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Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substances Restrictions in Electrical and Electronic Equipment (RoHS Directive)

Final Report – Pack 4

Excerpt of Pack 4
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Disclaimer

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6.0 Exemption Request No. 2013-1: “Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base for substrates in amperometric, potentiometric and conductometric electrochemical sensors”

Abbreviations

AQC	Automatic Quality Control
BGA	Blood Gas Analyser
ILI	Instrumentation Lab Inc.
IQM	Intelegent Quality Management
Pb	Lead
PVC	Poly Vinyl Chloride

Instrumentation Lab Inc. [8] (ILI) has carried out a RoHS compliance program to ensure compliance for equipment falling under the scope of RoHS and supplied to the EU by ILI. As a result of this compliance program the sensor card of the GEM Premier family of analysers has been identified as a component with a content of lead (Pb) exceeding the maximum concentration value of 0,1% as specified in Annex II of RoHS. ILI explain that the equipment falls under the scope of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on invitro diagnostic medical devices, and therefore also falls under the scope of RoHS, (cf Article 2, paragraph 4(22).)

Instrumentation Laboratory Inc.[9] has thus applied for an exemption for

> “*Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base for substrates in amperometric, potentiometric and conductometric electrochemical sensors.*”

[8] IL (2013a), Original application for Exemtion Rquest 2013-1“, available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/GEM_Card_Exemption_Final_-_public.pdf

[9] Op. cit. ILI (2013a)

6.1 Description of Requested Exemption

Sections 6.1 through 6.3 are heavily based on information provided by the applicant and other stakeholders and do not necessarily reflect the view of the consultants.

ILI[10] explain that Blood Gas Analysers (BGAs)[11] are used for blood testing and serve as a critical analytical instrument in hospital labs, operating rooms, emergency rooms and point of care at bedside across the global and EU health care sector. Blood testing is a core element to virtually all diagnostic and therapeutic procedures carried out in the health care sector today. Pb is used as a stabilizer in sensor cards used in the cartridges of the GEM family (the ILI BGA brand name) of critical care analysers. Cartridges are disposable, and function as the heart of the GEM analyser where the actual testing process takes place. The sensor card is the primary unit of the cartridge and represents a complicated and compact technological unit whose function is based on electrochemical processes taking place upon it during the testing process.

Compared to other existing technologies (traditional testing technologies – Automatic Quality Control (AQC)) on the market today the GEM analyser differentiates on a number of points: [12]

- The ILI BGA utilises a specific system, which is called “intelligent Management System” (iQM), which automatically detects, corrects, and documents all errors, and confirms resolution, ensuring patient safety and the highest quality of test results;
- In the ILI BGA, iQM continuously monitors process control solutions, reducing the time to error detection to minutes instead of the hours required by manual or automated traditional laboratory Quality Control (as regulated by CLIA in the United States and by applicable national legislation in EU Member States) that normally are run every 8 hours (see Table 6-1 for supporting data);
- iQM eliminates manual intervention to correct sensor errors such as clot catcher replacement and thereby significantly reduces the time needed for the testing process and enhances convenience of use. The reduced testing time will, in critical situations, improve significantly patient safety by producing rapid and correct results thereby reducing the need for doctors interpretation of results and the need for repeat testing;
- Furthermore in the ILI BGA, iQM results in a longer product lifetime of the Sensor Card compared to the existing AQC technology. The iQM system conducts quality control as an integrated part of the testing process whereas the AQC quality control counts as a separate test which will reduce significantly the overall cartridge life.

[10] Op. cit. ILI (2013a)

[11] ILI offer this type of analyzer under the brand name name GEM, which is later refered where relevant.

[12] Op. cit. ILI (2013a)

Table 6-1: Time to error detection, as presented by Dr. James Westgard at an iQM Workshop held in July 2002: Source ILI (2013b)[13]

Average Error Detection Time	pH	PO_2	PCO_2	Na^+	K^+	Ca^{++}	Gluc	Lact	Hct
iQM	3 min.	3 min.	3 min.	10 min.	3 min.	3 min.	7 min.	3 min.	3 min.
Traditional QC	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.

Statistical presentation of an average error detection time with a 95% confidence

Note: QC = quality control

In a later communication ILI[14] provide some insight as to what is considered traditional quality control (QC): "*Traditional QC refers to the assay of liquid quality control materials on an analyser, based on time schedules mandated by regulatory agencies (for example, every 8 hours is typical, as shown in the table above). These QC materials are stable over time, have assigned concentration values for certain analytes, and are usually provided in sealed glass ampoules. The materials are usually introduced externally by the user into the analyser. Correct measurement of the analyte concentrations allows the operator to conclude that functionality of the analyser is "in control" and may be used for measurement of patient samples*."

The sensor card has been manufactured from polyvinyl chloride (PVC), as early as the 1980s when the GEMStat and GEM 6 analysers were first launched, and the same molded card has been carried forward to the currently manufactured analysers (GEM Premier 3000, GEM Premier 3500, GEM Premier 4000 and GEM Premier 5000). According to the applicant PVC has specific advantages as a sensor card material for the electrochemical sensors used in the GEM products. Sensing membranes used for certain sensors (Na+, K+, Ca++, pH, pCO2) are based on PVC and are solvent cast directly on the sensor card from a solution of tetrahydrofuran (THF). Because THF is a strong solvent for PVC, there is strong adhesion between the cast membranes and the PVC card, which is a critical requirement for sensors to have long use life and shelf life.[15]

6.2 Applicant's Justification for Exemption

The PVC sensor card is produced by injection molding. Lead has been traditionally used as a thermal stabilizer to prevent breakdown of the polymer at the high temperatures required for the injection molding process. ILI has determined that the presence of lead in the PVC sensor card does not interfere with measurement of any analytes on the GEM family of analysers. However, alternative thermal stabilizers,

[13] ILI (2013b), Summary of Information presented at an IQM Workshop, submitted by applicant along with Application, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/iQM_Workshop.pdf

[14] ILI (2014a), Answers to 2nd round of clarification questions, submitted 18.03.2014

[15] Op. cit. ILI (2013a)

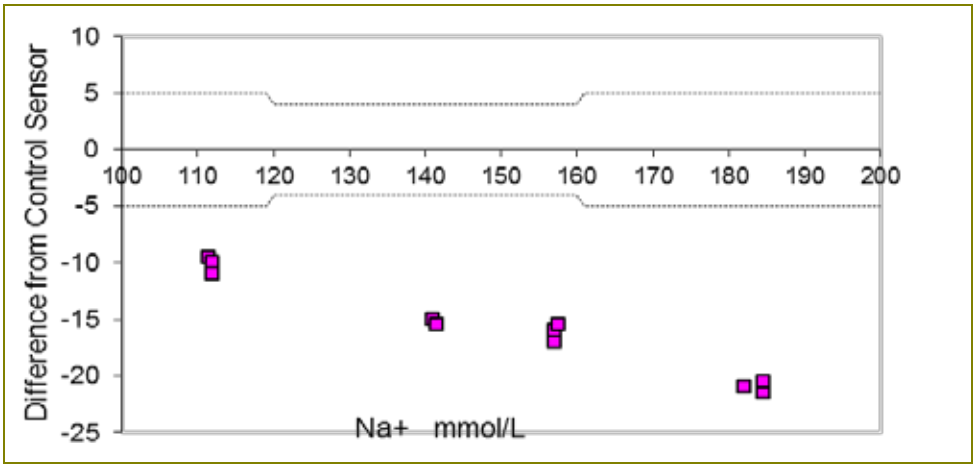
*Sections 6.1 through 6.3 are heavily based on information provided by the applicant and other stakeholders. Alterations have been made mainly to ensure comprehension and to avoid repetition.

such as tin, have been shown to produce interference, especially with measurement of electrolytes. [16]

ILI[17] was later asked to elaborate on the possible source of interference experienced with alternatives that have been tested. They state that "*The mechanism of interference is not completely understood. However, we speculate that metals, such as tin, present in the thermal stabilizers are blocking the ion carrier sites in the ion-selective membranes, preventing the ion carrier sites from complexing the ion of interest. This problem is not seen when lead is present in the thermal stabilizer.*"

They further supply Figure 6-1 below to illustrate the problem for the measurement of sodium ion, explaining that "*along the x-axis is the concentration of sodium (Na+) in blood samples. The y-axis is the difference between results obtained using a PVC sensor card stabilized with tin, minus results obtained using a PVC sensor card stabilized with lead (control sensor). For the tin-based card to be a direct replacement for the lead-based card, differences must lie within the dashed lines, which reflect acceptable bias from one device to another for measurement of sodium ion. Significant negative biases are seen, indicating unacceptable interference from the tin. Similar results are seen for measurement of other ions in blood, such as K+ and Ca++. These data were collected early in the service life of the sensor card. No data is available on how this interference may change throughout the service life of the sensor card*." [18]

Figure 6-1: Illustration of the Difference between Measurement of Sodium Ion Between a Tin Based Stabilizer Sensor Card and a Lead Based Stabilizer Sensor Card



Source: ILI (2014a)

[16] Op. cit. ILI (2013a)

[17] Op. cit. ILI (2014a)

[18] Op. cit. ILI (2014a)

ILI[19] explains that the continued use of lead in the sensor card of the GEM analysers is required while the search continues for an alternative thermal stabilizer. They provide a number of qualities that are to be provided by alternative stabilizers in order to ensure compatibility with the GEM system:

- Ø The alternative stabilizer must not interfere with measurement of any analyte on the system over the sensor card's service life.
- Ø To ensure comparable reliability, the product shelf life is required to be at least 9 months when stored at room temperature; and
- Ø The sensor card use life (operation within the cartridge) is required to be 4 weeks in the analyser, through which performance does not deteriorate.

In light of the requested exemption formulation, ILI explains that amperometric, potentiometric and conductometric electrochemical sensors are 3 subclasses of electrochemical sensors, used for measurement of different analytes in blood. All 3 types of sensors are built on the sensor cards used in the GEM 3000 and GEM 4000 devices. When evaluating alternative thermal stabilizers in the PVC sensor card, performance of all 3 types of sensors needs to be tested.[20]

ILI[21] claim that an exemption is justified as substitution is currently impractical as the possible alternatives do not provide sufficient performance over the product lifetime. It is further estimated that, assuming the exemption is granted, an amount of 25.89 kg of lead is expected to come onto the EU market annually through the sensor cards used in the GEM analyser.

ILI provides data as to the concentrations of lead in sensor cards manufactured for various models of their device (see Table 6-2 below). The PVC compounds shown in the table are explained to be commercially available products, supplied to Instrumentation Laboratory by compounding vendors specializing in vinyl resins. "*Specific formulations, except for lead content, are proprietary and unknown to us. The reason for choosing the lead content in a particular resin likewise is unknown to us, but is presumably related to ease with which the resin can be molded*."

[19] Op. cit. ILI (2013a)

[20] ILI (2013c), Answers to first clarification questions, submitted by the aplicant on 08.07.2013, avalable uner: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/Questionnaire-1_Ex_Req-2013-1_with_IL_Responses_revised_08_07_13.pdf

[21] Op. cit. ILI (2013a)

*Sections 6.1 through 6.3 are heavily based on information provided by the applicant and other stakeholders. Alterations have been made mainly to ensure comprehension and to avoid repetition.

Table 6-2: Comparison of various parameters of sensor cards of different device models. Source: ILI (2014a)

Product	PVC Compound	Weight of card (g)	Amount of lead in card (mg)	Percentage lead in card
GEM 3000/3500	CMX 2151 GRY 10	3.641	238.85	6.56%
GEM 4000	JLD 91221	5.163	96.55	1.87%
GEM 5000	CMX 2151 GRY 10	3.773	247.51	6.56%

6.2.1 Possible Design Alternatives

Concerning design alternatives, ILI[22] mention that their research is looking into alternatives for PVC in light of the understanding that the availability of this substance to industry is also decreasing, however at present such an alternative is not known.

6.2.2 Possible Substance Alternatives

ILI[23] state that in close cooperation with the supplier of the PVC material for the sensor card as well as independent scientific centres of excellence (Massachusetts's Institute of Technology – MIT – University of Massachusetts, Lowell, Department of Plastic Engineering) they have investigated the alternative thermal stabilizers Tin and Zinc, which are the only alternatives technically available today, *"The investigated alternative stabilizers have been shown to produce interference, especially with measurement of electrolytes, on the GEM family of instruments and cannot therefore be considered to be technically practical or viable alternatives as they impede the reliability of test results carried out with the sensor card when using the alternative stabilizer thereby preventing the analyser to perform its sole function*. "In this regard, ILI[24] elaborate that Pb-based cards were compared to performance of cards made with alternative (non-lead) thermal stabilizers from at least 3 different commercial sources. The alternatives included PVC cards with organo-tin thermal stabilizers and other metal-based stabilizers, proprietary to the suppliers of the PVC resins. In all cases, performance of the sodium ion sensor in the GEM 3000 and 4000 was adversely affected, producing incorrect readings, in the presence of metal-based thermal stabilizers other than lead. Early testing of non-metallic organic stabilizers is promising; however, more testing is required before a conclusion can be reached regarding suitability as a substitute for lead in sensor cards.

[22] Op. cit. ILI (2013a)

[23] Op. cit. ILI (2013a)

[24] Op.cit. ILI (2013c)

6.2.3 Environmental Arguments

ILI[25] do not use environmental arguments to support their request, however they provide some information as to the handling of waste created at the end-of-life of the sensor cards. ILI state that the GEM cartridge is treated as medical waste, and its disposal is handled in each country according to the local, state, and federal laws. In most cases, medical waste is incinerated in specific designated facilities according to national requirements and supervision of the respective EU Member States.

6.2.4 Road Map for Substitution

ILI[26] estimate that the search for practically and viable substitutes for lead as a stabilizer in the PVC material of the sensor card will possibly be concluded within the coming 4-5 years. Upon identification of the substitute, they state that additional time will be needed for development and approval of a new sensor card according to applicable EU legislation and other applicable requirements on Medical Devices. ILI[27] later elaborated some of the stages relevant in this regard:

- Screening of several PVC formulations using substitute stabilizers: 6 months
- Supplier agreements, scale up, and verification of lot to lot consistency: 6 months
- Verification and validation of a final PVC formulation in GEM 3000 and 4000 systems (detail below): 9 months
  - Use life testing in the GEM 3000 and 4000 systems
  - Evaluation of interfering substances
  - Evaluation of limits of detection
  - Method comparison to prove equivalency with existing product
  - Clinical studies at customer sites
  - Shelf life (stability) equivalent to existing product
- Submission to and approval by regulatory agencies: 6 months
- Total: 27 months

[25] Op. cit. ILI (2013a)

[26] Op. cit. ILI (2013a)

[27] Op cit. ILI (2013c)

*Sections 6.1 through 6.3 are heavily based on information provided by the applicant and other stakeholders. Alterations have been made mainly to ensure comprehension and to avoid repetition.

6.3 Stakeholders' Contributions

Radiometer Medical ApS[28] have submitted a contribution in support of the requested exemption. Radiometer uses lead as a thermal stabilizer in polyvinyl chloride (PVC) in a similar application. The PVC material is used for containing an electrochemical sensor and a sensor membrane for measurement of e.g. calcium (Ca++) and potassium (K+) in human blood samples. Radiometer explain that though the chemical properties of the material seem to be of a similar type, the physical environment is a little different, and therefore Radiometer propose a slightly changed wording, so the exemption will focus on the chemical properties of the materials and not on the surrounding materials:

"Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors."

Concerning possible substitutes, Radiometer has also tested an alternative stabilizer, which is applied in other sensor types, but for the device in question, the alternative resulted in poor performance when measuring K+ and Ca++ ions. The alternative material shows both a lower sensitivity and a number of unstable measurements during the 90 days lifetime test of the sensor. Its application as a substitute would result in poor and degrading performance, meaning significantly inferior clinical performance specifications. As for further alternatives, Radiometer explain that testing of alternative stabilizer materials is time consuming; each material needs to be tested for at least 90 days, and also a shelf stability test of 26 months has to be passed. Radiometer expects it will take at least 3-5 years to substitute lead as the stabilizer for the K+ and Ca++ sensors.[29]

Radiometer[30] also claims that the PVC base material needs to be compatible with the rest of the sensor unit; otherwise this cannot be assembled with the sensor membrane. This means that substituting the PVC material will require a major redesign, clinical re-validation and re-approval of the device by the authorities.

The Swedish Ministry of Environment[31] have submitted a contribution, expressing their concern that the exemption should be specified more clearly, to avoid its application to other uses than intended. The Ministry suggests the exemption be specified to only include equipment for medical diagnosis of human blood.

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[28] Radiometer (2013), Contribution to 2013 stakeholder 1 concerning Ex. Re. 2013-1, submitted by stakeholder on 07.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/20131107_Radiometer_Support_Re_ex_No__2013-1.pdf

[29] Op. cit. Radiometer (2013)

[30] Op. cit. Radiometer (2013)

[31] Swedish Ministry of Environment (2013), Contribution to RoHS Stakholder 2013 Consultation 1, submitted 11.11.2013, available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/SE_Comments_on_stakeholder_consultation_RoHS_Aug_Nov_2013.pdf

6.4 Critical Review

6.4.1 REACH Compliance - Relation to the REACH Regulation

Section 5.0 of this report lists entry 30 in Annex XVII of the REACH Regulation, stipulating that lead and its compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public. A prerequisite to granting the requested exemption would therefore be to establish whether the intended use of lead in this exemption request might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants' understanding, the restriction for substances under entry 30 of Annex XVII does not apply to the use of lead in this application. Pb used as a stabilizer in PVC used for sensor cards in blood analysis devices placed on the market, in the consultants' point of view is not a supply of lead and its compounds as a substance, mixture or constituent of other mixtures to the general public. Pb is part of an article and as such, entry 30 of Annex XVII of the REACH Regulation would not apply. Additionally, such medical devices are products that are not provided to the general public, but to users other than private ones, e.g. to hospitals, clinics etc.

No other entries relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status March 2014).

Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

6.4.2 Scientific and Technical Practicability of Lead Substitution

The relevance of the exemption request to devices of other manufacturers was unclear from the application. To justify an exemption for the device of a single manufacturer, the advantages of the device in comparison with devices on the market performing similar functions would need to be shown to be significant. ILI were thus asked if additional manufacturers market similar devices, and provided the following list in this regard:

- Radiometer Medical: ABL 800 and ABL 90 systems
- Siemens Healthcare: Rapidlab 800 and Rapidpoint 500 systems
- Abbott Laboratories: i-STAT handheld monitors

Radiometer Medical provided a contribution in support of the request (see section 6.3 above). Although an effort was made to contact the other suppliers to establish the relevance of this request to their devices, no response was received. From available literature[32] it can be understood that the Repidlab devices are similar in function and

[32] See "Siemens Rapidlab 800 Series (Model 865) System Analyzer" available under http://pathology.uchc.edu/pdf/uid1801.pdf

also have sensors for Na^+ (sodium), as well as K^+, Cl^-, and in some models Ca^{++}. The i-STAT devices are also understood to be similar[33]. Information on the Abbott webpage explained the following:

"*i-STAT cartridge technology streamlines traditional lab technology, yet contains many of the components found in complex lab testing systems. Each test cartridge contains chemically sensitive biosensors on a* ***silicon chip*** *that are configured to perform specific tests. To perform a test, 2 to 3 drops of blood are applied to a cartridge, which is then inserted in to the i-STAT handheld. Prior to running a test, each cartridge initiates a series of preset quality control diagnostics, from monitoring the quality of the sample to validating the reagent*."[34]

From this information, it can be understood that the card is based on silicon, and it is thus possible that the silicon mentioned is used instead of PVC. In this case it may also be that the use of silicon allows eliminating the use of lead. Despite the attempt to contact Abott, further information was not made available and so it could not be established if substitution of lead or of PVC (i.e., elimination of lead) had been achieved and if the alternatives would also be relevant for other BGAs, such as those manufactured by ILI and Radiometer.

The applicant, as well as one of the stakeholders, provides information and data showing, that though research of substitutes for lead, used as a stabilizer in PVC sensor cards, is on-going, a suitable alternative is yet to be found. In this regard the applicant claims that tested metal based stabilizers adversely affect the performance of the sodium ion sensor. Further research of non-metallic organic stabilizers is said to be promising, however more time is required to find and verify a possible alternative. In the consultants' opinion, it can be followed that the performance of tested alternatives does not match the requirements of the lead stabilizer, as it interferes with results. On the basis of the available information, substitution has not been shown to be practical at present.

6.4.3 Conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria is fulfilled:

- their **elimination or substitution** via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

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[33] See general device information available under http://www.abbottpointofcare.com/Products-and-Services/iSTAT-Cartridges.aspx

[34] http://www.abbottpointofcare.com/products-and-services/istat-cartridges.aspx; Last accessed 11.3.2014.

In the consultants' opinion, it can be followed that substitutes for lead, used as a stabilizer in PVC sensor cards, are not yet available for this specific application. Substitution is thus understood not to be scientifically or technically practical at present, in line with the first criteria detailed in Article 5(1)(a). From the submitted information it is also understood that elimination, through the use of a different material for the sensor card, is also not yet possible. In light of fulfilment of one of the Article 5(1)(a) criteria, an exemption would be justified.

Concerning the formulation of a possible exemption, the applicant had proposed the following wording:

"*Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base for substrates in amperometric, potentiometric and conductometric electrochemical sensors*".

Radiometer (2014) explains that despite the similarity in the operation of devices and in the chemical properties of the material, the physical environment in the Radiometer device is a little different. They propose changing "*base for substrates" to "base material"*. The consultants view this change to make the exemption somewhat more general. However as the application of lead is still otherwise limited, this change is understood to ensure that the exemption would be available to other blood analysis devices, so long as it is used as a stabilizer in PVC used for sensor applications.

As it is understood that the interferences were apparent in blood analysis, when testing sensor cards manufactured with alternative lead-free stabilizers, a limitation to such applications is also viewed to be relevant to eliminate the risk for misuse of the exemption. This is also in line with the concerns of the Swedish Ministry of Environment, who have recommended limiting the exemption for use in devices for analysis of blood samples. It can be understood that both the devices of the applicant and the supporting stakeholder (Radiometer) are used for analysis of blood. As the need for this exemption for use in other applications was not expressed by other stakeholders, the consultant agrees that the exemption wording should be adjusted in this regard.

The consultants thus discussed the following wording with the applicant as well as Radiometer who have expressed their need for the requested exemption for their devices:

'Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors used for analysis of blood in sub-category 8 in-vitro diagnostic devices.'

Radiometer[35] requested that the reference to "analysis of blood" be extended to "analysis of blood and other body fluids and body gases", explaining that "*intended use of this type of in-vitro diagnostic devices, besides analysis on blood samples, also includes tests on human body fluids such as pleural fluid samples and expired air samples*".

[35] Radiometer (2014), Answers to clarification questions concerning Ex. Re. 2013-1, submitted 14.03.2014

ILI[36] agreed to this adjustment, however conditioning their support with that of the EU COM. They explain that "*the revised wording was not known at the time of the stakeholder consultation and as any supporting documentation possibly submitted in support of the revised wording has not been available to Instrumentation Laboratory, we suggest that the EU Commission considers to draft a separate exemption to cover the additional equipment comprised by the revised wording as appropriate*".

In the consultants view, the addition of "other body fluids and body gases" to the exemption wording, results in an extension of its scope of applicability. In light of the extended scope, and as other stakeholders have not expressed their need for the exemption for additional devices beyond the suggested scope, the consultants cannot conclude that this change would exclude applicability of the exemption for devices already excluded from the original requested wording.

It should be said that it was not possible to clarify if the devices are also in use by the veterinary medical sector. To the consultants understanding, such products do not fall under Cat. 8 and would thus be excluded from use of the recommended exemption. As the applicant clearly stated that the device falls under the definitions of the in-vitro diagnostic medical devices directive, stakeholders requiring the device for applications falling under other categories would have been expected to express their support and need for this request, were it of relevance. As stakeholders have not clarified that the devices are also relevant for veterinary applications, the consultants cannot conclude that limiting the exemption to sub-category 8 in-vitro would have a negative impact on this sector.

The reference to diagnosis of blood, body fluids and body gases and to sub-category 8 in-vitro diagnostic devices is understood to limit the area of application considerably to the areas in which these devices are in use, as requested by the Swedish Ministry of Environment. It is further recommended to add a possible exemption to Annex IV as there is no evidence that the request is needed for non-medical devices.

As for the duration for which an exemption should be recommended, the applicant and Radiometer estimate that 4–5 years or 3–5 years (respectively) are expected to be needed before a substitute can be applied in products in use on the market. The contribution of Radiometer was made towards the end of 2013, and thus this period is understood to be relevant starting the beginning of 2014. As sub-category 8 in-vitro is only to come into scope of the RoHS Directive in mid-2016, it is understood that in practice, an exemption is requested for a few additional years in order to ensure substitution without having a negative impact on the relevant medical services. It can be understood that the exact time required would depend on the time needed before a suitable candidate is identified. As it is difficult to predict the time needed for this initial research the consultants do not oppose to the longer 5 year duration. The requested duration would result in an exemption available for use until the end of 2018, which practically means extending the exemption period by a further 2.5 years.

[36] ILI (2014b), Answers to 2nd round of clarification questions, submitted 20.03.2014

6.5 Recommendation

For the application of lead in PVC used as a base material for the manufacture of electro chemical sensors, the consultants recommend granting an exemption as follows:

'Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors used for analysis of blood and other body fluids and body gases in sub-category 8 in-vitro diagnostic devices.' *31.12.2018*

Should an exemption be added, it should be added to Annex IV of the RoHS Directive.

6.6 References Exemption Request 2013-1

ILI (2013a), Original application for Exemption Request 2013-1", available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/GEM_Card_Exemption_Final_-_public.pdf

ILI (2013b), Summary of Information presented at an IQM Workshop, submitted by applicant along with Application, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/iQM_Workshop.pdf

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