Consultation Questionnaire for Annex IV Ex. No. 27 (renewal request)

for *"Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in (a) magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy"*

Abbreviations and Definitions

COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
MRI	Magnetic Resonance Imaging

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 European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) 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=344).

Magnetic Resonance Imaging (MRI) is a 3D medical imaging technique used to examine soft tissue. It relies on a very powerful electromagnet and images are sensitive to any magnetic materials that are used in circuitry that is inside and close to the electromagnet. As a result, special non-magnetic components must be used which so far cannot be soldered with lead-free solders.

According to the applicant, substitution work has been underway since 2011 but is not yet complete and so more time is needed before MRI coils and circuits can be constructed with lead-free solders without negatively affecting image quality or EU healthcare provision.

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

[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.

For details, please check the applicant's exemption request at:
http://rohs.exemptions.oeko.info/index.php?id=344

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 2), 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 applicant has requested the renewal of exemption 27 in RoHS Annex IV with the current wording:

   "Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in
   (a) magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or
   (b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy"

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

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

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

2. Please provide information concerning possible substitutes or elimination possibilities at present or in the future so that exemption 27 could be restricted or revoked:

   a. Please detail substitution and elimination possibilities and for which part of the applications in the scope of the requested exemption they are relevant.

   b. Please provide information on research to find lead-free alternatives (substitution or elimination) that may cover part or all of the applications in the scope of the exemption request. COCIR states, for example, that special non-magnetic components have to be used to achieve high quality images. According to COCIR, the work on substituting these components in order to allow the use of lead-free solder or other lead-free alternatives has been underway since 2011.

   c. 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 which do not depend on using lead or other substances that are regulated under the RoHS Directive?
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 27 which are placed on the market per year?
    b. What are the volumes of additional waste to be generated should exemption 27 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 the exemption 27 not be renewed, 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.