Study to assess requests for two (-2-) exemptions, for mercury in pressure transducer and DEHP in a PVC base material, in Annex IV of Directive 2011/65/EU (Pack 25) – 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

Directorate-General for Environment

Directorate B - Circular Economy & Green Growth

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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 requests covered in this project and the name of the applicants concerned, as well as the final recommendations and proposed expiry dates are summarised in the table below (Table 1-1). Requests for two new exemptions listed in Annex IV were 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 exemptions requested for renewal, associated recommendations and expiry dates

Ex. Req. No.	Current exemption wording	Applicant/s	Recommendation	Duration and scope
Annex IV, 2021-1	*"Mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar."*	NETZSCH-Gerätebau GmbH	Mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar.	Until 31.12.2024 Category 9
Annex IV, 2021-2	*"Bis (ethylhexyl)-phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors, which are used in in-vitro diagnostic medical devices for the analysis of whole blood."*	Intertek	Withdrawn 14 March 2022	n.a.

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), le consultant a procédé à l'évaluation de deux nouvelles demandes d'exemption dans le cadre de la présente mission.

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

Les demandes d'exemption couvertes dans le présent projet et le nom des demandeurs concernés, de même que les recommandations finales et les dates d'expiration proposées, sont résumées dans le Tableau 2-1 ci-après. Des demandes de deux nouvelles exemptions énumérées à l'annexe IV ont été incluses dans la portée de ce projet. Le lecteur est invité à consulter les sections correspondantes du présent rapport pour plus de détails sur les résultats de l'évaluation.

Tableau 2-1: Récapitulatif des demandes d'exemption, des recommandations associées et des 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.

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

Ex. Req. No.	Termes des exemptions	Demandeurs	Recommandation	Duration et champs d'application
Annex IV, 2021-1	*"Transducteurs de pression à mercure en fusion pour rhéomètres capillaires à des températures supérieures à 300°C et à des pressions supérieures à 1000 bars".*	NETZSCH-Gerätebau GmbH	Transducteurs de pression à mercure en fusion pour rhéomètres capillaires à des températures supérieures à 300°C et à des pressions supérieures à 1000 bars	jusqu'au 31.12.2024, catégorie 9
Annex IV, 2021-2	*"Le bis (éthylhexyl)-phtalate (DEHP), en tant que plastifiant du polychlorure de vinyle (PVC), sert de matériau de base pour les capteurs électro-chimiques ampéro-métriques, potentio-métriques et conducto-métriques, qui sont utilisés dans les dispo-sitifs médicaux de diagnostic in-vitro pour l'analyse du sang total."*	Intertek	Retiré le 14 mars 2022	n.d.

Note : Comme dans le texte juridique de la directive RoHS, les virgules sont utilisées comme séparateur décimal pour les formules d'exemption figurant dans ce tableau, contrairement au point décimal utilisé comme séparateur dans le reste du rapport.

3. Introduction

3.1. Project scope and methodology

The scope of the study covers the evaluation of two new exemption requests. An overview on the exemption requests 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 30 November 2021 and was held for duration of ten weeks thus concluding 08 February 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 exemptions began. The requests were 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 exemptions evaluated in the course of the study appear in chapters 5 and 6 . The information provided by the applicants and by stakeholders is summarised in the first sections of the respective 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 29 September 2021, the evaluation of the new exemptions 2021-1, 2021-2 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:

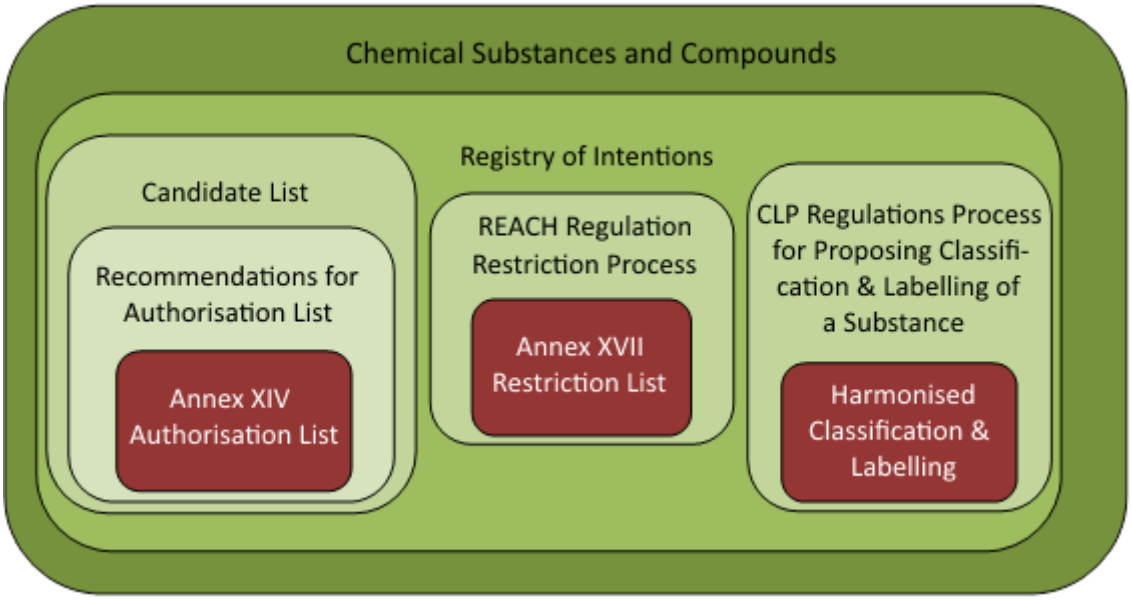
- on the list of substances of very high concern (SVHCs- the Candidate List);
- in the recommendations of substances for Annex XIV (recommended to be added to the Authorisation List);
- listed in REACH Annex XIV itself (the Authorisation List); or
- listed in REACH Annex XVII (the List of Restrictions).

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 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

[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

submit 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 May 2022, the consolidated version of the REACH legal text, dated 01.03.2022, 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%3A02006R1907-20220301. 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 under-stand 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-ethyl-hexyl) 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 exemptions 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 chapter 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 2021-1: "Mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar"

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

EEE	Electrical and Electronic Equipment
Hg	Mercury
LSFI	Large-scale fixed installations
LSSIT	Large-scale stationary industrial tools
NaK	Sodium potassium
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
WEEE	Waste Electrical and Electronic Equipment

5.1. Background of the exemption request

Netzsch Gerätebau GmbH has submitted a request for an exemption for Annex IV with the following wording:

> *"Mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar"*

The applicant seeks to use 100 % mercury in a melt pressure transducer in capillary rheometers as a medium to transmit pressure in extreme conditions (over 300°C and over 1000 bar). The exemption is requested for category 9 for monitoring and control instruments in industry for a duration of seven years.

Mercury is listed in Annex II of the RoHS Directive and thus needs an exemption. The exemptions listed in Annex III relate for example to lighting or lamps, reference electrodes or switches. Other currently approved exemptions regarding transducers address completely different functionalities, applications and hazardous substances.

Thus, they are not applicable in this case. They allow the use of lead alloys in special cases (e.g., cadmium alloys as electrical / mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers with sound pressure levels of 100 dB (A) and more). In electrical engineering, transducers are components that convert signals, for example electrical signals into sound.

5.2. Technical description of the requested exemption

Mercury is liquid in the range of operation from room temperature to over 300°C and above atmosphere pressure with a very low compressibility and reactivity. Mercury has a very high density, freezes at -38,8°C (normal pressure) and evaporates at 0,163 Pa (normal temperature), which means that mercury is liquid in a very large regime without changing much in compressibility or density. Due to these properties, mercury is used as a filling in the pressure transducer of the capillary rheometer to transmit the pressure of the probe to a sensor outside the high temperature and pressure area. The pressure transducer consists of a membrane, the transducer with filling, a measurement unit, a digital-analogue converter, and a data plug. Thus, it is an electrical measurement device. Common filling materials besides mercury are **Galinstan** and **sodium potassium**. The operation temperature in this application of the requested exemption ranges from room temperature to 440°C, the pressure is up to 2000 bar. The capillary rheometer analyses the viscosity e.g., of melted polymers to predict its behaviour e.g., for an extrusion process. Especially for high performance polymers, high temperatures are required to reach melting conditions. Capillary rheometers are laboratory devices for analysing purposes, their data are often directly transmitted to a computer that drives the rheometer and evaluates the viscosity in the pressure range of interest. The gained information can be fed into the adjustment of extruders. Capillary rheometers are not part of other devices or industrial tools.

In contrast, pressure transducers are also an elementary part of extruders and mercury is widely used as a transmission medium in this context.

The exemption request relates to pressure transducers in capillary rheometers at temperatures over 300°C and pressures over 1000 bar.

5.2.1. Amount of Hg used under this exemption

The applicant is requested to keep confidential the amount of mercury entering the EU market annually through the application for which the exemption is requested as confidential because the calculation is based on the number of sold equipment and its market share which are seen as trade secrets. When asked to provide the order of magnitude (or a generous upper bound) of the expected volume of mercury entering the EU market through this exemption request in total, the applicant suggested to report the following information: **Approximately less than 50 g/year**.

5.3. Applicant's justification for the requested exemption

5.3.1. Substitution, elimination or reduction of Hg

According to the applicant, two potential substitutes are very common as a filling in melt pressure transducers. However, they are limited with regard to their application range.

In lower pressure ranges (up to 1000 bar), mercury can be substituted by sodium potassium alloy (NaK). If these instruments are even used also at high pressure, the front membrane will be damaged due to the compressibility of NaK.

The applicant did not provide the number on the compressibility factor of the filling which keeps the membrane of the transducer intact in the range of operation. According to the applicant, in the range of operation, the compressibility needs to be the same as that applicable to mercury or has to be even lower than the former.

Another substitute is Galinstan, which is an alloy made of gallium, indium and tin. The applicant states that this alloy tends to react with the capillary material above 300°C.

The applicant does not manufacture the transducers himself, but only builds them into their rheometers and is thus dependent on a supplier. The applicant states: "*From our latest conversation with the supplier before applying for this exemption, we learned that there is no alternative for Hg-filled melt pressure transducers for the mentioned application ranges. Our supplier did a lot of testing with NaK and other filling materials, but they have not been successful yet. There is no foreseeable date as of now. Also, the market for this exemption is not big enough to sustain extensive research on filling media. Existing filling media were developed by nuclear and military research*" (Netzsch Gerätebau GmbH 2021b).

5.3.2. Environmental arguments

The applicant refers to the fact that the impacts of mercury are well known and that most manufacturers take back used/old/malfunction melt pressure transducers (take-back systems).

The applicant will raise customer awareness by a label on the pressure transducer, that their product is filled with mercury. All customers are "*professional users*" (Netzsch Gerätebau GmbH 2021a). The applicant has an "*agreement with his melt pressure transducer supplier that they will take back all melt pressure transducers. As they receive different melt pressure transducers from different industries, they have a recycle system in place*" (id.).

5.3.3. Socioeconomic impacts

The applicant did not provide information on socioeconomic impacts.

5.4. Stakeholder contributions

Two stakeholders handed in contributions.

5.4.1. Gefran spa

Gefran spa submitted a contribution in English and an addition in German, both on 2 February 2022 (Gefran spa 2022a; 2022b). Gefran spa ('Gefran') is the supplier of the pressure transducer for the capillary rheometer of Netzsch Gerätebau GmbH.

Gefran explains in its contribution that "*mercury-containing sensors may still be sold after 22-07-2017 [the date that the RoHS 2 Directive entered into force in Italy], provided that:*

(a) They can fulfil their function only if they are part of that equipment [LSFI], (not multitasking),
*(b) They can be replaced only by the same specific type of sensor (not interchangeable) [*If another type of sensor is applicable, the mercury-containing sensor cannot be sold.*],*
(c) *They are used as components in large-scale fixed installation or in large-scale fixed industrial tools, or for laboratory tools B2B for R&D purposes.*" (Gefran spa 2022b).

Gefran considers that this statement will be valid for the following years.

Gefran further explains that the Hg containing pressure transducers are used in extruders, extrusion plants and plastics processing plants. As examples for the equipment, Gefran provides the following:

- *large-scale fixed installations [LSFI]: installations that, because of their size and weight, need ISO containers of 20 feet and lorries of more than 44 tons, or industrial cranes, or reinforced foundation, or of more than 375 kW of power;*
- *large-scale fixed tools: even with a smaller dimension than that of the installations, still significantly greater than other stationary tools with the same application;*
- *products within the definition of "machinery" according to Directive 2006/42/EC;*
- *fixed installation: installation that is not easily removable and/or that is intended to be used during its life basically in a fixed place;*
- *Laboratory extruder for R&D purposes.*

Gefran therefore concludes that this equipment falls under the definitions of the RoHS Directive for large-scale fixed installation/stationary industrial tools. Thus, they are out of scope of the RoHS 2 Directive and "*the installation of mercury melt pressure transducers in such equipment is allowed*" (Gefran spa 2022b).

Concerning the technical feasibility of a substitution, Gefran supports the argumentation of the applicant. "*NaK is too compressible as a filling medium, and Galinstan changes its properties at continuous temperatures above 300°C."* (Gefran spa 2022a). In the same comment, Gefran describes its return system as follows: "*Defective mercury-containing GEFRAN melt pressure sensors can be taken back and sent to the main factory in Italia. There is a process (distillation in a closed vacuum system) where the mercury is removed from the capillary and collected or recycled separately"* (Gefran spa 2022a).

5.4.2. Dynisco Europe GmbH

Dynisco Europe GmbH manufactures Hg-filled pressure transducers as well as capillary rheometers containing them and can thus be considered as a competitor of the applicant.

Dynisco Europe GmbH submitted two statements on 7 February 2022, a filled in questionnaire in English (Dynisco Europe GmbH 2022b) and a complementary statement in German, which does not refer to the exemption request (Dynisco Europe GmbH 2022a). In the questionnaire, Dynisco states that they offer three models of rheometers containing Hg-filled pressure transducers.

- "*Generally, the optional pressure transducer improves the accuracy of the rheological measurement. Standard pressure sensors contain mercury as a fill fluid because they offer the best performance at high pressures and the best response time and resolution which is key to an accurate measurement in this application"* (Dynisco Europe GmbH 2022b). They consider "*the current design of our instruments as being RoHS compliant"* (id.) and "*agree on the argumentation of the applicant"* (id.). Asked for their recycling system, they explain that "*Pressure transducers can be sent in free of charge to our factory in the USA. Mercury-filled transducers are collected in Germany in a special container and sent for recovery to the factory in the USA on a regular basis. Dynisco operates under the guidance and advice from IMERC" (http://www.newmoa.org/prevention/mercury/imerc/guidance.cfm)* (id.).
- Regarding substitution, Dynisco states the following: "*Because of accuracy, resolution and service life we are currently only using mercury-filled transducers in capillary rheometers. Besides fluid-filled technology, fully electrical and optical alternatives exist (no-fill technologies). In certain areas they have limitations over mercury-filled transducers as well. These are concerning pressure range, service temperature and accuracy. The limitations which apply to almost all alternatives to mercury (alternative fill fluid or no-fill) have been discussed in the argumentation from Netzsch (>1000bar; >300°C)"* (id.).
- In the complementary statement, Dynisco stresses its judicial interpretation as follows: "*We consider the use of mercury-filled pressure transducers to be compliant with the RoHS Directive and the mercury regulation, as they are almost exclusively used in large stationary installations [ortsfeste Großanlage] (chemical, petrochemical, plastics and rubber processing). The application in capillary rheometers can also be regarded as stationary in our view, since these devices are usually used in laboratories and production environments (R&D, quality assurance). In applications outside the areas mentioned (food, animal feed, cosmetics, pharmaceuticals, etc.), alternative technologies (other filling media, filling media-free) are now being used. In addition, the use as a spare part is also permitted in the RoHS Directive"* (Dynisco Europe GmbH 2022a).

Dynisco Europe GmbH also submitted two statements from third parties (VDMA Factsheet zur Quecksilberverordnung 2021; DEKRA Assurance GmbH 2016):

- A Factsheet of the VDMA, the German association of the mechanical engineering industry, which does not relate to this exemption request (VDMA Factsheet zur Quecksilberverordnung 2021).

- A Statement of DEKRA dated from 13.10.2016 (DEKRA Assurance GmbH 2016). DEKRA is a German organisation that provides expert services ranging from vehicle inspections and industrial and construction inspection, testing and certification of products and systems, as well as training services. DEKRA concluded in its statement that the melt pressure sensors are exempt from Directive 2011/65/EU (RoHS 2). The interpretation of DEKRA is the following:

  "The melt pressure sensors specified above are not used "as such" but are part of a large system. They are screwed to the housing of the extruder to measure the melt pressure in the extruder. The rear end of the melt pressure sensors has electric connectors for input and output, it is connected to a monitoring and/or control device. Therefore, we can see that the melt pressure sensors are "equipment, which is specifically designed, and is to be installed, as part of another type of equipment" according to Art. 4 No. 4 c).

  From the definition that is given in the Art. No. 4 e), we can see that the extruder / extrusion line where the melt pressure sensor is installed matches the definition of a large-scale fixed installation. As "production lines" are explicitly mentioned in the official FAQ document Q3.1, this confirms our assumption.

  Therefore, the exemption of ***Article 2 No. 4 (c)***

  equipment, which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;

  is applicable" (DEKRA Assurance GmbH 2016).

5.5. Critical Review

5.5.1. Compliance with chemicals regulation and the Minamata Convention

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.

If granted, the exemption would allow the use of mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar.

Annex XVII of the REACH Regulation contains several entries restricting the use of mercury compounds as well as of mercury. In relation to the exemption request at hand, entry 18a could be of relevance as it restricts the use of mercury:

- […]
- No. 5 - in a number of specified measuring devices intended for industrial and professional uses, in particular barometers, hygrometers, manometers, sphygmomanometers, strain gauges to be used with plethysmographs, tensiometers, thermometers and other non-electrical thermometric applications, mercury pycnometers and mercury metering devices for determination of the softening point.
- […]…

Seeing as the exemption for mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar does not relate to these applications, it is concluded that a renewal of the exemption would not weaken the protection afforded by REACH through entry 18a.

Other entries of Annex XVII of the REACH Regulation relate to mercury compounds (entry 18 for anti-fouling, wood preservation etc.; entry 62 for phenylmercury compounds). As the request for exemption at hand uses mercury in its metallic form these entries are not applicable. No other relevant entries in regard to the use of mercury could be identified in Annex XIV and Annex XVII.

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

Relation to the Mercury Regulation

It should be noted that mercury is also restricted in certain applications through the Mercury Regulation (EU) 2017/852, implementing the international Minamata Convention on Mercury of 2013.

According to Article 5 of the Mercury Regulation, *the export, import and manufacturing of the mercury-added products set out in Annex II shall be prohibited as from the dates set out therein.* This prohibition shall not apply to products that are essential for civil protection and military uses or products for research, for calibration of instrumentation, or for use as a reference standard. Annex II of the Mercury Regulation covers specific applications of e.g., batteries or accumulators, bridges, switches or relays, various fluorescent lamp applications and high-pressure mercury vapour lamps, cosmetics, pesticides, biocides and topical antiseptics and non-electronic measuring devices that are also covered by REACH Annex XVII Entry 18a. Exceptions from Annex II are described for:

- *non-electronic measuring devices installed in large-scale equipment or those used for high precision measurement where no suitable mercury-free alternative is available;*
- *measuring devices more than 50 years old on 3 October 2007;*

- *measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.*

None of these provisions applies to the application here under evaluation: The mercury-containing melt pressure transducers are electronic measuring devices.

Besides, the Mercury Regulation sets provisions for "New mercury-added products and new manufacturing processes" which are defined as "not being manufactured prior to 1 January 2018" and requires that these need an exemption under the RoHS Directive. Literally, Article 8(1) of the Mercury Regulation stipulates that *"Economic operators shall not manufacture or place on the market mercury-added products that were not being manufactured prior to 1 January 2018 ('new mercury-added products') unless authorised to do so by means of a decision taken pursuant to paragraph 6 of this Article or allowed to do so under Directive 2011/65/EU of the European Parliament and of the Council".*

Dynisco and Gefran are of the opinion that such transducers have already been manufactured before 1 January 2018.

"*Melt pressure transducers, transmitters and sensors using a capillary system filled with mercury to transfer pressure from the measuring point the electronic sensor"* are listed in the inventory of EU COM of manufacturing processes involving the use of mercury or mercury compounds that were processes used prior to 1 January 2018 and of mercury-added products that were being manufactured prior to 1 January 2018 and of any applicable marketing restrictions.[5] This inventory was tasked to the European Commission in Article 8(7) of the Mercury Regulation:

"7. By 30 June 2018, the Commission shall make publicly available on the internet an inventory of manufacturing processes involving the use of mercury or mercury compounds that were processes used prior to 1 January 2018 and of mercury-added products that were being manufactured prior to 1 January 2018 and of any applicable marketing restrictions."

The figure below shows the relevant entry in part A of the inventory for electrical and electronic devices. Melt pressure transducers are listed under II. 6.

[5] *INVENTORY OF EXISTING MERCURY-ADDED PRODUCTS AND MANUFACTURING PROCESSES INVOLVING THE USE OF MERCURY OR MERCURY COMPOUNDS – Revision 1, 29 April 2019*

Figure 5-1: Inventory Table Part A: Existing Mercury-Added Products

INDICATIVE NON-EXHAUSTIVE LIST OF EXISTING MERCURY-ADDED PRODUCTS	INDICATIVE NON-EXHAUSTIVE LIST OF RELEVANT EU INSTRUMENTS
II. ELECTRICAL AND ELECTRONIC DEVICES **1)** Mercury switches as an electrical switch opening and closing a circuit or as a relay using mercury as the switching element, including e.g.: a) Tilt / vibration / float / pressure / temperature switch b) Displacement relay, wetted reed relay, contact relay **2)** Electrode using mercury as an electrical conductor to make contact with a non-metallic part of a circuit (e.g. semiconductor, electrolyte), including e.g.: a) Reference electrode (calomel) / saturated calomel electrode b) Reference electrode (mercury-mercurous sulphate electrode) c) Liquid mercury cathode d) Hanging mercury drop electrode e) Dropping mercury electrode f) Static mercury drop electrode, or SMDE **3)** Mercury vacuum pump using mercury to trap air **4)** Infrared light detectors using mercury-containing semiconductors **5)** Tensiometer using mercury to measure the surface tension of liquids or surfaces, soil moisture tension or the tension in a wire, fibre or beam **6)** Melt pressure transducers, transmitters and sensors using a capillary system filled with mercury to transfer pressure from the measuring point the electronic sensor **7)** Mercury target systems for the spallation neutron source using mercury as target material **8)** Seam-welding machines, gyroscopes and wetted slip rings using mercury as a lubricant to fill the space between the stator and the rotor	- ***Regulation (EU) 2017/852*** on mercury (Art. 5 and Annex II) - ***Directive 2011/65/EU*** on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Art. 2(4), 4, 5 and Annex IV).

Source: INVENTORY OF EXISTING MERCURY-ADDED PRODUCTS AND MANUFACTURING PROCESSES INVOLVING THE USE OF MERCURY OR MERCURY COMPOUNDS, 29 April 2019; https://circabc.europa.eu/sd/a/d198684c-0834-4f20-9682-dc66553ed066/Inventory%20art%208(7)%20Mercury%20Reg%2020190429.pdf

In this sense, compliance with the Mercury Regulation is understood to be established for such melt pressure transducers.

Relation to the Minamata Convention

At the fourth meeting of the Conference of the Parties to the Minamata Convention on Mercury,[6] the European Union proposed phase out dates for certain mercury-added products (UNEP/MC/COP.4/26/Add.1 2021), and based on this proposal, the Conference of the Parties decided to amend part I of annex A to the Convention. (UNEP/MC/COP.4/28/Add.1 2022). Accordingly, mercury-added products, melt pressure transducers, melt pressure transmitters and melt pressure sensors have to be phased out (i.e., not allowed to be manufactured, imported or exported) until end of 2025, except those installed in large-scale equipment or those used for high-precision measurement, where no suitable mercury-free alternative is available (see the excerpt in the figure below).

[6] The fourth meeting took part in two segments:
The first segment online, 1–5 November 2021 and the second segment 21–25 March 2022 at Bali, Indonesia.
https://www.mercuryconvention.org/en/meetings/cop4

Figure 5-2: Excerpt from the Decision MC-4/3: "Review and amendment of annexes A and B to the Minamata Convention"

UNEP/MC/COP.4/28/Add.1

Mercury-added products	*Date after which the manufacture, import or export of the product shall not be allowed (phase-out date)*
medium length (> 500 mm and ≤ 1,500 mm) with mercury content exceeding 5 mg per lamp long length (> 1,500 mm) with mercury content exceeding 13 mg per lamp	
Cold cathode fluorescent lamps (CCFL) and external electrode fluorescent lamps (EEFL) of all lengths for electronic displays, not included in the listing directly above	2025
Cosmetics (with mercury content above 1ppm), including skin lightening soaps and creams, and not including eye area cosmetics where mercury is used as a preservative and no effective and safe substitute preservatives are available[a]	2020
Pesticides, biocides and topical antiseptics	2020
The following non-electronic measuring devices except non-electronic measuring devices installed in large-scale equipment or those used for high precision measurement, where no suitable mercury-free alternative is available: (i) barometers; (ii) hygrometers; (iii) manometers; (iv) thermometers; (v) sphygmomanometers.	2020
Strain gauges to be used in plethysmographs;	2025
The following electrical and electronic measuring devices except those installed in large-scale equipment or those used for high precision measurement, where no suitable mercury-free alternative is available: (a) melt pressure transducers, melt pressure transmitters and melt pressure sensors	2025
Mercury vacuum pumps	2025
Tire balancers and wheel weights	2025
Photographic film and paper	2025
Propellant for satellites and spacecraft	2025

Source: (UNEP/MC/COP.4/28/Add.1 2022)

The applicant's justification for the requested exemption here at hand is based on the first criterion under RoHS Article 5(1)(a), which provides that an exemption can be justified if elimination or substitution of the restricted substances via design changes or materials and components which do not require any of the restricted substances listed is scientifically or technically impracticable. This means that an alternative is not available.

The use of mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar is considered not to fall under the exception cases, neither of large-scale nor for high-precision measurement. Still, in the discussed range of operation, there is no alternative available. Thus, a

recommendation to grant the exemption would conflict with the decision under the Minamata Convention and the future amendment of the EU Mercury regulation.[7] To avoid ambiguity between the exemption and upcoming laws, the recommendation must be limited to the end of 2024.

5.5.2. Scope of the Exemption

It is understood from the stakeholder contribution that the competitors of the applicant consider the expression *"laboratory tools B2B for R&D purposes"* (Gefran spa 2022b) to be applicable to capillary rheometers under the exclusion 2(4)(d) LSFI. This interpretation is a slight but important widening of the definition of LSFI and raises the key question of this exemption as to whether capillary rheometers are in the scope of the RoHS Directive.

The scope of the RoHS Directive includes all EEE and categorizes them in Annex I. The Directive explicitly does not apply to equipment and devices listed in Article 2(4) Those are:

"*(…)*

(c) equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;

(d) large-scale stationary industrial tools (LSSIT);

(e) large-scale fixed installations (LSFI);

(…) (j) equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis." (RoHS 2011).

Both, large-scale stationary industrial tools (LSSIT) and large-scale fixed installations (LSFI) are to be considered if their definitions apply to capillary rheometers in the given exemption request. In the Directive, they are defined as follows:

"*(3) 'large-scale stationary industrial tools' means a large-scale assembly of machines, equipment, and/or components, functioning together for a specific application, permanently installed and de-installed by professionals at a given place, and used and maintained by professionals in an industrial manufacturing facility or research and development facility;*

(4) 'large-scale fixed installation' means a large-scale combination of several types of apparatus and, where applicable, other devices, which are assembled and installed by professionals, intended to be used permanently in a pre-defined and dedicated location, and de-installed by professionals".

[7] The Decision MC-4/3 has to be transposed into EU law by April/May 2023 (in accordance with Art. 27(3)(c) of the Minamata Convention). In order to transpose COP Decisions into EU law, Art. 20 of the Mercury Regulation empowers the European Commission to adopt delegated acts. The delegated act concerning the amendment to Annex II of the Mercury Regulation is, by July 2022, in progress.

The environment, in which the machine needs to be installed is precisely defined and, according to the stakeholder contributions, generally applies to capillary rheometers, because capillary rheometers are laboratory devices to investigate material properties. The components of the large-scale systems can also be EEE and measurement devices, as long as they are installed by professionals, which is the case according to the stakeholder contributions. Dynisco explains that the application of mercury-filled pressure transducers in "*capillary rheometers can also be considered stationary, as these devices are generally used in laboratories and production environments (R&D, quality assurance)"* (Dynisco Europe GmbH 2022a). Also, Gefran states that the main area of usage of mercury-filled transducers is "*as a part of other devices*" (Gefran spa 2022a). Gefran "*verifies and ensures that 1. They can fulfil their function only if they are part of that equipment, (not multitasking) 2. They can be replaced only by the same specific type of sensor (not interchangeable)"* (Gefran spa 2022b).

In the opinion of the consultants, mercury-filled transducers cannot be used individually, they are part of a device like a capillary rheometer. The statement of Gefran is plausible because the devices in which pressure transducers are used generate high pressure, thus the attachment must be tight. Also, the transmission of measuring data and the protocol need to be specified according to the device.

The term "large-scale" is discussed in the RoHS 2 FAQ. It states that "it is not explained what "large- scale" means" but gives some examples. "As a general rule, bench top tools [..] do not fall within the category of large-scale stationary industrial tools." None of the indicative list of minimum requirements for large scale applies to capillary rheometers. "Size, movement or force of moving parts" are explicitly noted as criteria for LSIT, but pressure is not listed. The force of capillary rheometers is several kN (Netzsch Gerätebau GmbH), which might be an indication of being LSIT. If the term was a relative criterion, there would be small-scale and large-scale capillary rheometers. Such a differentiation is neither used by the manufacturers nor in legislation. All offered models are based on similar technical components and are similar in their physical dimensions. There are neither small-scale nor large-scale capillary rheometers on the market. The main difference for manufacturers and users is the range of operation determining if mercury-filled transducers are required or if they can be substituted by other technologies.

Concerning the physical dimensions, capillary rheometers are no large-scale technology. Most products measure less than a square meter or even stand on a table. Capillary rheometers weigh no more than a few hundred kilograms.

On the one hand, it can be concluded, that capillary rheometers are indeed fixed installations as they are mainly used in an R&D or industrial context, where the mercury-filled EEE is specifically designed for the capillary rheometer and installed by professionals only. On the other hand, capillary rheometers are no large-scale technology and are thus in the scope of the RoHS Directive.

Mercury-filled pressure transducers in extruders

Dynisco stated that there are extruders on the market, which are no large-scale installation, but which use mercury-filled pressure transducers. "*However, there is a small category of mobile/portable extruders that are commonly used on construction*

sites for welding or repairing plastic pipes. In special cases, these are equipped with a pressure transducer. Extrapolated to Europe, Dynisco estimated the production at 30-40 pieces per year. Each pressure transducer contains about 1 g of mercury. Many companies have switched to NaK already. Only as spare parts, Hg-filled devices are still taken. Here, too, mercury could be completely replaced. The pressure range above 1000 bar is usually relevant in injection moulding and polymer reactors, all stationary installations" (Mr. J. Lorenz 2022).

The expert statement of DEKRA Assurance GmbH (2016) explicitly refers to pressure transducers used in extruders ("*They are screwed to the housing of the extruder to measure the melt pressure in the extruder. The rear end of the melt pressure sensors has electric connectors for input and output").* According to this statement, extruders are in general comparable to production lines which are mentioned in RoHS 2 FAQ Q3.1 to be large-scale fixed installations. Thus, it concludes that the use of pressure transducers in extruders is out of scope of the RoHS Directive.

This argumentation is supported by Gefran spa (2022b).

We conclude that a widening of the scope of the exemption to small-scale extruders in the range of over 300°C and 1000 bar is not necessary, as this combination never occurs. For lower pressures, substitutions are technically feasible and already partly in place.

5.5.3. Recycling of mercury-filled pressure transducers

Gefran, the supplier of the transducer that the applicant is using, supports the description of the take-back system described in the exemption request. The take-back system delivers broken or disused pressure transducers to Gefran's manufacturing site in Italy. There, Gefran runs a distillation system, in which the mercury is separated and collected in a closed vacuum system and recycled in new products afterwards (Gefran spa 2022a).

The contribution of Dynisco supports that existing recycling systems for mercury-filled pressure transducers are common practice. *"Pressure transducers can be sent in free of charge to our factory in the USA. Mercury-filled transducers are collected in Germany as well in a special container and sent for recovery to the factory in the USA on a regular basis. Dynisco operates under the guidance and advice of IMERC"* (Dynisco Europe GmbH 2022b).

The Mercury Regulation defines sources of mercury, from which the mercury is regarded as waste and needs to be disposed. Recycling of EEE is not listed, thus the mercury does not need to be disposed and there is no obligation on reporting. Article 7 formulates obligations for interim storage. "*Interim storage of mercury … shall be carried out in an environmentally sound manner, in accordance with the thresholds and requirements set out in Directive 2012/18/EU*". The cited directive states that the "*operator is obliged to take all necessary measures to prevent major accidents and to limit their consequences for human health and the environment*." Netzsch describes the actions taken as follows: "*We are planning to inform the customers about the take-back system of the Hg-filled-melt pressure transducers, as well as a label, that those melt pressure transducers are Hg-filled. As all of our customers of the rheometers are professional users, we can expect them to estimate the risks and requirements with mercury-filled products and to make sure it will be recycled properly. We have an agreement with our melt pressure transducer supplier that they will take back all melt pressure transducers. As they receive different melt pressure transducers from different industries, they have a recycle system in place.*"

Gefran estimates the amount of mercury entering the EU market as a filling medium pressure transducer to be in the range between 2 and 2.5 kg. This is fifty times more than the upper bound Netzsch estimates for this exemption request. That is because pressure transducers are not only used in capillary rheometers but also in extruders, which is the main market for pressure transducers.

From communication with some of their customers who operate extruders, Gefran learnt that the operators concerned take care of all their mercury-containing pressure transducers together with other waste-containing hazardous substances. Others only return all their pressure transducers at once after many years. Gefran confirms that all pressure transducers they receive enter their recycling system. According to Gefran, the recycling rate for pressure transducers in the European market in 2021 was estimated at approx. 8-10 %. That means, approx. 8-10% of the weight of a pressure transducer are recycled.

The pressure transducers are installed and handled by professionals only. Thus, the risk of emissions of mercury into the environment and the danger to humans is

regarded to be low. Still, it is unclear why the recycling rate of pressure transducers is so low and whereto the mercury goes to in the other cases. The measures that the applicant promises to reduce harm to the environment and human health are in line with the Mercury Directive.

5.5.4. Scientific and technical practicability of substitution

The two common substitutes at lower temperature and pressure are Galinstan and **sodium potassium** (NaK) alloy. According to literature, the compressibility of sodium potassium is known to be about one order of magnitude larger than the compressibility of mercury (Foust; Domenico und Mifflin 1965; Foust 1972). Used at high pressures, the front membrane, separating the filling from the probe, would be damaged, as claimed by the applicant.

Galinstan reacts with the capillary material at high temperatures. Gefran agrees, that there are chemical problems "at permanent temperatures above 300°C" (Gefran spa 2022a).

Thus, neither of both is a suitable substitute for the range of operations formulated in the exemption request. Other materials and technologies such as filling-less pressure transducers, will not be available within a foreseeable future.

Both contributing stakeholders explicitly agree to this argumentation. In addition, Dynisco names two filling-less technologies. *"Besides fluid-filled technology, fully electrical and optical alternatives exist (no-fill technologies). In certain areas they have limitations over mercury-filled transducers as well. These are concerning pressure range, service temperature and accuracy*."(Dynisco Europe GmbH 2022b). Since 2017, Gefran has the ambition "*to propose to the market pressure sensors for high temperatures totally mercury-free, or without any filling fluid inside*" (Gefran spa 2022b). Assuming that this statement was based on research results, it indicates that there might be available substitutes in the upcoming years. Still, none of the stakeholders could estimate when the technology will be available in the high pressure and temperature range. This was put into context by Netzsch as follows: "*There is no foreseeable date as of now. Also, the market for this exemption is not big enough to sustain extensive research on filling media. Existing filling media were developed by nuclear and military research*."

Thus, it is plausible that substitution for the given range of operation is scientifically and technically impracticable for the time being. Against this background, we recommend granting the request for the requested exemption at hand, without any changes in the formulation. We propose to review the exemption after 5 years.

5.5.5. 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.

The environmental effect is limited as the approximated amount of mercury entering the market by this exemption would be less than 50 g per year from all companies on the European market, and proper recycling is ensured.

Substitution for the given range of operation (>300°C, >1000 bar) is scientifically and technically impracticable at the time being. Thus, the exemption should be permitted. Since research on filling-less transducers has been in progress for over five years and first applications are realised, we propose to review the exemption after 5 years. To avoid legal ambiguity between this exemption and the upcoming transposition of the Minamata COP Decisions into EU law in 2023 to restrict mercury pressure transducers until 2025, the timeframe of this exemption should be limited to the end of 2024.

5.6. Recommendation

In line with the above, the following formulation is recommended to grant the exemption with the following wording:

Exemption formulation	Duration and scope
Mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar	Until 31.12.2024 Category 9

5.7. References

DEKRA Assurance GmbH (2016): Contribution of Dynisco, Response to stakeholder consultation on RoHS Pack 25 (Mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar). Submitted on 17.01.2022, 2016. Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_25/contribution/Ex_2021_1_Pack25_contribution_Dynisco_add_DEKRA_Expert_Statement_2016_20220117.pdf, last accessed on 23 Feb 2022.

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6. Exemption 2021-2: "Bis (ethylhexyl)-phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors, which are used in in-vitro diagnostic medical devices for the analysis of 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

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.
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
CMR1345	Polymer resin that is discussed as a potential substitute for PVC
DEHP	Di-/Bis-(ethylhexyl) phthalate, $C_6H_4(CO_2C_8H_{17})_2$
EEE	Electrical and Electronic Equipment
EoL	End of Life
IL	Instrumentation Laboratory
ISE	Ion selective electrodes
PoC	Point of Care
PVC	Polyvinylchloride
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
WEEE	Waste Electrical and Electronic Equipment

6.1. Background of the exemption

The application for this exemption was submitted to the European Commission by the Instrumentation Laboratory (hereafter referred to as IL)[8] on 21st January 2021. An exemption was requested for DEHP, used as a plasticizer for the resin formulation of PVC. This polymer serves as a basis for sensor cards for electrochemical measurements of biochemical analytes and parameters in human blood such as pH, pCO2, Na+, K+, Ca2+ or lactate.

The EEE in which the sensor cards are used in and for which IL requests the exemption is IL's GEM Premier 4000 diagnostic medical analyser. Each GEM Premier 4000 cartridge contains one sensor card (Instrumentation Laboratory 2021a). The GEM Premier 4000 analyser is used for blood analysis and serves as a critical analytical instrument in hospital labs, operating rooms, emergency rooms and point of care at bedsides across the Global and EU Health Care Sector (Instrumentation Laboratory 2021b). The application was specified to fall under RoHS Annex I category 8 (medical devices). The request did not cover any other uses of DEHP containing PVC. The applicant requested a new exemption for the described use of DEHP in PVC for sensor cards for the GEM Premier 4000 proposing the following wording:

> *„Bis (ethylhexyl) phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of whole blood*" (Instrumentation Laboratory 2021b).

The exemption was requested for EEE Cat. 8 for a validity period of three years.

6.1.1. History of the exemption

In the RoHS Pack 17 study in 2019/20, COCIR had requested a new exemption for:

> *„Bis (ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids*" (COCIR 2018)

In its exemption request, COCIR expressed that "*DEHP is used as a membrane solvent for the ISE [ion selective electrodes – consultants comment] constituents*" (COCIR 2018). The general composition of the membranes is detailed as "*29 wt % PVC, 70 wt % DEHP and an ionophore that imparts specificity for the particular ion of interest*" (Oeko-Institut e.V., Fraunhofer-Institut IZM 2020; COCIR 2018).

In contrast to the membrane specifications provided by COCIR, IL specifies that DEHP is used as a plasticiser in the sensor card, and that the content of substance in homogeneous material is 1.14 wt % for the GEM Premier 4000 cartridges (Instrumentation Laboratory 2021b).

[8] Intertek Health, Environmental & Regulatory Services is specified in the application as the representative of the applicant and was insofar the addressee for all inquiries. Seeing, however, that Intertek does not manufacture and market the devices for which this request is applied, the answers provided by Intertek are understood by the consultant to represent answers of IL and are specified as such.

The study for RoHS Pack 17 recommended to grant the exemption for Annex IV with a slightly adapted wording: "*Bis(2-ethylhexyl) phthalate (DEHP) in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids*", for a duration of 7 years (Oeko-Institut e.V., Fraunhofer-Institut IZM 2020).

The wording in the Commission Delegated Directive (EU) 2021/1980 (European Commission 2021b), published in the Official Journal of the European Union on 15.11.2021, is identical to the recommendation given by the consultants in RoHS Pack 17 report (Exemption 45 in Annex IV to Directive 2011/65/EU, "Bis(2-ethylhexyl)-phthalate(DEHP) in ion-selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids. Expires on 21 July 2028").

As clarified by the European Commission in an email to the applicant in May 2021 (European Commission 2021a), "*Despite the similarity of the requested technical application for an exemption with the pending exemption decision for DEHP in ion selective electrodes under Pack 17, it was deemed after consultation that the current requested application is not consistent with this pending exemption wording*".

The consultants considered the possibility to merge the two exemptions, to reduce the administrative burden, while keeping enough specificity in the scope. This aspect was intended to be investigated with stakeholders, during a meeting planned for 15th March 2022. However, the meeting was cancelled because the exemption request was withdrawn by IL on 14th March 2022 (see paragraph 6.5).

6.2. Technical description of the requested exemption

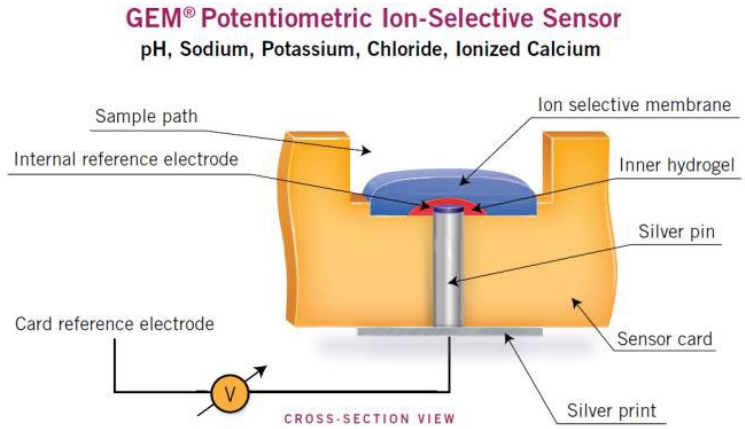
The applicant manufactures a diagnostic medical analyser, the GEM Premier 4000. The instruments are used to measure the blood of patients and provide an accurate measurement of specific analytes.

Within the analyser, the measurements are performed based on four different types of quantification methods, namely potentiometric, amperometric, conductometric, and spectrometric. While amperometric, potentiometric and conductometric quantification require an electrode, spectrometric measurements are based on effects of the analyte after a light-induced excitation, thus, work without any electrode. The electrodes and spectrometric components are part of the cartridge. According to the applicant, "*the GEM Premier 4000 contains both ion selective electrodes (potentiometric sensors), and well as amperometric sensors and conductometric sensors"* (Instrumentation Laboratory 2021a).

Based on the applicant's explanations, it is understood that within one cartridge four methods of quantifications of 16 parameters in total are applied for each blood sample. Thereof 6 parameters are measured with a potentiometric electrode (pCO2, pH, Na+, K+, Cl-, and Ca2+). The speciality of the potentiometric electrode is the fact that a so-called ISE is required based on the definition of an ISE being a sensor composed of an electrode with a selective membrane that seals to an underlying substrate (Figure 6-1). Asked whether it is right to understand that the sensor card applied in the GEM Premier 4000 is more than an ISE, the applicant further explains

that '*not all of sensors on the GEM Premier 4000 sensor card meet the definition of ISE defined above. The amperometric sensors differ because the membrane does not provide selectivity and instead utilizes enzymes to convert analytes of interest to measurable signals, and the conductometric sensor for hematocrit does not utilize a membrane at all.*' (Instrumentation Laboratory 2021a). An overview over the range of analytes, the corresponding quantification method, and whether they are relevant for the assessment of the present exemption request for DEHP is provided in Table 6-1.

Figure 6-1: Potentiometric Ion-Selective sensor



Source: (Instrumentation Laboratory 2021a)

Table 6-1: Range of analytes, corresponding quantification method and electrode

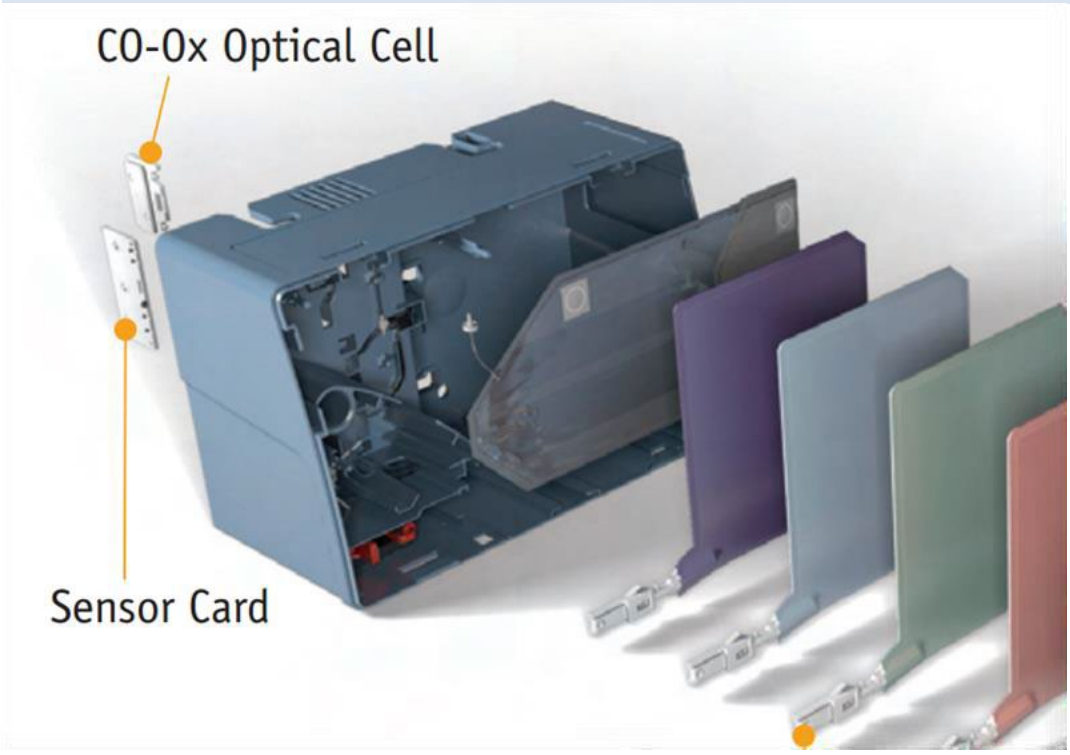
Analytes	Quantification method	Utilize an electrode using DEHP
pH	Potentiometric (ISE)	Yes
pCO_2	Potentiometric (ISE)	Yes
pO_2	Amperometric	Yes
Na^+	Potentiometric (ISE)	Yes
K^+	Potentiometric (ISE)	Yes
Ca^{++}	Potentiometric (ISE)	Yes
Cl^-	Potentiometric (ISE)	Yes
Haematocrit	Conductometric	Yes
Glucose	Amperometric	Yes
Lactate	Amperometric	Yes
tHb	Spectrophotometric	No
O_2Hb	Spectrophotometric	No
COHb	Spectrophotometric	No
MetHb	Spectrophotometric	No
HHb	Spectrophotometric	No
tBili	Spectrophotometric	No

Source: (Instrumentation Laboratory 2021a)

Regarding the component in which DEHP is used, the applicant specifies that '*the heart of the GEM Premier 4000 is the sensor card where the electrochemical measurements [author's note: namely potentiometric, amperometric and conductometric] of the […] analytes take place'* (Instrumentation Laboratory 2021c). As clarified by the applicant and shown in Figure 6-2, "t*he sensor card can be appropriately described as the underlying substrate for the membrane, or the "housing" of the membrane*" (Instrumentation Laboratory 2021a). The typical sensor card's weight is 5.1 g (Instrumentation Laboratory 2021b), thus small and light in comparison with the cartridge's weight of ~ 4kg (Instrumentation Laboratory 2021b). The sensor cards *'have an additional additive, DEHP, which is part of the resin [currently PVC] formulation'* (Instrumentation Laboratory 2021b): DEHP functions as a plasticizer to facilitate the injection moulding process of PVC, the host material. An important requirement of the functionality of DEHP and its substitutes is that it "*must not interfere with the measurement of any analyte on the system over the claimed product shelf-life (up to 6 months at room temperature) and use-life (up to 30 days in the analyser)*" (Instrumentation Laboratory 2021b).

It is not clear whether the exemption requested is necessary only for guaranteeing the supply of cartridges to analysers already on the market, or whether new GEM 4000 analysis devices use cartridges that contain DEHP-containing sensors as well. This was expected to be clarified in the evaluation which was stopped due to the withdrawal (see paragraph 6.5).

Figure 6-2: Cartridge and sensor card



Source: (Instrumentation Laboratory 2021b)

The consultants understand that these cartridges containing DEHP are consumables of the analysers, specifically the GEM Premier 4000, which are nevertheless to be considered as electrical and electronic equipment (EEE)[9]. The applicant clarifies that '*one sensor card is used for up to 30 days or 450 whole blood sample measurements. Each sample measurement provides simultaneous results for multiple analytes, including pH, pCO_2, pO_2, Na+, K+, Ca++, Cl-, hematocrit, glucose, and lactate. Therefore, each sensor card is used to report up to 4500 measured concentrations (450 whole blood samples x 10 analytes)*' (Instrumentation Laboratory 2021a). They are disposed of after the respective number of analyses has been completed. In addition, "*the sensor card containing DEHP is designed specifically for the GEM Premier 4000. Sensor cards for other type/models of instrument are not compatible with the GEM Premier 4000*" (Instrumentation Laboratory 2021a). It is understood that generally sensor cards (and the cartridges in which they are contained) must be compatible with the type of analyser and specific model that is in use in a specific medical facility. In this sense, the consultants understand that the exemption is at least in part concerned with the provision of such cartridges on the EU market, to ensure that devices already operative on the market can continue to be operated.

6.2.1. Amount of DEHP used under this exemption

The amount of the substance entering the EU market annually through the application [GEM Premier 4000 cartridges] for which the exemption is requested is stated to be in the range of 1-10 kg (Instrumentation Laboratory 2021b). This estimation does not cover cartridges of analysers other than the GEM Premier 4000 (Instrumentation Laboratory 2021a).

According to IL, the size of one cartridge is 25 x 16.5 x 16 cm and a typical cartridge weight is 4.08 kg, while the weight of a typical sensor card is 5.1 g (Instrumentation Laboratory 2021a). Based on the content of the substance in homogeneous material being 1.14 wt % for the GEM Premier 4000 cartridges (Instrumentation Laboratory 2021b), it might be assumed that each unit cartridge contains 46.5 g of DEHP. Nevertheless, it is not clear if the percentage content refers to DEHP in cartridges or sensor cards. This information was intended to be clarified by a specific question, in the second round of clarification questions.

6.2.2. Comparison to application evaluated in RoHS Pack 17

Based on the ROHS Pack 17 report (Oeko-Institut e.V., Fraunhofer-Institut IZM 2020), the PoC analysers presented by COCIR can quantify the same analytes and parameters, e.g., partial pressure of carbon dioxide (pCO2), pH, concentration of sodium and potassium ions. Quantification is based on a DEHP-containing ion-selective

[9] 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 29.10.2021).

electrode as well. It is understood that cartridges of the PoC analysers presented by COCIR in 2018/19 do not include other sensors including DEHP-containing parts.

According to the application submitted by COCIR (COCIR 2018), DEHP is used as a membrane solvent for the ISE constituents that are used in PoC analysers to measure the concentrations of analytes. COCIR estimates a total of 2.2 kilograms of DEHP entering the EU market annually through the application described for the exemption (COCIR 2018).

As mentioned earlier, the exemption requested in 2018 by COCIR was granted (Ex. 45) with the following wording "*Bis(2- ethylhexyl) phthalate (DEHP) in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids*" and expires on 28th July 2028.

Asked whether the current applicant IL/Intertek sees a possibility to merge Ex. 45 and the new exemption requested, the applicant proposed to remove the references to 'ion selective' and 'ionic' resulting in the following wording: *"Bis(2-ethylhexyl) phthalate (DEHP) in electrodes applied in point of care analysis of substances present in human body fluids and/or in dialysate fluids*". This is understood to be due to the fact that the IL GEM 4000 uses DEHP also in other than "ion selective" sensors, i.e., also for analysis of non-ionic substances.

6.3. Applicant's justification for the requested exemption

6.3.1. Substitution, elimination or reduction of DEHP

IL claims that it "*has been actively working to replace DEHP as a plasticiser in the PVC sensor card, working in close cooperation with commercial suppliers of PVC materials, academic institutions specializing in polymer chemistry and private consultants to identify alternatives for DEHP*" (Instrumentation Laboratory 2021b). The applicant claims that substitution is not yet possible, providing a roadmap ("project plan") for the substitution of DEHP in the cartridges, as reported in Figure 6-3. The consultants understand that the applicant's research has two directions: a drop-in-substitute for DEHP in the PVC and an alternative resin/polymer that does not require DEHP or rather allows the substation of the PVC. According to the project plan, various resins that should substitute PVC were tested in 2016/17 from which one (CMR 1345) was selected as a top candidate to conduct a study of alternatives for DEHP. Indeed, *"all resins tested prior to the current candidate (the CMR1345 resin), have shown issues of low amperometric oxygen sensor response and imprecise amperometric glucose sensor response"* (Instrumentation Laboratory 2021b). As clarified by the applicant, referring to Figure 6-1, *"only the orange portion labelled 'Sensor card' will be replaced by CMR 1345. (…) The membranes, hydrogels, pins, electrodes or silver print of the individual sensors will not be changed*" (Instrumentation Laboratory 2021a). Three drop-in-alternatives for DEHP, namely mineral oil, ester lubricant V-DSP and acrylic processing aid, were compared in an LCA. The initial plan was to complete the substitution project and start the controlled distribution of the RoHS-compliant resin between June and December 2022. However, the applicant has experienced delays, due to the increased demand to support the COVID pandemic. Thus, the applicant

requested the exemption for three years, assumed to be from January 2021 to January 2024.

The applicant explains the choices for current materials and substances as follows: PVC is used as sensor card material and the membrane used (i.e., PVC) should be of the same material to resist the solvent used in this analytical process. Indeed, *"PVC has specific advantages as a sensor card material for the electrochemical sensors used in the GEM Premier products. Sensor membranes used for certain sensors (Na+, K+, Ca++, pH, pCO2) are based on PVC membranes and are solvent cast directly on the sensor card from a solution of tetrahydrofuran (THF). Because THF is a strong solvent for PVC, there is strong adhesion between the cast membranes and the PVC card. This membrane adhesion to the PVC is a critical requirement for sensor function and promotes long use life and shelf life"* (Instrumentation Laboratory 2021b).

As to DEHP, it *"increases flexibility and reduces brittleness to improve durability and reliability under cyclical mechanical loading that the sensor card experiences during manufacturing and use in the GEM Premier 4000 analyser"* (Instrumentation Laboratory 2021b). Furthermore, DEHP does not interfere with the analyte measurements which is a crucial pre-condition for alternatives for DEHP.

According to the applicant, *"any change in the sensor card resin can directly impact analytical performance characteristics of this system. This is critical because the quality management system (…) has been designed around the analytical performance of sensor cards containing DEHP, based on cartridge sensor data collected over a 20-year time period"* (Instrumentation Laboratory 2021b).

Figure 6-3: Project plan, for the substitution of DEHP in PVC

Task Name	Notes	% Complete
Feasibility	2010	**100%**
Feasibility Testing with off the shelf tin-stabilized rigid PVC (Alpha Gary, Georgia Gulf, Roscom, ViChem, Viking Polymer, Emmanual/UMASS custom resins)	2010-2012	100%
New compounder Teknor Apex created various resin formulations at external supplier	2012 - 2016	100%
Resin Formulation development transitioned to in-house	2016	100%
Tested variations of stearates	Apr-May 2016	100%
Tested different organic based stabilizer formulations	Apr-Jul 2016	100%
Pellet blending 1	Jul 2016	100%
Pellet blending 2	Sep 2016	100%
Molding of cards	Jul-Sep 2016	100%
Raw material blend	Oct 2016	100%
Testing	Q4 2016	100%
Molding of cards	Oct 2016	100%
Testing	Q4 2016	100%
Optimize formulation	Jan 2017	100%
CMR: 5 formulations tested (new thermal stabilizers)	Oct 2016-May 2017	100%
Literature research for chemical compound to optimize formulations	Aug 2016	100%

Test 1: Included CMR 1328, 1331, 1334	Oct 2016	100%
Test 2: Included CMR 1331, 1332, 1333	Nov 2016	100%
Identified gap in glucose sample precision	Jan 2017	100%
CMR: 6 formulations tested (additional additives)	Mar 2017	100%
Raw material blends of six new formulations	May 2017	100%
Test 1: Included CMR 1344, 1347, 1348	Aug 2017	100%
Test 2: Included CMR 1345, 1346, 1349	Sep 2017	100%
Shelf Life Assessment	Dec 2017	100%
Design and Process Optimization		**100%**
Down select top 3 formulations from CMR additional additives	Dec 2017	100%
Performance testing, shelf life stability	Jan 2018	100%
Testing on all GEM platforms for top 3 candidates from CMR additional additives	Feb 2018	100%
GEM 4000 testing (all 3 resins)	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%
Process Validation - Sensor Card Molding		**90%**
Molding Validations on all platforms	Q1-Q4 2019	100%
GEM 4000 molding validation IQ/OQ	Aug-Oct 2019	100%
PQ Validation	Nov 2019	100%
Retaining ring samples Round 1	Q3 2019	15%
Molding parameters	Q3 2019	100%
Molding of sample parts	Q4 2019	100%
Review parts in house	Q4 2019	100%
Identified poor adhesion of retaining ring to RoHS Resin	Q4 2019	100%
Complete validation of dried retaining rings	TBD	15%
Retaining ring samples Round 2	Q4 2019	100%

Molding parameters	Dec 2019	100%
Molding of sample parts	Jan-Feb 2020	100%
Review parts in house	Feb 2020	100%
Pull force testing at supplier with Round 1 and Round 2 retaining rings	Feb 2020	100%
Retaining ring Validation	Jan 2020	100%
IQ/OQ	Feb 2020	100%
PQ	Feb 2020	100%
Review parts - determine need to dry resin	Feb 2020	100%
Risk Assessment for drying resin	Feb 2020	100%
Complete validation of dried retaining rings	Mar 2020	100%
Re-validation 4k cards with dried resin	Apr 2020	100%
Process Validation - Sensor Card Pinning		**100%**
Pin dried cards	May 2020	100%
Verification and Validation*		**15%**
Build Material for Verification & Validation	June 2020	100%
Analytical Verification	Jul – Nov 2020	50%
Method Comparison	Jul 2020	60%
Aqueous Precision	Aug 2020	60%
Use Life	Aug 2020	30%
Systems Verification	Oct - Nov 2020	0%
Shelf Life Verification	Jul 2020 - Mar 2021	20%
ELM Testing	Jul 2020	100%
Process Validation (Manufacturing)	Jul - Nov 2020	50%
Dried Resin Process Validation	Oct-Nov 2020	25%
ELM Testing	Dec 2020	0%
Dried Resin Analytical Testing	Dec 2020	0%
Release Documentation	Apr-May 2021	0%

Controlled Distribution of RoHS Resin	Jun-Dec 2022	0%

*Delay due to increased demand to support COVID-19

Source: (Instrumentation Laboratory 2021b)

Compared to other analytical methods and instruments that test human blood for the respective analytes and parameters, the advantage of this technology over others are explained to be the following: according to the applicant, the instrument combines an intelligent quality management (iQMTM), a disposable measurement cartridge, which can be stored up to 6 months at room temperature, and regular testing of the cartridges.

6.3.2. Environmental arguments

The results of a life cycle analysis of the current GEM Premier 4000 sensor card and identified alternatives are included as Annex to the application.

The environmental Life Cycle Assessment (LCA) is carried out for four additives used or potentially used in sensor cards: DEHP (Di-2-Ethyl Hexyl Phthalate), Mineral Oil (CAS# 8042-47-5), Ester Lubricant V-DSP (CAS#14117-96-5) and Acrylic Processing Aid (CAS# 9063-87-0). The applicant states that *"the three additives Mineral Oil, Ester Lubricant and Acrylic Processing Aid are potential alternatives to DEHP. DEHP is used as an additive on its own, in contrast to the other three additives, which must be used in a combination of all three to match the functional performance of DEHP"* (Instrumentation Laboratory 2021b).

LCA results are summarised below (according to IL; in all cases, a numerically lower result is a preferable result in environmental terms), cited from the application. Results are per one kilogram of DEHP, and appropriate amounts of the other three additives to achieve equivalent functional performance (i.e., the combination of 1.228 kg mineral oil, 1.404 kg ester lubricant and 1.404 kg acrylic processing aid).

- *"The LCA for DEHP showed a global warming potential or 'carbon footprint' of 3.48 kgCO2eq, Mineral Oil of 2.69 kgCO2eq, Ester Lubricant of 4.05 kgCO2eq and Acrylic Processing Aid of 3.79 kgCO2eq.*
- *The alternatives to DEHP are required in combination, so the true comparison is DEHP with a carbon footprint of 3.48 kgCO2eq versus the combined alternative additives with a carbon footprint of 10.54 kgCO2eq.*
- *The USEtox LCA results in the 'Human Toxicity, Cancer' category were 76 nanoCases for DEHP versus 441 nanoCases for the combination of the other three additives.*
- *The USEtox results in the 'Human Toxicity, Non-Cancer' category were 256 nanoCases for DEHP versus 2130 nanoCases for the combination of the other additives.*
- *The results for Cumulative Energy Demand (CED) were lower in all cases for DEHP than for the combination of the other additives; for example, in the 'Non-*

Renewable, Fossil' category, the result for DEHP was 97 Megajoules, while the result for the combination of the other additives was 251 Megajoules.

- *The Ecopoint method results showed that DEHP achieved a score of 1.4 mPt versus 5.1 mPt for the combination of the other additives" (Instrumentation Laboratory 2021b) .*

According to the applicant, *"the overall conclusion is that the LCA provides evidence that DEHP is likely to be the preferred solution in terms of environmental impact and human health. The environmental impacts of the alternative additives when considered individually are within the same order of magnitude, but they must be used in combination in the sensor card to achieve equivalent functional performance, which makes their combined environmental impacts significantly higher (less desirable) than those of DEHP"* (Instrumentation Laboratory 2021b).

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

6.3.3. Socioeconomic impacts

The applicant does not refer to socioeconomic impacts of substitution, as "*alternatives are currently not available*" (Instrumentation Laboratory 2021c) and no additional references or evidences are provided as to socioeconomic effects due to the finding that this is "*not relevant as alternatives are currently not available"* (Instrumentation Laboratory 2021c). Asked in the clarification questions to further comment socioeconomic impacts, the applicant replied:

> *"If the exemption application is rejected those instruments would need to be removed from service and disposed of. New capital equipment would need to be purchased by healthcare providing institutions. The new equipment would need to be validated by the healthcare providers. Hospital staff would need to be trained to operate the new equipment. Demand for this volume of equipment and installation activities could not be met in a short period of time and resulting in lack of availability of testing capacity."* (Instrumentation Laboratory 2021a)

Moreover, the applicant refers to the communications submitted to the Oeko-Institute in December 2017 by two European Healthcare institutions to support the request for renewal of the exemption 41 to Annex IV of RoHS Directive (requested by the same applicant, for "*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 two institutions confirmed the need to ensure continued availability of GEM analyser cartridges in order to ensure well-functioning healthcare operations as well as the safety of patients. In that case, the exemption regarded the whole GEM Premier Family (i.e., GEM Premier 3000, 3500, 4000 and 5000 models).

6.4. Stakeholder contributions

No stakeholder contribution was submitted.

6.5. Withdrawal of the exemption request: summary of the process

The assessment began following the closing of the stakeholder consultation. On 14 March 2022, IL withdrew the exemption. In the official communication of the withdrawal, Intertek clarified that the phase out of DEHP from the sensor card would be completed with new sensor cards not containing DEHP to be supplied to the EU market by 31 March 2022. Intertek wrote that "*due to the continued efforts and dedicated work on side of our client (i.e., IL) to phase out the use of DEHP in the sensor card, our client succeeded in finalizing the phase out of DEHP more quickly than initially expected at the time when the application was submitted*" (Intertek 2022).

The association COCIR who represents a number of other companies manufacturing PoC blood gas analysers was contacted and asked if it was aware of any of its members or other manufacturers that may rely on the requested exemption. A notification was also posted on the consultants' website and an email was sent to the stakeholders to inform them of the withdrawal of the exemption. The consultants received no indications from other stakeholders that the requested exemption was necessary for devices placed and/or operative on the EU market. It was thus concluded that the exemption is not needed. A critical review of the request is thus not included in this report.

6.6. Recommendation

The exemption was withdrawn, and it has not been clarified that it is needed by other stakeholders. A recommendation is thus not included in this case.

6.7. References

COCIR (2018): Original Application for Exemption, Request for exemption for "Bis (ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids". Submitted 17.07.2018., 2018. Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/application_COCIR_RoHS17_DEHP_Phthalates_in_ion_selective_electrods_20180708.pdf.

European Commission (2021a): Email sent to Instrumentation Laboratory on 4th May 2021, 2021.

European Commission: COMMISSION DELEGATED DIRECTIVE (EU) 2021/1980 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes for analysing human body fluids and/or dialysate fluids. In: Official Journal of the European Union. Online available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L1980.

Instrumentation Laboratory (2021a): Answers to 1st Questionnaire Exemption Request 2021-2 (Clarification Questionnaire). Received on 19.11.2021, 2021. Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_25/Ex_2021-2_Summary_Clarification_Questions_IL_Answers.pdf.

Instrumentation Laboratory (2021b): Application for Exemption, Request for exemption for "Bis (ethylhexyl)-phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors, which are used in in-vitro diagnostic medical devices for the analysis of whole blood". Submitted on 21.01.2021, updated on 24.11.2021, 2021. Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_25/Ex_2021_2_Application_form_Instrum_Lab_Intertek_20211124_update.pdf.

Instrumentation Laboratory (2021c): Original Application for Exemption, Request for exemption for "Bis (ethylhexyl)-phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors, which are used in in-vitro diagnostic medical devices for the analysis of whole blood". Submitted on 21.01.2021, 2021. Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_25/Ex_2021_2_Application_form_Instrum_Lab_Intertek_20211124_update.pdf.

Intertek (2022): Communication of the withdrawal of the exemption. Email with European Commission, 2022.

Oeko-Institut e.V., Fraunhofer-Institut IZM (2020): Study to assess three (3) exemption requests relating to Annex IV to Directive 2011/65/EU: request for amendment of existing exemption 31a; request for a new exemption for bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids; and request for a new exemption for DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils (Pack 17), Final Report for the European Commission DG Environment 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 (Oeko-Institut e.V. and Fraunhofer-Institut IZM (ed.)), 21 Apr 2020. Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/RoHS_Pack-17_April_2020_final.pdf.

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 in the following, 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 Latest application date (1)	Sunset date (2)	Exempted (categories of) uses
4. Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	21 August 2013(*) (b) By way of derogation from point (a): 14 June 2023 for uses in: — food contact materials within the scope of Regulation (EC) No 1935/2004; — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/ 82/EC, and/or Directive 2001/ 83/EC; — mixtures containing DEHP at or above 0,1 % and below 0,3 % weight by weight; (c) By derogation of point (a): 27 November 2023 for uses in medical devices within the scope of Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	21 February 2015 (**) (b) By way of derogation from point (a): 14 December 2024 for uses in: — food contact materials within the scope of Regulation (EC) No 1935/2004; — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/ 82/EC, and/or Directive 2001/83/EC; — mixtures containing DEHP at or above 0,1 % and below 0,3 % weight by weight; (c) By derogation of point (a): 27 May 2025 for uses in medical devices within the scope of Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	
5. Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7	21 August 2013(*) (b) By way of derogation from point (a): 14 December 2024 for uses in: — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; — mixtures containing BBP at or above 0,1 % and below 0,3 % weight by weight	21 February 2015(**) (b) By way of derogation from point (a): 14 December 2024 for uses in: — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; — mixtures containing BBP at or above 0,1 % and below 0,3 % weight by weight	

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements Latest application date (1)	Sunset date (2)	Exempted (categories of) uses
6. Dibutyl phthalate (DBP) EC No: 201-557-4 CAS No: 84-74-2	21 August 2013(*) (b) By way of derogation from point (a): 14 June 2023 for uses in: — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; — mixtures containing DBP at or above 0,1 % and below 0,3 % weight by weight.	21 February 2015(**) (b) By way of derogation from point (a): 14 December 2024 for uses in: — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; — mixtures containing DBP at or above 0,1 % and below 0,3 % weight by weight.	
7. Diisobutyl phthalate (DiBP) EC No: 201-553-2 CAS No: 84-69-5	21 August 2013(*) (b) By way of derogation from point (a): 14 June 2023 for uses in mixtures containing DIBP at or above 0,1 % and below 0,3 % weight by weight.	21 February 2015(**) (b) By way of derogation from point (a): 14 December 2024 for uses in mixtures containing DIBP at or above 0,1 % and below 0,3 % weight by weight.	
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 (**)	-
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 (**)	-

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements Latest application date (1)	Sunset date (2)	Exempted (categories of) uses
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 (**)	

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements Latest application date (1)	Sunset date (2)	Exempted (categories of) uses
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 (**)	
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 (**)	

(*) 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 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).