Clarification Questionnaire Exemption Request 2021-2

Exemption Request for „Bis (ethylhexyl) phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of whole blood"

INSTRUMENTATION LABORATORY ANSWERS – NON-CONFIDENTIAL VERSION

Abbreviations and Definitions

COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
CMR1345	Polymer resin that is discussed as a potential substitute for PVC
DEHP	Di-/Bis-(ethylhexyl) phthalate
EEE	Electrical and Electronic Equipment
IL	Instrumentation Laboratory
ISE	Ion selective electrodes
PVC	polyvinyl chloride
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment

Background

The Oeko-Institut has been appointed by the European Commission, within a framework contract[1], for the evaluation of applications for exemption from Directive 2011/65/EU (RoHS), to be listed in Annexes III and IV of the Directive.

Your organisations (Instrumentation Laboratory (IL) & Intertek Health, Environmental & Regulatory Services) have submitted a request for the renewal of the above-mentioned exemption, which has been subject to an initial evaluation. A summary of the main argumentation for justifying the request is provided below as a first basis to be used in the stakeholder consultation planned as part of this assessment.

Please read the summary of the argumentation provided to ensure that your line of argumentation has been understood correctly and provide answers to the questions that follow that address aspects requiring additional information and/or clarification.

[1] The contract is implemented through Framework Contract No. ENV.B.3/FRA/2019/0017, led by Ramboll Deutschland GmbH.

1. Summary of argumentation of applicant on the justification of the exemption

1.1. Background

DEHP is used as a plasticizer for the resin formulation of PVC. This polymer serves as a basis for disposable cartridges and sensor cards for electrochemical measurements of biochemical analytes and parameters in human blood such as pH, pCO2, Na+, K+, Ca2+ or lactate.

The EEE in which the sensor cards are used in and for which Instrumentation Laboratory (hereafter referred to as IL) and Intertek Health, Environmental & Regulatory Services (hereafter referred to as Intertek) request the exemption for IL's GEM Premier 4000 diagnostic medical analyser. The application belongs to EEE Cat. 8. The request does not cover any other uses of DEHP containing PVC.

The applicant requests a new exemption for the described use of DEHP in PVC for sensor cards for the GEM Premier 4000 proposing the following wording „*Bis (ethylhexyl) phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of whole blood*".

The exemption is requested for EEE Cat. 8 for a validity period of three years.

History of the exemption

In the RoHS Pack 17 study in 2019/20, COCIR had requested a new exemption for „*Bis (ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids".* The study recommended to grant the exemption for Annex IV with a slightly adapted wording: "*Bis(2-ethylhexyl) phthalate (DEHP) in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids*".

The wording in the Draft Commission Delegated Directive as set out in Commission Document C(2021) 5868 final, dated Brussels, 11.08.2021[2] is identical to the recommendation given by the consultant in RoHS Pack 17 report ("Bis(2-ethylhexyl)phthalate(DEHP) in ion-selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids. Expires on 21 July 2028"). Provided the Draft Commission Delegated Directive is adopted as drafted this exemption shall be granted for a validity period of seven years.

Due to differences in wording of the future Ex. 45 Annex IV and the wording of the requested exemption, it needs to be clarified if the present exemption request is an extension of scope or already covered under the Pack 17 exemption or made in light of lacking knowledge on the status of the Ex.

Volume of DEHP to be placed on the EU market through the exemption

The amount of the substance entering the EU market annually through the application for which the exemption is requested is stated to be 1-10 kg.

[2] https://ec.europa.eu/transparency/documents-register/detail?ref=C(2021)5868&lang=en (last accessed 29.10.2021)

1.2. Technical description

The applicant manufactures a diagnostic medical analyser, the GEM Premier 4000. The instruments are used to measure the blood of patients and provide an accurate measurement of specific analytes. The applicant details pH, pCO2, PO2, Na+, K+, Ca 2+, Cl-, glucose, lactate and hematocrit in this respect.

Regarding the component in which DEHP is used, the applicant specifies that '*the heart of the GEM Premier 4000 is the sensor card where the electrochemical measurements of the above mentioned analytes take place […] [the sensor cards] have an additional additive, DEHP, which is part of the resin [currently PVC] formulation'*: DEHP functions as a plasticizer to facilitate the injection molding process of PVC, the host material. An important requirement of the functionality of DEHP and its substitutes is that it should not interfere with the measurement of analytes.

The consultants understand that these cartridges containing DEHP are consumables of the analysers, specifically the GEM Premier 4000, which are nevertheless to be considered as electrical and electronic equipment (EEE)[3]. They are disposed of after the analysis has been completed. The consultant understands, that in addition, these must be compatible with the type of analyser model that are already being used by hospitals in the EU. In this sense, the consultants understand that the exemption is at least in part concerned with the provision of such cartridges on the EU market, so as to ensure that devices already on the market can continue to be operated.

1.3. Applicant's justification for the requested exemption

1.3.1. **Availability of alternatives** *(Substitution or Elimination, roadmap to substitution, reliability of substitutes)*

The applicant claims that substitution is not yet possible, providing a roadmap ("project plan") and proposes that DEHP can be replaced within the coming 3 years. However, the applicant explains the choices for current materials and substances as follows: PVC is uses as sensor card material and membrane used (i.e., PVC) should be of the same material to resist the solvent used in this analytical process. As to DEHP, it increases flexibility and reduces brittleness of PVC to improve durability and reliability in injection moulding. Furthermore, DEHP does not interfere with the analyte measurements which is a crucial pre-condition for alternatives for DEHP.

Compared to other analytical methods and instruments that test human blood for the respective analytes and parameters, the advantage of this technology over others are explained to be the following: According to the applicant, the instrument combines an intelligent quality management (iQMTM), a disposable measurement cartridge and regular testing of the cartridges.

A project plan has been submitted that structures the research for substitution of DEHP in the cartridges. The consultant understands that the applicant's research has two directions: A drop-in-substitute for DEHP in the PVC and an alternative resin/polymer that does not require DEHP or rather allows the substation of the same. According to the project plan, various resins that should substitute PVC were tested in 2016/17 from which one (CMR 1345) was selected as a top candidate to conduct a study of alternatives for DEHP. Three drop-in-alternatives for DEHP, namely Mineral oil, Ester lubricant V-DSP and Acrylic processing aid, were compared in an LCA. A clarification question shall verify whether this is correctly summarized.

[3] Cartridges are consumables with an equipment constituent meeting the specific definition of EEE in Article 3(1) and 3(2) of RoHS 2, comparable e.g. to printer cartridges, see FAQ 7.4. https://ec.europa.eu/environment/system/files/2021-01/FAQ%20key%20guidance%20document%20-%20RoHS.pdf (last accessed 29.10.2021).

1.3.2. Environmental and health arguments *(also LCA aspects)*

Preliminary results of a life cycle analysis of the current GEM Premier 4000 sensor card and identified alternatives are included as Annex to the application. Based on the preliminary report a full LCA for substitution of DEHP is promised to be submitted and will be based on the alternative substances used in the CMR1345 resin: Mineral oil (CAS# 8042-47-5), Ester lubricant, V-DSP (CAS#14117-96-5,) and Acrylic processing aid (CAS# 9063-87-0),

Preliminary results suggest that the three alternatives (for DEHP) are comparable to those of DEHP: '*Considering 18 environmental impact measures, the picture is mixed, with no substance being best by all measures. It should be noted that these are theoretical impacts assuming the substance all reaches the environment, but in the case of the sensor card the substance is encapsulated in the card.*'

No environmental and health arguments are provided in addition to the LCA.

1.3.3. Socioeconomic impacts

The applicant does not refer to socioeconomic impacts of substitution, as "alternatives are currently not available" and no additional references or evidences are provided as to socioeconomic effects due to the finding that this is "not relevant as alternatives are currently not available".

2. Clarification Questions

1. According to your application, the sensor cards provide the advantage, that they are disposable. However, it has not yet become clear whether one sensor card used per measurement of one analyte (e.g. Na+) / parameter (e.g. pH), or whether one sensor card is used per sample even when various concentrations and parameters are measured.

   a) How often can one sensor card be used?

      IL Response: A single GEM Premier 4000 sensor card is part of a multi-use disposable cartridge. One sensor card is used for up to 30 days or 450 whole blood sample measurements. Each sample measurement provides simultaneous results for multiple analytes, including pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, hematocrit, glucose, and lactate. Therefore, each sensor card is used to report up to 4500 measured concentrations (450 whole blood samples x 10 analytes).

      Note: The GEM Premier 4000 additionally provides tHb O_2Hb, COHb, MetHb, HHb, and tBili results for each sample , but these analytes are measured spectrophotometrically and do not rely on the sensor card (therefore not impacted by DEHP replacement).

   b) Is it correct to assume that the sensor cards that contain DEHP are designed specifically for each type/model of instrument, in this case the GEM Premier 4000.

      IL Response: That assumption is correct, the sensor card containing DEHP is designed specifically for the GEM Premier 4000. Sensor cards for other type/models of instrument are not compatible with the GEM Premier 4000.

2. You provide an estimation of 1- 10 kg of DEHP entering the EU market annually.

   a) Please specify the number of cartridges this corresponds to.

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b) Furthermore, please specify whether this encompasses only sensor cards for the GEM Premier 4000.

IL Response: The forecasted number of cartridges encompasses only GEM Premier 4000 cartridges. Each GEM Premier 4000 cartridge contains 1 sensor card.

c) Can you provide information about the typical size and weight range of the cartridges currently available on the EU market in order to give context for this data for stakeholders (public information).

IL Response: The following information is provided on the typical size and weight range of the cartridges:

- Typical cartridge dimensions: 25 x 16,5 x 16 cm
- Typical cartridge weight: 4.08 kg
- Typical sensor card weight: 5.1 g

3. Based on the Project Plan provided, it is understood that various resins that should substitute PVC were tested in 2016/17 from which one (CMR 1345) was selected as a top candidate to conduct a study of alternatives for DEHP. Three drop-in-alternatives for DEHP, namely Mineral oil, Ester lubricant V-DSP and Acrylic processing aid, were compared in an LCA.

a) Please explain whether this has been understood correctly.

IL Response: Yes, all three drop-in alternatives (Mineral, oil, Ester lubricant V-DSP, and Acrylic processing aid) are required in combination as a candidate to replace DEHP. All three alternatives are included in the LCA analysis.

b) So far, the applicant has provided a preliminary LCA for the comparison of DEHP-drop-in-substitutes. How do the alternatives compare from a functional performance point of view?

IL Response: The replacement of DEHP in the GEM Premier 4000 sensor card is on track with the project plan submitted as Appendix D with the exemption request form. As detailed in the testing summary, CMR 1345 met all defined performance criteria (Table 1 of Appendix B) and remains as the primary path forward for the GEM Premier 4000 platform. Further details can be found in Appendix B: Testing Summary for GEM Premier Systems with Sensor Card Resins Compliant with Directive 2011/65/EU submitted with the exemption request form.

c) When will the full LCA be available?

IL Response: The finalized LCA has been submitted with this response attached as updated versions of the confidential and non-confidential exemption request form as well as an updated version of Appendix F.

d) Will both, membrane and the “housing” of the membrane in the sensor card be replaced through the CMR 1345, or only the “housing” but not the membrane?

IL Response: Referring to the diagram shown below in Figure 1 which was included in the responses provided to the European Commission in March 2021, only the orange portion labelled ‘Sensor card’ will be replaced by CMR 1345. The sensor card can be appropriately described as the underlying substrate for the membrane, or the “housing” of the membrane. The membranes, hydrogels, pins, electrodes or silver print of the individual sensors will not be changed.

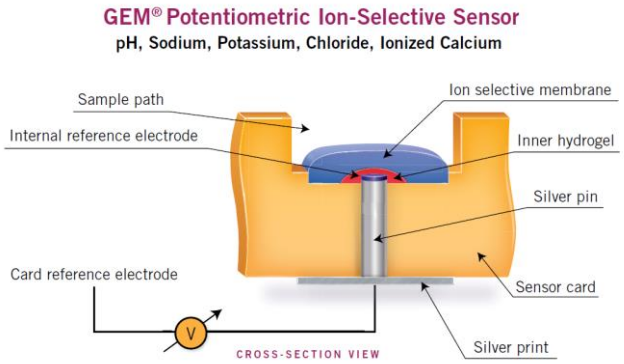

Figure 1. GEM Ion Selective Sensor

4. Your Exemption Request Form states that DEHP functions as a plasticizer in PVC which is understood as being an additive. In 2018, in its Exemption Request, the applicant, COCIR, expressed that "DEHP is used as a membrane solvent for the ISE". The general composition of the membranes is detailed as "29 wt % PVC, 70 wt % DEHP and an ionophore that imparts specificity for the particular ion of interest" (RoHS Pack 17 report[4]).

   In contrast to the membrane specifications provided by COCIR, you specify the content of substance in homogeneous material to be 1.14 wt % for the GEM Premier 4000 cartridges. Against this differences, in view of the technical specifications in the consultant's report for Pack 17 and based on your understanding, please explain your view as to the terms "solvent" and "additive" in this regard.

   IL Response: Within the IL exemption request form, the terms "solvent" and "additive" are used as follows. An "additive" is a component added to a mixture to impart a specific property to the mixture. In the IL exemption, DEHP is an additive used to increase the plasticity of the resin. A "solvent" is defined as a substance in which another material is dissolved or dispersed. We kindly suggest that Oeko Institute contact COCIR for their input on the use of these terms in their application for Ex 45.

5. The consultant bases its assessment of similarities and differences of the scope of COCIR's exemption request and the present exemption request on the explanations provided by IL/Intertek as an attachment to an E-Mail to the European Commission on April 15 2021. The consultant has received the respective document. If IL wishes to add information as to this explanation provided earlier, please in a response to this question comment on the difference in scope between the requested new exemption and the one to be granted based on the COCIR request.

   IL Response: Please refer to the communication with the European Commission of March, April and May 2021, which detailed the technical differences in scope between the present exemption request and the COCIR exemption request and asked the European Commission to confirm that the COCIR exemption request would cover the equipment and uses of DEHP defined in the present exemption request. However, the European Commission in the email send to us on 4th May 2021 concluded that "Despite the similarity of the requested technical application for an exemption with the pending exemption decision for DEHP in ion selective electrodes under Pack 17, it was deemed after consultation that the current requested application is not consistent with this pending exemption wording".

[4] https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/RoHS_Pack-17_final-final_May_2020.pdf

6. Based on your correspondence (E-mail to the European Commission on April 15 2021, incl. attachment), it is understood that the PVC sensor card is applied for measurement of blood concentration of certain ions, e.g. Na+, as well as for amperometric, conductometric and spectrophotometric. In the Exemption Request Form (submitted Jan 21 2021, page 1) you propose the wording of the requested exemption to specify "amperometric, potentiometric and conductometric electrochemical sensors". This does not include spectrophotometric measurements. While amperometric, potentiometric and conductometric measurements as well as measurement of ionic analytes require an (ion selective) electrode, photometric measurements are based on effects of the analyte after a light-induced excitation.

   a) Please specify which analytes and/or parameters are measured through photometric measurements through the means of GEM Premier 4000.

      IL Response: CO-Oximetry parameters (tHb, O_2Hb, COHb, MetHb, HHb) and total bilirubin are measured and reported through spectrophotometric methods on the GEM 4000 system along with the 3 other electrochemical methods described above. However, these spectrophotometric measurements are not performed on the sensor card and are not part of the exemption.

   b) Please explain whether it is right to understand that the sensor card applied in the GEM Premier 4000 is more than an ISE based on the definition of an ISE being a sensor composed of an electrode with a selective membrane that seals to an underlying substrate). Please elaborate on this in your answer.

      IL Response: The GEM Premier 4000 contains both ion selective electrodes (potentiometric sensors), and well as amperometric sensors and conductometric sensors. Not all of sensors on the GEM Premier 4000 sensor card meet the definition of ISE defined above. The amperometric sensors differ because the membrane does not provide selectivity and instead utilizes enzymes to convert analytes of interest to measurable signals, and the conductometric sensor for hematocrit does not utilize a membrane at all.

   c) Please provide an exhaustive list of measurements that are possible to conduct through the means of the GEM Premier 4000, please further specify whether for all these measurements an electrode using DEHP is required.

      IL Response: The measurements reported on the GEM Premier 4000 are listed below along with an indication of whether or not they utilize and electrode using DEHP.

Reported Measurement	Measurement Methodology	Utilize an electrode using DEHP
pH	Potentiometric (ISE)	Yes
pCO2	Potentiometric (ISE)	Yes
pO2	Amperometric	Yes
Na+	Potentiometric (ISE)	Yes
K+	Potentiometric (ISE)	Yes
Ca++	Potentiometric (ISE)	Yes
Cl-	Potentiometric (ISE)	Yes
Hematocrit	Conductometric	Yes

Glucose	Amperometric	Yes
Lactate	Amperometric	Yes
tHb	Spectrophotometric	No
O2Hb	Spectrophotometric	No
COHb	Spectrophotometric	No
MetHb	Spectrophotometric	No
HHb	Spectrophotometric	No
tBili	Spectrophotometric	No

7. Provided that the exemption request is rejected and the use of DEHP in sensor cards for the GEM Premier 4000 is seen not covered under RoHS Ex. 45, please provide an estimate of socioeconomic impacts with a special focus on impacts for health facilities.

   IL Response: If the present application is rejected by Competent EU Authorities and if the use of DEHP in sensor cards for the GEM Premier 4000 is seen not covered under RoHS Ex. 45, the negative socioeconomic impact for Healthcare Facilities will be significant.

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   - If the exemption application is rejected those instruments would need to be removed from service and disposed of.
   - New capital equipment would need to be purchased by healthcare providing institutions.
   - The new equipment would need to be validated by the healthcare providers.
   - Hospital staff would need to be trained to operate the new equipment.
   - Demand for this volume of equipment and installation activities could not be met in a short period of time and resulting in lack of availability of testing capacity.

   Please refer to the attached copies of communications submitted to the Oeko-Institute in December 2017, by the two European Healthcare institutions ASST-Bergamo Est and CHU de Clermont-Ferrand confirming the need to ensure continued availability of GEM analyzers in order to ensure well-functioning healthcare operations as well as the safety of patients.

8. Given the fact, that RoHS the Pack 17 Exemption official publication is pending, the final wording is not yet clear. However, provided that the suggested wording[5] as set out by the Commission in August 2021 will be the final legal wording, and provided that it will be clarified that your and COCIR's Exemption requests can be summarized, does your organisation have a preference for the current proposed wording for Ex. 45 ("Bis(2-ethylhexyl) phthalate (DEHP) in ion selective

[5] https://ec.europa.eu/transparency/documents-register/detail?ref=C(2021)5868&lang=en (accessed

electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids"), or do you prefer an amendment of the possible future exemption.

IL Response: As stated in our above answer to question 5 currently the European Commission has concluded that the present exemption request is not covered by the COCIR exemption request. However, subject to confirmation by competent EU authorities of an amendment of the wording of the COCIR exemption request to include the uses and equipment defined in the IL exemption request, we propose the following edits to the wording of the COCIR exemption request:

("Bis(2-ethylhexyl) phthalate (DEHP) in ~~ion selective~~ electrodes applied in point of care analysis of ~~ionic~~ substances present in human body fluids and/or in dialysate fluids")

9. If you think there is anything else that is relevant in addition to the questions above, please summarise it under this point.

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!

IL Response: Our above answers are provided in a confidential and a non-confidential version.

Finally, please do not forget to provide your contact details (Name, Organisation, e-mail and phone number) so that Oeko-Institut can contact you in case there are questions concerning your contribution.