Consultation Questionnaire for Annex IV Ex. No. 12 (renewal request with restricted scope)

for „Lead in metallic bonds creating superconducting circuits in MRI (Magnetic Resonance Imaging) or NMR (Nuclear Magnetic Resonance)"

Abbreviations and Definitions

FTMS	Fourier Transform Mass Spectrometer
JASTEC	Japan Superconductor Technology, Inc.
MRI	Magnet Resonance Imaging
NMR	Nuclear Magnetic Resonance
Pb	Lead
SQUID	Superconducting Quantum Interference Devices

Background

The Oeko-Institut and Fraunhofer IZM have been appointed by the European Commission, within a framework contract[1], for the evaluation of applications for exemption from Directive 2011/65/EU (RoHS 2), to be listed in Annexes III and IV of the Directive.

The Japan Superconductor Technology, Inc. (JASTEC) has submitted a request for the above mentioned exemption, which has been subject to a first completeness and plausibility check. The applicant has been requested to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation (http://rohs.exemptions.oeko.info/index.php?id=351).

JASTEC submitted the request to renew the exemption for MRI and NMR devices only. SQUID and FTMS detectors are excluded from the scope of JASTEC's requested exemption so that the exemption, should the renewal be granted as requested would be restricted in scope compared to the current wording of exemption 12: *"Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors".*

NMR spectrometers, used for chemical analysis, and MRI scanners, used for medical imaging, employ powerful electromagnets made with superconducting wires that are connected to each other and to the power supplies using superconducting solder bonds. Soldering has been found to be the only consistent and reliable method for making electrical connections and solders based on lead are the only materials that have a sufficiently high critical field value (the maximum allowable field where superconductivity persists) of over 1 Tesla to be used within the electromagnet cryostat. All lead-

[1] The contract is implemented through Framework Contract No. FWC ENV.A.2/FRA/2015/0008 of 27/03/2015, led by Oeko-Institut e.V.

free solder materials have much lower critical field values that are too small for a use in this application.

JASTEC has carried out trials using lead-free solders as substitutes, but the measured critical current values (at which non-dissipative current flows) were too low and were smaller than the currents typically used for NMR and MRI. Research into alternative bonding methods is published, but this work is at an early stage and will take many more years and may prove to be unsuitable.

The applicant requests a renewal of this exemption for the maximum possible validity period of seven years.

For details, please check the applicant's exemption request at:
http://rohs.exemptions.oeko.info/index.php?id=351

Questions

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:

1. The applicant has requested the renewal of exemption 12 in RoHS Annex IV based on the current wording but with limited scope:

   "„Lead in metallic bonds creating superconducting circuits in MRI (Magnetic Resonance Imaging) or NMR (Nuclear Magnetic Resonance)"

   The exemption request does not include SQUID (Superconducting Quantum Interference Devices) and FTMS (Fourier Transform Mass Spectrometer) detectors which are part of the currently still valid exemption 12 of Annex IV.

   Please explain why you either support or object the requested exemption. To support your views, please provide detailed technical argumentation / evidence in line with the criteria in Art. 5(1)(a) to support your statement.

   a. Do you agree with the scope of the exemption as proposed by the applicant?

   b. If you agree to the scope, are lead-free solutions available for SQUIDs and FTMS detectors?

   c. Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.

2. Please provide information concerning possible substitutes or elimination possibilities at present or in the future so that exemption 12 could be restricted or revoked;

   a. JASTEC states that only lead-containing solders so far have been found to provide the properties required to create reliable bonds in magnetic circuits of MRIs or NMRs. Do you share this argument?

   b. If lead-free solutions are available for SQUID and FTMS detectors, could they be used for MRI as well?

   c. JASTEC is not the only manufacturer of MRI devices. Do you know of other manufacturers of such devices who have a lead-free solution for the use of lead in the scope of the requested exemption?

3. Please provide information as to research initiatives which are currently looking into the development of possible alternatives for some or all of the application range of exemption 12.

   a. Please explain how the research is of relevance for the application in the scope of the requested exemption, i.e. how such a solution may help to substitute or eliminate lead in the future.

   b. Please provide a roadmap of such on-going research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages towards the substitution or elimination of lead.

4. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, please provide details in respect of the following:

   a. What are the volumes of EEE in the scope of exemption 12 which are placed on the market per year?

   b. What are the volumes of additional waste to be generated should the exemption 12 not be renewed or be renewed for less than 7 years?

   c. What are estimated impacts on employment in total, in the EU and outside the EU, should the exemption not be renewed or be renewed for less than 7 years? Please detail the main sectors in which possible impacts are expected – manufacturers of equipment in the scope of the exemption, e.g. producers of MRI devices, manufacturers in the supply chain, retail, users of MRI devices, etc.

   d. Please estimate additional costs associated with a forced substitution should exemption 12 not be granted, and how this is divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers).

In case parts of your contribution are confidential, please provide your contribution in two versions (public /confidential). Please also note, however, that requested exemptions cannot be granted based on confidential information!

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