Questionnaire Exemption Request No. 4

"Lead in solders used in mobile medical equipment"

Background

The Öko-Institut together with Fraunhofer IZM has been appointed within a framework contract for the evaluation of applications for granting, renewing or revoking an exemption to be included in or deleted from Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has applied for an exemption for "Lead in solders used in Directive 93/42/EEC Class IIa and IIb portable and mobile medical devices where the medical devices need to be transported on a cart or trolley, hand-held diagnostic devices, hand carried devices such as portable ventilators, those transported in a vehicle such as an ambulance or helicopter to the designated location of use and medical devices that are operated while being carried such as patient worn devices".

The applicant puts forward the following main arguments:

1. The applicant explains that medical equipment must have high reliability as unexpected failures can be fatal. Many types of medical devices may be constructed using lead-free solders but once medical devices are designed for mobile use, given the conditions typical of mobile equipment, use of lead solders cannot always be avoided. Equipment transported in ambulances, helicopters or around hospitals, often having life-critical functions, may suffer from high G impacts, severe vibration and experience frequent large temperature changes. Tin/lead (SnPb) solder has been found to be reliable under these conditions but research has shown that there is no lead-free substitute alloy that has the same or better reliability under all of these conditions.
2. According to the applicant mobile medical equipment may be categorized according to the Medical Device Directive, 93/42/EEC, classifications stated in Annex IX of the Directive and these include:
    a. Class IIB products – equipment in which malfunction may result in irrevocable harm to the patient within minutes – this includes automated CPR equipment, ventilators, Infant apnea monitors, CO2 sensors

   b. Class IIA equipment – malfunction may also have serious consequences although in general, les severe than class IIB – these include patient worn devices, portable ultrasound and portable monitors
3. The extreme conditions cited by the applicant, as conditions that mobile equipment may be susceptible to include:
   a. Severe vibration conditions
   b. Large temperature fluctuations
   c. High humidity conditions
   d. Shocks from being dropped or being or bumping into other objects
      a. All of these conditions are known to cause solders bonds to fail. According to the applicant tin/lead (SnPb) solders and lead-free solders are known to behave differently and research has shown that under some circumstances, lead-free solders are less reliable than SnPb.
4. The long-term field reliability of lead-free solders is uncertain as they are relatively new and so manufacturers have not been able to collect sufficient field data to reliably predict product lifetimes (for products with long service lives). Methods of estimating product lifetimes are being developed but there is some uncertainty because field data is not yet available to validate these predictions. The applicant mentions some testing that has been carried out with EE to assess tendency of malfunction under the above mentioned conditions. Though testing cannot as of yet be regarded as comprehensive, results cited by applicant demonstrate that comparison of tin/lead solder to lead free solders is complex. For example, in vibration testing and drop/shock testing, it has shown that tin/lead solders are superior to lead free solders. Testing results concerning temperature fluctuations are inconclusive and may vary depending on the rate of temperature change; composition of solder alloy etc. and results concerning susceptibility to corrosion were usually in favour of lead free solders. On this background, it is assessed that in order to fully establish any new alloy or materials' characteristics and properties as a suitable subtitute, it will take up to 8 years of effort and data collection.
5. The applicant states that in the EU, waste medical equipment is very unlikely to be recycled except by professional recyclers using well controlled safe processes. This is true as long as equipment is recycled within the EU where processes and methods are regulated.

The applicant has proposed a more specific wording for the exemption, mentioning the covered applications to which the exemption will apply should it be granted: "Lead in solders used in Directive 93/42/EEC Class IIa and IIb portable and mobile medical devices where the medical devices need to be transported on a cart or trolley, hand-held diagnostic devices,

hand carried devices such as portable ventilators, those transported in a vehicle such as an ambulance or helicopter to the designated location of use and medical devices that are operated while being carried such as patient worn devices".

Reference to an exemption which might be related to the request for exemption at hand can be found under results previous evaluations (http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_3/Request_3_4_Results_Previous_Monthly_Report_7_2006.pdf). The referenced exemption, referring to vibration conditions for "Lead in solders for transducers used in loudspeakers with sound pressure levels of 100 dB (A) and more for products that have to suffice the test requirements of the standard EN54-3" was reviewed and granted in 2006, set 2, request No 16. This exemption was reviewed again in 2009 and as there was no support for continuation throughout the stakeholder consultation, renewal was not granted.

For details, please check the applicant's exemption request at http://rohs.exemptions.oeko.info/index.php?id=134.

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 to support your statement.
2. The applicant provided in his request for exemption an analysis of possible alternatives, for each discussing the material specific properties. Is there any supporting / contradicting evidence that you can provide?
3. Are there any other arguments being relevant in the context of the evaluation of this request for exemption which are not raised in the questions above and that of importance?

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.