Consultation Questionnaire Annex IV Ex. No. 41 (renewal 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 blood and other body fluids and body gases“, to expire 31. December 2018 “

Abbreviations and Definitions

IL	Instrumentation Laboratory
Pb	Lead
PVC	Polyvinyl chloride

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.

Instrumentation Laboratory (IL) 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=281).

Instrumentation Laboratory applies for the renewal of exemption 41 of Annex IV of the Directive, 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 blood and other body fluids and body gases*". The exemption is currently valid until 31 December 2018. IL expects to be RoHS compliant within 7 years and requests a renewal until 31 December 2025.

This exemption was first evaluated in 2013 and the exemption was recommended as on the basis of available information substitutes were not yet available. At the time Radiometer Medical Aps (Radiometer) supported the request, explaining that the substitution of lead in the PVC of their sensor cards had also not yet been possible.

The applicant explains that GEM Premier diagnostic medical analyzers are used to measure blood of patients and provide clinicians with accurate measurements of specific analytes vital to medical diagnosis and patient treatment. The reported analytes include, among others, pH, pCO2, pO2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate and hematocrit. A sensor card is used in the GEM Premier family, where the electrochemical measurements of the above analytes take place. The sensor cards are produced from PVC and lead is currently used in the sensor cards as a stabilizer for this material.

[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.

IL specifies the contents of lead in the PVC in the range of 2.7-6.6 %/weight, depending on the analyzer model. Based on the 2017 forecast for GEM Premier cartridge shipments to the EU, the estimated total amount of lead contributed to the EU by the sensor card is estimated to be 48.14 kg. The lead weight related to lead in the PVC sensor cards placed on the EU market by all blood gas analyzer manufacturers is estimated by IL at 144.43 Kg. This is observed as a rough estimation as according to IL data is not publicly available as to the actual formulations of PVC used by different manufacturers.

IL explains that it has not been possible to find a stabilizer other than lead that works, without affecting the analytical performance of analyte measurements in the GEM Premier instruments. The alternative stabilizer must not interfere with measurement of any analyte on the system over the claimed product shelf life (up to 9 months at room temperature) and use life (up to 4 weeks in the analyzer). Such interference would impede the intended function of the analyzers. IL states that promising candidates for substitution include several organic-based stabilizers and stabilizers based on zinc or calcium-zinc. Candidates, considered as thermal stabilizers to replace lead in the sensor card, have been investigated and shown to produce interferences in relation to the sodium sensor, the oxygen sensor; and imprecisions in the measurement of glucose, lactate and hematocrit in blood.

Nonetheless the applicant explains that some of these alternative PVC thermal stabilizers, when used in addition to minimal quantities of lead in concentrations below 0.1% in the sensor card, have shown results moving in a positive direction to address the performance problems seen when the alternative thermal stabilizers are applied on their own. The focus of continued investigations thus includes optimizing the selection of an alternative thermal stabilizer to be used in addition to the presence of 0.098% lead (will likely contain tribasic lead sulfate) in the PVC resin of the GEM Premier sensor card. The presence of lead in the plastic sensor card appears to enhance performance and is required for proper functioning of certain sensors deposited on the PVC sensor card; specifically, pO2, glucose, lactate and hematocrit.

For details, please check the applicant's exemption request at:
http://rohs.exemptions.oeko.info/index.php?id=281

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 a renewal of exemption 41 of Annex IV of the RoHS Directive, with the existing wording as specified above.
    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. In this respect, please refer to alternative measuring technologies that can be used to cover part or all of the application scope of the GEM Premier blood analysis devices, and that would make the exemption and/or its parts obsolete.

   d. 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. Please provide information concerning possible substitutes or developments that may enable reduction, substitution or elimination, at present or in the future, of lead applied as a thermal stabilizer in polyvinyl chloride (PVC) of amperometric, potentiometric and conductometric electrochemical sensors used in in-vitro diagnostic medical devices for the analysis of blood;

   a. In this regard, please provide information as to alternatives that may cover part or all of the applicability range of lead in PVC sensor cards (for example in relation to the measurements of specific analytes);

   b. In your answer please refer not only to substance substitutes of lead within the PVC sensor cards, but also to possible substitution of PVC that would eliminate the need for lead in this application.

   c. 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 lead applied as a thermal stabilizer in polyvinyl chloride (PVC) sensor cards.

   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.

4. Radiometer Medical Aps (Radiometer) supported the request in the past. For other manufacturers of blood analysis equipment (for example Siemens Healthcare and Abbott Laboratories) it was not possible to clarify at the time whether lead was still used in their sensor cards.

   a. Please provide information as to the use of lead in the sensor cards of other blood analysis equipment manufacturers.

   b. Please specify whether other manufacturers have achieved lead substitution or elimination in this application or whether this is pending in the near future.

   c. If relevant please specify the application range (measurements of specific analytes) of respective equipment to clarify if limitations may apply to the application of certain substitutes.

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. The volume of PVC sensor cards, placed on the market in the EU was estimated by IL to be around 2,889 Kg per annum. Please specify if you support this estimation or provide an alternative estimation backed with relevant data and calculations.

b. The amount of lead to be avoided should the exemption not be granted (in the EU) was roughly estimated by IL as 144.3 Kg. Please specify if you support this estimation or provide an alternative estimation backed with relevant data and calculations.;

c. IL estimates that around 334,921 Kg of blood analyser equipment use PVC sensor cards and could no longer be used should the PVC cards no longer be available on the market. Please specify if you support this estimation or provide an alternative estimation backed with relevant data and calculations;

d. IL details impacts on employment in the EU and worldwide qualitatively, should the exemption not be renewed (see response to clarification questions).

    i. Please explain whether you support this view and which additional costs and benefits should be taken into consideration, should the exemption not be granted. Please refer in your answer to the main sectors in which possible impacts are expected – blood analysis device manufacturers, manufacturers of respective components, supply chain, retail, etc.

    ii. Please provide data, where available, to allow a quantification of such costs and benefits.

e. In the case that the exemption is not granted, IL expects medical care facilities using blood analysis devices to be impacted in relation to their ability to diagnose and treat patients. Subsequently patients would also be impacted (see response to clarification questions for further details).

    i. Please specify whether you support this view and estimate additional costs and/or benefits associated with a forced substitution should the exemption not be granted, and how they are to be divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers).

    ii. Please provide data, where available, to allow a quantification of such costs and benefits.

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.