

Response to: 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

Based on the application for exemption issued by COCIR and the consultation questionnaire from the Öko-Institut, Radiometer hereby respectfully provides the following input.

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?

Yes, Radiometer agree with the scope of this exemption. The scope covers an important use of DEHP in ion selective electrodes.

b. Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.

Radiometer agrees with the 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.

Radiometer has an ongoing project to substitute DEHP in our ion selective electrodes, but we have not yet succeeded in the substitution project.

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;

Radiometer cannot today point at a suitable substitute.

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

N/A

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).

The DEHP covers all the relevant electrodes at the sensor device and it is not possible for Radiometer to make a partial substitution.

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.

Our plan is to substitute DEHP before July 21, 2021.

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.

To Radiometer's knowledge the "lab-on-chip" technology will not be available for the foreseeable future.

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.

Radiometer uses DEHP in disposable sensor cassettes. The total amount of DEHP placed on the market in the EU is 35 g/year.

Further details have been submitted as a confidential document

Picture of the Radiometer sensor cassette containing DEHP:



Picture showing the position of the sensor cassette in the instrument:



Picture showing the instrument:



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.

The number of analysers per January 1, 2019 already placed on the market in the European Union is in total 7800.

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.

Radiometer has no knowledge about the total use of DEHP in the EU. The amount of DEHP placed on the EU market by Radiometer is 35 g/year, so 2.2 kg in total seems reasonable.

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

If accessories should not be available after 2021, the analysers cannot be used and must be scrapped. The amount of scrap from Radiometer equipment in this case is estimated to 73 ton.

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.

Details have been submitted as a confidential document

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).

The main cost will be replacement of all impacted point of care equipment. It is difficult for us to estimate the cost for replacement, as we do not know which equipment will be relevant as replacement. As the users are hospitals, most of the cost will be allocated to the public sector, apart from private hospitals and clinics. Radiometer does not know the share between public and private users of our equipment.

Apart from the cost of equipment for replacement a considerable cost must be expected to train the staff in the new equipment. We estimate the total replacement cost to be approximately € 130 million.

Further details have been submitted as a confidential document