1st 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 “

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 within a framework contract[1] for the evaluation of applications for new exemptions and the renewal of existing exemptions currently listed in Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.

COCIR has submitted a request for an exemption, which has been subject to a first evaluation. The information COCIR has referred has been reviewed and as a result we have identified that there is some information missing. Against this background the questions below are intended to clarify some aspects concerning the request at hand.

Questions

1. In your proposal for exemption wording you specify the exemption “for point of care analysis of ionic substances in human body fluids”. However, based on the information presented in the exemption application it can be understood that analysis is currently only performed on the following fluids: blood samples, pleural fluids and dialysate.
    a. Given that the wording proposed for the exemption implies a broader range of possible applications, please provide a complete list of human body fluids for which these type of ISE are actually used.

[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.

i. **Response to Q1a:**

The following body fluids are measured

1. Whole Blood
2. Serum
3. Plasma
4. Urine
5. Cerebral Spinal Fluid
6. Pleural fluid

Although dialysate is not a body fluid the instrument and sensors are used to measure this in cases of patients undergoing life saving dialysis. The results are used to adjust the dialysis settings such that a patient's blood is properly cleaned.

b. As it can be understood that the relevant electrodes are used in blood gas analysis PoC equipment, please clarify if the scope of the exemption could be limited to ion selective electrodes applied in point of care blood gas analysis equipment. If so, please provide an updated formulation for the exemption in this respect.

i. **Response to Q1b**

1. See answer 1a: the scope is limited to ion selective electrodes for point of care analysis of ionic substances in human body fluids and also other body fluids as noted above and in dialysis.

2. The application mentions that in a specific device available on the EU market, "this instrument analyses sodium, potassium, pH and pCO2 using DEHP-containing membranes with ion selective electrodes". Is the use of DEHP-containing membranes only common for these analytes or may DEHP be used with other analytes by other manufacturers/in other devices. If use cannot be limited to these analytes, what does it depend on?

i. **Response to Q2**

1. DEHP could be used for other analytes by other manufacturers/in other devices, but we have no information on other manufacturers' products. We expect interested manufacturers will contribute to the public consultation phase should they need this exemption to be extended to other products.

2. The use depends on achieving acceptable clinical performance such that the correct diagnosis treatment is provided. Also acceptable analytical performance.

3. You state in the application that "ion selective electrode membranes containing DEHP are manufactured outside of the EU". Please provide information about the manufacturers

currently placing this component on the EU market respectively the blood analysis equipment in which it is used.

i. **Response to Q3**

1. We are unable to provide specific information as we have no knowledge of other manufacturers' products. However some manufactures of similar components have production in the U.K. Denmark, Switzerland, Finland and Poland (https://danishstatevisit.hr/media/uploads/radiometer_morning_-_critical_care_testing_today.pdf). Another manufacture has bases in Spain and Italy (Werfen). We also expect other manufacturers/importers to contribute to the public consultation should they need the same exemption or to extend it to other products not covered by our dossier.

4. You provide an estimation of 2.2 kg of DEHP entering the EU market annually. This amount refers to 70 wt% of substance content in the homogenous material. Can you provide information about the typical size and weight range of ISE cartridges currently available on the EU market in order to give context for this data for stakeholders (public information).

i. Response to Q4

1. For one manufacture the weight of a cartridge is 1.34 kg. Therefore each unit cartridge contains 0.00021 weight% of DEHP.

2. Size is 29 x 26 x 20 cm

5. As justification for the use of DEHP in ISE cartridges, you refer to compatibility characteristics with "*existent analyser already on the market and in use within EU hospitals*". This has implications for premature obsolescence and therefore disposal of waste EEE in the event of forced substitution. Please provide more information about the estimated number of this specific type of IVD analysers currently on the market in the EU. In this respect please refer among others to:

   a. the total EU stock of PoC blood analysis devices and the stock of devices that could not be operated should the exemption not be approved;

   b. the estimated total annual sales of PoC blood analysis devices and the sales of such devices that could not be operated should the exemption not be approved;

   c. the estimated total annual sales of ISE cartridges for PoC blood analysis devices and the sales of such cartridges that would benefit from the exemption (i.e. that contain DEHP);

i. **Response to Q5a**

1. We cannot answer this with specific information as such market data is strictly confidential. However we can give high level information that is available in the public domain. In terms of stock, POC analysers are small benchtop devices and many are used in throughout hospital settings in contrast to large Central Lab Hospital instruments where typically 1-2 are in any one location. For one

manufacture it could be estimated that >3500 Central lab type instruments will be in place by 2020 (https://static.healthcare.siemens.com/siemens_hwem-hwem_ssxa_websites-context-root/wcm/idc/groups/public/@global/@press/documents/download/mda4/nzaz/~edisp/q4_fy-2018_press_presentation_en-05851799.pdf). Therefore for benchtop POC devices across several manufactures it can be estimated that >30,000 instruments could be in the EU (3500 X 3 instruments/per site x 3 manufactures). Presuming that one device has an average weight of 16.6kg and all need to be replaced, the total generated WEEE would be 500t. Replacing these 500t by new devices would also lead to additional RoHS substances entering the EU market (e.g. lead in steel up to 0.35%, lead in aluminium with up to 1.5%, lead in copper with up to 4%).
Assuming that 20% steel, 10% aluminium and 5% copper are being used, with a lead content of 0.35% in steel, 1.5% in aluminium and 4% in copper, the total weight of additional lead put on the market would be 2100kg (compared to a saving of 2.2 kg DEHP).

Total Weight of EEE which need to be replaced [kg]	**500.000**
% Steel	20,00%
% Aluminum	10,00%
% Copper	5,00%
% Lead content in Steel	0,35%
% Lead content in Aluminum	1,50%
% Lead content in Copper	4,00%
Total Weight of Lead entering the market by products replacing the installed base [kg]	**2.100**

In addition each instrument uses a range of cartridges (1-3), quality control materials and accessory consumables (e.g. syringes) all of which would be in stock. The cartridges would not be sold outside of the EU as there are other distribution centers which support the rest of the world. Manufacturing production and distribution centers are pre stocked based on forecast demand so all material is accounted for. In addition there is a limited shelf life so all stock would go to waste. Even if the manufacturer could sell outside of the EU the stock at the other centers would go to waste. Therefore millions of consumables would not be used and would become waste.

ii. **Response to Q5b**

1. One manufacture reported > $4.6 bn in revenue for all of their diagnostics business in 2018 and approximately $1.5 bn is earned in the EU (https://www.healthcare.siemens.com/press-room/press-features/pf-2018-q4.html) . Therefore approximately $0.45 bn can be

attributed to POC assuming 30% contribution. For another manufacture (http://filecache.investorroom.com/mr5ir_danaher/526/2018%20Danaher%20Investor%20%26%20Analyst%20Event.pdf) they report approximately $0.9 bn revenue and assuming 50% is EU ($0.45 bn) and multiplying by 3 manufactures yields > $1.3 bn total annual sales.

iii. **Response to Q5c**

1. We cannot estimate the sales of cartridges as this is strictly confidential. However the revenue noted above includes all cartridges and associated consumables. The major portion of revenue from POC devices comes from the consumable stream. One manufacture reports that 85% is attributed to consumable consumption (http://filecache.investorroom.com/mr5ir_danaher/526/2018%20Danaher%20Investor%20%26%20Analyst%20Event.pdf). Based Q5b, approximately at least $1.1bn would benefit from the exemption.

6. COCIR estimates that it shall take between 8 and 10 years (from mid-2018) to complete the stages necessary for the establishment of a possible substitute. This timeframe corresponds both to the development of a substitute for DEHP in the current design as also to the development of the alternative "lab-on-a-chip" analysis technique. Given that the DEHP restriction was decided upon in July 2015, please clarify which development stages, aimed at achieving compliance, have been conducted already since July 2015 and what stages remain to be completed. If relevant please provide the information for both substitution routes (DEHP substance substitution route and "lab-on-a-chip" technological elimination route).

i. Response to Q6

1. As stated in the submission substitutes were not found which would be compatible with the current analysers. The EU Directive on in vitro diagnostics devices mandate that such systems meet and maintain claims for sensitivity, specificity, reproducibility for example. The alternative plasticisers that were tested do not yield equivalent performance.

2. The "lab-on-a-chip" development is in feasibility phase and will take 8 to 10 years before complete replacement will be possible. This work began before 2015 and was not due to the DEHP ban but driven by the need for improved patient outcomes by way of improved performance, addressing gaps in user needs and user cost reduction.

7. As part of the evaluation, socio-economic impacts are also to be compiled and evaluated. For this purpose, please provide non-confidential details in respect of the following in relation to all EEE placed on the EU market through this exemption (i.e., where possible, not just by COCIR members):

a. Please confirm that the provided information related to the volume of EEE (answers to question 5) concerned and the respective amount of DEHP to be avoided, can be used to estimate the relevant values for a 7 year period should the exemption not be granted.

b. Please estimate possible amounts of waste to be generated through a forced substitution should the exemption not be granted. (if relevant please refer to answers of question 5)

c. Please estimate possible 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.

d. Please estimate possible health impacts in total, in the EU and outside the EU, in both scenarios (BAU and forced substitution). 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).

i. Response to Q7

1. **Response to Q7a:** We cannot give specific details as this information is confidential and we do not have information from other companies as their information is also confidential. However the value in Question 4 (2.2 kg DEHP) is the amount of DEHP that is estimated to enter the EU market annually in case the exemption is granted.

2. **Response to Q7b:** We cannot give specific details but can provide a rough estimate. Using the answer from Q4, (1.34 kg/cartridge and 12/year/analyser), Q5a (30,000 analysers at a weight of 16.6 kg (https://usa.healthcare.siemens.com/point-of-care/blood-gas/rapidpoint-500-systems/technical-specifications)), approximately 1000t of waste would be generated per year through a forced substitution should the exemption not be granted. For one manufacture (1000t/3) approximately >300t of waste would be generated. These estimates do not include all associated consumables and therefore the total waste would be >1000t per year.

3. **Response to Q7c:** All functions and a range of industries would be negatively impacted e.g. manufacturing, supply chain, service, R&D, marketing, quality, regulatory, Information technology, associated Distributors, medical services and hospitals.

4. **Response to Q7d:** One manufacture estimates that approximately 158 million measurements are made per year and 432K samples are measured each day world-wide

(https://www.radiometeramerica.com/en-us/about-radiometer/key-facts). Assuming 50% is in the EU and typically more than one sample is taken from each patient therefore roughly 40 million patients would be impacted for one manufacture. For 3 manufactures approximately 120 million patients would be negatively impacted per year. Alternatively assuming the data from question 5a where 30,000 instruments are in the EU and each uses 12 measurement cartridges/year and each cartridge can measure 500 samples yields approximately 180 million measurements or 90 million patients (2 samples/patient) are negatively impacted.

5. **Response to Q7e:** The health impact resulting from additional costs is a theoretical calculation because there is currently no alternative system with the same performance. There would be a large disposable cost for the >1000t of waste as compared to preventing approximately 2.2 kg of DEHP from being placed on the market. The Hospital would need to submit requests for proposal from new vendors and precede through new tender evaluations to replace their current systems. The Hospital would need to rewrite all existing contracts, service and distribution agreements. The Hospitals will need to establish new stocks of all consumables. Each Hospital would have to validate the clinical performance at their site before the replacement analysers can be put into use. The analysers must be connected to the Hospital Information Server network and may require new hardware. New procedures would need to written for the analysers. All users must be trained on the new analysers before reporting patient results. The overall impact to Hospital infrastructure is similar to that described in Exemption 41, Sec 7.4.5 (http://rohs.exemptions.oeko.info/index.php?id=281). In particular it can be estimated that > $250 million would be incurred by Hospitals to replace all systems. Healthcare systems, like any business operate on defined budgets and these costs would be unanticipated leading to other negative impacts. Similar companies such as Werfen and Radiometer have bases throughout the EU (Spain, Italy, Denmark, Switzerland, Finland and Poland) could be impacted as well. The impact will be felt directly by the end users in Hospitals and Clinics were these critical care devices could no longer be used. This will negatively impact patient care as proper treatment would not be given and put lives at risk. However as noted above and different from exemption request 41, these are just theoretical calculations as there is no alternative system available with the same performance.

Please note that answers to these questions are to be published as part of the available information relevant for the stakeholder consultation to be carried out as part of the evaluation of this 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.