Consultation Questionnaire Exemption Request No. 2019-1

Exemption for „ Bis (ethylhexyl)-phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids“ to be added to Annex IV

Abbreviations and Definitions

COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
DEHP	Bis (ethylhexyl)-phthalate
EEE	Electrical and electronic equipment
ISE	Ion selective electrodes
IVD	In-vitro diagnostics
PoC	Point of care

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 the above mentioned exemption, which has been 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=308).

According to the applicant, bis (ethylhexyl)-phthalate (DEHP) is an essential component of medical in-vitro diagnostics (IVD) analysers for the measurement of specific substances in body fluids —whole blood, plasma, serum, urine, cerebral spinal fluid, pleural fluid — as well as dialysate. Specifically, COCIR describes that DEHP is contained in the membrane solvent for the ion selective electrode (ISE) constituents that are used in point of care analysers used to measure the concentrations of the following analytes[2]:

- Partial pressure of carbon dioxide (pCO2);
- pH;

[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.

[2] The analytes detailed are those of relevance for the equipment addressed in the application (i.e., of certain manufacturers) in which DEHP is present. Nevertheless, COCIR explains in this respect that “*DEHP could be used for other analytes by other manufacturers/in other devices, but we have no information on other manufacturers' products*”, i.e. it is possible that the list of analytes is not exhaustive.

- sodium; and
- potassium;

These ISE are used in medical devices in the so called Point of Care (PoC) situations where results of body fluid analysis are required in the shortest time possible in order to enable quick therapeutic intervention. Therefore, time saving, reliability and the fact that only small samples of blood are required for the analysis, are described by COCIR as the advantages for the use of PoC analysers in comparison to other available alternatives.

COCIR explains that ion selective electrodes (ISE) for analysis of ions in blood or other body fluids are supplied to hospitals as components of disposable cartridges that also contain the chemicals used for analysis and carry out measurement, washing and waste disposal, aqueous quality controls and electronics. After its use, electrodes and membranes become bio-hazards and are sent for energy return since they are exposed to blood and thus considered medical waste, excluded from the WEEE Directive.

The applicant explains that ISE cartridges (containing DEHP) are designed specifically for each instrument, therefore new disposable cartridges must be compatible with PoC analysers already on the market. Many EU hospitals already own or will buy analysers that utilise ISE cartridges that contain DEHP before 21 July 2021. These hospitals cannot use cartridges designed for different instruments in their existing equipment, as they cannot be attached and would give incorrect results.

COCIR declares that this exemption is needed because alternatives to DEHP have been found to give less accurate and incorrect test results and alternative methods to ion selective electrodes are much too slow and may also give inaccurate results. Under these premises, COCIR requests a new exemption in Annex IV for the maximum validity period. According to the applicant, this exemption request is relevant to EEE in category 8, medical devices for in-vitro diagnostics (IVD). It is needed for equipment performing chemical analysis of blood gases, electrolytes, metabolites, total hemoglobin, and hemoglobin derivatives in arterial and venous whole blood samples, dialysate and other body fluids such as pleural fluids.

In addition to possible socio-economic impacts COCIR contends that without this exemption, hospitals would be forced to dispose of IVD analysers prematurely resulting in electrical equipment being disposed of before its normally expected end of life, leading to an increase in electrical waste. This exemption is therefore justified on the basis that substitution is not technically practical.

For details, please check the applicant's exemption request at:
http://rohs.exemptions.oeko.info/index.php?id=308

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 an exemption, proposing the following wording formulation:
   "Bis (ethylhexyl)-phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids."

a. Do you agree with the scope of the exemption as proposed by the applicant?
b. Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.
c. 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. If relevant, please also refer to the requested duration for the proposed exemption.

2. Please provide information concerning possible substitutes or developments that may enable reduction, substitution or elimination, at present or in the future, of *DEHP in ion selective electrodes for point of care analysis of ionic substances in human body fluids"*;

    a. In this regard, please provide information as to alternatives that may cover part or all of the applicability range of *DEHP in ion selective electrodes for point of care analysis of ionic substances in human body fluids*;

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

3. Please provide information as to research initiatives which are currently looking into the development of possible alternatives for some or all of the application range of *DEHP in ion selective electrodes for point of care analysis of ionic substances in human body fluids*.

    a. Please explain what part of the application range is of relevance for such initiatives (in what applications substitution may be possible in the future).

    b. Please provide a roadmap of such on-going research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.

    c. In this respect, please provide information as to the "lab-on-chip" technology described by the applicant, specifying the roadmap for development of relevant equipment, capabilities in relation to analysis of human body fluids, etc.

4. The consultants are aware that there are a number of manufacturers placing Point of Care devices for body fluid analysis on the EU market and using ion selective electrodes (ISE). E.g., Siemens Healthcare, Radiometer, Instrumentation Laboratories. Please provide information about the equipment of such manufacturers and whether they use DEHP as membrane solvent in disposable cartridges, i.e., for the measurement of certain analytes.

5. 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. Estimations about the number of PoC analysers using DEHP containing ISE currently on the market and the volume of EEE these represent.

    b. COCIR estimates 2.2 kilograms of DEHP entering the EU market annually through the application for which the exemption is requested. This amount of RoHS-restricted substance is therefore to be avoided should the exemption not be granted. Please indicate whether you agree with this estimation and provide additional information if needed.

    c. Estimations as to possible additional waste to be generated through a forced substitution.

d. Estimation 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 — manufacture, supply chain, retail, medical services, etc.

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).

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.