Questionnaire Exemption Request No. 2013-4

Exemption for Mercury used in high speed rotating electrical connectors (slip ring) with electrical conduction paths that have sealed liquid mercury, molecularly bonded to the contacts

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.[1]

ACIST Medical Systems has applied for an exemption for

"Mercury components used in high operating frequency (>50MHz) Intravascular Ultrasound Imaging Systems".

The applicant has explained that high speed rotating electrical connectors (slip ring), containing mercury, are used in high operating frequency intravascular ultrasound imaging systems. Such slip rings have an electrical conduction path including sealed liquid mercury, molecularly bonded to the contacts. The use of the mercury for the conduction path provides a virtually noise free signal between a mechanically rotating ultrasound element (transducer) and stationary electronics. This type of connection is used as the transducer is rotated at varying rotational speeds (0 – 3600 RPM) and prevents significant electrical noise which would affect the image quality obtained by the device.

The applicant puts forward the following main arguments.

- Possible substitutes for mercury in this application are not known to the applicant: "Based on current technology, substitution of any other material for Mercury within the slip ring is not possible because Mercury is the only conductive metal which is a liquid at room temperature. Use of any type of solid contact increases electrical resistance, decreases life through temperature build up and wear, introduces electrical noise through variation in resistance via mechanical non-uniformities, decreased bandwidth though introduction of resistance, and limits power handling through the need to reduce surface area of the contact."

[1] Contract is implemented through Framework Contract No. ENV.C.2/FRA/2011/0020 led by Eunomia

- Devices using the mercury based slip rings prevent significant electrical noise which would impact the image quality, possibly having consequences for patients.
- Devices using the mercury based slip rings operate with higher pull back speeds, reducing catheter in-situ dwell times, which in turn reduce the risk of catheter induced ischemia.

For details, please check the applicant's exemption request at:
http://rohs.exemptions.oeko.info/index.php?id=184

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).

The objective of this consultation and the review process is to collect and to evaluate information and evidence according to the criteria listed in Art. 5 (1) (a) of Directive 2011/65/EU (RoHS II), which can be found under:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT.

If you would like to contribute to the stakeholder consultation, please answer the following questions:

Questions

1. The information provided by the applicant addresses the need of an exemption for mercury in high speed rotating electrical connectors (slip rings) used in high operating frequency intravascular ultrasound imaging systems.
    a. Please state if the requested exemption is relevant for additional applications that are required to abide to the RoHS substance restrictions stipulated in Article 4(1).
    b. If so, please provide information to demonstrate why such an exemption would be justified according to the Article 5(1)(a) criteria.

2. From the information submitted, the applicant is not aware of possible substitutes or developments that may allow for substitution or elimination.
    a. Please provide information concerning possible substitutes or developments that may enable reduction, substitution or elimination, at present or in the future, of mercury in high speed rotating electrical connectors (slip rings) used in high operating frequency intravascular ultrasound imaging systems.

b. 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.

3. The applicant has proposed the following wording for this exemption:

"Mercury components used in high operating frequency (>50MHz) Intravascular Ultrasound Imaging Systems"

As the applicant has indicated that the relevant application falls under the scope of Annex I Category 8 (medical devices), should an exemption be granted it is to be added to Annex IV of the RoHS directive.

a. 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.
b. 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 provide detailed technical argumentation / evidence in line with the criteria in Art. 5 (1) (a) to support your statement.

4. The applicant has provided an estimation of the annual amount of mercury to be placed on the EU market, should the requested exemption be granted. This estimation is relevant only for mercury used in high speed rotating electrical connectors (slip rings) used in high operating frequency intravascular ultrasound imaging systems.

a. If this request for exemption is relevant for other applications, please quantify how much mercury is used in other relevant applications, for which the exemption is also relevant?
b. Please quantify how much mercury would be placed on the EU market, should the exemption wording be formulated to include this application.

Estimation is fine in case you do not have exact data. Please elaborate as to assumptions and calculations.

The applicant has stated that high speed rotating electrical connectors (slip rings) used in high operating frequency intravascular ultrasound imaging systems are currently not marketed in the EU. Please provide information as to the technologies in use at present for intravascular ultrasound imaging systems in terms of their level of performance and in terms of health and environmental impacts throughout the various life stages.

In case parts of your contribution are confidential, please clearly mark relevant text excerpts or provide your contribution in two versions (public /confidential).

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.