Consultation Questionnaire Annex IV Ex. No. 42 (renewal request)

for „Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation“

Abbreviations and Definitions

IVUS	Intravascular ultrasound imaging system
MHz	Megahertz
RPM	Rotations Per Minute

Background

The Oeko-Institut and Fraunhofer IZM have been appointed within a framework contract[1] for the evaluation of applications for the renewal of exemptions currently listed in Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.

ACIST Medical has submitted a request for the renewal of the above mentioned exemption, which has been subject to a first completeness and plausibility check. The applicant has been requested to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation (http://rohs.exemptions.oeko.info/index.php?id=300).

The exemption 42 of Annex IV that covers medical devices and monitoring and control instruments is currently valid until 30 June 2019. ACIST Medical requests a renewal of this exemption for an additional validity period of 7 years.

According to the applicant, high speed rotating electrical connectors (slip ring) containing mercury are used in high operating frequency intravascular ultrasound imaging systems (IVUS). 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.

According to the applicant non-mercury alternatives have been introduced and reviewed over the last several years. However there have been no alternatives identified that could meet the requirements in relation to signal transmission needed to maintain system performance for use in the ACIST IVUS System. These requirements are essential for the usability, safety, function and reliability of the system. Against this background the applicant concludes that currently there is not a suitable replacement for the mercury wetted slip ring available.

For details, please check the applicant’s exemption request at:
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_16/ACIST_Application_Renewal_IV_Ex_42_public_version2.PDF

[1] The contract is implemented through Framework Contract No. FWC ENV.A.2/FRA/2015/0008 of 27/03/2015, led by Oeko-Institut e.V.

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 [2]

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

Questions

1. The applicant has requested an exemption, proposing the following wording formulation: "*Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation"*.
    a. Do you agree with the scope of the exemption as proposed by the applicant?
    b. Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.
    c. Please explain why you either support the applicant's request or object to it. To support your views, please provide detailed technical argumentation / evidence in line with the criteria in Art. 5(1)(a) to support your statement.

2. Please provide information concerning possible substitutes or developments that may enable reduction, substitution or elimination, at present or in the future, of *"Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation"*;

    a. In this regard, please provide information as to alternatives that may cover part or all of the applicability range of electric rotating connectors used in intravascular ultrasound imaging systems;

    b. Please provide quantitative data as to application specifications to support your view.

3. Are there other technologies available to realise the conduction path between the rotating transducer and stationary electronics? Are there attempts for contactless signal transmission?

4. Are there other diagnostic procedures than ultrasound imaging systems which provide comparable results?

5. Please provide information as to research initiatives which are currently looking into the development of possible alternatives for some or all of the application range of electric rotating connectors used in intravascular ultrasound imaging systems.

    a. Please explain what part of the application range is of relevance for such initiatives (in what applications substitution may be possible in the future).

    b. Please provide a roadmap of such on-going research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.

[2] A consolidated version is available under:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011L0065-20171211

6. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, please provide details in respect of the following:
    a. Annual volume of EEE in the scope of the requested exemption made available on the EU market and worldwide;
    b. Amount of Mercury to be avoided should the exemption not be granted;
    c. Estimation of impacts on employment in total, in the EU and outside the EU, should the exemption not be granted. Please detail the main sectors in which possible impacts are expected – manufacturers of intravascular ultrasound imaging systems, companies in the supply chain, retail, etc.
    d. Please estimate additional costs associated with a forced substitution should the exemption not be granted, and how this is divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers).

In case parts of your contribution are confidential, please provide your contribution in two versions (public / confidential). Please also note, however, that requested exemptions cannot be granted based on confidential information!

Finally, please do not forget to provide your contact details (Name, Organisation, e-mail and phone number) so that Oeko-Institut/Fraunhofer IZM can contact you in case there are questions concerning your contribution.