Consultation Questionnaire Exemption Request 2022-1

Exemption Request for *„Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood"*

Abbreviations and Definitions

BUN	Blood Urea Nitrogen
CHO	Cyclohexanone
CMR1345	Colour master resin 1345. It is the polymer resin that is discussed as a potential substitute for PVC
EEE	Electrical and Electronic Equipment
IL	Instrumentation Laboratory
LCA	Life Cycle Assessment
POC	Point of Care
PVC	Polyvinyl Chloride
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
TBLS	Tribasic Lead Sulphate
THF	Tetrahydrofuran
%wt	Percentage by weight

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.

Instrumentation Laboratory (IL) & Intertek Health, Environmental & Regulatory Services have submitted a request for a new exemption, which has been subject to an initial evaluation. A summary of the main argumentation for justifying the request is provided below. The applicant has been requested to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation at:
http://rohs.exemptions.oeko.info/index.php?id=379

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

For further details, please check the applicant's exemption request under the above link.

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 2), 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 read the summary of the argumentation provided and answer the questions that follow.

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

1.1. Background

Lead (Pb) is a constituent material (6.5%wt) in the polyvinyl chloride (PVC) sensor card of the disposable cartridge used with the GEM Premier ChemSTAT analyser, which was released in December 2019. The applicant clarified that GEM Premier ChemSTAT analyser is still in production, and "*both existing and new GEM Premier ChemSTAT instruments require the use of Pb-containing sensor cards*" (IL - Instrumentation Laboratories 2022). Compared to the other GEM Premier models, GEM Premier ChemSTAT introduces two new sensors, for the measurement of creatinine and BUN. The resin CMR 2151 is used in the GEM Premier ChemSTAT sensor card. The current production sensor card resin contains Pb-based thermal stabilizer (tribasic lead sulphate, TBLS). TBLS is required for heat stability during injection moulding, i.e., to prevent breakdown of the PVC resin during high temperature injection moulding process required to produce the sensor card. The sensor card is a vital component in the GEM Premier ChemSTAT cartridges as it contains the electrochemical sensors used for measuring and reporting concentrations of critical care analytes in blood (pH, pCO_2, Na+, K+, Ca++, Cl-, glucose, lactate, haematocrit, creatinine, blood urea nitrogen and tCO_2).

The applicant requests a new exemption for the described use of Pb in PVC for sensor cards for the GEM Premier ChemSTAT proposing the following wording "*Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood*".

The application is part of a medical device which is under the scope of RoHS Annex I, category 8 (medical devices). The exemption is requested for a validity period of 24 months. The request does not cover any other uses of Pb containing PVC.

History of the exemption

An exemption is listed in RoHS annex IV for lead as a thermal stabiliser in polyvinyl chloride (Ex. 41 Annex IV). The exemption was initially granted in 2015, by Delegated Directive (EU) 2015/573, following an assessment of a request for a new exemption submitted by IL. The exemption was set to expire on 31 December 2018. Later, IL applied for a renewal of the exemption, whose extension was assessed during 2017-2019 (Oeko-Institut e.V. Institute for Applied Ecology, Fraunhofer-Institut for Reliability and Microintegration 2019). The assessment recommended the renewal until 1 April 2023, if the Commission agrees that environmental impacts of substitution justify an exemption, or an 18-month transition period in case of revocation.

According to the Commission Delegated Directive (EU) 2020/366 of 17 December 2019, the actual wording is "*Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases*". The expiry date of the exemption is 31 March 2022.

A renewal request was not made for this exemption 18 months ahead of its expiration, as required according to Article 5.5, directive 2011/65/EU, and it expired few days ago.

Volume of Pb 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 0.5-10 kg. Moreover, the applicant states "*As the newest product in the GEM family, GEM Premier ChemSTAT contributed less than 0.5 kg of lead annually in 2020*". The consultants understand that the GEM Premier ChemSTAT was only recently released to the market, explaining the difference between the 2020 volume of Pb and the estimated range. This understanding was confirmed by the applicant in his response to the clarification questions.

1.2. Technical description

The applicant manufactures a diagnostic medical analyser, the GEM Premier ChemSTAT. The instruments are used to measure the blood of patients and provide an accurate measurement of specific analytes. The applicant details pH, pCO2, Na+, K+, Ca 2+, Cl-, glucose, lactate, hematocrit, creatinine, BUN and tCO2 in this respect. The GEM Premier ChemSTAT enables rapid risk stratification and prioritization of acutely ill patients in the Emergency Department and other point-of-care locations. Furthermore, the addition of creatinine and BUN measurements to GEM Premier ChemSTAT aid in the diagnosis, monitoring and treatment of renal dialysis and metabolic diseases.

According to the submitted application, the GEM Premier ChemSTAT analyser offers a single, disposable measurement cartridge which can be stored up to 5 months at room temperature. Each cartridge has a use-life of 21 days or 450 samples, whichever is reached first (IL - Instrumentation Laboratories 2022). Regarding the component in which Pb is used, the applicant specifies that '*the sensor card is a vital component in the GEM Premier ChemSTAT cartridges as it contains the electrochemical sensors used for measuring and reporting concentrations of critical care analytes in blood".* There is one sensor card contained in each cartridge (IL - Instrumentation Laboratories 2022). The consultants understand that the sensor card has the same use-life span of the cartridge in which it is contained, and it is disposed with the cartridge. The consultants understand that these cartridges, containing Pb, are consumables of the analysers, specifically the GEM Premier ChemSTAT, which are nevertheless to be considered as electrical and electronic equipment (EEE)[2]. Cartridges are used for analysis for a limited duration and are disposed of after the analysis has been completed. Finally, the consultant understands that the exemption is concerned with the provision of such cartridges on the EU market, so as to ensure that devices already on the market as well as new devices can continue to be operated until a substitute is developed that is "reverse compatible" with such devices.

[2] 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 10.03.2022).

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 explains the choices for current materials and substances as follows: membrane adhesion to the PVC is a critical requirement for sensor function and claimed use life and shelf life. PVC has specific advantages as a sensor card material for the electrochemical sensors used in the GEM Premier ChemSTAT. Sensor membranes used for certain sensors (Creatinine, Blood Urea Nitrogen, Glucose, Lactate, Na+, K+, Ca++, pH, pCO2) are based on polymer membranes and are solvent cast directly on the sensor card from a solution of tetrahydrofuran (THF) and cyclohexanone (CHO). Because THF/ CHO is a strong solvent for the PVC card, there is strong adhesion between the cast membranes and the PVC card.

According to the applicant, "*any change to the sensor card resin can directly impact analytical performance characteristics of the GEM Premier ChemSTAT*", as well as "*the raw sensor results to inform the GEM Premier ChemSTAT intelligent Quality Management System (iQM™), which ensures high quality and accurate blood measurements*".

The applicant claims that the direct substitution of Pb has been pursued for more than 2 years. CMR 1345 has been selected as a lead-free sensor card resin candidate for GEM Premier ChemSTAT. In this resin, a combination of three substances is used as an additive, instead of Pb. Pb and a combination of these substances were compared in an LCA. The applicant requested to keep the identity of the substitutes confidential.

IL is testing CMR 1345 to ensure this sensor card resin change does not negatively impact the analytical performance characteristics, patient safety or effectiveness of the device, specifically for the sensors unique to the ChemSTAT platform – creatinine and BUN. A roadmap ("project plan") for the substitution of Pb is provided by the applicant. According to the plan, the Controlled Distribution of RoHS Resin will be accomplished by the end of 2023 (Q3-Q4).

The applicant claims to have experienced a delay in developing a lead-free material caused by changed hospital needs during the COVID-crises, i.e., the increased analyser and cartridge demand due to the critical role of blood gas analysis in the management of hospitalized patients with COVID-19. Thus, the applicant will not meet the expected date of March 2022, which was reported already in the application for renewal assessed within RoHS Pack 14 (IL - Instrumentation Laboratories 2017). Indeed, the applicant claims that "*due to the necessary shift in focus to meet customers' high demands, fewer GEM ChemSTAT RoHS sensor cards and cartridge were manufactured for research and development testing*". The consultant understands this to mean that testing was delayed as manufactured cards and cartridges were prioritised for use in health facilities. In his response to the clarification questions, the applicant explains that "*a single manufacturing line is responsible for sensor cards (i.e., all cards, both production cards and experimental Lead-free cards) for all GEM product lines (i.e., not only the GEM ChemSTAT analyzer). As a result of COVID-19, the increased demand for all GEM cartridges exceeded the capability of the manufacturing facility, and this meant that dedicated runs of non-production material needed to be deprioritized*" (IL - Instrumentation Laboratories 2022).

The unique features of GEM ChemSTAT require additional due diligence, thus extending the duration of the tests necessary for substitution. The applicant asserts that "*the increased complexity of Creatinine and BUN sensor designs make these new sensors more difficult to manufacture than sensors on other GEM platforms"*. Furthermore, "*the GEM Premier ChemSTAT was designed with*

unique reagents requiring more complex sensor calibration process". Finally, "*additional effort is required to ensure the analytical performance claims (Method Comparison, Precision, Use Life and Shelf Life) are met with the sensor card resin change"* because of *"the limited clinical data available on this newest product using the current production resin"*.

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 sensor cards.

From the application, it emerges that "*other competitive solutions on the market in the EU for POC creatinine measurements are either single use (generating more waste) or require burdensome consumables with different on-board stabilities and refrigerated storage conditions. Moreover, the competitive analyzers need hands-on time to be maintained and/or troubleshooted as often as daily or weekly basis. Conversely, the GEM Premier ChemSTAT is a self-contained system requiring very little operator interaction*".

The advantages of the use of multi-use cartridges are described by the applicant in the answer to the clarification questions (IL - Instrumentation Laboratories 2022). Besides, in the same document, the applicant states that the following competitive solutions exist for creatinine and BUN measurement:

- Competitors offering creatinine and BUN:
  - iSTAT (single use cards): CHEM8+ for creatinine and BUN. Crea for creatinine. EC8+ and 6+ for BUN.
  - Epoc (single use card)
  - ABL90 Flex w/Crea (multi-use, multi-cartridge)
  - Nova Stat Profile Prime (multi-use, multi-cartridge)
- Competitors offering only creatinine:
  - ABL800 Flex (traditional laboratory-style system)
  - Nova StatSensor (singe use strip)

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

The results of a life cycle analysis of the current additive (i.e., Pb) of the GEM Premier ChemSTAT sensor card and the identified alternative are included as Annex to the application. The results reported are calculated with the following carachetrisation methods: ReCiPe, USEtox, Cumulative Energy Demand and Impact 2002+. The cradle-to-grave ReCiPe LCA results show that Pb has a better performance in all the impact categories, except for "land use" and "mineral resource scarcity". On the other hand, if the methods USEtox or CED are selected, impacts are lower for Pb than for the alternative, in all the impact categories. Finally, the Ecopoint method results show that Pb achieved a score of 1.8 µPt versus 87.8 µPt for the combination of the other additives. The overall conclusion is that the LCA provides evidence that Pb has lower environmental impact (in terms of the results produced by LCA) than the combined alternatives.

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 evidence are provided as to socioeconomic effects due to the finding that this is "*not relevant as alternatives are currently not available*".

However, the applicant claims that "*without this submission being approved, the supply of point-of-care (POC) GEM Premier ChemSTAT analyzers that support hospitals and laboratories in the EU will be jeopardized, negatively impacting several hospitals in the EU Health Care Sector. If an exemption is not granted, it would require a delay in patient care as all hospitals using the GEM Premier ChemSTAT would need to convert to an alternate technology. This would require additional training on competitive analyzers, elevating risk of mistakes which may pose a threat to patient safety, thereby increasing cost to all EU Heath Care currently using the GEM Premier ChemSTAT*".

2. Questions for stakeholders

1. The applicant has requested an exemption, proposing the following wording formulation for a duration of 2 years:

> "*Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood"*

   a. Do you agree with the scope of the exemption as proposed by the applicant?

   b. Do you agree with the validation period requested?

   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.

2. Through the following questions we would like to understand better the situation of the market of amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen in whole blood.

   a. Please, describe the market of amperometric, potentiometric and conductometric electrochemical sensors used for this application.

   b. Please estimate how much lead can be placed on the market through the use of the required exemption by all manufacturers of equipment using such PVC sensor cards.

   c. If you are a manufacturer of a competitive solution, please clarify if your devices measure creatinine and/or BUN, if they require single-use or multi-use cards, and their content of PVC and Pb. Moreover, please, clarify if the appliances need multiple cartridges and/or highly trained operators who can operate the analysers, and which are the storage conditions for the cartridges and the cards.

   d. Would it be possible to use your cartridges and/or sensor cards in the GEM Premier ChemSTAT analyser?

3. Please provide information concerning possible substitutes for Pb as a thermal stabilizer in PVC used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and BUN in whole blood

    a. on the level of the material, thus, the substitution of PVC.

    b. on the level of thermal stabiliser, i.e., substitution of TBLS.

4. 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. Please estimate possible amounts of waste to be generated through a forced substitution should the exemption not be granted.

    b. 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, etc.

    c. 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, end-users).

5. Please provide any further information and/or data that you think is of importance to substantiate your views.

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 can contact you in case there are questions concerning your contribution.

3. Publication bibliography

IL - Instrumentation Laboratories (2017): Exemption Request Form for the renewal of Ex. 41 of Annex IV of Directive 2011/65/EU. Available online at http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_pack_14/Annex_IV_Ex_41/Application/RoHS_Form_V_Revised_final_non_confidential.pdf.

IL - Instrumentation Laboratories (2022): Clarification Questionnaire Exemption Request 2022-1. Available online at https://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack_26/Answer_to_clarification_questions_CS_ROHS_Exempt_AI_Mar_IL_2022_04-05_PUBLIC.pdf.

Oeko-Institut e.V. Institute for Applied Ecology, Fraunhofer-Institut for Reliability and Microintegration (2019): Study to assess eight (8) exemption requests in Annexes III and IV to Directive 2011/65/EU: “Renewal of exemptions III.41, IV.37, IV.41, and requests for new exemptions for lead and DEHP in certain NRMM engines applications, lead in solder and

hexavalent chromium to be used in mass spectrometers, lead in certain thermal cutoff fuses and lead in solders of certain applications used to identify radiation" (Pack 14) –Final - amended. Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation. Available online at https://data.europa.eu/doi/10.2779/285833.