Response to: Consultation Questionnaire Exemption Request No. 2020-1 (pack 19)

Exemption 12 for *„Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors"* to be added to Annex IV

Based on the application for exemption issued by JASTEC and the consultation questionnaire from the Öko-Institut, COCIR hereby respectfully provides the following input.

Q.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)*"

COCIR has submitted a separate exemption renewal request for exemption 11 *'Lead and its alloys as a superconductor and thermal conductor in MRI' which is similar in scope. Only one of exemption 11 or exemption 12 would appear to be needed to cover lead in superconducting bonds.*

Q.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?

COCIR agrees with this statement that lead containing alloys are essential to create reliable bonds for MRIs. COCIR cannot comment on uses in NMR.

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

No as the requirements are very different. Lead and its alloys are required to make superconducting and thermal bonds to superconducting electromagnet coils MRI scanners, without which MRI scanners would not produce the clear images essential for medical diagnosis. Only lead and its alloys are suitable for making bonds that are superconductors at the temperature required for the MRI magnet coils to be superconducting and also meet all of the essential requirements which include an ability to be formed into a reliable bond. This is explained in COCIR's exemption 11 renewal request.

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?

COCIR represents multiple MRI device manufacturers, all of whom require an exemption for lead in superconducting bonds to MRI magnets.

Q.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.

On-going research and timeframes of further stages are detailed in COCIRs exemption 11 renewal application.

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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.

Q.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:

The impact of the exemption are detailed in COCIRs exemption 11 renewal request.

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.

Without exemption 12 or exemption 11, EU hospitals would not be able to buy new MRI equipment that they need to treat patients. Old equipment becomes increasingly unreliable as it ages so that it will increasingly, as it ages, not be usable. Also, modern designs can provide superior diagnostic capability compared to older models. For some exams other diagnostic modalities, such as CT could be used, with the result of unnecessary exposure of patients to ionizing radiation. Therefore, there would be a gradual deterioration in overall health of EU citizens, as users of MRI devices, without this exemption.

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).

Forced substitution is impossible so the result would be deteriorating health of EU citizens.