Consultation Questionnaire   
Exemption 46 of RoHS Annex IV

Table 1: Currently valid wording, scope and applicability of the exemption

|  |  |  |
| --- | --- | --- |
| No. | Current exemption wording | Current scope and dates of applicability |

|  |  |  |
| --- | --- | --- |
| IV-46 | Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils. | Applies to categories 8 medical devices other than in-vitro diagnostic medical devices.  Expires on 1 January 2024. |

# ACRONYMS AND DEFINITIONS

COM European Commission

DoC Declaration of Conformity (with the legal requirements applicable to the respective medical device, e.g. the Regulation on Medical Devices ((EU) 2017/745)

EEE Electrical and electronic equipment

IVD In-vitro diagnostic medical devices

Lead-free not containing lead in the application in the scope of the exemption to be reviewed

Pb Lead

# Background and objectives of this review

Bio Innovation Service, UNITAR-SCYCLE and Fraunhofer IZM have been appointed[[1]](#footnote-2) by the European Commission for the evaluation of new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

COCIR requested the renewal of exemption IV-46 with the current wording until 1 January 2026.

Table 2: Requested renewal of the exemption

|  |  |  |
| --- | --- | --- |
| *No.* | *Requested exemption wording* | *Requested scope and dates of applicability* |

|  |  |  |
| --- | --- | --- |
| *IV-46* | *Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils.* | *Applies to categories 8 medical devices other than in-vitro diagnostic medical devices.*  *Expires on 1 January 2026.* |

A clarifciation questionnaire was not required in this case. The exemption renewal request, and – if submitted – supporting evidence from other stakeholders, are accessible on the consultation web page. **[[2]](#footnote-3)**

The stakeholder consultation is part of the review process for the exemption request at hand. It addresses third parties – not the applicants – to collect and to evaluate information and evidence according to the criteria listed in Art. 5(1)(a) of Directive 2011/65/EU.[[3]](#footnote-4)

**Summary of the exemption renewal request**

COCIR requests to extend the time period to replace the existing materials of MRI coil cable strain reliefs for tests to qualify adequate performance and redesign them, if necessary, after tests with the new identified materials.

In 2019 COCIR submitted the request for exemption 46 that was then published in 2021 with a the validity period expiring on 1 January 2024. Since then COCIR Companies have made progress according to the indicated timeline. Alternatives for all plastic parts have been identified and by 2024 all models of non-integrated coils will be placed on the market with cable covers, fixing belts and mattresses DEHP free.

Alternatives have been identified also for cable strain reliefs and already today all new models are placed on the European market DEHP free. Due to unexpected external events, the redesign of old models has been delayed and we expect a number of coils design will not be available DEHP free by that date (1 Jan 2024). While limited in number, such coils are still needed by hospitals in EU and due to their older design cannot be substituted with the newer designs due to compatibility issues. While the negative health and socio-economic impacts without this exemption is explained in section 6 of our renewal request, the overall amount of DEHP placed into EU market is going to be minimal.

We also note that if exemption 46 was worded using the “DoC approach” successfully included in exemption 27 and proposed for others, it would not have been required to submit this renewal as companies would have had enough time to phase out older designs, while ensuring DEHP free new designs.

**To contribute to this stakeholder consultation, please answer the below questions until 19 January 2024.**

**Please also see the applicants’ renewal request form and – if submitted – further information on the consultation web page[[4]](#footnote-5).**

# Questions

1. Please let us know whether you support or disagree with the renewal of the exemption for another 2 years beyond 2024. To support your views, please provide detailed technical argumentation / evidence in line with the criteria4 in Art. 5(1)(a). If applicable, please suggest an alternative wording and/or duration and explain your proposal.
2. COCIR provided information on the socioeconomic impacts that may arise if the exemption is not renewed until January 2026. Do you agree with the underlying data and assumptions, and with the conclusions?
3. Any additional information which you would like to provide?
4. Is there any additional information which you would like to provide?

**Please note that answers to these questions will be published as part of the evaluation of this exemption 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. Additionally, please also add “confidential” to the file name.**

**Please do not forget to provide your contact details (Name, Organisation, e-mail and phone number) so that the project team can contact you in case there are questions concerning your contribution.**

**It would be helpful for the review process if you could kindly provide the information in formats that allow copying text, figures and tables to be included in the review report.**

1. It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017 [↑](#footnote-ref-2)
2. Consultation web page: <https://rohs.biois.eu/requests2.html> [↑](#footnote-ref-3)
3. Directive 2011/65/EU (RoHS) available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT> [↑](#footnote-ref-4)
4. Consultation web page: <https://rohs.biois.eu/requests2b.html> [↑](#footnote-ref-5)