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"

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Disclaimer

Oeko-Institut and Fraunhofer IZM have taken due care in the preparation of this report to ensure that all facts and analysis presented are as accurate as possible within the scope of the project. However, no guarantee is provided in respect of the information presented, and Oeko-Institut and Fraunhofer IZM are not responsible for decisions or actions taken on the basis of the content of this report.

EUROPEAN COMMISSION

Directorate-General for Environment

Directorate B - Circular Economy & Green Growth

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7. Annex IV, Ex. 41

"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."

Declaration

In the sections that precede the "Critical review" the phrasings and wordings of stakeholders' explanations and arguments have been adopted from the documents provided by the stakeholders as far as required and reasonable in the context of the evaluation at hand. Formulations were only altered in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and definitions

IL	Instrumentation Laboratory
Pb	Lead
PPE	Platinized platinum electrodes
PVC	Polyvinyl chloride

7.1. Background

Instrumentation Laboratory (IL 2017a) (IL; 2017a) manufactures the GEM Premier diagnostic medical analyser. This instrument is used to analyse the blood of patients and provide clinicians with accurate measurements of specific analytes vital to medical diagnostics and patient treatment. The heart of the GEM Premier family is explained to be the sensor card where the electrochemical measurements of the above analytes take place. According to IL, due to the complex electrochemical processes in the sensor card, it has not been possible yet, to find a stabilizer other than lead that works without affecting analytical performance of analyte measurements of the various GEM models.

Continued use of lead in the sensor card of the GEM Premier analysers is required while the search continues for an alternative stabilizer. Against this background, IL (2017a) has applied for a renewal of Ex. 41 of Annex IV of the RoHS Directive. They request the renewal of the exemption, maintaining the existing wording:

> "*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. Expires on 31 December 2018*"

The IL equipment explained to be covered by this exemption is specified to fall under the RoHS Annex II category 8 sub-group: in-vitro diagnostic medical devices. (IL 2017a)

IL (2017b) states that the exemption is needed until 31st December 2025.

7.1.1. Amount of lead used under the exemption

In equipment falling under the scope of Ex. 41, lead is explained to be used as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors. The concentration of Pb used in the sensor cards varies between the GEM models. IL specifies that a concentration of 2.7% is applied in the GEM Premier 4000 model cartridges and a concentration of 6.6% is applied in the GEM Premier 3000, 3500 and 5000 model cartridges. IL estimates the amount of substance entering the EU market annually through applications for which the exemption is requested at 48.14 kg. This amount is explained to be based on the 2017 forecast for GEM Premier cartridge shipments to the EU, i.e. to represent only IL equipment benefiting from the exemption. This amount is stated to be sent to energy return at end-of-life, as it is comprises medical waste and thus cannot be recycled. (IL 2017a)

In a later communication, IL (2017b) explains the specific formulations of the PVC and sensor designs used by each manufacturer are generally proprietary information and for that reason it is not feasible for IL to provide the actual amount of lead placed on the EU market through blood analysers of all manufacturers. Nonetheless based on a rough estimation of IL it is assumed that 144.43 kg of lead are placed on the EU market annually through blood analysers.

7.2. Description of requested exemption

IL (2017a) requests the exemption to allow the continued use of lead in the sensor card of the GEM Premier analysers (GEM Premier 3000/3500/4000/5000 instruments) until an alternative stabilizer is found and applied. The alternative stabilizer must not interfere with measurements 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 analyser). To support the request, IL also provides results of an LCA to show that the current GEM Sensor Card performs better in environmental terms in comparison to the currently researched potential alternatives.

7.2.1. Applicant's justification for exemption

The sensor card in the disposable cartridge is made of polyvinyl chloride (PVC). Use of PVC as the sensor card material dates back to the 1980s when the GEM- Stat and GEM 6 analysers were first launched, and the same moulded card has been carried forward to the currently manufactured analysers (GEM Premier 3000, GEM Premier 3500, GEM Premier 4000 and GEM Premier 5000). The sensor card is located in the disposable cartridge which is used in these instruments. Electrochemical sensors for the following critical care analytes are located on the sensor card: partial pressure of oxygen and

carbon dioxide (pO2 and pCO2), pH, Na+, K+, Ca++, Cl-, glucose, lactate and haematocrit. (IL 2017a)

PVC has specific advantages as a sensor card material for the electrochemical sensors used in the GEM Premier products. Sensing membranes used for certain sensors (pH, Na+, K+, Ca++, pCO2) are based on PVC membranes 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. The PVC sensor card is produced by injection moulding. Lead compounds have been traditionally used as a thermal stabilizer to prevent breakdown of the polymer at the high temperatures required for the injection moulding process. IL has determined that the presence of lead in the PVC sensor card does not interfere with measurement of any analytes on the GEM Premier family of analysers. In fact, recent testing has shown that 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 haematocrit. (IL 2017a)

IL (2017a) states that data from the GEM Premier family of critical care analysers are used daily in hospitals around the world to make life-saving decisions regarding patient health. It is imperative that these data have the highest possible reliability and accuracy. At present IL claims that the reliability of the substances investigated as possible candidates for substitution is not ensured.

IL (2017a) admits that additional blood analysers exist on the market, such as the Siemens RapidPoint 500 and Roche Cobas 123), however claims that the GEM Premier analysers offer several advantages:

- According to IL the GEM analyzers utilize the Intelligent Quality Management (iQM™) system which automatically detects, corrects, and documents all errors, and confirms resolution ensuring patient safety and the highest quality of test results:
  - iQM™ reduces the time to error detection to minutes instead of the hours required by traditional manual or Automated Quality Control (AQC) that normally are run every 8 hours.
  - iQM™ also eliminates manual intervention to correct sensor errors, such as removal of blood clots from the system, thereby significantly reducing time needed for the testing process and enhancing ease of use. According to IL, the reduced testing time will, in critical situations, improve patient safety significantly by producing rapid and correct results and reducing the need for repeat testing.
  - IL explains that iQM results in a longer usable lifetime of the disposable cartridge, compared to other analyzers based on AQC technology. The iQM system conducts quality control as an integrated part of the testing process whereas AQC counts quality control samples as separate tests thus reducing available number of patient blood samples during cartridge life.
- The GEM Premier analyzers are said to be the only systems of their kind to offer a single, disposable measurement cartridge which can be stored up to 9 months at

room temperature. Other competing technologies utilize multiple cartridges to perform the same functions, some of which require refrigerated storage.

- It is further explained that every sensor card produced for the GEM Premier family of analysers is 100% tested at the factory to assure highest levels of quality to the customer, whereas other competing technologies use the concept of Acceptable Quality Limit (AQL) testing, where a sample of manufactured parts are tested to find whether the entire production lot meets the product specifications.

7.2.2. The availability of alternatives for lead in the platinization process

During the existing exemption period, IL has been working to replace lead as a thermal stabilizer in the PVC sensor card. IL explains that several initial candidates, considered as thermal stabilizers to replace lead in the sensor card, have been investigated and shown to produce: deterioration in accuracy of the sodium sensor, decreased sensitivity of the oxygen sensor, and increased imprecision for measurement of glucose, lactate and hematocrit in blood on the GEM Premier family of instruments. (IL 2017a)

IL (2017a) summarise the following findings from testing they have performed of PVC resins containing alternative thermal stabilizers, since 2012:

- All RoHS compliant resins had decreased sensitivity (slope) of the pO2 sensor.
- All resins containing organo-tin compounds resulted in deterioration in accuracy of the GEM Premier sodium sensor outside of product specifications. In addition, thioorgano-tin compounds resulted in increased glucose and lactate sensor imprecision outside of GEM Premier product specifications.
- CaZn stearate and Zn stearate stabilizers resulted in increased glucose and lactate sensor imprecision outside of product claims. These stabilizers also resulted in decreased pCO2 sensor slope (sensitivity).
- The majority of PVC resins containing organic based stabilizers (OBS) resulted in increased glucose and lactate sensor imprecision outside of product claims. However, two resins containing OBS stabilizers (Teknor Apex 8009B-1 and 8009B-2), considered proprietary formulations by the Teknor Apex Corp., passed specifications for glucose and lactate imprecision, but were significantly worse than that of production resin containing lead thermal stabilizer. Results were close to the limit and are considered at risk for not meeting product specifications with normal variation in product performance.
- Color Master 1304 resin, containing various thermal stabilizers plus 0.098% lead (in the form of tribasic lead sulfate, TBLS) met product specifications, however even these formulations were significantly worse than that of production resin containing lead thermal stabilizer. Results were close to the limit and are considered at risk for not meeting product specifications with normal variation in product performance.

IL (2017a) thus conclude that no RoHS-compliant resin has yet demonstrated acceptable performance for all sensors, although resins containing 0.098% lead have shown improved performance. The consistency of negative impact on glucose and

lactate precision and loss of pO2 sensor slope (sensitivity) across tests of different RoHS compliant resins containing various thermal stabilizers, leads IL to conclude that the problem is likely from the reduction of lead rather than from addition of some unknown interfering substance. Some of the alternative PVC thermal stabilizers initially researched, when used in addition to minimal quantities of lead in concentrations below 0.1% in the sensor card (i.e. lead in a concentration below the limit specified by the EU RoHS directive), have shown results moving in a positive direction to address the performance problems seen with the alternative thermal stabilizers alone. The focus of continued investigations thus includes optimizing the selection of an alternative thermal stabilizer in addition to presence of 0.098% lead in the PVC resin of the GEM Premier sensor card. Further details are given in the exemption application.

The EU Directive 98/79/EC on in-vitro diagnostic medical devices specifically mandates that a manufacturer must meet its product claims for analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection. Therefore the investigated alternative stabilizers are not technically practical or viable alternatives at this time as they impede the reliability of test results carried out with the sensor card, thereby preventing the analyser from performing its intended function within established product claims. (IL 2017a)

IL (2017a) concludes that presence of lead in the PVC sensor card is enhancing sensor performance, which is important to provide the optimum performance claimed in product publications. At present, the search continues for an alternative, RoHS compliant thermal stabilizer which will restore sensor functions to their original level of performance, consistent with product claims.

7.2.3. Environmental arguments

IL (2017a) has submitted a life-cycle analysis report as annex to its application. The LCA results are summarised in IL's application, from which the following has been reproduced (IL 2017a):

> "*The LCA analysed the current card, compared with two potential alternative cards. The results are shown for 1 GEM Premier 3000/3500 Sensor Card (the product). The whole life cycle of the product was analysed.*
>
> *[...] The LCA made the following assumptions:*

- *The card is manufactured in the US, and used in Europe*
- *The current card and the two alternatives are all assumed to provide the same functionality and lifespan*
- *Both potential alternative cards contain an Organic Based Stabilizer (OBS) to replace the lead in the current card*

> *The results of the LCA are as follows:*
>
> *[...]The carbon footprint results show that the current card has a carbon footprint of 10.5 gCO2eq, compared with 13.9 and 13.5 for the two alternatives*

(lower carbon footprint is better). The carbon footprint of the current card is 22% lower than the next lowest card.

The LCA also analysed other environmental measures [...] Considering 23 environmental impact measures, the current card was found to have the lowest environmental impacts in 20 categories, and the highest in the remaining 3 categories. The current card was found to consume less energy in its production, distribution, use and disposal than both alternative cards.

[...] the European LCA methodology used in this LCA [...] provide one approximate general human health parameter termed Human Toxicity. All three card configurations showed Human Toxicity results within the same order of magnitude. To further investigate human health issues, another LCA methodology was also applied, the US Environmental Protection Agency (EPA) methodology. This showed that the combined Human Toxicity values were not significantly different for the three cards, supporting the European methodology results."

Based on the results of the LCA, IL concludes that the current GEM Premier Sensor Card performs better in environmental terms than the potential alternatives.

7.2.4. Road map to substitution

IL (2017a) states that upon identification of the RoHS compliant resin, additional time will be needed for development and update of the EU compliance documentation required for medical devices for a new sensor card according to applicable EU legislation and other applicable worldwide regulatory requirements for medical devices. IL is confident that the successful replacement of lead as a stabilizer in the PVC material of the sensor card across the entire GEM Premier product line will be concluded within the coming 7 years. The exemption application includes details on the substitution project plan (see Table 7-1) and estimates RoHS Compliance of GEM Sensor Card Resin to be accomplished by April 1, 2022.

Table 7-1: Revised Project Plan: Duration column represents number of working days for each activity and start/finish dates columns include non-working days except Shelf Life testing.

Task Name	Duration (number of working days)	Start	Finish	% Complete
RoHS Compliance of GEM Sensor Card Resin	**1975 days**	**September 8, 2014**	**April 1, 2022**	**21%**
Procure vendors and resin materials	**180 days**	**September 8, 2014**	**May 15, 2015**	**100%**
Procure vendors and raw materials	90 days	September 8, 2014	January 9, 2015	100%
Mold and prepare sensor cards	90 days	January 12, 2015	May 15, 2015	100%
Screen new resin candidates	**330 days**	**May 18, 2015**	**August 19, 2016**	**100%**
Evaluate new resin candidates	180 days	May 18, 2015	January 22, 2016	100%
Optimize internal processes	90 days	January 25, 2016	May 27, 2016	100%
Data analysis and review	60 days	May 30, 2016	August 19, 2016	100%
Feasibility	**220 days**	**August 22, 2016**	**July 07, 2017**	**90%**
Select Top 2 resin candidates using GEM 3000	90 days	August 22, 2016	December 23, 2016	100%
Cartridge use life study GEM 3000	30 days	December 26, 2016	February 3, 2017	100%
Cartridge use life study GEM 4000	30 days	March 20, 2017	April 28, 2017	100%
Cartridge use life study GEM 5000	30 days	May 23, 2017	June 23, 2017	50%
Select top resin candidate (Data analysis and review)	10 days	June 26, 2017	July 07, 2017	0%
Design and Process Optimization	**270 days**	**June 26, 2017**	**July 6, 2018**	**0%**
Compounding and evaluation of new co-stabilizers with top resin using GEM 3000 candidate	90 days	June 26, 2017	October 27, 2017	0%
Cartridge use life study GEM 4000 - Optimized resins	30 days	October 30, 2017	December 8, 2017	0%
Cartridge use life study GEM 5000 - Optimized resins	30 days	December 11, 2017	January 19, 2018	0%
Data analysis and review to select top candidate	30 days	January 22, 2018	March 2, 2018	0%
Improve internal processes to get optimal performance of top resin candidate	90 days	March 5, 2018	July 6, 2018	0%
Pre-POP GEM 3000 and 4000	30 days	March 5, 2018	April 13, 2018	0%
Pre-POP GEM 5000 and ChemSTAT	30 days	April 16, 2018	May 25, 2018	0%
Data analysis	10 days	May 28, 2018	June 8, 2018	0%
Formal Design Review	5 days	June 25, 2018	June 29, 2018	0%
Process Validation - Resin Compounding	90 days	March 5, 2018	July 6, 2018	0%

Process Validation - Sensor Card Molding	**240 days**	**April 16, 2018**	**March 15, 2019**	**0%**
Mold Validation GEM 3000 sensor card	60 days	April 16, 2018	July 6, 2018	0%
Mold Validation GEM 4000 sensor card	60 days	July 9, 2018	September 28, 2018	0%
Mold Validation GEM 5000 sensor card	60 days	October 1, 2018	December 21, 2018	0%
Mold Validation GEM ChemSTAT sensor card	60 days	December 24, 2018	March 15, 2019	0%
Shelf Life	**240 days**	**June 30, 2018**	**February 24, 2019**	**0%**
Shelf life GEM 3000 sensor card	8 mons	June 30, 2018	February 24, 2019	0%
RoHS Compliance of GEM Sensor Card Resin	**1975 days**	**September 8, 2014**	**April 1, 2022**	**21%**
Procure vendors and resin materials	**180 days**	**September 8, 2014**	**May 15, 2015**	**100%**
Procure vendors and raw materials	90 days	September 8, 2014	January 9, 2015	100%
Mold and prepare sensor cards	90 days	January 12, 2015	May 15, 2015	100%
Screen new resin candidates	**330 days**	**May 18, 2015**	**August 19, 2016**	**100%**
Evaluate new resin candidates	180 days	May 18, 2015	January 22, 2016	100%
Optimize internal processes	90 days	January 25, 2016	May 27, 2016	100%
Data analysis and review	60 days	May 30, 2016	August 19, 2016	100%
Feasibility	**220 days**	**August 22, 2016**	**June 23, 2017**	**75%**
Select Top 2 resin candidates using GEM 3000	90 days	August 22, 2016	December 23, 2016	100%
Cartridge use life study GEM 3000	30 days	December 26, 2016	February 3, 2017	100%
Cartridge use life study GEM 4000	30 days	March 20, 2017	April 28, 2017	75%
Cartridge use life study GEM 5000	30 days	May 1, 2017	June 9, 2017	0%
Select top resin candidate (Data analysis and review)	10 days	June 12, 2017	June 23, 2017	0%
Design and Process Optimization	**270 days**	**June 26, 2017**	**July 6, 2018**	**0%**
Compounding and evaluation of new co-stabilizers with top resin using GEM 3000 candidate	90 days	June 26, 2017	October 27, 2017	0%
Cartridge use life study GEM 4000 - Optimized resins	30 days	October 30, 2017	December 8, 2017	0%
Cartridge use life study GEM 5000 - Optimized resins	30 days	December 11, 2017	January 19, 2018	0%
Data analysis and review to select top candidate	30 days	January 22, 2018	March 2, 2018	0%
Improve internal processes to get optimal performance of top resin candidate	90 days	March 5, 2018	July 6, 2018	0%

Source: IL (2017a)

7.2.5. Socio-economic aspects

In relation to the impact on employment, IL estimates (2017b) that 90% of the blood gas analyser offerings would no longer be acceptable for use due to the exemption not being granted and would jeopardize the capabilities of European medical educational facilities, hospitals, and clinics. This would have a significant impact on healthcare quality and treatment outcomes, especially in critical care and point-of-care departments. In addition, employment and operations would be impacted due to direct effect and business-to-business dependencies in areas such as those listed here:

- *"Werfen Affiliates in EU*
- *Other medical device manufacturers with headquarters and offices located in the EU and throughout the world (e.g. Radiometer HQ based in Denmark, etc.)*
- *Roncello, Italy IL facility, where the GEM products and ancillary devices are shipped to/from and stored*

- *EU local distributors/distribution centers for GEM analyzers*
- *Logistics and processing of Refurbished units (e.g. replace/rebuild/QC/parts management, etc.)*
- *Worldwide raw material, and sub-assembly manufacturers*
- *Worldwide processing service suppliers*
- *Sales force and Marketing for customers based in Europe*
- *Technical Support e.g. call center(s) and on-site Service would be impacted*
- *Hospitals and medical clinics would be adversely impacted due to limitations in analytical capabilities to enable physicians to diagnose and treat ailments.*
- *Hospital financial budgets would be adversely impacted due to a limited if any selection of currently RoHS compliant options and the changes that could be required in infrastructure which would impact time to make such a transition (e.g. LIS, LIM, revalidations, etc.).”*

IL (2017a) also details that for executing the substitution project plan it has allocated 2 full time employees and committed in excess of $2.5mm (USD) from 2017 until the end of 2021 and they are committed to provide more resources as and when needed for the success of this project in timely fashion.

In relation to the amount of EEE placed on the market through the application under the scope of Ex. 41 of RoHS annex III, IL (2017b) estimates that approximately 963 kg (or 0.74 m^3) is to be placed on the EU market per annum through sensor cards of the GEM blood analysers. As a rough estimation for EEE to be placed on the EU market annually through sensor cards of all blood analysers using PVC resin sensor cards, IL specify 2,889 kg (or 2.22 m^3). As blood analysers cannot operate without the sensor card, IL further provides estimations of the amount of EEE that would need to be scrapped were RoHS compliant sensor cards no longer available on the EU market. In relation to the IL GEM models, this is estimated to amount to 111,640 kg (or 316.84 m^3) and for all blood analysers using PVC sensor cards 334,921 kg (950 m^3). The EEE volume provided here is calculated from the dimensions of the GEM analysers and it is assumed that other manufacturers’ systems have similar dimensions as the GEM analysers.

IL (2017b) specifies that if the exemption is not granted, then it will become challenging for hospitals and other medical care facilities to have these critical care analysers to diagnose and treat patients that assure exceptional outcomes from well-equipped healthcare institutions. This scenario is guaranteed to impose great liabilities on medical practitioners limited in analytical measurement systems and consequently data to interpret for an accurate diagnosis and treatment plan. For the patient, this means a substantially higher margin for error by physicians to make good medical decisions to provide the proper care and sustain life. Consequently, patients with diminished health may not be able to aptly perform their job functions or care for themselves and family members due to the compromised quality of healthcare that would be possible without these medical equipment providing critical information. Based on an estimated total of greater than 19,000 analysers by all manufacturers placed in the EU, this accounts for approximately 282,159,600 tests (in the EU-28, the

population total was 508,401,000[12]). In conclusion, an exemption not being granted will assuredly impact health and safety. Therefore, the societal and economic magnitude is much larger for not permitting these medical devices than permitting their use while manufactures continue to explore and pursue RoHS compliant solutions.

7.3. Stakeholder contributions

During the stakeholder consultation, a contribution was received from a healthcare facility in Germany (dated 3.12.2017), stating that the facility (hospital and laboratory) vitally depends on results from blood gas analysers such as the Instrumentation Laboratory GEM Premier products. "*Currently we have 16 GEM 4000 and GEM 5000 analysers in use at our hospital. Per year we report over 175.000 patient results. Our patient population would be seriously and adversely impacted if these manufacturers were blocked from supplying these instruments. The current product technology is well known proven and has the necessary level of reliability. Reliability in performance of these analysers is vital and absolutely non-negotiable.*"

Two further healthcare providers submitted similar contributions in support of the request, however, these were submitted after the consultation had closed. As the contributions do not provide additional information, they are not further reproduced here.

7.4. Critical review

7.4.1. REACH compliance – Relation to the REACH Regulation

According to Article 5(1)(a) an exemption may "*not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006*". If granted, the exemption would allow the use of lead in the PVC sensor cards of blood analyser devices. The REACH Regulation has thus been consulted in this respect.

Annex XIV of the REACH Regulation lists a few substances, the use of which would require an authorisation in the EU:

- Lead chromate – used in printing inks, paints and to colour vinyl, rubber and paper[13];
- Lead sulfochromate yellow –used as a pigment, a dye and as a paint and coating additive[14];

[12] IL states that this figure is based on information sourced from "Population on 1st January by age and sex", Eurostat. Retrieved 14 June, 2017. http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=proj_15npms&lang=en

[13] Data on uses from Pubchem: https://pubchem.ncbi.nlm.nih.gov/compound/lead_chromate#section=Top

[14] Data on uses from Pubchem: https://pubchem.ncbi.nlm.nih.gov/compound/53488191#section=Use-and-Manufacturing

- Lead chromate molybdate sulphate red –understood to be used as a pigment;

Seeing as the exemption for lead as a stabilizer in sensor cards of blood analysers does not regard pigments nor substances used in paints and dyes, it is concluded that a renewal of the exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

Annex XVII of the REACH Regulation contains several entries restricting the use of lead compounds:

- Entry 16 restricts the use of lead carbonates in paints;
- Entry 17 restricts the use of lead sulphates in paints;
- Entry 63 restrict the use of lead and its compounds in jewellery and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children.
- Entry 28 and entry 30 stipulate that various lead 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.

In the consultants view, the exemption for lead as a stabilizer in sensor cards of blood analysers does not regard paints or jewellery, nor components that could be expected to be placed in the mouth by children under normal or foreseeable use. Furthermore, the use of lead as a stabilizer of PVC sensor cards used in blood analysers is not a supply of lead compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, entry 28 and entry 30 of Annex XVII of the REACH Regulation would not apply. It is concluded that a renewal of the exemption would not weaken the protection afforded by REACH through entries 16, 17, 28, 29 and 63.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status April 2018). 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.

7.4.2. Scientific and technical practicability of substitution

IL argues the justification of the exemption first and foremost on the basis of the lacking reliability of the substitutes it has tested in its effort to comply with the substance restrictions:

- Though candidates have been identified that could be used to substitute lead as a stabilizer in IL's PVC sensor cards, their testing reveals that they do not provide the same reliability over time as the current stabilizer. IL (2017a) summarises some of the findings, for example specifying that all tested RoHS compliant resins resulted in decreased sensitivity (slope) of the pO2 sensor, that resins containing organo-tin compounds resulted in deterioration in accuracy of the sodium sensor, etc. (see Section 7.2.2 for further findings).

- The consistency of negative impact on glucose and lactate precision and loss of pO2 sensor slope (sensitivity) across tests of different RoHS compliant resins containing various thermal stabilizers, leads IL (2017a) to conclude that the problem is likely linked to the reduction of lead rather than to the addition of some unknown interfering substance. IL intends to focus further research on optimizing the selection of an alternative thermal stabilizer in addition to the presence of 0.098% lead in the PVC resin of the GEM Premier sensor card.

It can be understood that a wide range of substitutes exist, however their successful implementation as substitutes depends on finding the correct resin in terms of it providing comparable performance to that of the original resin. The consultants understand this compatibility to be affected from various factors, i.e the choice of resin can result in non-reliability of the sensor cards on various levels. The substitute is required not to affect the use life (once inserted in the device) and shelf life of the sensor card itself (comprised of a PVC resin). It may also not affect neither the use life nor the shelf life of the sensors for each of the measured parameters - these sensors are required to provide reliable measurements throughout their expected lifetime (1 month of use, 9 months shelf-life). In other words, both a general decreased sensitivity as well as deterioration in the reliability of results in relation to all or to one specific sensor throughout the use of a card would render a substitute not acceptable.

Investigation of the status of substitution of other producers of blood analysers suggests that research into the proper substitute is a result of tedious trial and error testing, however it is also observed that for a few manufacturers the exemption renewal is not needed.

- **Radiometer** contributed to the stakeholder consultation of the former evaluation process in 2013 through support of the request. Radiometer was contacted in February 2018 to clarify if its equipment would also require the renewal of the exemption. It responded that Radiometer will substitute the PVC with lead before the exemption expiration deadline. "*After several attempts we have found a solution that works for our specific use of the PVC. We are not sure how other manufacturers use the PVC with lead, but the substitution might be difficult and in any case the approval process is long for materials used in IVD*." (Radiometer 2018)
- **Siemens Healthineers** has also confirmed that its devices that made use of RoHS Annex IV, Ex. 41 in the past shall no longer need this exemption once it expires on 31 December 2018. Here too, the search for the suitable substitute is understood to have been a tedious process.
- As for **Abbott's I-STAT**, it is understood from IL's answers to clarification questions that it uses a silicon cartridge, eliminating the need for the lead stabilizer. Nonetheless, the I-STAT is a smaller device (handheld) that provides the service of single used tests, where silicon has traditionally been used (IL 2017b) and is not understood to be comparable. Though it is possible that materials used for single use test sensor cards would not provide the necessary reliability for multi-use test sensor cards, data is not available to allow a conclusion on this aspect, i.e. as to the feasibility of silicon as a suitable alternative material for

producing the sensor cards used for multi-use testing in equipment such as that of IL or as to the opposite.

As for substitutes for lead in the PVC cards, it is understood that some manufacturers have found suitable alternatives and shall complete the substitution before the current expiration date of the exemption, i.e. 31.12.2018. This raises a question as to whether the GEM blood analysers can be seen as comparable to equipment of other producers or whether they offer certain advantages that may justify the continued use of lead in this case. In terms of comparability of devices, various factors need to be considered.

A first aspect of importance regards the variety of analytes that can be tested by different equipment. Sensors for such analytes are located on the PVC sensor card and in the consultants view it is plausible that the precision of their measurement can be affected by its composition. In relation to the GEM blood analysis devices, IL (2017a) has detailed the following parameters: partial pressure of oxygen and carbon dioxide (pO2 and pCO2), pH, Na+, K+, Ca++, Cl-, glucose, lactate and haematocrit. To check comparability, a few devices were compared in terms of the measureable analytes - see Table 7-2. This comparison is not comprehensive but is assumed to provide a first basis to draw conclusions as to comparability of this aspect.

Table 7-2: Comparison of measurable analytes of various blood and blood gas analyses devices, compiled on basis of available specifications

	Manufacturer	Radiometer	IL	Siemens Healthineers	
	Model	**ABL90 FLEX**	**GEM Premier 5000**	**Rapid Point 500**	**RAPIDLab 348EX Blood Gas System**
Measured analytes:		**Given as specified or not in available specifications**			
Sub-groups	**Analyte**				
pH/ blood gas:	pH (acidity)	Specified	Specified	Specified	Specified
	pCO2 (carbon dioxide tension)	Specified	Specified	Specified	Specified
	pO2 (oxygen tension)	Specified	Specified	Specified	Specified
Oximetry:	ctHb (total hemoglobin concentration)	Specified	Specified	Specified	Specified
	sO2 (oxygen saturation)	Specified	Specified	Specified	Not specified
	FO2Hb (fraction of oxyhemoglobin in total hemoglobin	Specified	Specified	Specified	Not specified
	FCOHb (fraction of carboxyhemoglobin in total hemoglobin)	Specified	Specified	Specified	Not specified
	FHHb (fraction of deoxyhemoglobin in total hemoglobi	Specified	Specified	Specified	Not specified
	FMetHb (fraction of methemoglobin in total haemoglobin	Specified	Specified	Specified	Not specified
	FHbF (fraction of fetal hemoglobin)	Specified	Not specified	Not specified	Not specified
	ctBil (concentration of total bilirubin in plasma)	Specified	Specified	Specified	Not specified
Electrolytes:	cK+ (potassium ion concentration)	Specified	Specified	Specified	Specified
	cNa+ (sodium ion concentration)	Specified	Specified	Specified	Specified

	Manufacturer	Radiometer	IL	Siemens Healthineers	
	cCa2+ (calcium ion concentration)	Specified	Specified	Specified	Specified
	cCl– (chloride ion concentration)	Specified	Specified	Specified	Specified
Metabolites:	cGlu (D-glucose concentration)	Specified	Specified	Specified	Not specified
	cLac (L(+)-lactate concentration)	Specified	Specified	Specified	Not specified
Haematocrit:	Hct	Not specified	Specified	Not specified	Specified
	HCO3-	Not specified	Not specified	Not specified	Specified
	ctCO2	Not specified	Not specified	Not specified	Specified
	Calculated analytes - analytes marked in green text when they correspond to those not directly measurable.	Not specified	BE(B), BE(ecf), tHb(c), Ca^{++} (7.4), Anion gap (AG), P/F ratio, pAO_2, CaO_2, CvO_2, p_{50}, O_2cap, $sO_2(c)$, O_2ct, HCO_3 – std, TCO_2, HCO_3 – (c), A-aDO_2, paO_2/pAO_2, RI, CcO_2, a-vDO_2, Q_{sp}/Q_t (est), Q_{sp}/Q_t, Hct(c)	Not specified	ctHb, O2SAT, O2CT, HCO3-act, HCO3-std, ctCO2, Beb, BEecf, pO2(A-a), pO2 (a/A), pO2/FiO2, Ca++(7.4), Anion Gap,

Sources:
Radiometer: http://www3.hscni.net/stlabs/webhb/poct/documents/poctabl90man.pdf
Instrumentation Laboratory: http://www.instrumentationlaboratory.com/en/gem-premier-5000
Siemens Healthinieers: https://static.healthcare.siemens.com/siemens_hwem-hwem_ssxa_websites-context-root/wcm/idc/groups/public/@de/@lab/documents/download/mdax/odmw/~edisp/dx-de-rapidpoint500-technspezifikation-00882771.pdf; and https://static.healthcare.siemens.com/siemens_hwem-hwem_ssxa_websites-context-root/wcm/idc/groups/public/@global/@lab/documents/download/mdaw/mtg5/~edisp/rapidlab_348ex_brochure_final_2_web-00173655.pdf

From the comparison specified in Table 7-2, it is apparent that different devices have slight differences in terms of the analytes measured. In each case, many of the analytes compared can be measured, whereas a few are measurable only by some equipment (for example FHbF and haematocrit are not directly measurable in most devices), though they may be calculated on the basis of measured parameters in some cases. Though this comparison shows that each device has a different range of parameters that can be measured (or derived based on other measurements) it does not allow concluding whether devices of a specific manufacturer have a preference over those of others.

To confirm this assumption, the German Healthcare facility that submitted the stakeholder contribution was contacted and provided additional information (M.D. 2018b). The representative, which provided feedback is a M.D. which has specialised in laboratory medicine and which has over 17 years of experience in this area, including being responsible for the analytical activities of a few medical facilities over the last decade. To begin with, it was emphasized that blood analysis equipment in the focus of this exemption request is considered “point-of-care” equipment. This means that such equipment is used by medical practitioners to measure various blood parameters in proximity to where the patient is being taken care of (emergency rooms, intensive care units, operation rooms). Such devices provide results within relatively short periods (e.g., between 30-95 seconds from blood sample introduction) and are of importance to allow rapid diagnosis and decisions as to further care. The

alternative of sending blood samples to the central laboratory requires more time and also does not provide results for parameters unique to blood gas analysis devices (pH, pO2, pCO2, HCO3-see below).

"Blood gas analyzers require a fast turnaround-time, small amounts of blood and need to measure fast and accurate. Also they need to be as simple as possible since most staff that uses these kinds of instruments are not medical technicians but nurses or doctors. Nevertheless most modern blood gas analyzers measure not only typical blood gas analytes (i.e. pH, pO2, pCO2, HCO3-) but also other critical analytes that are mandatory in an acute care setting (i.e. glucose, hemoglobin, potassium)". (M.D. 2018a)

As for the preferences of medical facilities towards specific equipment, it was explained that these differ from blood analysis devices used in central laboratories, where it is quite common to use devices of multiple manufacturers and types. In contrast, in blood gas analysis at point-of-care, though some facilities use equipment of a few manufacturers, there is a growing tendency to use equipment of a single manufacturer and at that, to prefer the use of a single device or a small number of devices. (M.D. 2018b).

It was further elaborated (M.D. 2018a) that "*in a typical German hospital setting, the blood gas analyzers are usually from one vendor and preferably only one model is used. Reasons for this are standardization and harmonization as well as a general contract or a winning bid after a tender. Multiple instruments mean higher cost and require intensive training of staff. Also different instruments produce different values since measurement of certain analytes are not standardized. If you have only one type of blood gas analysers you get same results on every instrument in the hospital. Also standardization is advantageous in case of a system failure. The staff can quickly change to a similar instrument in a different ward"*.

To support this point, two examples were given of different German health facilities, one using 16 GEM devices manufactured by IL and the other using a similar number of blood gas analysis devices of Radiometer (M.D. 2018b).

To summarize, it can be understood that facilities may have a tendency towards using equipment of a single vendor. In contrast, as there are a number of manufacturers providing facilities with such equipment (different facilities shall have different preferences) it can be concluded that in general the relevant analyte measurements can be provided with equipment of different manufacturers and are not unique to the IL devices. As explained in Section 7.4.5, there are different considerations for deciding as to the provider of blood gas analysis devices, many of which are not related to the technical specifications of a single device but rather to aspects of its operation within the facility and the costs thereof.

In this sense, other devices could be used to substitute the GEM devices, however it is noted that in practice this would result in various impacts as detailed in Section 7.4.3 and Section 7.4.5 (waste management aspects, risk of emissions as well as costs for health care facilities, additional waste from scrapped devices prior to end-of-life, use of resources for manufacturing new devices, etc.).

A few other aspects were mentioned by IL that could be considered as possible benefits of its equipment.

- IL (2017a) stated that other competing technologies utilize multiple cartridges to perform the same functions, some of which require refrigerated storage. Refrigerated storage could mean that some equipment may have additional energy consumption relating to this requirement. Nonetheless, from the review of publicly available information on devices of other manufacturers, it can be understood that IL is not the only manufacturer of devices that do not require refrigerated storage. It is understood that the Siemens Rapidpoint 500[15] also uses a single cartridge which contains "*all components required to measure the critical analytes in a single cartridge - without gas tanks and reagent bottles*". Nonetheless, quality control (QC) is understood to take place in a separate component, whereas in the GEM devices these two functions are combined into a single unit. The Radiometer ABL90 FLEX blood gas analyser[16] is also understood to have separate locations for the sensor card and for the solution pack which is relevant for QC, though reagents are not stored separately.
- From the comparison of the time to results of various equipment it is observable that the GEM requires between 45 to 90 seconds for results from sample introduction (IL 2018), in comparison to for example the Siemens Rapidpoint 500 (60 seconds). However, the GEM results are continuously monitored for error detection and correction through the iQM system. Specifications of Siemens and Radiometer devices reviewed were not completely clear on this point; quality control was specified to be automatic and intervals for calibration were specified between 30 minutes to 8 hours, depending on the calibration type. However quality control and calibration are understood not to be the same and thus it is difficult to conclude from one as to the other. Furthermore, this aspect does not seem to be related to the use of lead in the PVC sensor cards and would not justify an exemption. The use of lead or of a substitute resin is understood to affect the reliability of measurements performed within the sensor card, i.e. the various sensors are not as reliable over time when alternative resins are used. Though the sensor card and the process control components are assembled in a single unit in GEM devices, they are considered by the consultants as separate components[17]. In other words it can be concluded that the use of lead is not necessary to ensure the continuous quality control.

7.4.3. Environmental arguments

IL provides a detailed life cycle analysis comparing the lead based resin to possible alternatives that they have been testing. Though the analysis suggests that the lead based resin has environmental advantages over other resins tested, the comparison is on the basis of the GEM equipment and the resins tested by IL. It does not allow concluding as to the comparability of substitutes applied by other producers and the

[15] See information on Siemens Rapidpoint 500 under: https://www.healthcare.siemens.co.uk/blood-gas/blood-gas-systems/rapidpoint-500-systems

[16] See page 32 in user's manual: http://www3.hscni.net/stlabs/webhb/poct/documents/poctabl90man.pdf, last accessed 13.06.2018

[17] See illustration provided under: http://www.instrumentationlaboratory.com/en/gem-premier-3000

lead based resin used by IL in the GEM devices. In this sense, on the basis of available data, it is not possible to conclude whether the GEM lead based resin has a total lower environmental impact than substitute resins applied in PVC sensor cards used in equipment of other producers or not.

Another two aspects are of importance for the evaluation of this request regarding waste management and the risks for emissions of lead at this stage.

Blood gas devices are professional medical devices, constructed as complex electronic devices for performing tasks related to blood gas analysis. Both purchase and disposal of these devices are understood to be performed on a business to business level (disposal sometimes leading to a refurbishment of the device rather than its management as waste). In this sense, it can be understood that the devices, including their complex electronics are expected to be disposed of properly. Scrapping of the devices prior to end-of-life results in the premature end-of-life of complex electronics, e.g. printed circuit boards, etc. Furthermore, the sensor card, which analyses bodily fluids (e.g., blood) needs to be retrieved and disposed of as medical waste. Sensor cards are collected by health facilities and sent for respective treatment (incineration) in the EU where it is expected that emissions are controlled as required by relevant legislation.

Though a revoke of the exemption would prevent lead from being placed on the market through the sensor cards, it seems that this would not achieve any direct benefits in terms of emission prevention or improved waste management:

- Lead emissions through its use in the sensor card are not expected - lead does not emit during use; nor are uncontrolled emissions expected in light of cards not being sent to proper waste treatment; whereas the treatment of the cards as medical waste is expected to be performed according to EU standards and to avoid emissions.
- The waste management of blood-gas analysis equipment is not understood to be affected by the compliance of the sensor cards with the substance restrictions, i.e. equipment is to undergo the same waste management regardless of whether sensor cards contain lead (IL equipment) or not (compliant competitors).
- In contrast, the fact that IL equipment shall not be operable once the sensor cards are denied market access would mean that relevant devices, expected to contain a significant amount of electronics and respective resources, would be scrapped early. Though this negative impact on the environment could be justified should positive environmental and/or health impacts be expected, the fact that actual emissions of lead can be expected to remain unchanged suggests that this is not the case.

7.4.4. Roadmap to substitution

IL requests the exemption for an additional 7 years, i.e. until 31 December 2025. The information that IL provides see Table 7-1) as to their revised project plan begins with a total estimation of the time necessary to achieve compliance and specifies 1 April 2022 as the final date for this process. It is also specified in their application that they

expect to complete updating the CE technical file of their devices by January 2022 (IL 2017a).

Aside from this data specified for the total process, the stages specified with the latest dates are (IL 2017a):

- Shelf life GEM 3000 sensor card specified to end on 24 February, 2019.
- Process Validation - Sensor Card Moulding specified to end on 15 March 2019 - this stage covers mould validation of sensor cards of GEM 3000, GEM 4000, GEM 5000 and GEM CHEMSTAT, only the last of which is expected to end at this date.

IL were asked about the time needed to complete compliance and responded in October 2017 that "*the selection of a resin candidate was planned to occur by 23rd June 2017 according to the Revised Project Plan provided in Table 3 of the application received on 16th June. We've tested substantial resin candidates that have demonstrated limitations in performance for our GEM products; therefore, none have been suitable to replace the existing resin formulation*" (IL 2017b). In this sense the consultants understand that the revised project plan provides insight as to the time needed to achieve compliance, but is not updated in relation to the actual time needed to achieve compliance. From this plan, it can be understood that were a suitable resin candidate identified by 23 June 2017, compliance could be achieved by April 2022, i.e. within ca. four years and nine months. Assuming a candidate were to be selected by now (September 2018), it would be plausible that compliance could be achieved by 1 April 2023.

7.4.5. Socio-economic aspects

IL provides some information as to the various socio-economic impacts that could result should the exemption no longer be available. Information is summarised in the table below.

Table 7-3: Possible impacts related to a scenario in which the exemption is no longer available

Impact area	General	Impact related to IL equipment	Impact related to all equipment benefiting from the exemption in the past
Lead avoided on the market and in the waste stream	Lead not to be placed on the market through PVC sensor cards using lead based stabilizers.	48.14 kg of lead to be avoided on the market	144.43 kg of lead to be avoided on the market – assumed an overestimation as some devices have achieved compliance without the exemption.
Generation of additional waste EEE	Possible equipment to be scrapped should PVC sensor cards no longer be available	111,640 kg (or 316.84 m^3) of waste could be generated if sensor cards are not available.	334,921 kg (or 950 m^3) of waste could be generated if sensor cards are not available. This is assumed to be an overestimation as some devices have achieved compliance without the exemption.
Employment	Impacts on producers of blood analysers	Employment in offices and facilities related to the manufacture and distribution of equipment in the EU would be affected (manufacture facilities,	Employment in facilities related to the manufacture of non-compliant devices would be affected (see detail in relation to IL equipment). As for producers of compliant equipment such as for example Radiometer and Siemens, these are not expected to

Impact area	General	Impact related to IL equipment	Impact related to all equipment benefiting from the exemption in the past
		suppliers, Werfen affiliates in the EU, Roncello Italy facility, EU distributors, marketing and servicing of the GEM analysers, logistics and processing of refurbished units).	have negative impacts and could also experience an increase in business should sales increase where other devices are not yet compliant. It is assumed that such impacts could be temporary or limited in range, depending on how fast compliance of the GEM devices and possibly of other non-compliant equipment is achieved.
Other impacts	▪ Impacts on European medical educational facilities, hospitals, and clinics. This would impact healthcare quality and treatment outcomes, especially in critical care and point-of-care departments. Hospitals and medical clinics would be adversely impacted due to limitations in analytical capabilities to enable physicians to diagnose and treat ailments.	▪ Based on information provided by IL (2018) equipment is understood to account for around 30% of the EU market share (and up to 40-50 % in some member States). Impacts were not further quantified.	▪ Based on information provided by IL (see section 0), equipment of other producers is understood to account for around 67% of the market share (slightly below 12,700 devices). Nonetheless, it can be understood that a share of this equipment is compliant (e.g., Radiometer, Siemens). Facilities using such equipment would not be affected (or would be affected less, depending on their blood analysis "portfolio").
	▪ Impacts on patients (health) for which the same level of medical care cannot be guaranteed. This may subsequently affect businesses should the rate of illness of the EU population rise.	▪ Impacts are in relation to an approximate total of 94,078 thousand tests performed with the GEM devices.	▪ Impacts are in relation to an approximate total of 282,160 thousand tests, though as some producers have reached RoHS compliance without the exemption, this is understood to be an overestimation.

Though a rough estimation is provided in relation to all relevant blood analysis equipment placed on the EU market, it seems that at least some of the producers of alternative equipment have substituted lead and would thus not be negatively affected from a scenario in which the exemption were no longer available. In this sense, though it cannot be excluded that additional producers may place equipment on the market for which the exemption is needed, it is concluded that the estimation IL provides in relation to its own equipment is probably closer to the impacts actually expected than the figures provided for the complete market.

There is concern in relation to blood analysis devices placed on the market before the exemption is to expire (31.12.2018). Without the PVC sensor cards, equipment legally placed on the market before this data would effectively no longer be operable once the stock of sensor cards of a specific facility is exhausted. Though it can be understood that research is being undertaken to develop substitutes that can be applied in the sensor cards used in models already on the market, a lack of supplies at present would result in idle equipment in the short term and could result in equipment being

scrapped before its end-of-life, should a longer period be needed to find and apply substitutes. To reduce the negative impact of a non-exemption scenario on health facilities already working with the GEM equipment (or with other non-compliant equipment), it would be important to ensure further supply of PVC sensor cards for existing equipment.

In this respect, Recital 20 of the Directive states that "*As product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available*". Article 4(f) of the Directive further stipulates that the RoHS substance restrictions shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of "*EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned*". In relation to this recital and article, the consultants understand the intention of the legislator to have been to ensure that equipment placed on the market in the past could still be repairable, even in cases of a malfunction requiring the supply of a part no longer compliant with the Directive.

In the case of Ex. 41, however, it is not clear whether the PVC sensor card can be seen as a spare part. Replacement of the card is part of standard operation and not understood to be a malfunction requiring repair. Replacement is also not understood to support reuse, updating of functionalities or upgrading of capacities as once the card is replaced functionalities and capacities would be restored to their previous level. And yet without replacements for the sensor card the equipment would become non-functional.

Thus, in relation to impacts on end-users, where the PVC sensor card is not yet RoHS compliant, it is assumed that a revoke scenario of the exemption will result in non-operability of the devices already on the market once the stock of sensor cards is exhausted (shelf life of the IL sensor cards is up to 9 months). This would require replacing all relevant devices. For estimating impacts on end-users, it needs to be considered to what degree health facilities may be dependent on devices expected not to be compliant such as the IL Devices. As explained above, health facilities are likely to have preferences in relation to the devices they purchase:

> "*The decision process towards new blood gas systems is highly sophisticated, time and money consuming. You have to evaluate the pros and cons of the different manufactures and instruments on the market. Than you have to look closely at the analytical and technical performance of the instruments. For example you will have to evaluate how long it takes until the measurement is performed (so called turn-around-time), how much blood is needed for the measurement, how often the instrument needs service or maintenance and a lot of other issues".* (M.D. 2018a)

Given the expected costs of a single device, the German Healthcare facility estimates costs of such a scenario:

On investment costs: "In regards to our hospital, this equals investment costs of over 300.000 € [...] If you identified all the crucial points you will most certainly need a Europe-wide tender, since the instruments and reagents are not cheap. After

the bidding you will need to revaluate everything. Often the winner of the tender is required to demonstrate the instrument under real life conditions at the hospital. This whole process can take up to one year.

Afterwards you will also need to connect the new instruments to your hospital information system, most often by middleware. The connection requires further expenses [...] I estimate these costs at 20.000 €.

After that all staff that uses the instruments (nurses, doctors) need training. The training and its proper documentation is required by law. In our hospital around 1.200 employees were trained after we implemented the IL Werfen blood gas systems in 2007. If you train every employee at our hospital for only 1 hour this equals 1.200 hours of unproductive work time." (M.D. 2018a)

In the case of a request for exemption renewal which is denied, the exemption expires and the EU COM is required by the Directive to grant a transition period of between 12-18 months. It is noted that should the exemption expire (end of 2018), health facilities using IL equipment that would purchase new equipment would only have a short period to implement the shift from IL equipment to other suppliers. It is not clear how much time would be needed for the health sector to become aware of the need to replace existing equipment. The German Health facility estimated around a year to complete respective tendering processes, acquisition and installation of equipment and training of staff for its facility specified to have a moderate size and to operate 16 devices.

To give context to the depreciation of these investments it is noted that the average service life of blood gas analysers was estimated to be between *"5 to 7 years, depending on several facts like service and maintenance. In a heavily used environment and not properly taken care this is sometimes shorter, but I have also seen instruments running more than 8 years without any problem.* (M.D. 2018a). This also gives an idea of the relevant stock that would need to be replaced - non-compliant devices purchased over the last 5 to 7 years. Devices could also be refurbished, allowing an extension of the service life, thus it is assumed that replacement would apply to older devices as well.

Furthermore, from the available data it is apparent that IL has a significant market share and it is not clear how fast competitors could fulfil a possible supply gap. IL was thus asked to provide information as to their market share to allow understanding the amount of devices that could be affected. IL (2018) specifies their market share in the EU to be in the order of 30 % of devices, accounting for 40-50 % of the national market share in some EU countries. IL further estimate the total blood gas device stock in the EU to be in the order of 30,000 devices, with annual sales of between 3,000 to 5,000 devices per year.

The estimated IL market share of 30 % would mean that the stock of IL devices in operation in the EU accounts for around 9,000 devices and that IL annual sales would account for around 1,200 devices (based on a total of 4,000 devices sold per year).Based on the cost estimations of the German health care facility and assuming that all facilities using IL equipment are medium sized hospitals, operating around

15 devices, would suggest that 500 facilities would need to spend a total of 228 million € to replace all IL devices currently in use. These costs need to be seen in perspective of the prevention of an annual amount of ~48 kg of lead being placed on the market through the sensor cards needed to operate these devices. To give further context, assuming 9,000 IL Devices are affected, would mean that the phase-out would cost an average of 25,333 € per device to be replaced, including updating of middleware and training of staff. Assuming IL would require until April 2023 to achieve compliance, 156.6 kg of lead related to the sales of three years and three months (the time between the current expiration date and expected compliance) would be prevented. Additional costs and benefit factors may apply as detailed below, however these have not been quantified and are thus not addressed in this estimation.

Additional costs of relevance to such a scenario include:

- The cost to the environment of devices that would need to be scrapped before end-of-life as they could no longer be used without the PVC sensor card. It is possible that some devices could be sold for refurbishment, reducing the number of devices to be scrapped. It is however understood that such devices could no longer be placed on the EU market as refurbished devices and it is thus not clear if the total IL EU market share (stock of ~9,000 devices) could benefit from this practice. As a further option, should consumers decide to retain devices until the substitution is achieved, this would require additional space for storing equipment in facilities at a certain cost, though reducing the environmental costs of additional scrap;
- From the perspective of environmental costs, additional resources would also be needed to produce the replacement devices for the scrapped ones (i.e. before the end-of-life of devices are to be replaced).

It is concluded that the socio-economic costs of an exemption revoke scenario would particularly be considerable for health care facilities, in light of the understanding that this would require replacing all non-compliant devices still in use within a relatively short period, i.e., at minimum all 9,000 IL devices currently in operation in the EU. In this respect it should also be noted that this investment is for the most part to be perceived as an unexpected one, meaning that it is not planned for in health budgets and shall require a reallocation of resources from other health investments to allow realisation. Thus, despite the understanding that replacement is possible, a phase-out would not just create financial costs for health facilities but also have an impact on the investment in other services at the time of replacement and in this sense subsequently on the services (their range and/or quality) provided to patients.

It is obvious that an exemption revoke shall result in a loss of business for IL, affecting its general market share in the EU at least temporarily. Though it is possible that some facilities would revert back to IL equipment with time, once substitution is achieved, it is assumed that this may not be the case in all facilities and in any case would be expected to be a gradual process. In contrast, competitors which have achieved RoHS compliance would benefit from the phase-out of blood-gas devices, expanding their market share to replace IL devices. As for impacts related to other health services, some of these may be device related, also affecting manufacturers (though not necessarily the same ones).

In terms of use of resources, a phase-out is also expected to result in costs related to the early scrapping of replaced devices and related to the manufacture of new replacement devices. Devices at end-of-life are generally replaced with new ones; also resulting in the scrapping or use of new resources (i.e. impacts are not additive). However, the difference to an exemption renewal scenario in which these impacts incur gradually, as devices reach end-of-life, is that in case of revoke the impacts are expected to incur within a short period (at latest 9 months after sensor card stocks are exhausted). In contrast, where the exemption is renewed, sensor cards are being developed to be compatible with older equipment, meaning that a natural phase-out is not underway.

As for the placing of Pb on the market through the sales of sensor cards needed for operation of devices, here the benefit is not just related to new blood gas devices placed on the market but also to devices already in operation. The quantities of lead estimated by IL to be placed on the EU market are related to all sensor cards placed on the market, i.e. those to be used in new equipment as well as those to be used in already operative equipment. This quantity shall be avoided completely should the exemption be revoked, and vice versa. Nonetheless, the avoidance of this amount of lead understood not to affect the potential for lead emissions, which are not expected regardless of the use of lead (see Section 7.4.3).

7.4.6. Conclusions

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

I. 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**;
II. the **reliability** of substitutes is not ensured;
III. 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.

In the review of Ex. 41 of Annex IV of the Directive, in relation to scientific and technical progress, it can be understood that alternative resins are available on the market. Some producers (e.g. Radiometer, Siemens Healthineers), have finalized testing of such resins and can already implement them as substitutes in equipment, whereas others, such as IL are still in the process of testing and certifying an alternative for use in their equipment.

IL has provided sufficient information to show their efforts into the search after a substitute. Though in their case, available resins which have been tested have not been found to be sufficiently reliable, at least for some producers reliability has been established and alternatives are to be applied to allow compliance of sensor cards of blood analysers of respective equipment, so that the exemption shall no longer be needed after 31.12.2018 for such equipment. Though the IL equipment may have an advantage over other equipment in terms of the continuous quality control that it provides, this function is not understood to be affected by the use of lead and thus an

exemption is not considered justifiable on this basis. It could also not be concluded that the devices have a wider range of technical capabilities in relation to the parameters that can be measured. Though the replacement of existing devices is considered to have high costs, in theory it is understood to be possible for users to replace existing non-compliant devices of one manufacturer with those of others.

As for information related to environmental impacts, a comparison of the resins used by manufacturers who have established compliance and between the resins used in the GEM PVC sensor cards is not possible on the basis of available information. Nonetheless, as sensor cards are in contact with bodily fluids, it can be understood that they are to be treated at end-of-life as medical waste. In this sense, all cards can be expected to be collected and sent to proper waste treatment, preventing possible emissions related to improper treatment. Though the revoke of the exemption shall remove lead from the market (positive impact) this is not expected to affect the potential for lead emissions during the sensor card lifecycle phases. In parallel, the revoke shall result in a premature scrapping of equipment which would otherwise be operable with the sensor card once it achieves compliance. **The prevention of lead** (ca. 48 kg per annum or **157 kg** assumed IL shall achieve compliance by April 2023) **thus needs to be weighed against the negative impact related to premature end-of-life of blood-gas equipment (111,640 kg** or 316.84 m^3 of WEEE). The composition of this WEEE is not clear. It can be assumed to contain various heavy metals (for example in printed circuit boards) and is thus not to be perceived as completely harmless. Though it is clear that a substitution shall result in both positive and negative impacts on the environment and possibly on health, it cannot be concluded whether the total negative impacts caused by substitution are likely to outweigh the benefits thereof.

As the PVC sensor is understood to be inherent to the function of GEM blood analysers (and possibly also to the function of non-compliant equipment of other manufacturers), it can furthermore be concluded that the discontinuation of the exemption can be expected to have a considerable impact on health service providers using equipment already on the market, as such devices shall become non-functional once PVC sensor cards cannot be replaced. Such equipment has been stated to account for a large share of the market (GEM devices are understood to have a ~30 % market share of blood analysers in the EU (IL 2018)). The renewal of the exemption would prevent the expected impacts on health facilities as devices already on the market (and understood to comprise a significant part of the EU stock) could continue to be used. An exemption revoke would further avoid costs related to resources through premature scrapping of existing devices and premature production of new devices - in both cases the volume is estimated at ~112 tonnes or 317 m^3 of equipment. It would also however prevent the placing of Pb on the EU market, estimated to relate to 48 kg Pb per year or ~157 kg assuming IL achieve compliance by April 2023, though this is not understood to result in actual benefits in the form of decreased Pb emissions.

In the consultants' opinion, possible costs related to a scenario of exemption revoke would be significant, particularly for health facilities, as the PVC card is not expected to benefit from the Article 4(f) spare part exclusion and all relevant blood gas

equipment would thus become non-operable once the stock of PVC sensor cards is exhausted (assumed at latest 9 months after the end of a transition period).

If in the European Commission's view, the removal of ca. 157 kg of lead from the market (not expected to affect Pb emissions) does not justify the negative impact of scrapping devices (ca. 112 thousand kg), for which compliant sensor cards are still in development, the exemption should be renewed on the basis of fulfilment of the third Article 5(1)(a) main criteria.

Should a renewal be considered, it would be recommended to provide it for the period assumed to be needed by IL to achieve compliance. As specified in Section 7.2.4, this is assumed to require four years and nine months, once a substitute is selected. It is assumed that time has gone by since the last communication with IL and research into further candidates (i.e., resins that include less than 0.1 % Pb) may have progressed. Though testing of candidates until suitability is concluded requires some time, it is assumed to be a stage that could be reached in the short future, or that may have already been achieved in the last months. Under the assumption that a suitable candidate has been identified by the time of writing of this report, September 2018, an exemption valid until the April 2023 should provide sufficient time for achieving compliance, while also allowing application for renewal should this process prove more challenging.

7.5. Recommendation

Substitutes have become available and are understood to be applied reliably by other blood gas manufacturers. Nonetheless, it is not clear whether the negative impacts of substitution would outweigh the benefits thereof or not. If the European Commission does not regard the premature generation of ca. 112 thousand kg of WEEE to be justified by the prevention of ca. 157 kg of lead coming on the market (no change to emissions), an exemption on the basis of the Article 5(1)(a) main criteria (III) could be granted. Socio-economic impacts, particularly for health care facilities faced with the need to phase-out all relevant blood-gas devices in operation ca. 9 months following a transition period are also in support of an exemption renewal, though not sufficient to justify an exemption on their own. Should the exemption be granted, the current formulation of Ex. 41 of Annex IV should be retained, providing a validity until April 2023.

Exemption	Duration
Annex IV, Ex. 41: 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.	31.03.2023

Otherwise, the exemption is recommended for revoke, providing a transition period of 18 months to ease the transition.

Exemption	Duration
Annex IV, Ex. 41: 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.	A transition period is recommended for 18 months.

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