Consultation Questionnaire Exemption Request No. 2019-2

Exemption for „DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils“ to be added to Annex IV

Abbreviations and Definitions

DEHP	Bis(2-ethylhexyl) phthalate
DEHT	Diethylhexyl terephthalate
MRI	Magnetic Resonance Imaging
PVC	Poly Vinyl Chloride

Background

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

GE Healthcare has submitted a request for the addition of the above mentioned exemption to Annex IV of the RoHS 2 Directive, which has been subject to a first completeness and plausibility check. The applicant has been requested to answer questions for clarification and to provide additional information. Both the original exemption request and the response to clarification questions are available on the request webpage of the stakeholder consultation (http://rohs.exemptions.oeko.info/index.php?id=309).

MRI is a scanning technique where the patient is exposed to a strong magnetic field and radio waves. The human tissue then emits weak radio frequency signals that are received by antennas - the coils - in close proximity to the part of the human body that is examined. The received signal is used to generate detailed images of the human body, including e.g. muscles, blood vessels and internal organs. There are a number of different coils depending on the specific part of the body that is scanned.

GE Healthcare requests an exemption for the plasticizer DEHP in coil cable strain relief devices made of PVC. These devices, also called strain relief boots, should prevent the flexible cables that connect the Magnetic Resonance Imaging (MRI) coils with the image processing system from fracturing by repeated bending. GE Healthcare states that so far no reliable alternative material could be identified.

[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.

GE Healthcare explains that the following main requirements have to be fulfilled by a substitute:

- Materials used for coils, including cables and strain reliefs must not adversely affect image quality, therefore the material has to be non-magnetic and have small proton signals.
- Biocompatibility which means that alternative material also have to be approved for human skin contact according to ISO standards on biological evaluation of medical devices.
- The strain relief boots have to serve over a long service lifetime of a coil which is indicated to be about 8 years and has to withstand repetitive bending.

GE Healthcare states that tests with substitute polymers and PVC with an alternative plasticiser have been carried out, but did not meet the above mentioned requirements. A third option, which eliminates the need for strain relief boots, is the development of digital wireless coils which is explained to be a theoretical substitute being under research by different stakeholders.

GE Healthcare claims that there would be negative health and socio-economic impacts if the exemption should not be granted.

The applicant requests an exemption until January 2024.

For details, please check the applicant's exemption request at:
http://rohs.exemptions.oeko.info/index.php?id=309

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 applicant has requested an exemption, proposing the following wording formulation:
   "DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils"
   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 DEHP in plastic strain relief devices for MRI coil cables;
   a. In this regard, please provide information as to alternatives that may cover part or all of the applicability range of *"DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils"*;

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

3. The consultant is aware that there are other manufacturers placing MRI scanners on the EU market, e.g., Siemens, Phillips and Toshiba. Please provide information about the equipment of such manufacturers and whether they use DEHP containing PVC strain relief devices for coil cables.

4. 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 DEHP in plastic strain relief devices for MRI coil cables (also development of alternative technologies e.g., digital wireless coils).

   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.

5. 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 in relation to all EEE placed on the EU market through this exemption:

   a. Please estimate possible amounts of waste to be generated through a forced substitution should the exemption not be granted. In this respect, please clarify whether devices placed on the market before the 22 July 2021 could still be serviced with new coils, through the spare parts provision stipulated in Commission Delegated Directive (EU) 2015/863[2].

   b. Please estimate possible 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 – manufacture, supply chain, retail, etc.

   c. 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.

[2] From the soon to be amended Annex II to the RoHS Directive: "*The restriction of DEHP, BBP, DBP and DIBP shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019, and of medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2021*".. See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015L0863