Clarification Questionnaire for Exemption Request No. 2019-4

Exemption for „*Bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils*“

Abbreviations and Definitions

COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
DEHP	Bis-(2-ethylhexyl) phthalate
MRI	Magnetic Resonance Imaging

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.

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has submitted a request for the above mentioned exemption as a new exemption in Annex IV, which has been subject to a first evaluation. As a result we have identified that there is some information missing. The questions below are intended to clarify these aspects concerning the request at hand.

Questions

1. You propose as wording for your exemption request DEHP “*in plastic components in MRI detector coils*“. This wording comprises a wide scope:
    a. Please provide an exhaustive list of the plastic components for which you request the exemption.

       All the applications requiring DEHP are listed in the dossier: bushing, cable cover, fixing belts, mattress.

    b. If it is possible to reformulate the exemption request by listing the specific plastic components or by listing specific categories (see also question 2(c)), please provide a reformulation of the exemption request.

       Bis-(2-ethylhexyl) phthalate (DEHP) in flexible polymers in bushing, cable covers (sheathing and insulation), fixing belt components and mattresses including their coverings in MRI detector coils

[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.

This wording restricts the scope to only 4 articles. However, we are concerned that the terms are not clearly defined (the exemption cannot provide any definition or guidance) and so may not be clearly understood by Market Surveillance Authorities, manufacturers or users, which is why we proposed the original wording.

A part from the indicated applications, there are no other uses of flexible polymers in MRI coils, therefore the generic wording will not open for any misuse of the exemption. The limited time requested as extension also contributes to ensure the quantities estimated in this dossier will be placed on the market (no loopholes).

2. The plastic components that are listed, e.g. bushing, cable cover, fixing belt and mattress, have very different functionalities:
    a. Please explain how the different functionalities influence the possibilities to apply substitutes.

    In all the listed parts, flexibility of the plastic is the reason why DEHP is used. Despite the different function of the articles containing DEHP listed in the dossier, the obstacle to finding an alternative plasticizer/alternative polymer is the interference with the MRI image quality and the biocompatibility (an alternative is not suited if it has lower physical performances). There are many alternative plasticizers or polymers that can be used to provide the required physical properties, but the ones tested so far are unsuitable (interference with image or biocompatibility tests failure). A potential alternative has been identified with promising results so far, but more time is required after the July 2021 when the restriction is imposed on medical devices to continue the testing, gaining approvals, etc.

    b. What properties or function is DEHP required to provide for each of these component types and what level of performance would be necessary for a substitute to be considered suitable?

    While many alternatives are available the following performances must be met, as described in Section 4B (see also table 1, page 7 of the original application dossier) to be considered alternatives:

    - **Biocompatibility testing can include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity, subchronic toxicity, genotoxicity, etc.**
    - **Low proton signal to avoid interfering with the MRI image;**
    - **Low distortion of magnetic fields to avoid interfering with the magnets that align the protons in the body; and**
    - **The material shall not build up electrostatic energy that could be released during imaging which would hamper the MRI causing distortion of the image.**

    c. Can different components for which the exemption required be associated with component categories in cases where DEHP is required to fulfil the same function/properties?

The 4 articles requiring this exemption are quite different in functionality even if DEHP is used for flexibility, therefore we do not think they can be reconducted to an article category.

d. Please explain whether different roadmaps and validity periods for the different plastic components are applicable.

Several alternative polymers are under testing, that would allow the components to be used in all the applications requiring DEHP. An additional 2 years beyond 2021 are required to validate the alternative, gain approvals and start the production of coils.

3. During the evaluation of the exemption request of GE Healthcare for "*Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils*", COCIR provided additional information on practices from different MRI coil manufacturers and communicated that one member company stated not to need DEHP in MRI imaging coils due to *"a totally different design with no need for a cable strain relief. Only one of their coils (a very old design) has a cable strain and this cable strain relief is without DEHP.* We concluded that the evidence that one manufacturer does not need the requested exemption shows that substitution is possible.

As we stated in the dossier, we expect that substitution will be possible. Due to the range of alternative plasticizers or polymers and due to the extensive testing requirements, substitution would require a small extension of the deadline of 2 years.

Against this background, please provide details on socio-economic impacts in relation to all EEE placed on the EU market through this exemption. If COCIR can only obtain data for MRI manufacturers that are members of COCIR, please estimate how the specified data relates to the total EU market of MRI devices:

COCIR manufacturers represent 100% of the EU market for MRI.

a. Please estimate the related volume of EEE concerned and the respective amount of DEHP to be avoided should the exemption not be granted.

COCIR estimates 14 Kgs of DEHP are used annually in MRI coils placed on the EU market. The extension of the exemption for 2 years will therefore allow 28 kg, in the worst-case scenario, to be placed on the EU market as part of MRI coils.

b. 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 MRIs placed on the market could still be serviced with coils from other manufacturers.

Coils are specifically designed for one or more MRI models (depends on the technology). There are a few cases of 3rd party manufacturers that produce coils for specific MRI models. While some coils could be provided by such 3rd parties, hospitals would have no alternatives should they need to acquire new coils, or to replace old ones.

If the exemptions renewal is not granted, this would not cause generation of waste as coils in use can continue to be used and repaired.

c. Please explain the possible health impacts, e.g. on hospitals, if the usual supply with coils changes.

This is already included in the exemption request – see section 8 (D)

The negative consequence is that hospitals will not be able to buy the new coils they need. This would mean:

- **Hundreds of hospitals in EU will not be able to perform certain scans. We estimate 2 million patients may be affected per year until alternatives are validated and coils manufactured (this number does not include the machines already indicated by GE and the corresponding number of patients).**
- **If patients cannot be diagnosed using MRI in some hospital just for the lack of appropriate coils, that may require rerouting them to other hospitals, with all the problems associated with delayed diagnosis.**
- **It is also relevant to realize that waiting lists for MRI examinations are already long in many EU countries and this is going to make the situation worse. For instance, already today, patients are prescribed CT scans due to waiting time for MRIs.**
- **In EU the percentage of old MRIs is increasing[2]. An easy way for hospitals to increase the performance of old MRIs is to purchase new coils with higher performances. Even when hospitals will be able to continue diagnose patients, this would be done with older coils and new ones will not be available for at least 2 years.**

d. 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 – EU healthcare, manufacture, supply chain, retail, etc.

We do not expect an impact on employment

e. 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).

Manufacturers will not be able to sell their coils for at least 2 years. This will affect the companies' turnover but even worse, it will reduce resources for research and development of new better coils and equipment which would have allowed superior diagnostic capability or superior medical procedures and treatments. These types of improvement in performance results in clearer

[2] Due to the limited time to research for sources we just link some newspaper articles:
https://www.rtbf.be/info/societe/detail_plusieurs-mois-d-attente-avant-de-subir-un-examen-irm?id=9912541
https://www.magevola.it/famiglia/diritti-e-doveri/nazionale/sanita-lista-attesa-lunga/

images that enable doctors to be able to detect tumours and other harmful conditions much earlier and this improves the likelihood of recovery and recovery is likely to be faster for the public and so incur smaller costs to hospitals

Considering most of resources are already diverted to find an alternative to DEHP, the expiration of the exemption would also cut the sales, reducing even the resources for R&D. This is going to have far reaching consequences on R&D programs delaying some important innovation for years.

Please also provide cost estimations for the health impacts, e.g. for EU hospitals.

As hospitals will not be able to purchase most of the coils they need, not granting the exemption would imply cost savings for hospitals, at the expense of patients. In case patients can be rerouted to nearby hospitals this would add transportation costs, but will increase waiting time for other patients. If alternative examinations are prescribed, such as CT, this would also translate into increased radiation dose for patients that would have not required it. Also CT is often unsuitable as an alternative to MRI and therefore the scan will result in lower quality diagnostic outcome.

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.