultation, renewal was not granted.

For details, please check the applicant's exemption request at <http://rohs.exemptions.oeko.info/index.php?id=131>.

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).

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

Questions

1. 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 please provide detailed technical argumentation / evidence to support your statement.
2. The applicant provided in his request for exemption an analysis of possible alternatives, for each discussing the material specific properties. Is there any supporting / contradicting evidence that you can provide?
3. Are there any other arguments being relevant in the context of the evaluation of this request for exemption which are not raised in the questions above and that of importance?

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.