Study to assess request for one (-1-) exemption, for lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood, in Annex IV of Directive 2011/65/EU (Pack 26) – Final Report

Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation

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Disclaimer

Oeko-Institut has 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 is not responsible for decisions or actions taken on the basis of the content of this report.

EUROPEAN COMMISSION

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1. Executive summary – English

With contract No. 090202/2021/856224/ENV.B.3 implementing Framework contract No ENV.B.3/FRA/2019/0017, a consortium led by Ramboll Deutschland GmbH, has been requested by DG Environment of the European Commission to provide technical and scientific support for the evaluation of exemption requests under the RoHS 2 regime. In the currents study, the work has been undertaken and peer reviewed by Oeko-Institut.

1.1. Background and objectives

The RoHS 2 Directive 2011/65/EU entered into force on 21 July 2011 and led to the repeal of Directive 2002/95/EC on 3 January 2013. The Directive can be considered to have provided for two regimes under which exemptions could be considered, RoHS 1 (the former Directive 2002/95/EC) and RoHS 2 (the current Directive 2011/65/EU).

- The scope covered by the Directive is now broader as it covers all electrical and electronic equipment (EEE; as referred to in Articles 2(1) and 3(1));
- The former list of exemptions has been transformed into Annex III and may be valid for all product categories according to the limitations listed in Article 5(2) of the Directive. Annex IV has been added and lists exemptions specific to categories 8 and 9;
- The RoHS 2 Directive includes the provision that applications for exemptions have to be made in accordance with Annex V. However, even if a number of points are already listed therein, Article 5(8) provides that a harmonised format, as well as comprehensive guidance – taking the situation of SMEs into account – shall be adopted by the Commission; and
- The procedure and criteria for the adaptation to scientific and technical progress have changed and now include some additional conditions and points to be considered. These are detailed below.

The new Directive details the various criteria for the adaptation of its Annexes to scientific and technical progress. Article 5(1)(a) details the various criteria and issues that must be considered for justifying the addition of an exemption to Annexes III and IV:

- The first criterion may be seen as a threshold criterion and cross-refers to the REACH Regulation (1907/2006/EC). An exemption may only be granted if it does not weaken the environmental and health protection afforded by REACH;
- Furthermore, a request for exemption must be found justifiable according to one of the following three conditions:
  - Substitution is scientifically or technically impracticable, meaning that a substitute material, or a substitute for the application in which the restricted substance is used, is yet to be discovered, developed and, in some cases, approved for use in the specific application;

  - The reliability of a substitute is not ensured, meaning that the probability that EEE using the substitute will perform the required function without failure for a period of time comparable to that of the application in which the original substance is included, is lower than for the application itself;
  - The negative environmental, health and consumer safety impacts of substitution outweigh the benefits thereof.
- Once one of these conditions is fulfilled, the evaluation of exemptions, including an assessment of the duration needed, shall consider the availability of substitutes and the socio-economic impact of substitution, as well as adverse impacts on innovation, and life cycle analysis concerning the overall impacts of the exemption; and
- A new aspect is that all exemptions now need to have an expiry date and that they can only be renewed upon submission of a new application.

Against this background and taking into account that exemptions falling under the enlarged scope of RoHS 2 can be applied for since the entry into force of the Directive (21.7.2011), the consultant carried out evaluation of two new exemption requests in this study.

1.2. Key findings – Overview of the evaluation results

The exemption request covered in this project and the name of the applicant concerned, as well as the final recommendations and proposed expiry dates are summarised in the table below (Table 1-1). A request for a new exemption listed in Annex IV was included in the scope of this project. The reader is referred to the corresponding sections of this report for more details on the evaluation results.

Table 1-1: Overview of the exemption requested , associated recommendation and expiry date

Ex. Req. No.	Requested exemption wording	Applicant/s	Recommendation	Expiry date and scope
Annex IV, 2022-1	*"Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood"*	Instrumentation Laboratory (IL) represented by Intertek Health, Environmental & Regulatory Services	Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood.	31st December 2023 Category 8

Note: As in the RoHS legal text, commas are used as a decimal separator for exemption formulations appearing in this table, in contrast to the decimal point used throughout the rest of the report as a separator

2. Executive summary: French - Note de synthèse: Français

Conformément aux termes du contract-cadre ENV.B.3/FRA/2019/0017, un consortium mené par Ramboll Deutschland GmbH a été chargé par la direction générale (DG) de l'environnement de la Commission européenne afin d'apporter son concours technique et scientifique à l'évaluation des demandes d'exemption suivant le nouveau régime de la directive RoHS 2. Les travaux ont été réalisés par l'Oeko-Institut.

2.1. Contexte et objectifs

La directive RoHS 2011/65/UE est entrée en vigueur le 21 juillet 2011, ce qui a entraîné l'abrogation de la directive 2002/95/CE le 3 janvier 2013. Il est possible de considérer que la directive a prévu deux régimes qui ont permis de prendre en compte les exemptions, à savoir le régime RoHS 1 (l'ancienne directive 2002/95/CE) et le régime RoHS 2 (la directive actuelle 2011/65/UE).

- Le champ d'application couvert par la directive est désormais plus large sachant qu'il englobe l'intégralité des équipements électriques et électroniques (EEE ; tel que mentionné dans les articles 2(1) et 3(1));
- L'ancienne liste d'exemptions a été transformée en annexe III et est susceptible de s'appliquer à toutes les catégories de produits conformément aux limitations énumérées dans l'article 5(2) de la Directive. L'annexe IV a été ajoutée et énumère les exemptions spécifiques aux catégories 8 et 9;
- La directive RoHS 2 inclut la disposition selon laquelle les demandes d'exemption doivent être déposées conformément aux termes de l'annexe V. Cependant, même si un certain nombre de points sont déjà énumérés dans cette annexe, l'article 5(8) prévoit qu'un format harmonisé et des lignes directrices détaillées prenant en compte la situation des PME, seront adoptés par la Commission européenne; et
- La procédure et les critères relatifs à l'adaptation au progrès scientifique et technique ont fait l'objet de modifications et comportent désormais certains points et conditions supplémentaires qu'il est nécessaire de prendre en considération. Ces derniers sont détaillés ci-dessous.

La nouvelle directive détaille les différents critères relatifs à l'adaptation de ses annexes au progrès scientifique et technique. L'article 5(1) énumère les différents critères et questions qui doivent être considérés pour justifier l'ajout d'une exemption aux annexes III et IV:

- Le premier critère est susceptible d'être perçu comme un critère de seuil et renvoie au règlement REACH (1907/2006/CE). Une exemption peut uniquement être accordée si elle ne fragilise pas la protection environnementale et sanitaire offerte par le règlement REACH;

- De plus, une demande d'exemption doit être déclarée légitime selon l'une des trois conditions suivantes :
  - Une substitution est irréalisable d'un point de vue scientifique ou technique. Autrement dit, un matériau de substitution ou un substitut pour l'application dans laquelle la substance faisant l'objet d'une restriction est utilisée, doit encore être découvert, développé et, dans certains cas, jugé apte à une utilisation dans l'application spécifique;
  - La fiabilité d'un substitut n'est pas garantie. En d'autres termes, la probabilité que les EEE recourant à un substitut assurent la fonction requise sans connaître de défaillance pendant une durée comparable à celle de l'application dans laquelle la substance d'origine est incluse, est inférieure à celle de l'application;
  - Les impacts négatifs de la substitution sur l'environnement, la santé, et la sécurité des consommateurs l'emportent sur ses avantages.
- Dès lors que l'une de ces conditions est remplie, l'évaluation des exemptions, estimation de la durée nécessaire comprise, devra tenir compte de la disponibilité des substituts et de l'impact socio-économique de la substitution, ainsi que les effets néfastes sur l'innovation et une analyse du cycle de vie concernant les impacts globaux de l'exemption; et
- Le fait que toutes les exemptions doivent désormais présenter une date d'expiration et qu'elles peuvent uniquement être renouvelées après soumission d'une nouvelle demande, constitue un aspect inédit.

Face à un tel contexte, et compte tenu du fait que les exemptions soumises au champ d'application élargi de la Directive RoHS 2 peuvent être demandées depuis l'entrée en vigueur de la directive (le 21 juillet 2011), les experts ont réalisé l'évaluation d'une nouvelle demande d'exemption dans le cadre de la présente mission.

2.2. Les principales conclusions – Synthèse des résultats de l'évaluation

La demande d'exemption couverte dans le présent projet et le demandeur concerné, de même que la recommandation finale et la date d'expiration proposée, sont résumées dans le Tableau 2-1 ci-après.

Une demande de nouvelle exemption à l'annexe IV a été incluse dans la portée de ce projet. Le lecteur est invité à consulter la section correspondante du présent rapport pour plus de détails sur les résultats de l'évaluation.

Tableau 2-1: Récapitulatif de la demande d'exemption, la recommandation associée et la dates d'expiration

Traduction en français fournie par souci de commodité. En cas de contradictions entre la traduction française et la version originale anglaise, cette dernière fait foi.

Table 2-1: Récapitulatif des demandes d'exemption, des recommandations associées et des dates d'expiration

Dem. ex. n°	Termes de l'exemption demandée	Demandeur	Recommandation	Date d'applicabilité et champs d'application
Annex IV, 2022-1	*«Le plomb en tant que stabilisateur thermique dans le polychlorure de vinyle (PVC) employé comme matériau de base dans les capteurs électrochimiques ampérométriques, potentiométriques et conductométriques qui sont utilisés dans les dispositifs médicaux de diagnostic in vitro pour les analyses de la créatinine et de l'azote uréique sanguin dans le sang total »*	Instrumentation Laboratory (IL) represented by Intertek Health, Environmental & Regulatory Services	Le plomb en tant que stabilisateur thermique dans le polychlorure de vinyle (PVC) employé comme matériau de base dans les capteurs électrochimiques ampérométriques, potentiométriques et conductométriques qui sont utilisés dans les dispositifs médicaux de diagnostic in vitro pour les analyses de la créatinine et de l'azote uréique sanguin dans le sang total	31 décembre 2023 Catégorie 8

Note: As in the RoHS legal text, commas are used as a decimal separator for exemption formulations appearing in this table, in contrast to the decimal point used throughout the rest of the report as a separator

3. Introduction

3.1. Project scope and methodology

The scope of the study covers the evaluation of one new exemption request. An overview on the exemption request is given in Table 1-1 in the Executive Summary.

In the course of the project, a stakeholder consultation was conducted. The stakeholder consultation was launched on 07 April 2022 and was held for duration of six weeks thus concluding 19 May 2022.

The specific project website was used in order to keep stakeholders informed on the progress of work: http://rohs.exemptions.oeko.info. The consultation held during the project was carried out according to the principles and requirements of the European Commission. Stakeholders who had registered at the website were informed through email notifications about new steps within the project.

Information concerning the consultation was provided on the project website, including a general guidance document, the applicant's documents, a specific questionnaire and a link to the EU CIRCA website. Public contributions submitted were published on the EU CIRCA website.

Following the stakeholder consultation, an in-depth evaluation of the exemption began. The request was evaluated according to the relevant criteria laid down in Article 5 (1) of the RoHS 2 Directive, as shown in the section on background and objectives on page 7.

The assessment of the exemption evaluated in the course of the study appear in chapter 5. The information provided by the applicant and by stakeholders is summarised in the first section of the chapter. This includes a general description of the application and requested exemption, a summary of the arguments made for justifying the exemption, information provided concerning possible alternatives and additional aspects raised by the applicant and other stakeholders. In the Critical Review part, the submitted information is discussed, to clarify how the consultants evaluate the various information and what conclusions and recommendations have been made.

3.2. Project set-up

As of 23 February 2022, the evaluation of the new exemption 2022-1 of Annex IV of Directive 2011/65/EU was assigned by the Commission.

The overall study has been led by Yifaat Baron and is managed by Katja Moch.

4. Links between the RoHS Directive and the REACH Regulation

Article 5 of the RoHS 2 Directive 2011/65/EU on "Adaptation of the Annexes to scientific and technical progress" provides for that:

> "*inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006*".

Regulation (EC) No 1907/2006 on the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH) regulates the manufacturing, use or placing on the market of chemical substances on the Union market. REACH, for its part, addresses hazardous substances through processes of authorisation (substances of very high concern) and restriction (substances of any concern):

- Substances that may have serious and often irreversible effects on human health and the environment can be added to the candidate list to be identified as Substances of Very High Concern (SVHCs). Following the identification as SVHC, a substance may be included in Annex XIV of the REACH Regulation (Authorisation list): "List of Substances Subject to Authorisation". If a SVHC is placed on the Authorisation list, companies (manufacturers and importers) that wish to continue using it, or continue placing it on the market, must apply for an authorisation for a specified use. Article 22 of the REACH Regulation states that:
  "Authorisations for the placing on the market and use should be granted by the Commission only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable."
- If a Member States or the European Chemicals Agency (ECHA) upon request of the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that it is not adequately controlled, it shall prepare a restriction dossier. ECHA has also the initiative to prepare a restriction dossier for any substance in the authorisation list if the use of that substance in articles poses a risk to human health and the environment that is not adequately controlled. The provisions of the restriction may be made subject to total or partial bans, or conditions for restrictions, based on an assessment of the risks and the assessment of the socio-economic elements.

The approach adopted in this report is that once a substance has been included into the Annexes related to authorisation or restriction of substances and articles under the REACH Regulation, the environmental and health protection afforded by REACH may be weakened in cases where an exemption would be granted for these uses under the provisions of RoHS. This is essentially the same approach as it has first been adopted for the re-evaluation of some existing RoHS exemptions 7(c)-IV, 30, 31 and 40, (Zangl et al. 2012) and in the following for the evaluation of a range of requests

assessed through previous projects in respect of RoHS 2 (Gensch, C., Baron, Y., Blepp, M., Deubzer, O., Manhart, A., Moch, K. 2012). Substances for which an authorisation or restriction process is underway may be discussed in some cases in relation to a specific exemption, in order to check possible overlaps in the scope of such processes and of requested RoHS exemptions and to identify the need for possible alignments of these two legislations.[1]

When evaluating the exemption requests, with regard to REACH compliance, we have checked whether the substance / or its substitutes are:

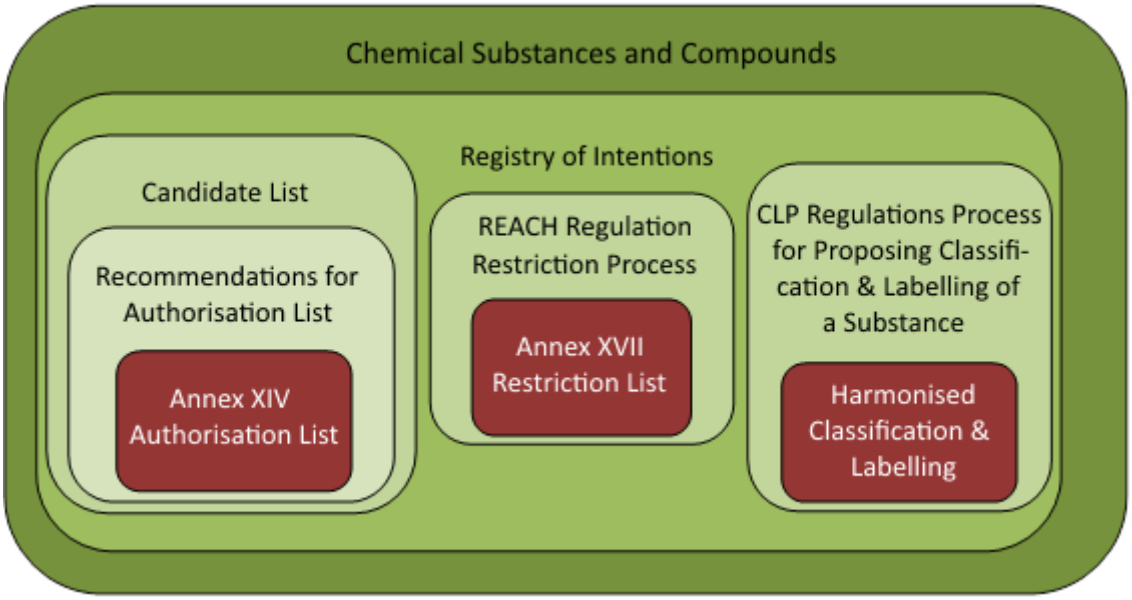
- on the list of substances of very high concern (SVHCs- the Candidate List);
- in the recommendations of substances for Annex XIV (recommended to be added to the Authorisation List);
- listed in REACH Annex XIV itself (the Authorisation List); or
- listed in REACH Annex XVII (the List of Restrictions).

As ECHA is *"the driving force among regulatory authorities in implementing the EU's chemicals legislation"*, the ECHA website has been used as the reference point for the aforementioned lists, as well as for the register of the amendments to the REACH legal text.

The figure below (Figure 4-1) shows the relationship between the two processes under REACH as well as the process on harmonized classification and labelling under the CLP regulation (Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging). Substances included in the red areas may only be used when certain specifications and or conditions are fulfilled.

[1] In 2014, the European Commission has prepared a Common Understanding Paper regarding the REACH and RoHS relationship in 2014 with a view to achieving coherence in relation to risk management measures, adopted under REACH and under RoHS:
REACH AND DIRECTIVE 2011/65/EU (RoHS) A Common Understanding; Ref. Ares(2014)2334574 - 14/07/2014 at http://ec.europa.eu/DocsRoom/documents/5804/attachments/1/translations

Figure 4-1: Relation of REACH Categories and Lists to Other Chemical Substances



Source: Own illustration

Before reaching the "Registry of Intentions" as shown in the figure above, there are additional activities and processes in order to identify substances of potential concern conducted by the ECHA together with the Member States and different ECHA Expert Groups.[2] If a Member State evaluates certain substance to clarify whether its use poses a risk to human health or the environment, the substance is subject to a Substance Evaluation. The objective is to request further information from the registrants of the substance to verify the suspected concern. Those selected substances are listed by ECHA in the community rolling action plan (CoRAP).[3] If the Substance Evaluation concludes that the risks are not sufficiently under control with the measures already in place and if a Risk Management Option (RMO) analyses does not conclude that there are appropriate instruments by other legislation / actions, the substance will be notified in the Registry of Intentions.

The following bullet points explain in detail the above-mentioned lists and where they can be accessed:

- Member States Competent Authorities (MSCAs) / ECHA, on request by the Commission, may prepare Annex XV dossiers for identification of SVHCs, Annex XV dossiers for proposing a harmonised Classification and Labelling, or Annex XV dossiers proposing restrictions. The aim of the public Registry of Intentions is to inform interested parties of the substances for which the authorities intend to submit

[2] For an overview in these activities and processes see the ECHA webpage at: https://echa.europa.eu/substances-of-potential-concern

[3] Updates and general information can be found under: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances. The list can be found on the following page: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

Annex XV dossiers and, therefore, to facilitate timely preparation of the interested parties for commenting later in the process. It is also important to avoid duplication of work and encourage co-operation between Member States when preparing dossiers. Note that the Registry of Intentions is divided into three separate sections: listing new intentions; intentions still subject to the decision-making process; and withdrawn intentions. The registry of intentions is available at the ECHA website at: https://echa.europa.eu/registry-of-intentions;

- The identification of a substance as a Substance of Very High Concern and its inclusion in the Candidate List is the first step in the authorisation procedure. The Candidate List is available at the ECHA website at https://echa.europa.eu/candidate-list-table;
- The last step of the procedure, prior to inclusion of a substance into Annex XIV (the Authorisation list), involves ECHA issuing a Recommendation of substances for Annex XIV. The previous ECHA recommendations for inclusion in the Authorisation List are available at the ECHA website at

  https://echa.europa.eu/previous-recommendations;
- Once a decision is made, substances may be added to the Authorisation List available under Annex XIV of the REACH Regulation. The use of substances appearing on this list is prohibited unless an Authorisation for use in a specific application has been approved. The Annex can be found in the consolidated version of the REACH legal text;
- In parallel, if a decision is made concerning the Restriction on the use of a substance in a specific article, or concerning the restriction of its provision on the European market, then a restriction is formulated to address the specific terms, and this shall be added to Annex XVII of the REACH Regulation. The Annex can be found in the consolidated version of the REACH legal text; and

As of July 2022, the consolidated version of the REACH legal text, dated 01.05.2022, was used to reference Annexes XIV and XVII: The consolidated version is available at the EUR-Lex website: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX-%3A02006R1907-20220501 . Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

- In what cases granting an exemption could "weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006" (Article 5(1)(a) of the RoHS Directive).
- Where processes related to the REACH Regulation should be followed to understand where such cases may become relevant in the future.

In this respect, restrictions and authorisations as well as processes that may lead to their initiation, have been reviewed, in respect of where RoHS Annex II substances are mentioned (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) as well as bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl

phthalate (DiBP).[4] Compiled information in this respect has been included in Tables 1 and 2, which appear in Appendix 1.

The information has further been cross-checked in relation to the exemption evaluated in the course of this project. This has been done to clarify that the Article 5(1)(a) threshold-criteria quoted above is complied with in cases where an exemption is to be granted / its duration renewed / its formulation amended / or where it is to be revoked and subsequently to expire as an exemption. The considerations in this regard are addressed in the separate chapters in which the exemption evaluation is documented under the relevant section titled "REACH compliance – Relation to the REACH Regulation" (Section 5.5.1).

[4] The four phthalates, DEHP, BBP, DBP and DIBP have been added to the Annex according to Commission Delegated Directive (EU) 2015/863 of 31 March 2015.

5. Exemption 2022-1: "Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood"

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 or completed 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

BUN	Blood Urea Nitrogen
CHO	Cyclohexanone
Crea	Creatinine
CMR 1345	Colour master resin 1345. It is the polymer resin that is discussed as a potential substitute for PVC.
CMR 2151	Colour master resin 2151. It is the resin currently used by the applicant for the production of sensor cards.
DEHP	Bis(2-ethylhexyl) phthalate
EEE	Electrical and Electronic Equipment
EoL	End of Life
IL	Instrumentation Laboratory
LCA	Life Cycle Assessment
PAK	Cartridge
PoC	Point of Care
POCT	Point-of-care-testing
PVC	Polyvinyl Chloride

RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
TBLS	Tribasic Lead Sulphate
THF	Tetrahydrofuran
QC	Quality control
XX wt %	Following a number, this formulation refers to the percent weight of a substances from a component or from the homogenous material within which it is contained, depending on used formulation.
WEEE	Waste Electrical and Electronic Equipment

5.1. Background of the exemption

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

The applicant IL requests a new exemption for the described use of Pb in PVC for sensor cards for the GEM Premier ChemSTAT proposing the following wording (IL - Instrumentation Laboratory 2021):

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

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

History of the exemption

An exemption was listed in RoHS Annex IV for lead as a thermal stabiliser in polyvinyl chloride (Ex. 41 Annex IV) and recently expired. The exemption was initially granted in 2015, by Delegated Directive (EU) 2015/573, following an assessment of a request for a new exemption submitted by IL. The exemption was set to expire on 31 December 2018. Later, IL applied for a renewal of the exemption, whose extension was assessed

during 2017-2019 within the project RoHS Pack 14 (Oeko-Institut e.V. Institute for Applied Ecology, Fraunhofer-Institut for Reliability and Microintegration 2019). The assessment recommended the renewal until 1 April 2023, if the Commission agrees that environmental impacts of substitution justify an exemption, or an 18-month transition period in case of revocation.

According to the Commission Delegated Directive (EU) 2020/366 of 17 December 2019, the actual wording was

"Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases".

The expiry date of the exemption was set 31 March 2022 (European Commission 2019). A renewal request was not made for this exemption 18 months ahead of its expiration (i.e., by 30 September 2020) and it is thus expired.

5.2. Technical description of the requested exemption

The applicant manufactures a diagnostic medical analyser, the GEM Premier ChemSTAT. The instruments are used for medical diagnostic testing at or near the point of care (PoC)—that is, at the time and place of patient care, to analyse the blood of patients and provide an accurate measurement of specific analytes on a single whole blood sample. The applicant details sodium (Na+), potassium (K+), ionized calcium (Ca++), chloride (Cl-), glucose (Glu), lactate (Lac), hematocrit (Hct), creatinine (Crea), blood urea nitrogen (BUN), total carbon dioxide (tCO_2), pH, and partial pressure of carbon dioxide (pCO_2), in this respect. The other on-market GEM Premier systems report all these analytes except Crea, BUN and tCO_2 (IL - Instrumentation Laboratory 2022c).

The GEM Premier ChemSTAT enables rapid risk stratification and prioritization of acutely ill patients in the Emergency Department and other point-of-care locations. Furthermore, the addition of creatinine and BUN measurements to GEM Premier ChemSTAT aids in the diagnosis, monitoring and treatment of renal dialysis and metabolic diseases. GEM ChemSTAT is the only IL device with BUN, tCO_2 and Creatinine analytes reported (IL - Instrumentation Laboratory 2022a). The applicant clarified that "*the new parameter tCO_2 measured on the GEM Premier ChemSTAT is based on the pCO_2 sensor, which is the same sensor across all other on-market GEM systems (same sensor fabrication, design and materials). The other on-market GEM Premier systems have already released to the EU market a RoHS-compliant sensor card PVC without Pb. For that reason, this application is specific to the incremental risk of Pb-free resin on the new Crea and BUN sensors" (IL - Instrumentation Laboratory 2022c).* Indeed, all analytes except for BUN and CREA can be measured with sufficient accuracy with a RoHS-compliant resin (IL - Instrumentation Laboratory 2022d).

The GEM Premier ChemSTAT system has two primary components: the instrument and a disposable, multi-use cartridge (PAK). According to the submitted application, the GEM Premier ChemSTAT analyser offers a single, disposable measurement cartridge which

can be stored up to 5 months at room temperature. Moreover, the cartridge "*has a use-life of 21 days or 450 samples, whichever is reached first*" (IL - Instrumentation Laboratory 2022a). As clarified by the applicant, "*the cartridge (PAK) houses the sensor card, solutions, sampler, and waste bag. The sensor card serves as a substrate for a set of electrochemical sensors. There is one sensor card contained in each cartridge*" (IL - Instrumentation Laboratory 2022a). Regarding the component in which Pb is used, the applicant specifies that "*the sensor card is a vital component in the GEM Premier ChemSTAT cartridges as it contains the electrochemical sensors used for measuring and reporting concentrations of critical care analytes in blood"* (IL - Instrumentation Laboratory 2021). The sensor card is an integral component of the cartridge and therefore has the same use-life (IL - Instrumentation Laboratory 2022c).

The PVC material used for sensor card manufacturing is rigid/hard PVC. The leaded PVC is virgin (non-recycled) before being molded into the sensor card shape (IL - Instrumentation Laboratory 2022b).

The consultant understands that these cartridges, containing Pb, are consumables of the analysers, specifically the GEM Premier ChemSTAT, which are nevertheless to be considered as electrical and electronic equipment (EEE)[5]. Cartridges are used for analysis for a limited duration and are disposed of at the end of their use life. The consultant understands that the exemption is concerned with the provision of such cartridges on the EU market, so as to ensure that devices already on the market can continue to be operated until a substitute is developed that is "reverse compatible" with such devices. The applicant clarified that at this time "*both existing and new GEM Premier ChemSTAT instruments require the use of Pb-containing sensor cards*" (IL - Instrumentation Laboratory 2022a).

5.2.1. Amount of Pb used under this exemption

The amount of the substance entering the EU market annually through the application for which the exemption is requested is estimated to be in the range of 0.5-10 kg. The applicant states "*As the newest product in the GEM family, GEM Premier ChemSTAT contributed less than 0.5 kg of lead annually in 2020*" (IL - Instrumentation Laboratory 2021). The consultant understands that the GEM Premier ChemSTAT was only recently released to the market, explaining the difference between the 2020 volume of Pb and the estimated range. This view was confirmed by the applicant, who stated that "*the forecast for GEM Premier ChemSTAT is increasing after product launch in 2019. The increase in annual lead contribution is driven by the number of instruments sold, and there will be no change to lead content per cartridge*" (IL - Instrumentation Laboratory 2022a). As regards the end-of-life, "*the GEM Premier ChemSTAT cartridge is treated as medical waste, and its disposal is handled in each country per their local, state, and federal laws.* (IL - Instrumentation Laboratory 2021). In most case, this amount is stated to be sent to energy return at end-of-life, as it cannot be recycled (IL - Instrumentation Laboratory 2021).

[5] Cartridges are consumables with an equipment constituent meeting the specific definition of EEE in Article 3(1) and 3(2) of RoHS 2, comparable e.g., to printer cartridges, see FAQ 7.4. https://ec.europa.eu/environment/system/files/2021-01/FAQ%20key%20guidance%20document%20-%20RoHS.pdf (last accessed 10.03.2022).

5.3. Applicant's justification for the requested exemption

5.3.1. Substitution, elimination or reduction of Pb

IL - Instrumentation Laboratory (2021) requests the exemption to allow the continued use of lead in the sensor card of the GEM Premier ChemSTAT analysers 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 5 months at room temperature) and use life (up to 21 days or 450 samples in the analyser).

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

IL states that CMR 1345 has been selected as a RoHS-compliant sensor card resin candidate for GEM Premier ChemSTAT. IL is testing CMR 1345 to ensure this sensor card resin change does not negatively impact the analytical performance characteristics, patient safety or effectiveness of the device, specifically for the sensors unique to the ChemSTAT platform – creatinine and BUN.

The substitution project must be completed to address all analytical performance risks for BUN and Crea on a RoHS-complaint resin (IL - Instrumentation Laboratory 2022d). The alternative to replace Pb consists of a combination of three substances; however IL requested to keep the substances identities as confidential. A roadmap ("project plan") for the substitution of Pb is provided by the applicant. According to the plan (Figure 5-1), the Controlled Distribution of RoHS Resin will be accomplished in the second half of 2023 (Q3-Q4). The applicant confirmed that the substitution project is progressing as planned and is still expected to be finalized between 2023 Q3 and Q4. IL is working diligently to expedite this timeline (IL - Instrumentation Laboratory 2022d).

Figure 5-1: Project plan, for the substitution of Pb in PVC

Task Name	Notes	% Complete
Design and Process Optimization	Dec 2017	100%
Down select top 3 formulations from CMR additional additives	Jan 2018	100%
Analytical Performance testing, partial shelf life stability up to 3 Months	Feb 2018	100%
Testing on all GEM platforms for top 3 candidates from CMR additional additives	Apr-May 2018	100%
Repeat testing on all GEM platforms for top 3 candidates	Aug-Sep 2018	100%
Design Review	Oct 2018	100%
Material properties testing	Aug 2018	100%
Down select top 2 resins	Oct 2018	100%
Feasibility	2019	100%
1345 and 1346 Feasibility	Jan 2019	100%
1345 + 1346 Method Comparison and Precision Testing	Apr – May 2019	100%
Additional 1345 + 1346 MC and Prec. Testing	Sep – Oct 2019	100%
1345 Creatinine Investigation	Nov 2019	100%
1345 + 1348 MC and Prec. Testing	Jan 2020	100%
1345 Creatinine interference testing	Mar 2020	100%
1345 Shelf Life Testing	Jun-Oct 2020	100%
1345 Use Life Testing	Jul 2020	100%
Creatinine CVP Optimization	Aug – Nov 2020	100%
Feasibility Review	Jan 2021	100%
Performance Testing to exit Feasibility	Jan - Jun 2021	100%
Process Validation - Sensor Card Molding*		90%
Molding Validations on all platforms	Q1-Q4 2019	100%
Risk Assessment for drying resin	Feb 2020	100%
ChemSTAT molding validation IQ/OQ	Aug 2020	100%
PQ Validation (SMC)	Aug 2020	100%
Pin Cards	Dec 2020	100%
Manufacturing Validation	Mar-May 2021	100%
PQ Validation Report	Q4 2021	0%

Analytical Verification – 1*		25%
Build Material for Verification	Mar-Sep 2021	30%
Analytical Verification	Apr-Sep 2021	10%
Method Comparison	Q4 2021	0%
Aqueous Precision	Q4 2021	0%
Use Life	Q4 2021	0%
Systems Verification	Q4 2021	0%
Shelf Life Verification	Apr-Dec 2021	50%
ELM Testing	Q3 2021	100%
Verification Reports for Analytical Verification – 1	Q1 2022	0%
Testing ~500 Clinical Samples over 10 RoHS CMR1345 resin lots	Q1-Q2 2022	0%
Analytical Verification – 2 (contingency)		0%
Build Material for Verification	Q2-Q3 2022	0%
Analytical Verification	Q3-Q4 2022	0%
Method Comparison	Q3 2022	0%
Aqueous Precision	Q3 2022	0%
Use Life	Q3 2022	0%
Systems Verification	Q4 2022	0%
Shelf Life Verification	Q3 2022 – Q1 2023	0%
Verification Reports for Analytical Verification – 2	Q2 2023	0%
Release Documentation	Q3 2023	0%
Controlled Distribution of RoHS Resin	Q3-Q4 2023	0%

*Delay due to increased demand to support COVID-19

Source: (IL - Instrumentation Laboratory 2021)

The applicant claims to have experienced a delay in developing a RoHS compliant material caused by changed hospital needs during the COVID-crises, i.e., the increased analyser and cartridge demand due to the critical role of blood gas analysis in the management of hospitalized patients with COVID-19. Thus, the applicant will not meet the expected date of March 2022, which was reported already in the application for renewal assessed within RoHS Pack 14 (IL - Instrumentation Laboratory 2017). Indeed, the applicant explains that "*due to the necessary shift in focus to meet customers' high demands, fewer GEM ChemSTAT RoHS sensor cards and cartridge were manufactured for research and development testing*" (IL - Instrumentation Laboratory 2021). The consultant understands this to mean that testing was delayed as manufactured cards and cartridges were prioritised for use in health facilities. The applicant clarified that "*a single manufacturing line is responsible for sensor cards (i.e. all cards, both production cards and experimental Lead-free cards) for all GEM product lines (i.e. not only the GEM ChemSTAT analyzer). As a result of COVID-19, the increased demand for all GEM*

cartridges exceeded the capability of the manufacturing facility, and this meant that dedicated runs of non-production material needed to be deprioritized. 12 planned runs of 60 cards each (720 total cards) of RoHS material" (i.e., CMR 1345) *"were delayed, leading to delays in verification and validation studies"* (IL - Instrumentation Laboratory 2022a).

According to the applicant, "*any change to the sensor card resin can directly impact analytical performance characteristics of the GEM Premier ChemSTAT*", as well as "*the raw sensor results to inform the GEM Premier ChemSTAT intelligent Quality Management System (iQM™), which ensures high quality and accurate blood measurements*" (IL - Instrumentation Laboratory 2021).

The unique features of GEM ChemSTAT require additional due diligence, thus extending the duration of the tests necessary for substitution. The applicant asserts that "*the increased complexity of Creatinine and BUN sensor designs make these new sensors more difficult to manufacture than sensors on other GEM platforms"*. Furthermore, "*the GEM Premier ChemSTAT was designed with unique reagents requiring more complex sensor calibration process*" (IL - Instrumentation Laboratory 2021). Finally, "*additional effort is required to ensure the analytical performance claims (Method Comparison, Precision, Use Life and Shelf Life) are met with the sensor card resin change"* because of "*the limited clinical data available on this newest product using the current production resin"* (IL - Instrumentation Laboratory 2021).

Due to the earlier applications of IL for Pb in Point of Care (PoC) devices, it is clear that the company has been aware of the necessity to substitute Pb for over 10 years and working in this direction. Asked to explain why this new device was designed with Pb-containing sensor cards, the applicant states that the "*development of RoHS compliant resin for sensor card on the GEM Premier family of analyzers is a continual process, in which newly developed products build on released products. A RoHS-compliant material was in exploration phase (candidate RoHS resin was not finalized) during ChemSTAT development prior to design lock. Therefore, the development of Creatinine and BUN sensors was continued on Pb-based resin*". Indeed, "*due to the complex nature of Creatinine and BUN sensor designs and the increased interaction of sensor enzymes with the PVC resin compared to other sensors on the GEM platform, a parallel path was taken to develop creatinine sensors on established Pb-based sensor cards while selecting a RoHS complaint resin based on well-established sensors. This parallel path was chosen to quickly iterate and finalize RoHS compliant resin selection on all other GEM Premier platforms first. Efforts to convert GEM Premier ChemSTAT to RoHS material ramped up immediately after launch in 2019 and are actively being pursued"*.

Compared to other analytical methods and instruments that test human blood for the respective analytes and parameters, the advantage of this technology over others are explained to be the following: according to the applicant, the instrument combines an intelligent quality management (iQMTM), a single disposable measurement cartridge, which can be stored up to 5 months at room temperature, and a rigorous testing procedure of the sensor cards. According to the applicant, "*iQMTM is an active quality management program designed to provide continuous monitoring of the analytical processes before and after sample measurement in real-time, automatic error detection, automatic correction of the system and automatic documentation of all corrective*

actions, thus replacing the use of traditional external quality controls, iQM performs continuous quality checks to monitor the performance of the cartridge, sensors, and reagents throughout the cartridge use life" (IL - Instrumentation Laboratory 2021).

From the application, it emerges that "*other competitive solutions on the market in the EU for POC creatinine measurements are either single use (generating more waste) or require burdensome consumables with different on-board stabilities and refrigerated storage conditions. Moreover, the competitive analysers need hands-on time to be maintained and/or troubleshooted as often as daily or weekly basis. Conversely, the GEM Premier ChemSTAT is a self-contained system requiring very little operator interaction*" (IL - Instrumentation Laboratory 2021).

Asked to provide more details on the competitive solutions, the applicant filled in the following Table 5-1(IL - Instrumentation Laboratory 2022c). The applicant claims that "*GEM Premier ChemSTAT is the only whole blood system in the market that measures Crea, BUN, tCO2 and other standard critical care parameters, using a multi-use cartridge stored at room temperature housing all components necessary to operate the system*" (IL - Instrumentation Laboratory 2022c).

The benefits of using a multi-use cartridge are explained to be the following:

- "*Multi-use cartridges automate the most labor- and skill-intensive processes, reducing sampling errors and cartridge waste*
- *Multi-use cartridges can be coupled with quality management software that ensures performance and integrity of each cartridge. Single use cartridges are limited to quality control (QC) checks on one or more cartridges per lot*
- *Multi-use cartridges do not consume tests with QC checks. Single use cartridges must be used as part of the QC process and are not able to be used for patient tests*
- *Multi-use cartridges reduce burden of inventory management with just one PAK for up to 450 tests rather than 450 individual cartridges*" (IL - Instrumentation Laboratory 2022a)

Table 5-1: Comparison of GEM Premier ChemSTAT with the competitive solutions

Manufacturer	Model	Does the device measure Na^+, K^+, Ca^{++}, Cl^-, Glu, Lac, Hct, pH, pCO_2	Does the device measure creatinine?	Does the device measure BUN?	Does the device measure tCO_2?	Is the device cartridge-based, using multi-use sensor cards?	Does the device require more than one consumable?	Can cartridges/cards be stored at room temperature?
Instrumentation Laboratory	GEM Premier ChemSTAT	Yes	Yes	Yes	Yes	Yes	No	Yes
Abbott	i-STAT CHEM8+	No pH, pCO_2 or Lac	Yes	Yes	No*	No, single use card increasing patient cost and turnaround time.	No	No
	i-STAT Crea	No	Yes	No	No			
	i-STAT EC8+ and 6+	No Lac	No	Yes	No*			
Siemens Healthineers	epoc	Yes	Yes	Yes	No*	No, single use card increasing patient cost and turnaround time.	No	Yes
Radiometer	ABL90 Flex w/Crea	Yes	Yes	Yes	No	Yes	Yes, multiple consumables require replacement every 2 weeks for Crea and Urea	No, both sensor cassette and solution pack are refrigerated
	ABL800 Flex	Yes	Yes	No	No	No, traditional laboratory system, not intended for point-of-care use	Yes, sensors and calibration solutions require replacement every 2 weeks	No
Nova Biomedical	StatSensor	No	Yes	No	No	No	No	No
	Stat Profile Prime Plus	Yes	Yes	Yes	No*	Yes	Yes, separate components (sensor cards, calibrator cartridge and QC cartridge) that require replacement separately.	No, sensor cards requires refrigeration; other components stored at room temperature

*tCO_2 is a calculated parameter on i-STAT, epoc and Stat Profile Prime Plus based on reported pH and pCO_2 and other assumptions. GEM Premier ChemSTAT measures bicarbonate/tCO_2 similar to laboratory based chemistry systems (eg: Roche cobas).

Source: (IL - Instrumentation Laboratory 2022c)

Furthermore, "*GEM Premier ChemSTAT reports measured tCO_2/ bicarbonate similar to laboratory-based chemistry systems (e.g.: Roche cobas). The benefit of measured versus calculated tCO_2/bicarbonate is that the calculation makes assumptions for certain parameters in the equation that are not appropriate for all patient populations, particularly those who are critically ill. Measurement of tCO_2/bicarbonate does not require such assumptions*" (IL - Instrumentation Laboratory 2022c). Nevertheless, since the tCO_2 sensor does not rely on Pb, the consultants believe that this specification is not relevant as regards the exemption assessment.

The applicant states that "*Due to the proprietary nature of sensor and cartridge designs it is challenging to know specific chemicals or stabilizers used in competitive devices and therefore we are not aware of their use of Pb*" (IL - Instrumentation Laboratory 2022c).

5.3.2. Environmental arguments

The alternative considered to replace Pb in the product consists of a combination of three substances, accounting for a weight of 11.2 grams per kilogram of sensor cards. The two scenarios were compared in an LCA. Asked to explain why the LCA compares one kilogram of material, the applicant clarified that that the weight of the sensor card with the resin containing Pb is the same (i.e., 5.1 gr) as the weight of the sensor card with the resin containing the three alternative substances.

The results of a life cycle analysis of the current additive (i.e., Pb) of the GEM Premier ChemSTAT sensor card and the identified alternative are included as Annex to the application. According to the applicant, "*the overall conclusion is that the LCA provides*

evidence that Pb has lower environmental impact (in terms of the results produced by LCA) than the combined alternatives" (IL - Instrumentation Laboratory 2021).

More in detail, the results of the LCA performed according with the Recipe impact assessment method show that lead performs better than the alternative in all the impact categories, except for mineral resource scarcity. Lead has lower environmental impacts in all the impact categories also if LCA results are calculated following the USEtox, Cumulative Energy Demand or Impact 2002+ methods.

It is understood that the disposal phase would not change in case of substitution of Pb.

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

5.3.3. Socioeconomic impacts

The applicant does not refer to socioeconomic impacts of substitution, as "*alternatives are currently not available*" and no additional references or evidence are provided as to socioeconomic effects due to the finding that this is "*not relevant as alternatives are currently not available*" (IL - Instrumentation Laboratory 2021).

However, the applicant claims that "*without this submission being approved, the supply of point-of-care (POC) GEM Premier ChemSTAT analyzers that support hospitals and laboratories in the EU will be jeopardized, negatively impacting several hospitals in the EU Health Care Sector. If an exemption is not granted, it would require a delay in patient care as all hospitals using the GEM Premier ChemSTAT would need to convert to an alternate technology. This would require additional training on competitive analyzers, elevating risk of mistakes which may pose a threat to patient safety, thereby increasing cost to all EU Heath Care currently using the GEM Premier ChemSTAT*" (IL - Instrumentation Laboratory 2021).

Asked to quantify the number of devices in service in EU, the applicant clarified that they are less than 100, while the number of hospitals using the GEM Premier ChemSTAT is currently less than 50 (IL - Instrumentation Laboratory 2022c). Moreover, an increase in sold products is foreseen; based on previous product launches, IL forecast that more than 130 analysers will be in the EU market by the end of 2024, in use in 12 EU countries, while the number of hospitals using the GEM Premier ChemSTAT is expected to be more than 50 by the end of 2024 (IL - Instrumentation Laboratory 2022c).

Asked to provide estimates of impacts caused by the rejection the exemption (i.e., socioeconomic impacts with a special focus on impacts for health facilities, possible impacts on employment in total, in the EU and outside the EU, and additional costs associated with a forced substitution), the applicant clarifies that data specific for the GEM ChemSTAT are not available. However, based on the socio-economic analysis provided as part of our REACH Authorization application submitted in 2019 for 2 models of the same family (i.e., GEM Premier 4000 and 5000 analysers), "*it can be estimated that the combined negative economic impact in terms of the GEM ChemSTAT instrument will be more than 1,5 million euro per year for period up to 12 years. This includes the negative impact for both our company, as well as the negative impact on our suppliers and customers (Health Care Institutions) based in the EEA. The negative impact also includes the monetized negative impact on employment and the benefit for our*

competitors supplying alternative instruments". Indeed, "*a substantial negative impact on employment for both suppliers and our own company cannot be avoided*". (IL - Instrumentation Laboratory 2022a).

The socio-economic analysis submitted by IL in 2019 as part of the REACH Authorization application focuses on IL business related to the production of lysing bags contained in disposable cartridges, which are used in two Blood Gas Systems (i.e., GEM Premier 4000 and 5000 analysers) and contain OPnEO [4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated], a substance added to Annex XIV of the European Union's REACH Regulation due to its classification as an endocrine disruptor (IL - Instrumentation Laboratory 2019). However, this study does not refer to the same device neither to the same substance.

Asked again to quantify any negative impacts on environment and/or health (e.g., premature scrapping of devices, impacts on the accuracy of diagnostics) associated with a forced substitution, should the exemption not be granted, as well as other socio-economic impacts such as costs for health facilities, by referring only to this model of analyser, i.e., GEM Premier ChemSTAT analyser, the applicant estimates that "*pulling the ChemSTAT off of the market would for example have the following specific negative impacts:*

- *Example from our calculator – a hospital running 8,000 samples per year (450 samples every 21 days) will have $13,000 increased cost of ownership with ABL837 chemistry laboratory analyzer compared to ChemSTAT*
- *Moving back to lab from point-of-care testing will increase test result turn-around time by 60 minutes potentially delaying patient care. The resulting negative impact on patient safety and satisfaction, including additional cost due to possible complications, cannot be excluded.*
- *If a customer needed to replace a ChemSTAT, purchase of multiple analyzers or analyzers with considerably more consumables would be required. In any case, cost is driven up by increased need for purchasing various consumables with competitors*
- *Long lead time to purchase new equipment and healthcare budget restrictions; countries that use the procurement and tender process could take years*
- *Impact supply chain of alternate analyzers which may result in shortages, which may impact patient care*

  (…)
- *Additional training and evaluations/validations*
  - *May take 3-6 months for evaluation, validation, and training*
- *Increased IT burden for time to integrate to hospital records*
  - *May take 6 months to integrate with IT system to be fully functional*
- *Time for a new analyzer to be fully operational = 1 year or longer*". (IL - Instrumentation Laboratory 2022c)

The applicant concludes that "*the combined negative impact calculated as annualized value (including impact on environment, health and safety) is expected to be as >1 million euro per year for the period 2022 – 2024*." For the following years, "*the negative impact is expected to be >1.3 million euro based on the projected increased number of*

GEM Premier ChemSTAT analyzers placed on the EU market". (IL - Instrumentation Laboratory 2022c)

Moreover, IL submitted two support letters. The first one was written by Dr. med. H. Stiegle, the laboratory director of a regional laboratory network in Essen, Germany (Medizinisches Versorgungszentrum für Labormedizin und Mikrobiologie Ruhr GmbH). The doctor explains that all their GEM Premier ChemSTAT analysers are roughly one and a half year old and were bought in December 2020. Moreover, he highlights that the GEM Premier ChemSTAT is one of the few point-of-care-testing (POCT) analysers that is capable to measure a basic metabolic panel including the extremely important parameter creatinine in a short turn-around-time. According to the director, the system is easy to use, provides all reagents in one cartridge, requires only minimum time for training and instructions and shows excellent agreement to lab results. Per year there are roughly 50.000 patient samples measured by our instruments providing fast and reliable basic metabolic panel results especially for emergency rooms patients. All instruments are connected by a POCT middleware to their laboratory information system as well as to the various hospital information systems. Thus, If GEM Premier ChemSTAT could no longer be used, the impact on the patient care would be great, especially in the emergency rooms since patient samples needed to be transported to the central lab by car, therefore massively prolonging time. This would have a huge financial impact on the laboratory, since they would need to buy new instruments, investing roughly 120.000 €. Finally, the doctor states that the decision process towards new systems is highly sophisticated, time and money consuming, as well as the connectivity and training of all users (Dr. med. H. Stiegler 2022).

A second support letter was written by Dr. Carlo Introini, Director of the Department of Urology at the hospital Galliera in Genoa, Italy. He declares that "*in relation to clinical needs, the parameters like BMP, including lab-quality creatine, plus Hct, Lac, pH and pCO2, with calculated renal function parameters, eGFR (MDRD) and eGFR (CKD-EPI) currently provided to our institution through whole-blood testing system measures, are crucial in the clinical management of our patients"* (Dr. Carlo Introini 2022). Thus, the "*patient population would be adversely impacted if these parameters couldn't be analysed through accurate, fast, simple instruments such as the ChemStat Analyzer*" (Dr. Carlo Introini 2022).

5.4. Stakeholder contributions

A stakeholder consultation was launched on 07 April 2022 and was held for a duration of six weeks thus concluding 19 May 2022. No stakeholder contribution was submitted. Some competitors of the applicant were directly contacted by the consultant to understand the situation of the market (see paragraph 5.5.2).

5.5. Critical Review

5.5.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultant as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The evaluation thus includes a review of possible incoherence of the requested exemptions with the REACH Regulation.

Annex XIV of the REACH Regulation lists substances, the use of which would require an authorisation in the EU. As of July 2022, REACH Annex XIV includes four lead compounds, lead chromate, lead sulfochromate yellow, lead chromate molybdate sulphate red and tetraethyllead (for the latter, however, the sunset date is not yet reached). However, these are not the lead compound that is used in this application, which is tribasic lead sulphate. Generally, there are seven lead compounds[6] usually present in PVC according to the recital in the Commission Regulation (EU) 2022/586 amending Annex XIV of (REACH)[7] which basically meet the criteria for classification as toxic for reproduction (category 1A) and therefore meet the criteria for inclusion in Annex XIV. As however, these substances are mainly present in recycled polyvinyl chloride (PVC) and cannot be removed with the current technology, the Commission is working on a Regulation to prohibit the use of lead and its compounds in PVC articles and restrict the placing on the market of PVC articles containing more than 0,1 % lead, with some derogations, under REACH Annex XVII (see below).

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;8
- Entry 17 restricts the use of lead sulphates in paints;9
- Entry 19 refers to arsenic compounds but includes a few lead compounds and restricts their use as a fouling agent, for treatment of industrial water or for treatment of wood;

[6] These seven lead compounds are: dioxobis(stearato)trilead; fatty acids, C16-18, lead salts; trilead dioxide phosphonate; sulfurous acid, lead salt, dibasic; [Phthalato(2-)]dioxotrilead; trilead bis(carbonate) dihydroxide and lead oxide sulfate.

[7] Commission Regulation (EU) 2022/586 of 8 April 2022 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0586&from=EN

[8] https://echa.europa.eu/documents/10162/22dd9386-7fac-4e8d-953a-ef3c71025ad4

[9] https://echa.europa.eu/documents/10162/ffd7653b-98cc-4bcc-9085-616559280314

- Entry 28 and 30 stipulate 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;[10]
- Entry 63 restricts the use of lead and its compounds:[11] in jewellery or in gunshot in or around wetlands. Furthermore, it shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0.05 µg/cm² per hour (equivalent to 0.05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. There are some derogations for specific articles e.g., keys and locks, including padlocks. Furthermore, articles within the scope of the RoHS Directive are derogated.
- Entry 72 stipulates that various lead compounds shall not be used in clothing textiles or footwear[12].

The requested exemption does not regard paints or jewellery or textiles, nor components that could be expected to be placed in the mouth by children under normal or foreseeable use. Furthermore, the use of lead in the materials in the scope of this exemption is not a supply of lead compounds as a substance, mixture or constituent of other mixtures to the general public. Rather lead is part of an article and as such, entry 28 and 30 of Annex XVII of the REACH Regulation would not apply. It is concluded that a grant of the exemption would not result in an overlap and would therefore not weaken the protection afforded by REACH through entries 16, 17, 19, 28, 30 and 72.

Entry 63 restricts the use of lead and its compounds in articles supplied to the general public. Articles within the scope of the RoHS Directive benefit from a derogation from these provisions. The consultant understands that this is to provide legal coherence as the RoHS Directive restricts lead with a maximum concentration value tolerated by weight in homogeneous materials of 0.1% and specifies some specific exemptions for the use of lead. This view is supported in the Common Understanding Communication, which specifies: "*The simplest way to avoid duplications and/or inconsistencies for a given substance already included in RoHS is, to exclude EEE within the scope of RoHS from the scope of a proposed REACH restriction also covering EEE*".

In April 2022, the consultant had a meeting with the policy officers of the European Commission working on the proposal for a REACH restriction on lead and its compounds in PVC polymers and copolymers. The proposal would amend entry 63 to REACH Annex XVII. It would prohibit the use of lead and lead compounds in PVC articles. Moreover, it would prohibit the placing on the market of PVC articles containing a concentration of

[10] See the conditions of restriction and the various Appendices (substance lists) at: https://echa.europa.eu/substances-restricted-under-reach

[11] https://echa.europa.eu/documents/10162/851fb88e-9867-c5a0-bf15-2678ad831be6

[12] https://echa.europa.eu/documents/10162/8db10905-d535-0a04-0af5-7628a210dc28

lead equal or greater than 0,1% of the PVC. The officers explained that no derogation for the application described in the requested exemption is foreseen. As regards the timeline, the period after which a restriction becomes applicable after its publication is specific for each restriction. REACH does not establish any legal maximum or minimum duration for the transitional period. 18 or 24 months are the transitional periods more often used for the enter into application of restrictions, but there is the possibility to restrict with no transitional period. For Pb in PVC, the transitional period is currently under discussion with Member States in the REACH Committee.

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.

Against this background, the exemption could be granted, but the potential conflict with the restriction of use of lead and its compounds in PVC has to be considered, which occurs if no transition period is granted or if the transition period ends before the deadline of the exemption itself.

5.5.2. Scientific and technical practicability of substitution

To understand the practicability of substitution of lead in sensors which measure creatinine and BUN, the consultants investigated the status of substitution of other producers of comparable blood analysers. Considering the formulation of the exemption request, devices that can measure BUN and creatinine should be considered. From the analysis conducted within Pack 14 for the renewal of Ex. 41 of Annex IV of the RoHS Directive, it was already clear that some manufacturers of similar devices (i.e., Radiometer, Siemens Healthineers) were planning to substitute Pb in PVC by the end of 2018. The consultant verified that the status of the substitution directly with these two manufacturers, and both confirmed they do not need an exemption for Pb in PVC anymore. However, they also clarified that it would not be possible to use their cartridges and/or sensor cards in the GEM Premier ChemSTAT analysers, given that both physical dimensions and the technology are different. Other manufacturers were also contacted, but not all of them replied. It emerged that one of the competitors makes use of two exemptions for a device which is comparable to GEM Premier ChemSTAT analyser: the exemption 7(c)-I to Annex III, which covers the use of lead in glass or ceramic (matrix compound) of the sensor card, and the exemption 45 to annex IV, which covers the use of DEHP in ion-selective electrodes. Exemption 7(c)-I to Annex III addresses a different matrix compound of the sensor card (glass or ceramic) then the exemption here at hand (rigid PVC). Exemption 45 to annex IV refers to a different restricted substances (DEHP) that furthermore has a different function (membrane solvent for the ion selective electrode constituents). The manufacturer reported that approximately 31 g of DEHP are placed on the market per year under this exemption. Another manufacturer stated that lead is present in the sensor-based measurement cartridges used on its benchtop blood gas platforms, covered by exemption 1a to Annex IV. Here, lead is used in a different application (in pH glass electrodes and ion selective electrodes equipped with a pH glass electrode) and has a different function (to form intermediate layer for the connection between stem tube and pH-responsive glass or pH glass membrane for complex shapes). In summary, these uses are not relevant for the exemption under analysis.

As regards the range of analytes measured, the comparison presented in Table 5-1 shows that not all the competitive devices of the GEM Premier ChemSTAT analyser can measure both BUN and creatinine. However, this does not allow concluding whether devices of a specific manufacturer have advantages over those of others.
According to (Oeko-Institut e.V. Institute for Applied Ecology, Fraunhofer-Institut for Reliability and Microintegration 2019), facilities may have a tendency towards using equipment of one 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. In this sense, other devices could be used to substitute the GEM devices. Given the low number of devices on the market, it is assumed that the competitors could fulfil a possible supply gap quite fast.

A few other aspects were mentioned by IL that could be considered as possible benefits of its equipment and that might justify the continued use of lead:

- Use of multi-use sensor cards: this has an advantage, also in terms of waste generation;
- Requirement of only one consumable: other competing technologies utilize multiple cartridges to perform the same functions; this has an advantage, also in terms of waste generation;
- Storage of cartridges and cards at room temperature, without need of refrigeration. Refrigerated storage could mean that some equipment may have additional energy consumption relating to this requirement.

The applicant argues the justification of the exemption also on the basis of the quality control system. Nevertheless, as already pointed out in the final report of pack 14 (Oeko-Institut e.V. Institute for Applied Ecology, Fraunhofer-Institut for Reliability and Microintegration 2019), 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. In other words, it can be concluded that the use of lead is not necessary to ensure the continuous quality control.

The applicant is committed to the substitution of lead in its devices. The exemption request was submitted on 8 October 2021, asking for a duration of 24 months, consistently with the planned end date of the substitution project.

5.5.3. Environmental arguments and socioeconomic impacts

In the assessment of impacts of substitution, it should be considered that all 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 very close to the impacts actually expected.

Regarding environmental aspects, IL provides a life cycle analysis comparing the lead-based resin to the alternative that they have been testing. Though the analysis suggests that the lead-based resin has environmental advantages over the other resin tested, 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.

However, another aspect is of importance for the evaluation of this request: As blood analysers cannot operate without the sensor card, equipment legally placed on the market would effectively no longer be operable once the stock of sensor cards of a specific facility is exhausted (shelf life of the IL sensor cards is up to 5 months, and exemption 41 expired on 31st March 2022). 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. Thus, the maximum amount of EEE that would need to be scrapped were RoHS compliant sensor cards no longer available on the EU market can be estimated as equal to 1.9 tonnes, considering that GEM Premier ChemSTAT analyser has a weight of 19.1 kg[13]. Moreover, the use of resources for manufacturing new devices should be taken into account.

As already showed in the final report of RoHS pack 14 (Oeko-Institut e.V. Institute for Applied Ecology, Fraunhofer-Institut for Reliability and Microintegration 2019), 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 prior to the end of life. Though this negative impact on the environment could be justified if positive environmental and/or health impacts are expected.

As regards socio-economic impacts, impacts on the health facilities and on patients should be considered. On this regard, the two letters submitted by health facilities clarify the adverse impacts on health system and on patients. It is obvious that an exemption revoke can result in a loss of business for IL. In contrast, competitors who have achieved

[13] http://anyflip.com/xlyyh/lcsp/

RoHS compliance would benefit from the phase-out of blood-gas devices, expanding their market share to replace IL devices.

Additional costs of relevance to a substitution 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. 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).

5.5.4. 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.

Other manufacturers of similar devices have already finalized the substitution of lead in the sensors. IL is the only manufacturer who needs this exemption. IL has provided sufficient information to show their efforts into the testing of the substitute. Indeed, the substitution project is progressing: as shown in the plan (Figure 5-1), the phase not yet fulfilled at this point in time is the second part of analytical verification, which includes method comparison, aqueous precision, use life verification, systems verification, shelf life verification, and finally the release of the documentation and the controlled distribution of the new resin. The substitution project is expected to be finalised in the period between 2023 Q3 and Q4. IL has not met the initially planned end date (March 2022): the applicant experienced a delay in developing a RoHS compliant material caused by changed hospital needs during the COVID-crises, i.e., the increased analyser and cartridge demand due to the critical role of blood gas analysis in the management of hospitalized patients with COVID-19.

Though the IL equipment may have an advantage over other equipment in terms of the continuous quality control that it provides, this unique function is not understood to be affected by the use of lead and thus an exemption is not considered justifiable on this basis.

The multi-use nature of IL sensor cards allows the reduction of waste. Other benefits of IL devices are the requirement of only one consumable, and the possibility to store the cartridges at room temperature, which grants energy savings.

However, 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 sensor cards are in contact with body 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 undesired waste routes. Though the rejection of the exemption removes lead from the market (positive impact) this is not expected to affect the potential for lead emissions during the sensor card lifecycle phases.

There are however other aspects that may support the third criterion, that 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: the generation of additional waste, the negative impacts on health service providers and patients, caused by the premature scrapping of existing devices and the need to replace them.

The rejection results in a premature scrapping of equipment which would otherwise be operable with the sensor card once it achieves compliance. The prevention of lead (0.5-10 kg per annum or 14.2[14] kg maximum, assumed IL will achieve compliance by end of 2023, as planned by the applicant) thus needs to be weighed against the negative impact related to potential premature end-of-life of blood-gas equipment (1.9 tonnes of WEEE). The composition of this WEEE is not clear. Following the assessment conducted under Pack 14 (Oeko-Institut e.V. Institute for Applied Ecology, Fraunhofer-Institut for Reliability and Microintegration 2019), it can be assumed to contain for example in printed circuit boards, that might contain e.g. lead in solders and is thus not to be perceived as completely harmless.

As the PVC sensor is understood to be inherent to the function of GEM Premier ChemSTAT blood analysers, it can furthermore be concluded that the rejection of the exemption can be expected to have a considerable impact on health service providers using equipment already on the market, as such devices can become non-functional as long as PVC sensor cards cannot be replaced. As a consequence, a negative impact on patients can also be expected. However, the number of devices on the market and the number hospitals using the GEM Premier ChemSTAT are currently quite low (less than 100 and less than 50, respectively).
Granting the exemption would prevent the expected impacts on health facilities as devices already on the market could continue to be used. Granting the exemption would further avoid costs related to resources through premature scrapping of existing devices - this volume is estimated at ~ 1.9 tonnes of equipment and as a consequence the production of new devices.

[14] A period of 1 year and 5 months was assumed for this calculation (considering from 1st August 2022 to 31st December 2023)

5.6. Recommendation

An exemption on the basis of the Article 5(1)(a) main criteria (III) can be granted. The negative impacts of a substitution of lead would be the premature waste of medical devices and socio-economic impacts for health care facilities faced with the need to phase-out all relevant blood-gas devices in operation in the EU stock are also in support of granting the exemption.

The consultants recommend the formulation proposed by the applicant:

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

As regards the validity period, the future REACH restriction for lead in PVC has to be considered. Considering an average typical duration of 18 months as transition period for a restriction and assuming that the restriction will be adopted in December 2022, Pb in PVC will be restricted by approximately June 2024. Considering the planned timeline provided by the applicant, substitution is expected by end of 2023. Thus, if the exemption is granted, 31st December 2023 is recommended as expiration date.

5.7. Literaturverzeichnis

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Appendix

Aspects relevant to the REACH Regulation

Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

a) In what cases granting an exemption could "weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006" (Article 5(1)(a), pg. 1)
b) Where processes related to the REACH regulation should be followed to understand where such cases may become relevant in the future;

Compiled information in this respect has been included, with short clarifications where relevant, in the following tables:

Table A-1 lists those substances appearing in Annex XIV, subject to Authorisation, which are relevant to the RoHS substances dealt with in the requests evaluated in this project. As can be seen, at present, exemptions have not been granted for the use of these substances.

Table A-1: Relevant entries from Annex XIV: List of substances subject to authorisation

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
4. Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	21 August 2013 (*)	21 February 2015 (**)	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/ 2004, Directive 2001/82/EC, and/or Directive 2001/83/EC
5. Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7	21 August 2013 (*)	21 February 2015 (**)	
6. Dibutyl phthalate (DBP) EC No: 201-557-4 CAS No: 84-74-2	21 August 2013 (*)	21 February 2015 (**)	
7. Diisobutyl phthalate (DiBP) EC No: 201-553-2 CAS No: 84-69-5	21 August 2013 (*)	21 February 2015 (**)	
10. Lead chromate EC No: 231-846-0 CAS No: 7758-97-6	21 Nov 2013 (*)	21 May 2015 (**)	-
11. Lead sulfochromate yellow (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2	21 Nov 2013 (*)	21 May 2015 (**)	-

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
12. Lead chromate molybdate sulphate red (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8	21 Nov 2013 (*)	21 May 2015 (**)	-
16. Chromium trioxide EC No: 215-607-8 CAS No: 1333-82-0	21 Mar 2016 (*)	21 Sep 2017 (**)	-
17. Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid EC No: 231-801-5 CAS No: 7738-94-5 Dichromic acid EC No: 236-881-5 CAS No: 13530-68-2 Oligomers of chromic acid and dichromic acid EC No: not yet assigned CAS No: not yet assigned	21 Mar 2016 (*)	21 Sep 2017 (**)	-
18. Sodium dichromate EC No: 234-190-3 CAS No: 7789-12-0 10588-01-9	21 Mar 2016 (*)	21 Sep 2017 (**)	-
19. Potassium dichromate EC No: 231-906-6 CAS No: 7778-50-9	21 Mar 2016 (*)	21 Sep 2017 (**)	-
20. Ammonium dichromate EC No: 232-143-1 CAS No: 7789-09-5	21 Mar 2016 (*)	21 Sep 2017 (**)	-
21. Potassium chromate EC No: 232-140-5 CAS No: 7789-00-6	21 Mar 2016 (*)	21 Sep 2017 (**)	
22. Sodium chromate EC No: 231-889-5 CAS No: 7775-11-3	21 Mar 2016 (*)	21 Sep 2017 (**)	
28. Dichromium tris(-chromate) EC No: 246-356-2 CAS No: 24613-89-6	22. Jul 2017 (*)	22 Jan 2019 (**)	
29. Strontium chromate EC No: 232-142-6 CAS CAS No: 7789-06-2	22 Jul 2017 (*)	22 Jan 2019 (**)	

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
30. Potassium hydroxyoctaoxodizincatedichromate EC No: 234-329-8 CAS No: 11103-86-9	22 Jul 2017 (*)	22 Jan 2019 (**)	
31. Pentazinc chromate octahydroxide EC No: 256-418-0 CAS No: 49663-84-5	22 Jul 2017 (*)	22 Jan 2019 (**)	
55. Tetraethyllead EC No: 201-075-4 CAS No: 78-00-2	01 Nov 2023	01 May 2025	

(*) 1 September 2019 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without that spare part, and for the use of the substance (on its own or in a mixture) for the repair of such articles where that substance on its own or in a mixture was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.

(**) 1 March 2021 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without those spare parts, and for the use of the substance (on its own or in a mixture) for the repair of such articles, where that substance was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.

For the substances currently restricted according to RoHS Annex II: cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls and polybrominated diphenyl ethers and their compounds, as well as bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DiBP), we have found that some relevant entries are listed in Annex XVII of the REACH Regulation. The conditions of restriction are presented in Table A-2 below.

Table A-2: Conditions of Restriction in REACH Annex XVII for RoHS Substances and Compounds

Designation of the substance, group of substances, or mixture	Conditions of restriction
8. Polybromobiphenyls; Polybrominatedbiphenyls (PBB) CAS No 59536-65-1	1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin. 2. Articles not complying with paragraph 1 shall not be placed on the market.
16. Lead carbonates: (a) Neutral anhydrous carbonate (PbCO 3) CAS No 598-63-0 EC No 209-943-4 (b) Trilead-bis(carbonate)-dihydroxide 2Pb CO 3 -Pb(OH) 2 CAS No 1319-46-6 EC No 215-290-6	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
17. Lead sulphates: (a) PbSO 4 CAS No 7446-14-2 EC No 231-198-9 (b) Pb x SO 4 CAS No 15739-80-7 EC No 239-831-0	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
18. Mercury compounds	Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use: (a) to prevent the fouling by micro-organisms, plants or animals of: the hulls of boats, cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, any totally or partly submerged appliances or equipment; (b) in the preservation of wood; (c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture; (d) in the treatment of industrial waters, irrespective of their use.

18a. Mercury CAS No 7439-97-6 EC No 231-106-7	1. Shall not be placed on the market: (a) in fever thermometers; (b) in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers). 2. The restriction in paragraph 1 shall not apply to measuring devices that were in use in the Community before 3 April 2009. However, Member States may restrict or prohibit the placing on the market of such measuring devices. 3. The restriction in paragraph 1(b) shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) barometers (except barometers within point (a)) until 3 October 2009. 5. The following mercury-containing measuring devices intended for industrial and professional uses shall not be placed on the market after 10 April 2014: (a) barometers; (b) hygrometers; (c) manometers; (d) sphygmomanometers; (e) strain gauges to be used with plethysmographs; (f) tensiometers; (g) thermometers and other non-electrical thermometric applications. The restriction shall also apply to measuring devices under points (a) to (g) which are placed on the market empty if intended to be filled with mercury. 6. The restriction in paragraph 5 shall not apply to: (a) sphygmomanometers to be used: (i) in epidemiological studies which are ongoing on 10 October 2012; (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers; (b) thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers until 10 October 2017; (c) mercury triple point cells which are used for the calibration of platinum resistance thermometers. 7. The following mercury-using measuring devices intended for professional and industrial uses shall not be placed on the market after 10 April 2014: (a) mercury pycnometers; (b) mercury metering devices for determination of the softening point. 8. The restrictions in paragraphs 5 and 7 shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.

Designation of the substance, group of substances, or mixture	Conditions of restriction
23. Cadmium CAS No 7440-43-9 EC No 231-152-8 and its compounds	For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (1). 1. Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material): • polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21] • polyurethane (PUR) [3909 50] • low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] • cellulose acetate (CA) [3912 11] • cellulose acetate butyrate (CAB) [3912 11] • epoxy resins [3907 30] • melamine-formaldehyde (MF) resins [3909 20] • urea-formaldehyde (UF) resins [3909 10] • unsaturated polyesters (UP) [3907 91] • polyethylene terephthalate (PET) [3907 60] • polybutylene terephthalate (PBT) • transparent/general-purpose polystyrene [3903 11] • acrylonitrile methylmethacrylate (AMMA) • cross-linked polyethylene (VPE) • high-impact polystyrene • polypropylene (PP) [3902 10] Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material. By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011. The first and second subparagraphs apply without prejudice to Council Directive 94/62/EC (13) and acts adopted on its basis.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be restricted. 2. Shall not be used or placed on the market in paints with codes [3208] [3209] in a concentration (expressed as Cd metal) equal to or greater than 0,01 % by weight. For paints with codes [3208] [3209] with a zinc content exceeding 10 % by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0,1 % by weight. Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,1 % by weight of the paint on the painted article.' 3. By way of derogation, paragraphs 1 and 2 shall not apply to articles coloured with mixtures containing cadmium for safety reasons. 4. By way of derogation, paragraph 1, second subparagraph shall not apply to: — mixtures produced from PVC waste, hereinafter referred to as 'recovered PVC', — mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0,1 % by weight of the plastic material in the following rigid PVC applications: — (a) profiles and rigid sheets for building applications; (b) doors, windows, shutters, walls, blinds, fences, and roof gutters; (c) decks and terraces; (d) cable ducts; (e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC in compliance with paragraph 1 above. Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: '*Contains recovered PVC*' or with the following pictogram:  In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications: (a) equipment and machinery for: — food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] — agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] — cooling and freezing [8418] — printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: — household goods [7321] [8421 12] [8450] [8509] [8516] — furniture [8465] [8466] [9401] [9402] [9403] [9404] — sanitary ware [7324] — central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited. 6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below: (a) equipment and machinery for the production of: — paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of: — industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431] — road and agricultural vehicles [chapter 87] — rolling stock [chapter 86] — vessels [chapter 89] 7. However, the restrictions in paragraphs 5 and 6 shall not apply to:

Designation of the substance, group of substances, or mixture	Conditions of restriction
	— articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. 8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons. 10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. 11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.
28. Substances which are classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively.	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:

Designation of the substance, group of substances, or mixture	Conditions of restriction
29. Substances which are classified as germ cell mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or Appendix 4, respectively.	— either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.
30. Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively.	
47. Chromium VI compounds	1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement. 2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1. 3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1. 5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather. 6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part. 7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.

Designation of the substance, group of substances, or mixture	Conditions of restriction
51. The following phthalates (or other CAS and EC numbers covering the substance): Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0 Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4 Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7 Diisobutyl phthalate (DiBP) CAS No.: 84-69-5 EC No.: 201-553-2	1. Shall not be used as substances or in mixtures, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material, in toys and childcare articles. 2. Shall not be placed on the market in toys or childcare articles, individually or in any combination of the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material. In addition, DiBP shall not be placed on the market after 7 July 2020 in toys or childcare articles, individually or in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material. 3. Shall not be placed on the market after 7 July 2020 in articles, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article. 4. Paragraph 3 shall not apply to: (a) articles exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin; (b) aircraft, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft; (c) motor vehicles within the scope of Directive 2007/46/EC, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles; (d) articles placed on the market before 7 July 2020; (e) measuring devices for laboratory use, or parts thereof; (f) materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/2011(*); (g) medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof; (h) electrical and electronic equipment within the scope of Directive 2011/65/EU; (i) the immediate packaging of medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC; (j) toys and childcare articles covered by paragraphs 1 or 2. 5. For the purposes of paragraphs 1, 2, 3 and 4(a),

Designation of the substance, group of substances, or mixture	Conditions of restriction
	(a) 'plasticised material' means any of the following homogeneous materials: — polyvinyl chloride (PVC), polyvinylidene chloride (PVDC),polyvinyl acetate (PVA), polyurethanes, — any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings, — surface coatings, non-slip coatings, finishes, decals, printed designs, — adhesives, sealants, paints and inks. (b) 'prolonged contact with human skin' means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day. (c) 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children. 6. For the purposes of paragraph 4(b), 'aircraft' means one of the following: (a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EC) No 216/2008 or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation, signed on December 7, 1944, in Chicago; (b) a military aircraft. (*) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).'
62. (a) Phenylmercury acetate EC No: 200-532-5 CAS No: 62-38-4 (b) Phenylmercury propionate EC No: 203-094-3 CAS No: 103-27-5 (c) Phenylmercury 2-ethylhexanoate EC No: 236-326-7 CAS No: 13302-00-6 (d) Phenylmercury octanoate EC No: -	1. Shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0,01 % by weight. 2. Articles or any parts thereof containing one or more of these substances shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01 % by weight.

Designation of the substance, group of substances, or mixture	Conditions of restriction
CAS No: 13864-38-5 (e) Phenylmercury neodecanoate EC No: 247-783-7 CAS No: 26545-49-3	
63. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. 2. For the purposes of paragraph 1: (i) 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) 'any individual part' shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*); (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate paragraphs 1 to 5 of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm 2 per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size. 8. By way of derogation, paragraph 7 shall not apply to: (a) jewellery articles covered by paragraph 1; (b) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Directive 69/493/ EEC; (c) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/ 87) unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500 ° C; (e) keys and locks, including padlocks; (f) musical instruments; (g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5 % by weight; (h) the tips of writing instruments; (i) religious articles; (j) portable zinc-carbon batteries and button cell batteries; (k) articles within the scope of: (i) Directive 94/62/EC; (ii) Regulation (EC) No 1935/2004; (iii) Directive 2009/48/EC of the European Parliament and of the Council (**); (iv) Directive 2011/65/EU of the European Parliament and of the Council (***) 9. By 1 July 2019, the Commission shall re-evaluate paragraphs 7 and 8(e), (f), (i) and (j) of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 7, including the requirement on coating integrity, and, if appropriate, modify this entry accordingly. 10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	--- (*) OJ L 326, 29.12.1969, p. 36. (**) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1). (***) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).
67. Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) CAS No 1163-19-5 EC No 214-604-9	1. Shall not be manufactured or placed on the market as a substance on its own after 2 March 2019. 2. Shall not be used in the production of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article, or any part thereof, in a concentration equal to or greater than 0,1 % by weight, after 2 March 2019. 3. Paragraphs 1 and 2 shall not apply to a substance, constituent of another substance or mixture that is to be used, or is used: (a) in the production of an aircraft before 2 March 2027. (b) in the production of spare parts for either of the following: (i) an aircraft produced before 2 March 2027; (ii) motor vehicles within the scope of Directive 2007/46/EC, agricultural and forestry vehicles within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council (*) or machinery within the scope of Directive 2006/42/EC of the European Parliament and of the Council (**), produced before 2 March 2019 4. Subparagraph 2(c) shall not apply to any of the following: (a) articles placed on the market before 2 March 2019; (b) aircraft produced in accordance with subparagraph 3(a); (c) spare parts of aircraft, vehicles or machines produced in accordance with subparagraph 3(b); (d) electrical and electronic equipment within the scope of Directive 2011/65/EU. 5. For the purposes of this entry 'aircraft' means one of the following: (a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EU) No 216/2008 of the European Parliament and of the Council (***) or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation; (b) a military aircraft.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	(*) Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OL L 60, 2.3.2013, p. 1). (**) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24). (***) Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79 19.3.2008, p. 1).

As of July 2022, the REACH Regulation Candidate list includes various substances of relevance for RoHS. Proceedings concerning the addition of these substances to the Authorisation list (Annex XIV) have begun and shall be followed by the evaluation team to determine possible discrepancies with future requests of exemption from RoHS (new exemptions, renewals and revocations).