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Öko-Institut e.V.
Institut für angewandte Ökologie
Institute for Applied Ecology

"Study to assess three (3) exemption requests relating to Annex IV to Directive 2011/65/EU: request for amendment of existing exemption 31 a; request for a new exemption for Bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids; and request for a new exemption for DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils "

Project Description Pack 17 – 2018/2019

Carl-Otto Gensch
Yifaat Baron
Katja Moch
Oeko-Institut e.V. - Institute for Applied Ecology, Germany (Project Management, Lead Partner)

Dr. Otmar Deubzer
Fraunhofer Institute for Reliability and Microintegration IZM (Partner)

Head Office Freiburg
P.O. Box 17 71
79017 Freiburg
Street address
Merzhauser Strasse 173
79100 Freiburg
Tel. +49 761 45295-0

Office Berlin
Schicklerstrasse 5-7
10179 Berlin
Tel. +49 30 405085-0

Office Darmstadt
Rheinstrasse 95
64295 Darmstadt
Tel. +49 6151 8191-0

info@oeko.de
www.oeko.de

Fraunhofer IZM

Table of Contents

1. Background

The RoHS Directive (2011/65/EU) on the restriction of the use of certain hazardous substances in electrical and electronic equipment requires "*that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II*" (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers and the phthalates dibutyl phthalate(DBP), bis(2-ethylhexyl)phthalate (DEHP), diethyl phthalate (DEP) and diisobutyl phthalate (DIBP). These provisions "*shall not apply to the applications listed in Annexes III and IV*" (Article 4). These Annexes are to be adapted to scientific and technical progress on the basis of the provisions listed in Article 5.

With contract No. 070201/2018/792335/ENV.B.3 Implementing Framework contract No ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut for Applied Ecology, has been requested by DG Environment of the European Commission to provide technical and scientific support for the evaluation of exemption requests under the RoHS 2 regime. The work is being undertaken by the Oeko-Institut and Fraunhofer IZM. The work has been requested in view of providing technical and scientific support for the evaluation of applications for granting, renewing or revoking an exemption to be included in or deleted from Annexes III and IV of the RoHS Directive 2011/65/EU.

2. Objectives

The objectives of this project can be outlined as follows:

- Provide a dedicated website which ensures that involved stakeholders will receive all necessary information and can contribute to online consultations (http://rohs.exemptions.oeko.info);
- Execute a clear technical and scientific assessment on whether requests for new exemptions are justified in line with the criteria given in Article 5(1)(a);
- Provide for the involvement and consultation of stakeholders (inter alia producers of electrical and electronic materials, components and equipment, recyclers, treatment operators, environmental organisations, employee and consumer associations), according to Article 5(7);
- Provide a clear and unambiguous wording for the preparation of a Draft Commission Decision for those exemptions, where on the basis of the result of the consultation and the evaluation, an exemption can be justified.

3. Scope

In agreement with the Commission, three exemption requests will be evaluated, two new exemption requests and one request on the amendment of an existing exemption (the evaluation of application for the renewal of the exemption 31a listed in Annex IV).

Table 3-1 gives an overview on the three exemption requests:

Table 3-1: Exemption requests that will be evaluated during this project as specified in the terms of reference

No.	Wording according to the terms of reference	Applicant
Requested renewal / amendment of existing exemption		
Annex IV, 31a	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	COCIR
Request of new exemptions		
2019-1	Bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids	COCIR
2019-2	Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils	GE Healthcare

4. Project set-up

The overall project is led by Carl-Otto Gensch. At Fraunhofer IZM the contact person is Otmar Deubzer. The project team at Oeko-Institut consists of the technical experts Yifaat Baron and Katja Moch.

The exemption evaluation will be performed in close co-operation with the European Commission and stakeholders (electrical and electronic industry and its associations, NGOs, independent experts etc.). This includes:

- Central communication access for stakeholders via the project-specific e-mail account rohs.exemptions@oeko.de;
- Project-specific website at http://rohs.exemptions.oeko.info/ where relevant documents and project activities will be published;
- Information for stakeholders via website and via mailing lists for which stakeholders can register;
- Preparation and management of stakeholder consultation on exemption requests via project website;
- Technical and scientific evaluation of stakeholder input and further procedure for receiving a sound basis with a high level quality of data and information and for cross-checking information for technical correctness and confidentiality issues;
- Stakeholder workshop or meetings where necessary.

5. Time schedule

Assignment of project tasks to Oeko-Institut and Fraunhofer IZM started 12 December 2018 and will run over a period of 8 months, thus ending 11 August 2019. An interim report shall be delivered to the European Commission during March 2019. The final report is due at the end of the project. The stakeholder consultation is planned to be launched in the first quarter of 2019.