

Questionnaire Exemption Request No. 9

“Lead in solders and solderable coatings used on non-magnetic components and circuits that are used in magnetic fields or are associated with circuits used inside strong magnetic fields”

Background

COCIR applies for an exemption for “Lead in solders and solderable coatings used on non-magnetic components and circuits that are used in magnetic fields or are associated with circuits used inside strong magnetic fields”.

The applicant puts forward the following main arguments.

- a) Medical devices such as Magnetic Resonance Imaging (MRI) and analysis techniques using very powerful magnets cannot use magnetic materials in their construction. Magnetic materials would be strongly attracted and could cause damage, and they may distort the magnetic resonance image. This disables the use of standard electronic components containing nickel, which is magnetic. Special nonmagnetic, nickel-free components are used.
Reliable solder joints on such nickel-free component terminations are difficult to produce with lead-free solders. Manufacturers have encountered poor yields and high rates of failures. Poor reliability is unacceptable for health critical medical devices.
- b) Suitable lead-free solder alloys and production processes are not available. The applicant therefore requests an exemption to give manufacturers sufficient time to complete their research and obtain the reliability data that will be needed to obtain approval under the Medical Devices Directive.

For details, please check the applicant’s exemption request at <http://rohs.exemptions.oeko.info/index.php?id=116>. 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 in line with the criteria in Art. 5 (1) (a) to support your statement.
2. Do you agree with the scope of the exemption as proposed by the applicant? Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.
3. The applicant does not propose an expiry date, which means that the exemption would have a maximum validity until 2021. Do you agree with this expiry date, or would an earlier expiry be feasible in the face of upcoming lead-free solutions?
4. Do you consider any other aspects or details to be of importance, which have not yet been taken into account?

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.