Consultation Questionnaire, Annex IV, Ex. 31a (amendment request)

Exemption for „Bis (ethylhexyl) phthalate, Dibutyl phthalate, Di-isobutyl phthalate and Benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer“ to be added to Annex IV

Abbreviations and Definitions

BBP	Benzyl butyl phthalate
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
DEHP	Bis (ethylhexyl) phthalate
DBP	Dibutyl phthalate
DiBP	Di-isobutyl phthalate
EEE	Electrical and electronic equipment
MD	Medical devices
MRI	Magnetic resonance imaging
OEM	Original equipment manufacturer
PCB	Printed circuit boards
RRSM	Repair, refurbishment, servicing and maintenance

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. [1]

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has submitted a request for a new exemption (the Terms of Reference of this project refer to an amendment request for the existing exemption 31a of Annex IV of the Directive). The above mentioned wording formulation is proposed for this purpose and it is mentioned that this formulation could be combined with the existing exemption 31a of Annex IV of the Directive which reads as follows:

[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.

> "*Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer*."

The request was 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=310).

According to the applicant, RoHS-restricted phthalates – bis (ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-isobutyl phthalate (DiBP) and benzyl butyl phthalate (BBP) – are added to polymers (including rubber), adhesives, sealants, paints and lacquers to provide the function of a plasticiser, a processing aid or to give flexibility in a variety of components.

COCIR lists a few examples of applications of relevance for medical devices (MD):

- Printed circuit boards (PCBs);
- X-ray tubes (including PCBs, cables, housing, etc.);
- Magnetic resonance imaging (MRI) coils;
- Detectors and components of detectors (e.g. radiation detectors); and
- Transducers with associated cables.

These parts are removed from used MD during refurbishment, repair, servicing or maintenance (RRSM) and are reused for the same purposes in other MD (i.e. in RRSM of MD). Refurbished and reused parts and equipment are, according to COCIR, as good as new parts in addition to being available at lower costs to hospitals. The applicant also describes how parts that are recovered and refurbished remain within a "closed-loop" thereby contributing to reduce the material flows of equipment and parts arriving at end-of-life (i.e. waste phase) prior to fulfilment of their full service life potential.

Parts that are produced for medical devices after 21 July 2021 will not contain the four restricted phthalates. However, recovered parts already in the market may contain these substances and due to the chemical analytical methods available[2] it is not possible to determine their presence non-destructively in every single component. In addition to this, the information available along the supply chains does not provide a way to verify if (or which) phthalates were used in components prior to the restriction[3]. In that case, after July 2021 it will not be possible to determine compliance with the RoHS Directive of parts harvested from and used for RRSM activities and therefore, all unusable recovered parts will become waste.

As justification for this amendment, COCIR contends that the overall negative health, safety and environmental impacts of manufacturing relevant parts and equipment anew are higher than using refurbished parts and equipment. The main arguments supporting this statement are:

[2] Destructive methods for chemical analysis of phthalates would prevent reuse of the parts. Presence of phthalates cannot be determined non-destructively if analysis is carried out according the method in EN 62321-8 which is solvent extraction from small particles of polymer followed by gas chromatography-mass spectroscopy.

[3] As there was no restriction of these substances before March 2015 and the concentration in the supplied article was below the threshold limit that triggered communication obligations according to REACH Article 33, suppliers had not collected information on the use of these four phthalates.

- Larger environmental impacts due to the unnecessary wasting of older parts and manufacturing of new ones.
- Higher costs for hospitals and clinics in EU
- Longer downtimes when new parts have to be made before the device can be repaired. Delays in availability of spare parts for faulty equipment has a direct impact on health of EU citizens due to delays in providing treatment

COCIR also presents life cycle Assessment information that compares the impacts of building new medical devices with the use of refurbished equipment in X-ray systems and MRI. To illustrate, the applicant included the following table:

Table 1:Results of life cycle assessment comparison of new and refurbished MRI and X-ray systems

Impact	Size of impact of refurbished system compared with a new system	
	MRI	X-ray system
Climate change	27%	3%
Human toxicity	32%	6%
Terrestrial ecotoxicity	28%	5%

Source: COCIR 2018 Application request for exemption

COCIR argues that this new exemption for the four RoHS-restricted phthalates will allow the reuse of recovered parts, regardless of where or when the medical devices they have originated from, were placed on the market. In the same way as Exemption 31a (published 12.02.16) this request for exemption is based on the basic principle of the EU Circular Economy recognizing that the environmental benefits of reusing parts are often higher than manufacturing a new part. The applicant also refers to the Waste Framework Directive which according to COCIR recognizes that life extension is always a better option than recycling or replacement with new manufactured products.

According to the applicant, this exemption request is relevant to EEE in category 8 ─ medical devices such as MRI, CT, PET, SPECT, ultrasound imaging, patient monitors, in vitro-diagnostic medical devices─, but might eventually also be relevant to EEE under category 9 (namely electron microscopes).

Under these premises, COCIR requests the exemption for the maximum validity period.

For details, please check the applicant's exemption request at:
http://rohs.exemptions.oeko.info/index.php?id=310

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 a new exemption, proposing the following wording formulation:
   "Bis (ethylhexyl) phthalate, Dibutyl phthalate, Di-isobutyl phthalate and Benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer."

   Alternatively, with the argument that both exemptions are necessary to ensure repair and refurbishment activities, and that, renewing a single exemption would require less efforts in the future, the applicant proposes the possibility of merging this new exemption with the existing exemption 31a in Annex IV with the following wording formulation:

   "Bis (ethylhexyl) phthalate, Dibutyl phthalate, Di-isobutyl phthalate, Benzyl butyl phthalate, Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer".

   It is noted that Ex. 31a of Annex IV of the Directive is currently also available to electron microscopes. COCIR have mentioned electron microscopes in the context of the current exemption, but could not provide information to support this scope. Information is necessary to clarify the relation of such equipment to the requested exemption.

   a. COCIR request the exemption for equipment falling under Category 8 (Medical Devices). Do you agree with this scope? If you do not, please provide data and information to support the need of the exemption for additional categories or product-groups (e.g. electron microscopes).
   b. If you support the exemption, which of the wording formulation alternatives do you consider more appropriate for this exemption?
   c. Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.
   d. 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. COCIR requests the exemption for all medical devices, including in vitro diagnostic medical devices, and their accessories, but mainly provides supporting data for medical imaging devices. Please provide information and data to support the request for other than medical imaging devices falling under Cat. 8 of RoHS Directive Annex I.

3. Please provide information concerning possible substitutes or developments that may enable reduction, substitution or elimination, at present or in the future, of "*Bis (ethylhexyl) phthalate, Dibutyl phthalate, Di-isobutyl phthalate, Benzyl butyl phthalate, Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories"*;

a. In this regard, please provide information as to alternatives that may cover part or all of the applicability range of the requested exemption (if relevant please also refer to other than medical devices for which the Ex. Is needed);

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

4. 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. COCIR has estimated that about 2200 tonnes of parts and 1000 tonnes of equipment (total 3200 tonnes) are refurbished and then reused in the EU annually. Please provide related information in case you do not agree with these reported EEE volumes.
b. COCIR estimates less than 2 tonnes per year for the RoHS-restricted phthalates present in EEE waste. This is based on an average of 0.1% of the total of recovered and reused parts[4]. Please indicate whether you agree with these estimations and provide additional information.
c. Please provide estimations as to possible additional waste to be generated through a forced substitution.
a. Please provide estimations 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 — health services providers, manufacture, 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, health service providers, patients).

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.

[4] COCIR estimated, based on expert opinion, that phthalates in "*plastic likely to contain phthalates*" can amount to a 0.1% of the weight of parts of medical imaging devices, that are, for the most part, made of heavy metals and alloys.