Questionnaire 1 (Clarification) Exemption 26 of RoHS Annex IV

Requested wording for the renewed exemption:

i) Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions:

(a) solders on printed circuit boards;
(b) termination coatings of electrical and electronic components and coatings of printed circuit boards;
(c) solders for connecting wires and cables;
(d) solders connecting transducers and sensors.

Requested validity:
• Low helium content MRI (<10 kg per scanner): Maximum validity period of at least 7 years
• Standard MRI: Until 30 June 2027

ii) Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C.

Requested validity:

Categories 8 and 9 equipment: Maximum validity period of at least 7 years

1. Acronyms and Definitions

MRI magnetic resonance imaging

2. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

COCIR has submitted a request for the renewal of the above-mentioned exemption, which has been subject to a first review. As a result we have identified that there is some information missing. Against this background, the questions below are intended to clarify some aspects concerning the request at hand.

We ask you to kindly answer the below questions until 21 August latest.

3. Questions

1. It seems that lead-free solutions are available for applications in the scope of exemption 26-I for standard MRI after June 2027.

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

a. Could you please give insights into these lead-free approaches?

b. Could they be expanded to other applications as well?

The current situation is the MRI manufacturers are carrying out research into lead-free substitutes. Each manufacturer has their own proprietary designs of MRI and so is likely to be investigating different substitution strategies, however as results of this research has not yet been patented, it is not possible for MRI manufacturers to divulge this information. It seems reasonable to assume that options being considered for 26-I are likely to be both the redesign of the MRI and use of various lead-free solder alloys. Manufacturers are also likely to be considering these options as substitutes for other applications, but this is expected to take longer.

It is important to note that unlike failures in any other MRI part, failure of a single solder bond within the magnet cannot be easily repaired. It is of the utmost importance to ensure failures are repaired in the shortest time possible to allow the hospital to continue running the imaging equipment. Any downtime of the equipment would delay the imaging and diagnosis of patients and in small hospitals (who own only one MRI) will require the transfer of patients to other hospitals sometime in other cities, increasing the strain on MRI imaging. For this reasons MRI are designed to be easily repairable. Broken parts are swiftly replaced with new ones or with refurbished ones (which may be covered by exemption 31a). Availability of parts is crucial. Unfortunately though, the magnet is the main component of an MRI (typically weighing 5 tons, out of 8, on average) and as such the magnet cannot be substituted. The entire MRI would need to be de-installed from the hospital, shipped for repair and then reshipped back causing a downtime of at least several weeks.

For this reason, the reliability of the magnet and its component electronics must be absolute with an expected lifetime of at least 13 years including a second life as a refurbished MRI. Testing of alternatives is a rigorous process to ensure a suitable solution which cannot be rushed.

2. Exemption 25 of RoHS Annex IV will expire in June 2021.

   a. Which solutions were found to avoid the use of lead in applications in the scope of exemption 25?

   b. Can (some of) these solutions be applied to applications in the scope of exemption 26 as well?

These connectors are not used in any products made by COCIR's members, so COCIR is not able to answer this question. However it is possible that renewal of 25 was not requested because these applications are covered by other exemptions and there is no need for this use of lead to be covered by two exemptions.

3. Exemption 27 was reviewed recently, and it was found that lead-free solutions have become available that allowed to restrict the exemption scope and validity period. Can these lead-free solutions as well be applied for applications in the scope of exemption 26?

The lead-free solutions described in COCIRs exemption 27 renewal request refer to printed component in coils, which are placed next to patients and so are not used at very low temperatures. Only certain types of capacitors, resistors and inductors with limited properties can be printed and so all other electronic components must be used as discrete devices that are soldered to printed circuit boards. As explained in the exemption renewal request, research by MRI manufacturers has shown that at low temperatures, lead-free solders become very hard and brittle so that in cold MRI circuits which also experiences severe vibration, these

solder bonds suffer from fatigue cracking and rapidly fail. Exemption 27 covers applications that are not at low temperature and solder alloys are significantly more ductile at ambient temperature than at temperatures below -20°C.

Exemption 27 mentions the use of printed components in coils, which if this approach was to be applied for applications in the scope of exemption 26 would require the redesign of all PCBs in the MRI, with testing at temperatures below -20°C. The timeframes for the completion of such a tasks would be a substantial amount of time.

4. In the application for exemption 11 of Annex IV you describe spot welding as a potential technique to eliminate the use of lead, and about approaches to overcome the low critical current of the welded bonds. You mention in the request for exemption 26 that the temperatures of welding are too high and would destroy the polymer insulation of circuit laminates and electronic components so that welding cannot be used. Would this not happen as well if welding was applied for lead solder applications in the scope of exemption 11?

   Spot welding (described in COCIR's exemption 11 request) was researched by the University of Oxford as a possible alternative method for bonding Niobium alloy wires.

   Welding is a much higher temperature process than soldering as it involves melting the base metals of the two items being joined, typically joining two similar metals together. Soldering introduces a new low melting point metal filler material to join parts together. Often, the two metals of the parts are different, and the alloy of the solder is another type of metal entirely. The solder alloy has a much lower melting point than that of the other parts being joined. For example, a lead solder operation typically occurs slightly above the 183°C melting point of 63Sn37Pb solder. In order to join copper wires by welding, the 1085°C melting temperature of copper would need to be exceeded. Even if the copper melting temperature is exceeded only locally at the wire joint, the excellent thermal conductivity of copper wire puts nearby components at extreme risk of being subjected to temperatures higher than they can withstand.

   For exemption 11, wires are embedded in copper metal so there are no polymeric materials present that would be damaged by the very high welding temperature. Exemption 26 is for applications in which bonding to polymer laminates and to electronic components, which contain polymers and so high temperature bonding processes are technically impractical as they would destroy the polymeric materials.

Please note that answers to these questions will be published as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.