1st 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“

Abbreviations and Definitions

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

Background

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

GE Healthcare has submitted a request for the renewal of the above mentioned exemption, which has been subject to a first evaluation. The information GE Healthcare has referred has been reviewed and as a result we have identified that there is some information missing. Against this background the questions below are intended to clarify some aspects concerning the request at hand.

Answers in Green Font

Questions

1. Please provide information of other manufacturers of MRI.

    a. Other manufacturers include, Siemens, Toshiba, Phillips and additional start-up or emerging companies.

2. We assume that PVC or the plastic strain relief device is provided by a supplier. How does GE Healthcare specify the material requirements to the supplier?

    a. These are custom designed parts by GE. GE specifies the selected material on an Engineering Drawing Specifying the material supplier, product brand name, hardness (durometer) and color.

3. As for the evaluation of substitute plasticisers in PVC, GE healthcare provides results on MRI proton signal intensity measurements.

[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.

a. As for the information provided in Table 1 and Table 2 on results for more flexible materials, please provide more explanation on how this information has to be understood in relation to image intensity and image contrast.

   i. The flexible materials cause more proton signal or disturbance to the image and therefore must be further from the area of interest than the more rigid materials.

b. What is meant by durometer value 65 and 90?

   i. Durometer is a measurement of hardness or flexibility. 65 durometer is a material that is easily flexed and 90 durometer is much firmer and almost rigid. Due to higher plasticizer content in the flexible material, it creates a greater proton signal.

c. Are there different requirements on strain reliefs that are attached at the coil or that are attached at the end of the cable which is understood to be more far away from the imagine zone?

   i. Yes, the 65 durometer strain reliefs may not be within the imaging zone as they fail for proton signal got both the existing and proposed vinyl. The 90 durometer passed requirements to be adjacent to the imaging zone for both the existing and proposed vinyl. The proposed vinyl has more signal than the existing vinyl but, it would still be acceptable adjacent to the image zone. We would not place the 90 durometer parts directly in the imaging zone as both produce more signal than is preferred.

d. How do the material of which the equipment is composed and the isolation of the cable influence the proton signal and the image quality?

   i. If a proton signal producing part is directly in the imaging zone, it will produce distortion or image artifacts in the image. This could result in a mis-diagnosis of an abnormality (tumor) or prevent a real abnormality from being discovered if the image is occluded. This could result in unnecessary treatment or surgery, a need to repeat imaging or possibly prevent a patient from getting treatment whom needs it.

4. For possible alternatives, GE Healthcare refers to an innovation of digital coil design by citing another MRI manufacturer, Philips, in the footnote.

   a. Is it correct to understand that digital coils are already on the market or when are they expected?

      i. Searching on the Internet, we are finding research and preliminary patents in this area but, have not identified a commercial product.

   b. Is GE Healthcare developing digital coils as well?

      i. This has been considered by all major manufacturers based on my research on the Internet. Specific plans of all suppliers are confidential however, we estimate that the market is 5-8 years away from implementation providing they make a commitment to pursue.

c. Is it correct to understand that in digital coils there is no more need for the DEHP containing plastic stain reliefs, i.e. that digital coils would eliminate the need for using DEHP in the application at hand?

   i. A digital wireless coil would eliminate the need for a cable with strain reliefs. The challenges to transmit in the magnetic field, maintain data confidentially, supply power to the remote device are all challenges in front of industry.

d. Can digital coils be expected to replace all MRI in which non-digital coils are still use and by when?

   i. Currently, it is difficult to predict the research and development leading to a wireless digital coil. If we started today, we estimate 5-8 years to commercialize and gain regulatory approval. The life of a coil in the market is about 8 years. Current coils in use today will need to be serviced and repaired throughout their life. Obsolescence and replacement before their natural end of life would be a great burden to the medical community.

5. As for a roadmap for substitution, please specify what kind of biocompatibility tests have to be performed as you state that medical staff will be instructed to route the cables and associated stain reliefs away from patient skin?

   For short term contact with intact skin the following standards apply.

Document Number	Revision	Document Name
ISO 10993-1	Edition 5, 2018 Oct	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-5	Edition 3, 2009 June	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Edition 3, 2010 Aug	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensi-tization

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 in relation to all EEE placed on the EU market through this exemption (i.e., not just by GE Healthcare):

   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].

      i. We estimate 38,000 kg of total waste generated containing in excess of 670kg of DEHP through forced substitution if the exemption is not granted.

[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

ii. Yes, the coils placed on the market before the 22 July 2021 could still be serviced through the spare parts provision.

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 which possible impacts are expected – manufacture, supply chain, retail, etc. .

i. Manufacturing and Supply Chain will be affected.

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).

i. A forced substitution would result in a cost to GE for *Engineering, Research, and Implementation and, Scrap due to Obsolescence* consistent with the estimates in the original application. For the medical industry the cost is difficult to estimate, and it is unknown whether the industry will support any cost due to forced substitution.

Please note that answers to these questions are to be published as part of the available information relevant for the stakeholder consultation to be carried out as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.