Questionnaire No. 14

"Lead in alloys as a superconductor and thermal conductor in devices that depend on superconductivity for their operation"

Background

The Öko-Institut together with Fraunhofer IZM has been appointed for the technical assistance in reviewing the requests for exemptions from the requirements of the RoHS Directive 2011/85/EU (RoHS II) by the European Commission. You have submitted the above mentioned request for exemption which has been subject to a first completeness and understandability check.

As a result we have identified that there is some information missing and a few questions to clarify before we can proceed with the online consultation on your request. Therefore we kindly ask you to reformulate your request taking the following points into consideration.

Questions

The exemption request is covered by Annex IV exemption 11 "Lead in alloys as a superconductor and thermal conductor in MRI"

1. Please explain why you consider category 9 equipment not to fall under the scope of this existing exemption. The phrasing of exemption 11 does not restrict it to category 8 equipment.

   In the ERA report 2006-0383 section 10.11.4 it states Nuclear Magnetic Resonace (NMR) and Magnetic Resonance Imaging (MRI), use superconducting magnets. Managing the use of liquid helium requires a refrigeration unit (Cryo-cooler) that is the device which the Pb is required related to this exemption. In the final exemption 11 wording, the only application of the generated magnetic field is Magnetic Resonance Imaging (MRI), This does not cover sufficient applications for category 8 as noted in the ERA report 2006-0383 nor any category 9 applications. **Consequently we suggest to align wording of our request to "Lead in alloys as a superconductor and thermal conductor in NMR, MRI and MEG".**

   Understanding differences between NMR and MRI is as follows. **Nuclear magnetic resonance** is the study of molecular structure by means of the interaction of radiofrequency (RF) electromagnetic radiation with a collection of nuclei immersed in a magnetic field. **Magnetic resonance imaging** is a branch of NMR that uses manipulations of the magnetic field to encode spatial information into the NMR signal. This enables an MRI experiment to produce an image. NMR is very widely used because its flexibility enables analysis of solids, liquids, liquid crystals and even nano materials. Even "squishy" materials – such as gels, resins or tissue samples – which are very hard to analyse with any other technique, can be analysed. Furthermore samples can be analysed in a non-destructive fashion. In **biological NMR**, the technology is used by pharmaceutical companies in drug discovery; note also this is not a MRI medical application. NMR can determine the structure of proteins and nucleic acids in complex molecules.

2. Please explain in more technical detail for which application the exemption should be valid: “superconductors and thermal conductor in devices that depend on superconductivity” is not specific enough. Could you elaborate more on this specific application?

   In an MRI system the lead in alloys as a superconductor and thermal conductor is required in a device that is used as part of thermal management of the cryogenic liquid helium bath. As stated in ERA report “Additional Exemptions from the RoHS directive needed by the medical industry section 3.2.1 and ERA report 2006-0383 section 10.11.4. The device is known as a cryocooler. This is the device that is dependent on the use of Pb for its operation. These devices are used in many applications that required refrigeration down to cryogenic temperatures. Agilent Technologies and our OEMs require the use of these devices in both their MRI and NMR products.

3. Please indicate in more detail the functionality and technical necessity of lead superconductor and thermal conductor in devices that depend on superconductivity in the mentioned applications(MRI, NMR, FTMS).We would need to understand which technical properties of the substances are needed for the specific applications.
   The requirements of the of these units and technical necessities of lead are described above and in section ERA report “Additional Exemptions from the RoHS directive needed by the medical industry” section 3.2.1. The field generated by a superconducting magnet can be used for many applications, including and not limited to MRI and NMR.

4. Please, specify the type and quantity of the leadin absolute numbers and in percentage by weight in homogenous material.Please also provide an estimate of the

annual quantities of the lead used in particular applications(MRI, NMR, FTMS, MEG Systems).

This data can only be supplied by the cryo-cooler vendors, as these cold heads are bought-in by Agilent Technologies, Inc.

5. In the COCIR study report in section 3.2.1it is reported that substitutes are available (rare earth metal as nickel alloy, helium).

   Why have no research activities yet been done on these mentioned possible substitutes and whatwas the outcome to prove your argumentation that no success is guaranteed?
   The study gives several reservations concerning substitutes including "all rare earth metals are strongly paramagnetic and so would be highly detrimental to the sensitivity of these machines." Data on true availability of potential substitutes can only be supplied by the cryo-cooler vendors, as these cold heads are bought-in by Agilent Technologies, Inc.

Please provide test results/protocols that clearly indicate that superconductors and thermal conductors containing lead cannot be substituted by lead-free applications.
Suppliers of the cryo-coolers that use lead are working on theoretical alternatives.

Please give information on current research activities on substitutions for lead in *"superconductor and thermal conductor in devices that depend on superconductivity*" carried out by yourself and/or other sector players.Please refer to relevant studies. Is there a timeline for the next ten years for possible substitutes?
Suppliers of the cryo-coolers that use lead are working on theoretical alternatives but not ready to release data until their alternatives are available.

Please indicate if the negative environmental, health and/or consumer safety impacts caused by substitution are likely to outweigh the environmental, health and/or consumer safety benefits. If existing, please refer to relevant studies on negative impacts caused by substitution.
At end of life units using lead today are returned to the vendor for refurbishment so the units do not enter the waste stream. It is not known if potential substitutes can be easily recycled, re-used or if the negative environmental, health and/or consumer safety impacts caused by alternatives outweigh the benefits of leaded cryo-coolers. It is important to note the

function of a cryo-cooler is to condense and recycle helium so that none is lost. According to renowned expert on helium Professor of physics, Robert Richardson from Cornell University in Ithaca, New York, we are wasting our supplies of the inert gas helium and will run out within 25 to 30 years, which will have disastrous consequences for hospitals and industry[1].

6. You are proposing an exemption valid until 2021 and claim that in many products, substitution is impractical as the design and qualification effort required is equivalent to that for a wholly new product introduction. Will research and market penetration of alternatives, as well as innovation cycle in superconductors and thermal conductors in devices that depend on superconductivity for their operation allow a complete substitution after 2021? (It is clear that you cannot give perfect forecast for the technical and market developments for the next ten years. Nevertheless, a sound and justified outlook could help in the evaluation and stakeholder process).

Research and market penetration of alternatives is dependent on innovation by market vendors. Given the reservations established by ERA's research that are backed up by communications with our vendors, we cannot predict when cry coolers that do not employ lead for thermal management will be available and proven for use in NMR or MRI and other applications. Although there is a high probability of their availability by 2021, timing is beyond the control of producers of superconducting magnets or their OEMs.

[1] http://www.physorg.com/news201853523.html