Study to assess seven (7) exemption requests relating to Annex III and IV to Directive 2011/65/EU: request for renewal of exemptions 6(a), 6(b), 6(c), 7(a) and 7(c)-I of Annex III; request for renewal of exemption 27 of Annex IV; and request for a new exemption for lead in bismuth lead strontium calcium copper oxide superconductor cables and wire and lead in electrical connections to these wires to be added to Annex IV (Pack 18) – 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

July 2020

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Disclaimer

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

EUROPEAN COMMISSION

Directorate-General for Environment

Directorate B - Circular Economy & Green Growth

Unit B3 - Waste Management & Secondary Materials

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1. Executive summary – English

Under Framework Contract no. ENV.A.2/FRA/2015/0008 of 27/03/2015, a consortium led by Oeko-Institut was 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. The work has been undertaken by the Oeko-Institut and Fraunhofer Institute IZM, and has been peer reviewed by the two institutes.

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 in to 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 consultants carried out evaluation of two exemptions in this study: one request for renewal an existing exemption, exemption 27 of Annex IV, and one request for a new exemption of Annex IV.

The scope of the study as indicated in the title has changed: The assessment of the request for renewal of exemptions 6(a), 6(b), 6(c), 7(a) and 7(c)-I of Annex III has been suspended. The applicant, who submitted a renewal request for exemptions 6(a), 6(b), 6(c), 7(a) and 7(c)-I of Annex III of the RoHS Directive to the Commission could not provide despite several clarifying consultations sufficient information to proceed with the assessment. Due to time constraints linked to the duration of the contract, it was decided consensually not to continue the assessment of the five above mentioned exemptions under this contract.

An additional task was requested to be performed under this study that covered an update of the data provided by the analysis model developed in the course of the "Study to assess socio-economic impact of substitution of certain mercury-based lamps currently benefiting of RoHS 2 exemptions in Annex III". This update has been published as a separate report on 10 July 2020[1] and is documented in the report at hand in the Appendix A.2. The model used for calculations of impacts in this study has also been published[2].

1 Baron, Y. ; Gensch C.-O. (2020): Update of the data provided by the analysis model developed in the course of the "Study to assess socio-economic impact of substitution of certain mercury-based lamps currently benefiting of RoHS 2 exemptions in Annex III"; Performed under the study request No.07.0201/2019/811056/ENV.B.3; 10 July 2020; https://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/RoHS_SEA_Lamps_2020_Revision-Final_10072020.pdf;

2 The VHK Oeko-Institut Combined Model for RoHS can be viewed here: https://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/VHK_Oeko_Combined_Model_RoHS_CFL_LFL_20200707_clean.xlsx

1.2. Key findings – Overview of the evaluation results

The exemption requests covered in this project and the applicants concerned, as well as the final recommendations and proposed expiry dates are summarised in Table 1-1. One request for the renewal of an existing exemption and one request for a new exemption, both of 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 exemption requests, associated recommendations and expiry dates

Ex. Req.	Exemption wording	Applicant	Recommendation	Expiry date and scope
Existing exemption				
Annex IV, 27	Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in (a) magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy.	COCIR	Grant the exemption with restricted scope: Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors c) of MRI non-integrated coils with a certification* issued by a notified body before 30 June 2020. d) in MRI equipment including integrated coils, which are used in-magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment with a certification* issued by a notified body before 30 June 2024.	30 June 2027
Request for a new exemption				
2019-3	Lead in bismuth lead strontium calcium copper oxide superconductor cables and wire and lead in electrical connections to these wires	Sumitomo	Grant exemption as requested	30 June 2027

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 contrat-cadre ENV.A.2/FRA/2015/0008 du 27/03/2015, un consortium mené par l'Oeko-Institut 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 et le Fraunhofer IZM (Institut Fraunhofer pour la fiabilité et la microintégration), et fait l'objet d'un examen par des pairs des deux instituts.

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.

Dans ce contexte, et compte tenu du fait que des exemptions relevant du champ d'application élargi de la directive LdSD 2 peuvent être demandées depuis l'entrée en vigueur de la directive (le 21 juillet 2011), les consultants ont procédé à l'évaluation de deux exemptions dans le cadre de cette étude : une demande de renouvellement d'une exemption existante, l'exemption 27 de l'annexe IV, et une demande d'une nouvelle exemption de l'annexe IV.

La portée de l'étude, telle qu'indiquée dans le titre, a changé : l'évaluation de la demande de renouvellement des exemptions 6(a), 6(b), 6(c), 7(a) et 7(c)-I de l'annexe III a été suspendue. Le demandeur, qui a soumis à la Commission une demande de renouvellement des exemptions 6(a), 6(b), 6(c), 7(a) et 7(c)-I de l'annexe III de la directive LdSD, n'a pas pu fournir, malgré plusieurs consultations de clarification, des informations suffisantes pour procéder à l'évaluation. En raison de contraintes de temps liées à la durée du contrat, il a été décidé de manière consensuelle de ne pas poursuivre l'évaluation des cinq exemptions susmentionnées dans le cadre de ce contrat.

Une tâche supplémentaire a été demandée dans le cadre de cette étude, qui portait sur une mise à jour des données fournies par le modèle d'analyse élaboré au cours de "Study to assess socio-economic impact of substitution of certain mercury-based lamps currently benefiting of RoHS 2 exemptions in Annex III" [Étude visant à évaluer l'impact socio-économique du remplacement de certaines lampes à mercure bénéficiant actuellement d'exemptions de la directive RoHS 2 dans l'annexe III]. Cette mise à jour a été publiée dans un rapport séparé le 10 juillet 2020[3] et est documentée dans le rapport en question à l'annexe A.2. Le modèle utilisé pour le calcul des impacts dans cette étude a également été publié[4].

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

Les demandes d'exemption couvertes par ce projet et les demandeurs concernés, ainsi que les recommandations finales et les dates d'expiration proposées sont résumées dans le tableau 1 1. Une demande de renouvellement d'une exemption existante et une demande de nouvelle exemption ont été incluses dans le champ d'application de ce projet. Le lecteur est invité à se reporter aux 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.

[3] Baron, Y. ; Gensch C.-O. (2020): Update of the data provided by the analysis model developed in the course of the "Study to assess socio-economic impact of substitution of certain mercury-based lamps currently benefiting of RoHS 2 exemptions in Annex III"; (Mise à jour des données fournies par le modèle d'analyse développé au cours de l'"Étude visant à évaluer l'impact socio-économique du remplacement de certaines lampes à base de mercure bénéficiant actuellement de dérogations à la directive RoHS 2 dans l'annexe III"); réalisée dans le cadre de la demande d'étude n° 07.0201/2019/811056/ENV.B.3; 10 juillet 2020 https://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/RoHS_SEA_Lamps_2020_Revision-Final_10072020.pdf

[4] Le modèle combiné Oeko-Institut VHK pour la directive RoHS peut être consulté ici: https://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/VHK_Oeko_Combined_Model_RoHS_CFL_LFL_20200707_clean.xlsx

Dem. ex. n°	Termes de l'exemption demandée	Deman-deur	Recommandation	Date d'expiration et champ d'application
Exemption en vigueur				
Annexe IV, Ex. 27	Le plomb dans les soudures, les revêtements des extrémités des composants électriques et électroniques et des cartes de circuits imprimés, les raccordements de fils électriques, les écrans et les connecteurs protégés, qui sont utilisés dans: a) les champs magnétiques situés dans un rayon de 1 mètre autour de l'isocentre de l'aimant des équipements médicaux d'imagerie par résonance magnétique, y compris les moniteurs individuels conçus pour être utilisés dans cette zone; ou b) les champs magnétiques situés à 1 mètre de distance au maximum des surfaces externes des aimants de cyclotron ou des aimants servant au transport et au réglage de l'orientation des faisceaux de particules utilisés en hadronthérapie	COCIR	Le plomb dans les soudures, les revêtements des extrémités des composants électriques et électroniques et des cartes de circuits imprimés, les raccordements de fils électriques, les écrans et les connecteurs protégés, qui sont utilisés dans: c) de bobines d'IRM non intégrées avec une certification* délivrée par un organisme notifié avant le 30 juin 2020. d) dans les appareils d'IRM, y compris les bobines intégrées, qui sont utilisés dans les champs magnétiques dans la sphère de 1 m de rayon autour de l'isocentre de l'aimant dans les appareils médicaux d'imagerie par résonance magnétique avec une certification* délivrée par un organisme notifié avant le 30 juin 2024.	30 juin 2027
Demande de nouvelle exemption				
2019-3	Plomb dans le bismuth plomb strontium calcium oxyde de cuivre câbles et fils supraconducteurs et plomb dans les connexions électriques à ces fils	Sumitomo	Accorder l'exemption demandée	30 juin 2027

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

3. Introduction

3.1. Project scope and methodology

The scope of the project covers the evaluation of two exemptions: one for exemption renewal and one request for a new exemption both of Annex IV. The scope of the study as indicated in the title has changed as explained in the section on background and objectives on page 9.

An overview of 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 03 December 2019 and was open for eight weeks until 27 January 2020.

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 applicants' documents for each of the exemption requests, results of earlier evaluations where relevant, a specific questionnaire and a link to the EU CIRCA website. No contributions were made to either of the exemptions.

Following the stakeholder consultations, an in-depth evaluation of the exemptions was carried out. The requests were evaluated according to the relevant criteria laid down in Article 5 (1) of the RoHS 2 Directive, as described in the section on background and objectives on page 9.

The evaluations of the exemptions are presented in chapter 5. The information provided by the applicants and by stakeholders is summarised in the first sections of the respective chapters. 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 applicants 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. The general requirements for the evaluation of exemption requests as set by the European Commission may be found in the technical specifications of the project.[5]

[5] Cf. https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_18/Technical_Specification_RoHS_Pack18.pdf

3.2. Project set-up

Assignment of project tasks to Oeko-Institut, started in 20 August 2019. The overall project has been led by Carl-Otto Gensch. At Fraunhofer IZM the contact person is Otmar Deubzer.

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,[6] and in the following for the evaluation of a range of requests assessed through previous projects in respect of RoHS 2.[7] 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.[8]

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.

6 See Zangl, S.; Blepp, M.; Deubzer, O. (2012) Adaptation to Scientific and Technical Progress under Directive 2011/65/EU - Transferability of previously reviewed exemptions to Annex III of Directive 2011/65/EU, Final Report, Oeko-Institut e.V. and Fraunhofer IZM, February 17, 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Re-evaluations_transfer_RoHS_I_RoHS_II_final.pdf

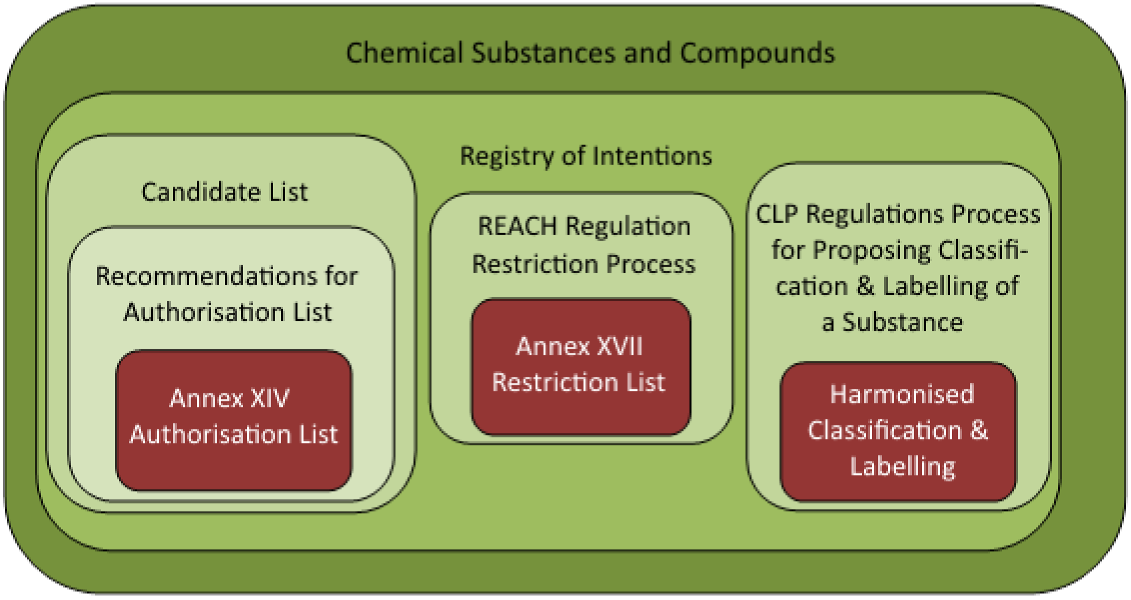
7 Gensch, C., Baron, Y., Blepp, M., Deubzer, O., Manhart, A. & Moch, K. (2012) Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive), Final Report, Oeko-Institut e.V. and Fraunhofer IZM, 21.12.2012 http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/RoHS_V_Final_report_12_Dec_2012_final.pdf

For further reports, see archive of reports of Oeko-Institut e.V. and Fraunhofer IZM at http://rohs.exemptions.oeko.info/index.php?id=164

8 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.[9] 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).[10] 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

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

10 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 April 2020, the consolidated version of the REACH legal text, dated 28.04.2020, 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:02006R1907-20200428. Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

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

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

ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DiBP).[11]

Compiled information in this respect has been included, with short clarifications where relevant, in Tables 1 and 2, which appear in Appendix 1.

The information has further been cross-checked in relation to the exemption evaluated in the course of this project. This has been done to clarify that the Article 5(1)(a) threshold-criteria quoted above is complied with in cases where an exemption is to be granted / its duration renewed / its formulation amended / or where it is to be revoked and subsequently to expire as an exemption. The considerations in this regard are addressed in the separate chapter in which the exemption evaluation is documented (Chapter 5 and 7) under the relevant section titled "REACH compliance – Relation to the REACH Regulation" (Section 5.5.1 through Section 7.5.1).

[11] 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. Request for partial renewal of exemption 27 of Annex IV

The current wording of exemption 27 of Annex IV is as follows:

"Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in

(a) magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or

(b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy."

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

COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
EEE	Electrical and electronic equipment
EoL	End of life
LSFI	Large scale fixed installations
Lead-free	Describing the status where lead is substituted and/or eliminated in the applications in scope of exemption 27
MD	Medical devices
OEM	Original equipment manufacturer
RF	Radio frequency
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment

5.1. Background and history of the exemption

Exemption 27 of Annex IV was originally applied for by COCIR (2011) in 2011 who claimed that "The time required could be as much as nine years" to find lead-free solutions. The Commission followed the recommendation of the evaluators Gensch et al. 2012 and granted the exemption as exemption 27 of Annex IV for seven years from 2014 on with the below wording.

> "*Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in*
> *(a) magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or*
> *(b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy*."

In 2019, COCIR (2019 a) applied for the continuation of the exemption for another seven years from the current expiry date on 30 June 2020 until 30 June 2027, however without part b) of the current exemption:

"Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere."

5.2. Technical description of the requested exemption

Gensch et al. 2012 describe in detail the technical background of the requested exemption.[12]

5.2.1. Amount of lead used under the exemption

The lead is used in tin-lead solders with a 37 % share of lead. COCIR (2019 a) indicate the use of lead in solders benefiting from the exemption at around 200 kg per year in the EU, even though no accurate total is available. COCIR (2019 a) substantiate the estimated total stating that MRI manufacturers estimated 100 kg in 2006. Assuming that the market size of MRI coils and circuits using lead solder has doubled since 2006, results in the 200 kg of lead per year in the EU.

This figure is not congruent with COCIR's earlier estimates in the initial application for this exemption. The report of Gensch et al. 2012 indicates an estimated 250 kg of lead used in 2011 already. COCIR (2020 a) put forward the significant uncertainty over the amount of lead used because MRI manufacturers do not measure the quantity of

12 C.f. Gensch et al. 2012 page 79 et sqq, https://circabc.europa.eu/sd/a/42ccb088-4c26-4e3a-8a0c-218ea738964c/RoHS_V_Final_report_12_Dec_2012_Final.pdf

solder that they use. MRI manufacturers can only make estimates, and these vary depending on when these estimates are made so that 200 kg and 250 kg are both within the margins of uncertainty.

It can be assumed that the lead use under the exemption is probably in the range of several hundred kilograms.

5.3. Applicant's justification for the requested exemption

COCIR (2019 a) explain that lead solders are used for the following reasons:

- Components used within 1 m around the isocentre of magnets in MRI devices, cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy must be free of magnetic materials, which would distort the image quality. Such components can therefore not contain nickel, which is magnetisable. Soldering with lead-free solders to such nickel-free surfaces does not yield reliable solder bonds.
- Lead-free solders for component coatings and solder joints are prone to tin pest if put into cold environments like e.g. in or close to coils of MRI devices. This severely affects the reliability of the solder joints.

Therefore, several applications require the use of lead-free solders:

- Lead in solders used for making connections to non-magnetic components in separately supplied MRI radio frequency (RF) send and receive coils that are used with MRI for imaging specific parts of patients' bodies
- Lead in solders used for making connections to non-magnetic components in body and posterior coils that are integral to MRI
- Lead in the solderable coatings of non-magnetic electronic components used in the superconducting magnet assembly and ancillary equipment

The detailed justification COCIR (2011) provided in 2011 for this exemption in the report of Gensch et al. (2012a)[13] still reflects the current technical situation[14] according to COCIR.

5.3.1. Substitution or elimination of lead

COCIR (2019 a) explain that patients in an MRI device are exposed to a very powerful magnetic field. "RF [radio frequency, note of the consultants] send and receive coils" are located around the patient and inside the magnetic field. These coils transmit RF signals which excite magnetised protons in the soft tissue of the patient and the protons then emit characteristic signals that are received and measured by these coils.

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13 C.f. Gensch et al. 2012a, page 83 et sqq.

14 See also COCIRs exemption request submitted 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_9/9_COCIR_-_Exemption_request_-_Lead_solder_magnetic_field.pdf

Necessity to use non-magnetic materials and components

COCIR (2019 a) highlight that one of the essential characteristics of the coils and the electronic circuitry that is connected to each coil is that these must be non-magnetic because any magnetic materials degrade the weak RF signals resulting in distorted MRI images. Magnetic metals such as nickel, even in very small electronic components, can have a magnetic susceptibility that is sufficient to degrade the image quality reducing the ability to detect small features such as tumours or blood clots. The types of electronic components used in MRI devices are essentially the same as those used in other electrical equipment such as discrete components like capacitors, inductors and resistors. However, COCIR explains that the components used are, however, special “non-magnetic” versions of discrete components like capacitors. The most common termination coating used for standard electrical components in most electrical products is tin electroplated over a nickel-plated barrier layer on a copper or copper alloy lead-frame. Nickel barriers prevent the inter-diffusion between the thin tin coating and copper substrate during storage where tin and copper would react to form an unsolderable copper-tin intermetallic phase. However, nickel is strongly ferromagnetic and so usually cannot be used within the region of the RF coils or close to the electromagnet.

According to COCIR (2019 a), components used for MRI within the magnetic field or connected to send and receive coils need to be soldered to create the electronic circuits and so components having nickel-free solderable coatings need to be used. These non-magnetic components are manufactured specifically for MRI devices and similar applications. The choice of terminal materials is very limited as the metal used for the outer surface must be wetted by solder easily and quickly to form a reliable bond, but must not degrade during storage of the components before their use so that soldering becomes impossible. COCIR (2019 a) reference their 2011 exemption application describing the difficulties and unreliable results when using lead-free solders on non-magnetizable, nickel-free components.

Table 5-1: Properties of lead and lead-free coating materials

Coating material	Advantages and disadvantages
Tin (Sn)	Good solder wetting properties but susceptible to tin whiskers if deposited onto copper without a nickel barrier layer. Not recommended by iNEMI[2]. Very low magnetic susceptibility.
Tin/lead (Sn/Pb)	Good solder wetting, resistant to tin whiskers without nickel barrier layer. Lead also has a very low magnetic susceptibility.
Tin alloys: Tin/copper, tin/silver and tin/bismuth alloys	Susceptible to tin whiskers especially tin/copper. iNEMI recommends tin/silver and tin/bismuth should be used only with nickel barrier layers. SnAg coatings are not thoroughly researched and SnBi has diamagnetic properties that may affect sensitivity.
Gold (Au)	Cannot be deposited as thin coatings on copper as interdiffusion occurs resulting in copper at the surface which oxidises and then cannot be easily soldered. Thick gold coatings cannot be used as gold forms a very brittle intermetallic compound with tin (with all types of tin based solders) which causes rapid bond failure.
Silver (Ag)	Low magnetic susceptibility but tarnishes during storage becoming unsolderable. Also suffers from fairly rapid interdiffusion with copper (see gold above).
Silver/palladium (Ag/Pd)	Applied as thick film material instead of copper and avoids need for an outer coating. Solder wetting is however inferior and there is a risk of weak solder bonds. Palladium also has a relatively high magnetic susceptibility and tests have shown that components with Ag/Pd terminations give inferior sensitivity of the MRI image. The magnetic susceptibility of components with AgPd is about three times that of tin plated copper.
Copper	Very low magnetic susceptibility but cannot be used without a coating of an oxidation resistant solderable material such as tin or tin/lead because it rapidly oxidises and becomes unsolderable. Copper readily diffuses into tin, gold and silver and so nickel barriers are used when magnetic properties are not important. Electroplated tin deposited onto copper is more susceptible to tin whiskers than where a nickel barrier layer is used.

Source: COCIR (2011) referenced by COCIR (2019 a)

Replacement of discrete components

COCIR (2019 a) explain that since 2014 manufacturers of MRI devices have carried out research to replace lead solders and only recently have been able to produce a small number of coil designs without lead solders by not using discrete components. One approach that is being used by manufacturers is to redesign coils using flexible laminate without discrete components and so avoiding the need for soldering. This possible approach is to incorporate passive components such as capacitors into flexible laminates by screen printing thick-film dielectrics. This avoids the reliability concern over soldering to discrete non-magnetic components as the capacitors are screen- or stencil-printed directly onto the circuitry.

According to COCIR (2019 a), this research showed that it is not possible to simply replace discrete components with printed dielectric materials because the dimensions and electrical characteristics of printed dielectrics are different to discrete capacitors. Therefore, every coil would need to be redesigned to develop "lead-free" versions. To redesign one type of coil, test for reliability, carry out clinical trials and gain Notified Body approval requires very significant effort from trained engineers.

Limitations of time and skilled workers for coil redesign

COCIR (2019 a) state that each MRI manufacturer offers hospitals a very large number of different coil types which are required for imaging different parts of the body. One manufacturer currently supplies over 130 different types of coils. The number of skilled engineers globally who are able to redesign coils, carry out testing, clinical trials and apply for Notified Body approval is very limited. MRI manufacturers can either increase the numbers of engineers by poaching from competitors, who would then have fewer resources for substitution research, or train more employees, which will take many years, probably more than 10, and these new employees will not have the same experience as existing engineers. MRI engineers are also required to develop new products and solve manufacturing issues when they arise as well as work on substitution so that more effort on substitution can only be made at the detriment of new medical diagnosis developments and this would have a negative impact on healthcare in the EU.

Legal aspects

COCIR (2019 a) say that the current range of coils will also be needed as replacement spare parts for MRI devices that are placed on the market while exemption 27 is in effect. These replacement spare parts would, however, be excluded from RoHS by Article 4(4)(f). Nevertheless, hospitals will also want to buy additional new coils to use with their MRI, which are not replacements, and so these coils would need this exemption.

5.3.2. Environmental arguments and socioeconomic impacts

Delaying product innovations and development

COCIR (2019 a) is afraid that diverting MRI engineers away from new product development to changing existing coil designs would negatively affect future health of EU citizens. This is because the only reason for development of new medical devices is to produce new designs with superior diagnostic capability. In the example of MRI, recent innovations have been to develop digital coils to replace analogue ones. One manufacturer claims that digital coils have 40 % better signal to noise ratio than analogue designs.[15] This type of improvement in performance results in clearer images that enable doctors to be able to detect tumours and other harmful conditions much earlier and this improves the likelihood of recovery and recovery is likely to be faster and so incur smaller costs to hospitals. This type of development would not be possible if the engineers were diverted to redesign existing products for compliance purposes, but without performance improvement. Quantitative life cycle comparison of

[15] C.f. https://www.philips.co.uk/healthcare/education-resources/technologies/mri/dstream

the two scenarios of a) developing new medical devices, or b) replacing lead in current designs, is not possible as the positive and negative impacts of each scenario are not directly comparable with each other and some impacts are for hypothetical future developments and so cannot be quantified.

Table 5-2: Impacts of focussing on development of new products vs. redesigning current lead-soldered coils

Impact	New medical devices	Replace lead
Mining, refining and production of materials	Impossible to quantify as materials of new designs will be product dependent. however, new products should usually have a smaller overall impact to older designs because medical device manufacturers try to avoid using hazardous substances in new designs as required by Medical Device Regulation standards.	Alternatives to lead are not benign. The US EPA comparison of lead solders with lead-free solders showed that the impacts overall were different and that neither could be determined to be superior.[16]
Use phase	Fewer deaths, faster recovery, lower hospital costs. Number of each will be product dependent, however, it is usually impossible to quantify as there are so many variables that also affect these variables as well as the effect of a new design.	No impact, unless the substitute is less reliable then patient health would be negatively impacted
End of life	All medical devices are collected and recycled as required by the WEEE directive. As medical devices such as MRI are used only by professionals, 100 % are likely to be recycled. The impact of recycling new products is likely to be similar to older designs although there may be a smaller overall impact as manufacturers try to avoid hazardous substances in new designs.	Recycling of coils is carried out for metals recovery using smelters. This process is designed to accept a wide variety of materials (apart from circuit boards) including lead which is safely recovered with emissions very closely controlled to comply with the EU Industrial Emissions Directive. Therefore, the comparative impact of recycling coils with lead or without lead is likely to be very small.

Source: COCIR (2019 a)

COCIR (2019 a) sum up their overall result from the three life cycle phases for the above options in the below Table 5-3.

16 https://www.epa.gov/sites/production/files/2013-12/documents/lead_free_solder_lca_summary.pdf (as referenced by the applicant)

Table 5-3: Overall result of the comparison

Impact	New medical devices	Replace lead
Mining, refining and production of materials	Potential positive benefit	Neutral according to US EPA
Use phase	Potentially a very large positive benefit	No effect or slightly negative
End of life	Potential positive benefit	Neutral or slightly positive

Source: COCIR (2019 a)

Although COCIR (2019 a) deems it impossible to compare quantitatively the development of a hypothetical new medical device with replacement of lead solders in coils, it appears that new medical device development would give a significant overall health and environmental benefit compared to lead substitution in existing medical devices. COCIR claim that this result is probably unique to medical devices where new products are designed to save lives and cure illnesses.

Impact on EU healthcare in case the exemption is not continued

COCIR (2019 a) declares that the practical inability of manufacturers to redesign all RF coils and other parts of MRI to replace lead solders for the reasons explained above would mean that EU hospitals cannot buy all of the types of coils that they will need after exemption expiry. As a result, medical staff will not be able diagnose illness of their patients using MRI which is the best and often the only diagnostic technique available. If tumours, blood clots, the causes of strokes, etc. cannot be diagnosed using MRI, patients could at worst die and, at best, their treatment would be severely delayed. This is one of the main justifications for this exemption, but other reasons as explained above should also be considered.

5.4. Stakeholder contributions

No stakeholder contributions were received.

5.5. Critical review

5.5.1. REACH compliance – Relation to the REACH Regulation

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

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV as an element. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by*" the REACH Regulation.

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

- Lead chromate – used in printing inks, paints and to colour vinyl, rubber and paper[17];
- Lead sulfochromate yellow – used as a pigment, a dye and as a paint and coating additive[18];
- Lead chromate molybdate sulphate red – understood to be used as a pigment;

As the exemption for lead in solders used within the scope of the requested exemption does not regard pigments nor substances used in paints and dyes, it is concluded that a renewal of the exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

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

- Entry 16 restricts the use of lead carbonates in paints;
- Entry 17 restricts the use of lead sulphates in paints;
- Entry 19 refers to arsenic compounds but includes a few lead compounds and restricts their use as a fouling agent, for treatment of industrial water or for treatment of wood;
- Entry 63 restricts the use of lead and its compounds in jewellery and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children;
- Entry 28 and entry 30 stipulate that various lead compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;
- Entry 72 stipulates that various lead compounds shall not be used in clothing.

The exemption for lead in solders used within the scope of the requested exemption does not regard paints or jewellery, nor components that could be expected to be placed in the mouth by children under normal or foreseeable use. Furthermore, the use of lead in solders in the scope of the requested exemption is not a supply of lead compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, entry 28 and entry 30 of Annex XVII of the REACH Regulation would not apply. It is concluded that a renewal of the exemption would not weaken the protection afforded by REACH through entries 16, 17, 19, 28, 29, 63 and 72.

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

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

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status March 2020). Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

5.5.2. Legal aspects – coils as spare parts

COCIR base the justification for the renewal of this exemption to a large part on the fact that MRI devices that are already placed on the market need to be supplied with coils. COCIR (2020 a) negate that supplying coils to such MRI devices could be in compliance with Art. 4(4), which allows the use of *cables* or *spare parts* for

- the repair,
- the reuse,
- the updating of functionalities or upgrading of capacity

for the following EEE relevant in the context of this exemption request:

- medical devices placed on the market before 22 July 2014
- EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

According to Art. 3(27), "'spare part' means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part".

COCIR (2020 a) explains that faulty coils may be replaced. Hospitals, however, purchase sets of coils according to the kind of examinations they need to perform, and they can always expand their capabilities by buying new ones for other body parts. These additional coils are not replacements and Art. 4(4)(a) is not applicable. COCIR (2020 a) further point out that exemption 27 is also needed for other lead-free circuits of MRI as well as coils.

According to COCIR (2020 a), MRI devices are constructed to apply different coils, which, however, must not all be actually contained in the device, meaning there is space left for additional coils if needed. Actually, MRI scanners are supplied without coils as these are sold separately to hospitals. Each type of coil is plugged into the MRI scanner when it is being used and then disconnected. Coils are located adjacent to the patient's body or limbs and connected by wires to the scanner. They are stored elsewhere when not needed, far from the MRI as they could interfere with the image quality. Coils are very different in shape and function, from endorectal coils to full body coils.

5.5.3. Scope of the requested exemption

The current exemption 27 of Annex IV consists of a part a) and a part b). COCIR (2019 a) request the continuation of the exemption without part b). To exclude misunderstandings, the applicant was asked for the reason. COCIR (2020 a) explain that, when the exemption was initially requested, the scope of the RoHS Directive was not yet clear, in particular the definition of "*large scale fixed installation*" (LSFI). When COCIR applied for this exemption in 2011, they extended the scope of the exemption also to particle therapy installations. Given the interpretation of LSFI in the RoHS 2 FAQ[19]-document published in December 2012, COCIR (2019 a) were confident that particle therapy installations, that weigh several hundred tons, are LSFI and therefore out of the scope of the RoHS Directive. They therefore decided to drop the corresponding part b) of the exemption wording.

5.5.4. Scientific and technical practicability of substitution or elimination

According to COCIR (2019 a), manufacturers of MRI devices only recently have been able to produce a small number of coil designs without lead solders by avoiding the use of discrete components, c.f. section 5.3.1 on page 25. According to COCIR (2020 a), these coils have completely different, new designs, and they do not require exemption 27. COCIR (2020 a) state that the exemption will not be needed anymore once enough new lead-free coils will be available for all applications and all MRI models installed. According to COCIR (2020 b), all new coils, whether digital or analogic, will transition to lead-free solutions. Currently, lead-free coils are still a small percentage of the total needed by EU hospitals to keep providing healthcare.

As to substitution or elimination of lead in MRI devices other than coils, COCIR (2019 a) claim that the use of lead is unavoidable because

- using lead-free solders with non-magnetic components and low temperatures gave poor and unsatisfactory reliability;
- not all components are available as non-magnetic and lead-free solderable types;
- MRI circuits close to the magnet suffer from severe vibration;
- Alternative bonding techniques to eliminate lead are not viable.

The applicant was asked why the technical approach applied for lead-free coils by using printed components cannot be used for MRI circuitries as well to eliminate the use of lead solders in the scope of exemption 27. COCIR (2020 b) replied that coils use relatively few types of components and new designs can be made with greatly reduced numbers of solder bonds and both of these changes enable greater reliability of coils. MRI circuits are highly complex with large numbers of electronic components and solder bonds. Non-magnetic components such as inductors, electrolytic capacitors, diodes or transformers cannot be integrated in the coils. COCIR (2020 b) highlight in this context that in particular semiconductors are usually not produced as non-magnetic versions as only a few applications, such as MRI and NMR, require such non-magnetic components (very small number of applications).

[19] RoHS 2 FAQ, 12 December 2012, https://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf

Since the manufacturers explained that they can produce all new coil designs using lead-free solders and finishes, the consultants asked COCIR whether the new lead-free coils use semiconductors and, if so, how the use of lead could be avoided nevertheless.

COCIR (2020 c) explain that coils have to be differentiated in integrated and non-integrated coils. Integrated coils are part of the MRI device like a component, they cannot be purchased separately. They are designed together with the MRI device and thus to be redesigned to lead-free soldering independently from the rest of the MRI device. The above-described successful efforts to produce lead-free coils therefore refer to non-integrated coils.

COCIR (2020 c) state that these integrated coils contain at least one semiconductor, and that the approaches used for these coils actually can be used for MRI equipment circuitry other than non-integrated coils. Harmful interference of semiconductors and magnetic components with image quality is avoided by minimizing the amounts of nickel, by careful component selection and by circuit design, followed by extensive testing. For example, if small amounts of magnetic material are spaced evenly around the magnet, their effect can be cancelled out. Capacitors, resistors and inductors are only recently available as non-magnetic lead-free solderable versions and so these are now being used. Due to the greater complexity of MRI circuitry in comparison to non-integrated coils, as well as environmental effects of low temperatures and severe vibration, the transition to lead free requires more time to complete than for the non-integrated coils.

Concerning the timeline, COCIR (2020 c) say that designing of new lead-free models of MRI has been underway since about 2014, and has been undergoing system testing. The next step is reliability testing of the new MRI designs which should be starting soon and is expected to take two to three years if no failures are found. If this testing identifies poor reliability, further redesign work would be needed followed by more testing. Non-magnetic components that could be soldered with lead-free solders were not available in 2014 when exemption 27 was originally granted, so this work could not start earlier.

5.5.5. Environmental arguments and socioeconomic impacts

COCIR's arguments related to the socioeconomic impacts of not granting the continuation of the exemption in section 5.3.2 on page 28 are plausible.

New MRI devices cannot be placed on the market without exemption 27 before lead-free solutions are available, which is not achieved by June 2020, when the exemption expires. A supply gap would occur after June 2020 for MRI devices.

If the exemption is not granted, the legal situation that coils do not comply with the definition of spare parts would not allow supplying MRI devices in the current stock with coils unless they replace defect coils in MRI devices which were placed on the market prior to the exemption's expiry. The usability of the MRI devices would be restricted, and hospitals and other entities operating MRI equipment would have to buy new MRI devices prematurely – which, however, would not be available either if exemption 27 is not granted - if they cannot extend their range of MRI examination possibilities with new coils. According to COCIR (2020 d), purchasing a new MRI device requires an investment at least 1.5 million EUR and up to 3 million EUR for the most common models. From up to 3 Tesla to 7 or 9 Tesla prices can be several times higher, but those are quite uncommon.

The consultants can follow the argument that supply gaps may occur without exemption 27 being renewed, and that patients' health and even lives could be endangered. These supply gaps can, however, be avoided even if exemption 27 is restricted in scope provided the timing of scope exclusions is aligned to the technical development schedules of new design lead-free coils and MRI devices.

5.5.6. 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.

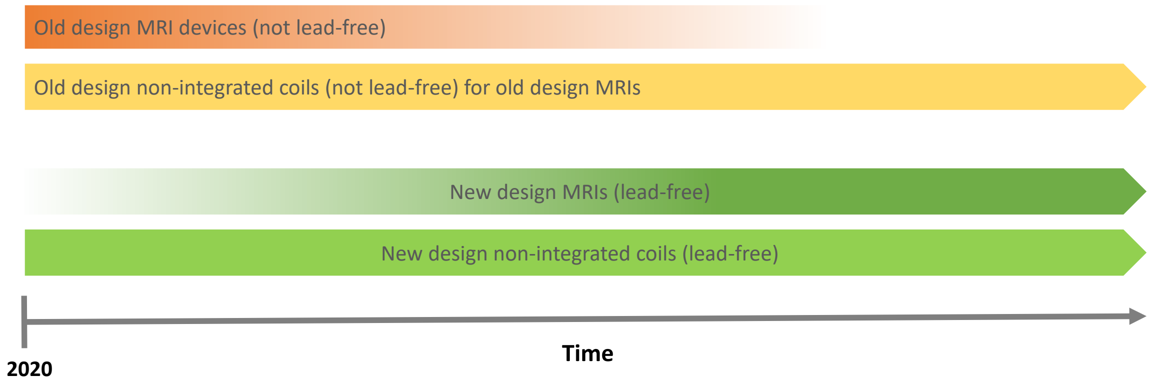
From the information provided by the applicant it can be concluded that substitution and elimination of lead for the applications in scope of the requested exemption 27 are scientifically and technically practicable for non-integrated[20] coils and for MRI devices including their integrated coils. This applies, however, only for non-integrated coils and MRI devices which are newly designed to facilitate lead-free solder use or otherwise eliminate the use of lead.

Exemption 27 is still required for old design non-integrated coils. Since non-integrated coils do not comply with the legal definition of "spare part" in Art. 3(27), supplying hospitals with these coils for their old design MRI devices would not be possible if the exemption is not renewed. These old design MRI devices cannot use new design lead-free non-integrated MRI coils.

Further on, exemption 27 is also required to secure the supply of MRI devices for the EEA market until all models are redesigned and can thus be made RoHS compliant without exemption 27. Design, testing and qualification, and approval by Notified Bodies for these lead-free models will still require time. Once all models of lead-free MRI devices are approved by Notified Bodies, producers can place their full range of MRI devices on the market and supply gaps will not occur. Exemption 27 will then no longer be needed for MRI devices, but only for the non-integrated coils to secure the continued supply for the older design MRI devices which are operated in hospitals and other medical entities. Figure 5-1 illustrates the situation.

[20] MRI devices contain integrated coils which follow the redesign cycles of the MRI device and therefore have to be differentiated from the non-integrated coils.

Figure 5-1: Placing on the market of lead-free MRI devices and lead-free non-integrated coils



Given the fact that substitution and elimination of lead are scientifically and technically practicable, the continuation of exemption 27 in its current wording and scope might infringe Art 5(1)(a), which requires restricting the scope of exemption 27 at least to those applications where substitution and elimination of lead are practicable and avoid endangering human health and lives.

Exclusion of newly designed non-integrated coils from the exemption scope

COCIR (2020 e) explain that the newly designed non-integrated ones do no longer depend on exemption 27. The applicant and the consultants therefore agreed to restrict exemption 27 to older coil designs and to exclude newly designed non-integrated coils from the scope of exemption 27:

> *Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors of MRI non-integrated coils with a certification issued by a notified body before 30 June 2020.*

To enable a clear differentiation between the old and new design non-integrated coils, the related dates of first certification can be used. Non-integrated coils as well as MRI devices including their integrated coils need a certificate by a notified body before they can be placed on the market according to *Directive 2006/42/EC (Medical Device Directive) or Regulation (EU) 2017/745 (Medical Device Regulation)*. The date of the first certification can therefore serve as a clear point in time to exclude newly designed, lead-free non-integrated coils from the scope of exemption 27. The Medical Device Directive, according to COCIR (2020 e), will be repealed and replaced by the Medical Devices Regulation. Since the Medical Device Regulation requires re-approval of non-integrated coils that have already been approved under the Medical Device Directive, and because certificates have to be renewed periodically, it is important to use the date of the first certification.

Non-integrated coils with a certification date after June 2020 will thus be excluded from the scope of exemption 27, while non-integrated coils with an earlier certification date secure the supply to MRI equipment which is being operated in hospitals and which can only operate with the older design non-integrated coils. The severe socioeconomic impacts described further above can thus be avoided despite of the exemption scope restriction.

Exclusion of newly designed MRI equipment including integrated coils from the exemption scope

For MRI equipment other than non-integrated coils COCIR (2020 e) stated that two to three years are required to test newly designed lead-free models assuming the tests are positive. Otherwise, more time might be needed. Certification would require additional time in both cases. MRI devices use integral body coils for whole body scans, which are useful for detecting secondary tumours. The integrated coils are covered by the MRI scanner's CE marking and certification. Those coils' design and the materials used are chosen at the beginning of the MRI lifecycle when the new MRI scanner is designed. Integral coils thus are like components of MRI scanners. Hospitals cannot buy integrated coils as they are not sold separately except as replacement spare parts to repair faulty integrated coils.

To exclude newly designed lead-free MRI equipment other than non-integrated coils from the exemption scope, the date of the first certification is proposed to be used like for the non-integrated coils. Given the above timelines, it was agreed with the applicant to set the date of first certification of 30 June 2024. MRI equipment other than non-integrated coils certified after June 2024 would be excluded from the scope of exemption 27.

The below table shows the resulting exemption wording, with part d) reflecting the exclusion of MRI equipment including the integrated coils:[21]

Exemption		**Dates of applicability and comments**
27	*Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors*	Expiry on 30 June 2027 **Certification means a DoC was released for the first time for the product type (not on a serial number level) under either Directive 93/42/EC (Medical Device Directive or Regulation (EU) 2017/745 (Medical Device Regulation), whichever occurs first.*
c)	*of MRI non-integrated coils with a certification* issued by a notified body before 30 June 2020.*	
d)	*in MRI equipment including integrated coils, which are used in-magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment with a certification* issued by a notified body before 30 June 2024.*	

[21] The current exemption 27 of Annex IV already has a part a) and b) so that the revised wording could be added as part c) and e).

As to the above exclusion of serial number level certificates, COCIR (2020 h) explain that the "product type" is not clearly defined and could therefore erroneously be interpreted as referring to serial numbers of products which would mean that the exemption would expire in July 2020.

The proposed rewording of exemption 27 was elaborated in cooperation with the applicant in several discussion rounds. COCIR (2020 g) wanted to provide further input related to this wording, which, however, could not be received within the available time frame. COCIR (2020 i) stated that it was not possible to find an agreement between companies in the available time frame. Experts are taking into account the Medical Device Directive (MDR) and are looking for a wording that is 100 % MDR and RoHS compliant. COCIR (2020 i) therefore agree to proceed with the above wording with the caveat that further in the exemption evaluation process, an amended wording might be proposed to the European Commission.

Setting the expiry date

From July 2024 on, lead-containing MRI devices with the first certification date after 30 June 2024 can no longer be placed on the EEA market. From this time on, step by step new design lead-free MRI models are supposed to have passed the test and validation phase, and the certification by Notified Bodies. It will, however, take time until the producers can offer their entire MRI model portfolio with these new lead-free designs to hospitals and other customers. COCIR (2020 a) stated that the number of skilled engineers globally who are able to redesign, carry out testing, clinical trials and apply for Notified Body approval is limited and cannot be increased easily, which limits the pace of designing new types and models of MRI equipment which can replace the older ones. In this transition period, old design MRI models with certification before July 2024 can still be placed on the market to fill supply gaps for MRI models which are not yet available with new designs.

COCIR (2020 f) expect that by 30 June 2027, manufacturers will be in a position to offer their full product portfolios with the new lead-free designs, or might otherwise apply for the continuation of the exemption. After June 2027, the exemption may no longer be needed for MRI devices. The consultants therefore recommend granting the exemption for seven years until 30 June 2027.

After June 2020, lead-soldered non-integrated coils in the scope of part c) with the first certification date before July 2020 can still be placed on the market until the exemption expires in June 2027. They will be required to secure the supplies for the older MRI models that are already placed on the market. Non-integrated coils with a certification date after June 2020 must be lead-free and can otherwise no longer be placed on the market.

5.6. Recommendation

The consultants recommend continuing the exemption with a changed wording and a narrowed scope. Substitution and elimination of lead are scientifically and technically practicable for newly designed MRI equipment and coils so that Art. 5(1)(a) requires excluding these devices from the exemption scope. To ensure the supplies of EU hospitals with MRI equipment and non-integrated coils are not interrupted, the consultants recommend a transition period for devices with first certifications prior to certain dates. The consultants agreed on the following new wording with the applicant:

Exemption		**Dates of applicability and comments**
27	*Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors*	Expiry on 30 June 2027
c)	*of MRI non-integrated coils with a certification* issued by a notified body before 30 June 2020.*	**Certification means a DoC (Document of Conformity) was released for the first time for the product type (not on a serial number level) under either Directive 93/42/EC (Medical Device Directive or Regulation (EU) 2017/745 (Medical Device Regulation), whichever occurs first.*
d)	*in MRI equipment including integrated coils, which are used in-magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment with a certification* issued by a notified body before 30 June 2024.*	

The consultants recommend the expiry date 30 June 2027, which is the maximum seven years. All MRI equipment placed on the market after the expiry date of the exemption will have to be RoHS-compliant without applying exemption 27, regardless of its date of first certification. By then, all types and models of MRI equipment produced under exemption 27 in the manufacturers' product range must be replaced by newly designed lead-free ones to secure the supply of equipment for the EU market.

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7. Request 2019-3

"Lead in bismuth lead strontium calcium copper oxide superconductor cables and wire and lead in electrical connections to these wires"

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

Bi2212	a phase of BSCCO
Bi2223	optimum superconducting phase of BSCCO
BSCCO	bismuth strontium calcium copper oxide
EEE	electrical and electronic equipment
EoL	End of life
Gd123	a specific material phase of GdBCO
GdBCO	gadolinium, barium and copper as mixed oxides; type of REBCO
HTS	high temperature superconductor
K	Kelvin, temperature, 0 K is equivalent to around 273.15 °C
JASTEC	Japan Superconducting Technology Inc.
LBSCCO	lead-doped BSCCO
LBi2223	lead-doped Bi2223
LTS	low temperature superconductor
MgB_2	magnesium boride
MRI	magnetic resonance imaging
Nb_3Sn	Niobium-tin (superconducting material)
NbTi	Niobium titanium (superconducting material)
NMR	nuclear magnetic resonance

Ramp-up	Operation of first start or restart of an MRI device after e.g. repairs with interruption of the magnetic field to achieve full operation
RoHS	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment (RoHS 2)
T	Tesla, unit for magnetic flux density/field strength; also used for temperature
T_C	critical temperature, temperatures below which a material becomes superconducting
Sumitomo	Sumitomo Electric Industries, Ltd, applicant
YBCO	Yttrium, Barium, Copper oxide as mixed Oxides, type of REBCO
YGdBCO	Yttrium, Gadolinium, Barium and Copper as mixed Oxides; type of REBCO

Definitions

Critical current density J_C	electrical current above which a superconducting material loses its superconductivity
Critical field strength H_C	maximum magnetic field strength below which a material maintains its superconducting properties
Critical temperature T_C	temperature below which a material becomes a superconductor
Current density	electric current per unit area of the cross section of a conductor

7.1. Background

Sumitomo (2019 a) manufacture superconductor cables and wires, and superconducting coils and magnets. They use a superconducting bismuth strontium calcium copper oxide (BSCCO) material with small additions of lead (lead-doping) for manufacturing, among others, superconducting magnets, coils and cables for nuclear magnetic resonance imaging (MRI), nuclear magnetic resonance (NMR) devices.

Sumitomo (2019 a) therefore requested the following new exemption for this material:

„Lead in bismuth lead strontium calcium copper oxide superconductor cables and wire and lead in electrical connections to these wires"

The exemption is requested to be added to RoHS Annex IV and to be valid for the seven years maximum validity period.

7.2. Technical description of the requested exemption

7.2.1. Uses of lead-doped BSCCO superconducting wires

Sumitomo (2019 a) state that superconducting electromagnets achieve superior resolution and sensitivity, which are especially important for NMR and MRI. The resolution e.g. of NMR spectra is proportional to the magnetic field, the sensitivity generally proportional to the magnetic field to the power of 3/2.

NMR spectral analysis of very large complex molecules such as proteins is only possibly with the very high resolution achieved by superconducting electromagnets. Spectra of very low concentrated substances also can only be obtained by powerful superconducting electromagnets.[22]

According to Sumitomo (2019 a), lead-doped bismuth strontium calcium copper oxide (**L**BSCCO, **L**Bi2223) superconducting wires can or will be used in various devices:[23]

- Powerful electromagnets for NMR spectrometers (RoHS category 9) -
  Increasing the magnet's field strength enables the spectrometer to analyse more complex molecules such as protein's dissolved in water, which cannot be analysed using conventional NMR spectrometers.[24] These spectrometers are likely to be the first commercial electrical equipment placed on the EU market to use LBi2223 and these can be sold in the EU as soon as this exemption has been granted.
- Powerful magnets for MRI devices (RoHS category 8) -
  Increasing the field strength of medical and veterinary MRI electromagnets increases the image quality so that smaller features can be visualized.[25] Clearer images will also enable health professionals to more accurately determine what type of feature, such as a tumour etc., is being examined. This is clearly a benefit for detection of small tumours, damage to small blood vessels, etc. allowing more accurate and earlier diagnosis and treatment.
- Analytical equipment -
  Analytical equipment that utilises Bi2223 superconducting coils to measure the characteristics of magnetization and other properties of magnetic materials.[26] These instruments are commercially available in Japan and could be sold in the EU when this exemption is granted.

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22 This is illustrated by the increase in spectral detail obtained by increasing from 42.5 MHz to 300MHz at http://www.process-nmr.com/WordPress/?p=388: reference as cited by the applicant

23 "Research, Fabrication and Applications of Bi-2223 HTS Wires", edited by K. Sato, World Scientific Series in Applications of Superconductivity and Related Phenomena, Vol I. Published by World Scientific Publishing Co. Pte. Ltd, 2016, ISBN 978-981-4749-25-1. Reference as cited by the applicant

24 "Recent Developments in High-Temperature Superconducting Magnet Technology (Review)", Hideaki Maeda and Yoshinori Yanagisawa, IEEE Transactions on Applied Superconductivity, Vol. 24, No. 3, June 2014; reference as cited by the applicant

25 This is clearly illustrated for an increase from 3 T to 7 T by the images from https://www.news-medical.net/news/20160712/Increasing-access-to-MRI-scanning-an-interview-with-Jane-Kilkenny.aspx

26 B-H curve tracer https://www.j-ndk.co.jp/product/jikisokutei/bh_curve_tracer.html#sub_03 and a High Temperature Superconducting Type of Vibrating Sample Magnetometer http://www.toeikogyo.co.jp/english/products/sei-01/vsm-5hsc.html; reference as cited by the applicant

- The windings of electric motors -
  Some uses of motors, such as in electric vehicles and in ships would be excluded from RoHS as these are forms of transport, but other uses may be in scope.
- Cables rated at 250 V and less -
  Such cables are in scope of the RoHS Directive. Superconducting power cables rated at more than 400 V may be used in data centres or for other applications.
- Electromagnets for the controlled melting of silicon in single crystal manufacture -
  This equipment is usually deployed in production lines which will be regarded as large-scale fixed installations, but smaller scale equipment used for research or small-scale batch production may be in scope of RoHS.

Sumitomo (2019 a) further explain that at present, the smallest magnetic field strength for which Bi2223 is likely to be used in electromagnet coils of NMR is 9.4 T. The smallest magnetic field strength for MRI, for magnetic field strength measurements, etc. is 1.5 T. If there are shortages of helium in the future, lower field strength magnets may need to also use Bi2223 electromagnets as these can operate without liquid helium as a refrigerant, but Bi2223 is not likely to be used for MRI of less than 1.5 T.

Devices which are already available, but cannot be placed on the EU-market without the requested exemption, are analysis equipment measuring characteristics of magnetization as well as other properties of magnetic materials, i.e. a B-H curve tracer[27] and a high temperature superconducting type of vibrating sample magnetometer[28].

7.2.2. Crucial properties of superconductors and solders

Crucial properties of wires, coils, and solders used in superconductors

Sumitomo (2019 a) list the requirements which wires, and coils made with these wires, must meet to construct reliable superconducting electromagnets:

- It must be possible to fabricate the material into flexible superconducting wire with sufficient tensile strength;
- Wires must be sufficiently strong and have sufficient current carrying capacity for compact electromagnet coils;
- Wires and coils should exhibit insignificant magnetic field distortion, drift and hysteresis;
- Field strengths inside coils must be high, e.g. for MRI and NMR applications;
- For NMR and MRI, a high magnetic field ramp rate is a significant advantage so that the strong magnetic field can be restored as this reduces the time before the equipment can be used;
- Coils must be reliable and not fail catastrophically in normal use.

27 C.f. https://www.j-ndk.co.jp/product/jikisokutei/bh_curve_tracer.html#sub_03, only available in Japanese

28 C.f. http://www.toeikogyo.co.jp/english/products/sei-01/vsm-5hsc.html

As to the solders used in applications of relevance for this exemption, Sumitomo (2019 a) say that they must exhibit the following properties:

- Low electrical resistivity;
- Ductile at very low temperature;
- Able to withstand cyclic stresses;
- Easy to make in consistently high quality;
- Bonds must be reliable over expected > 25 years lifetime;
- Low melting point solder bonding (<195 °C) with at least 25 °C lower temperature than the tin-silver coating on the superconducting wire;
- Resistant to corrosion and oxidation;
- Shock resistant as sudden and strong forces are imposed when magnetic field is switched on or off.

Sumitomo (2019 a) state that high power electrical connections need to be made to the BSCCO superconductor. Forming of bonds needs to be easy to carry out to ensure that 100 % of bonds are of good quality with very low electrical resistivity. Research has shown that a thin lamination coating of tin-silver-copper (SAC) lead-free solder alloy with a melting point of 219 °C on the superconducting wire improves the strength of the material. To further increase the strength of superconducting wires, they can be coated with stainless steel, nickel alloys or copper alloys. While soldering to copper is straightforward, it is very difficult to solder to stainless steel and nickel alloys and so these must first be coated with tin which is deposited by electroplating. Solder coating of this tin is straightforward. Sumitomo (2020 a) indicate the resulting sequence of layers from inside to the outside on the superconducting wire as follows:

1) Ag alloy-sheathed BSCCO (Type H) wire
2) SAC solder
3) Tin coating
4) Nickel alloy tape, OR stainless steel tape
5) Tin coating
6) SAC solder

According to Sumitomo (2020 b) only SAC solder is needed for LBSCCO laminated with copper alloy as layer no. 4) instead of nickel alloys or stainless steel. No further tin layer 5) needs to be applied. Copper, however, does not provide the same strength to the wire as nickel alloy and stainless steel so copper cannot be used when high strength is needed.

In any case, Sumitomo (2019 a) state, it is necessary to make solder bonds to the ends of the superconducting wires without melting the SAC solder coating and so an alloy with a lower melting point must be used.

Tin-lead (SnPb) solder was selected with a melting point of 183 °C, which is sufficiently lower than 219 °C so that it can be used without melting or delaminating the SAC coating. This alloy is ductile at the very low temperatures used, has low electrical resistivity at low temperature, and there are many years of low temperature usage experience with this alloy. The temperatures that the solder bonds will experience during operation are typically:

- About 4 K for NMR devices;
- 20 to 40 K for other magnet applications;
- About 65 to 80 K in cable applications.

At these temperatures and at very high magnet field strengths, SnPb will not be a superconductor. To minimise resistive heating, it must have a very low electrical resistivity. Additionally, due to the powerful magnetic fields, the solder bond must be reliable when exposed to cyclic stresses.

Important characteristics of superconductors

Sumitomo (2019 a) highlight the following crucial properties of superconducting materials:

- High critical temperature T_c
  The critical temperature is the temperature below which a conductor becomes superconducting, i.e. exhibiting zero electrical resistance. A high TC is important because the material will remain a superconductor even if the temperature were to rise, as long as it does not exceed the T_c.
- High critical field strength H_C
  The critical field strength H_C is the field strength at which a superconductor looses its superconductivity. A high H_C is important for electric motors and electromagnet applications. Applications such as MRI and NMR require very high field strengths. Over 24 Tesla have been achieved with LBi2223, and it is important that superconductivity is not lost at these high values.
- High critical current density J_C
  The critical current density is the current density at which a superconductor loses its superconductivity. For many applications including power transmission, NMR and MRI, it is necessary to pass very large currents. NMR sensitivity and MRI image quality are proportional to the magnetic field strength which in turn depends on the current being passed. J_C is reduced, however, when the cable is exposed to a strong magnetic field and it is also temperature dependent. So, a high critical current density is required when exposed to a powerful magnetic field and at temperatures approaching the critical temperature.

Sumitomo (2019 a) highlight the importance that the critical temperature, critical magnetic field strength and critical current density are all high to achieve the performance that is required, as well as to avoid catastrophic failures when a large current is passed through a superconducting wire losing or "quenching" its superconductivity, i.e. due to exceeding a critical parameter.[29] When the coil becomes resistive, the passage of current generates heat which can cause thermal runaway resulting in a fire when the coil's bonding materials (adhesives and resins) burn. These

[29] See slide 9 from https://www.slideshare.net/DebiPrasadDash3/superconductivity-68227517; source as referenced by the applicant

bonding materials are required to prevent moving of the superconducting wires by electro-magnetic forces which occur when NMR and MRI operate, and through rapid temperature changes such as when coils are cooled with liquid helium.

Functions of lead in BSCCO and related solders

Sumitomo (2019 b) state that lead is a constituent of solder used to make reliable electrical connections. Lead in BSCCO facilitates manufacturing superconducting wires and cables that have zero electrical resistance below the critical temperature (Tc), which is higher compared to other superconductors. Superconductors with high critical temperatures have many technical advantages over the niobium-alloy low temperature superconductors that are currently used in NMR spectrometers and MRI scanners. Research has shown that the material that gives the best overall performance and reliability is BSCCO. Powerful superconducting electromagnets have been constructed using LBSCCO for NMR and other applications.

The use of LBSCCO allows the generation of more powerful and more stable magnetic fields than using other copper oxide superconductors, and these magnets have also been found to be more reliable than those made with other materials. Electrical connections are made to the superconducting wires using eutectic lead/tin solder because this has proven to be reliable and has low electrical resistivity at low temperatures. NMR spectrometers and other products that use LBSCCO cannot be sold in the EU until this exemption is granted.

7.2.3. Amount of lead used under the exemption

Sumitomo (2019 a) explains that the superconducting material contains around 7 % of lead by weight. Solder alloys used for electrical connections contain about 36 to 37 % lead. Sumitomo (2019 a) calculate the quantity of lead in the bismuth-strontium-calcium-copper-oxide (BSCCO) wires and the lead solder in electrical connections as follows:

The first main use in the EU of the BSCCO superconducting material is expected to be in 1GHz nuclear magnetic resonance (NMR) spectrometer electromagnets. Approximately 100 kg of BSCCO wire will be used in each spectrometer and the lead content of the BSCCO-filled silver wire is 1.8 %. So, the total amount of lead is 1.8 kg per NMR spectrometer. Five units of 1 GHz NMR magnets are expected to be sold in the EU during the next 10 years, resulting in 9 kg of lead in 10 years or 0.9 kg per year on average.

The quantity of lead that will be used in the EU in other applications in scope of RoHS like MRI equipment is not known as manufacturers of other types of equipment have not yet determined their future plans for EU sales. However, Sumitomo (2019 a) speculate that MRI may eventually require up to 100 km wire per year containing 14.4 kg of lead. This is, however, uncertain and this quantity will not be required until commercial MRI devices using BSCCO are developed and approved.

With respect to lead in solders, Sumitomo (2019 a) further on explain that nuclear magnetic resonance (NMR) devices contain about 40 bonds with 0.005 to 0.02 g (average 0.01 g) of lead per solder bond. As one NMR is expected to be sold every two years, the total amount of lead per year is 0.2 g. The other lead uses like MRI equipment- c.f. the next section - are expected to require about 400 bonds per year each containing 0.05 g of lead. Based on the above data, Sumitomo (2019 a) calculate the annual total use of lead in solder bonds with 2 g per year for the EU.

Overall, Sumitomo (2019 a) indicate the total amount of lead in the EU for applications in the scope of the requested exemption with ca. 1 kg per year for NMR devices on average during the next 10 years and eventually another 14.4 kg for MRI devices per year, plus smaller amounts for other applications. The overall total would thus be slightly more than around 15.4 kg.

7.3. Applicant's justification for the requested exemption

7.3.1. Substitution of lead in BSCCO

According to Sumitomo (2019 a), lead doping of Bi2223 gives multiple benefits compared with undoped Bi2223 and is also superior to other BSCCO phases:

- The optimum superconducting phase is Bi2223, but other inferior BSCCO phases can also form when the superconductor is synthesised. Lead doping has been found to promote the formation of the optimum Bi2223 phase as the only phase.[30] A patent by Yamada compares different phases to show that the LBi2223 phase has a higher critical temperature than undoped Bi2223, Bi2212 and also aluminium doped Bi2223 and other compositions.[31] Majewski showed that lead doping ensures that only the superior Bi2223 phase is formed when the lead and bismuth concentrations are within specific concentration ranges although the formation temperature is also critical.[32]
- Lead increases the critical temperature (Tc) of the Bi2223 superconducting phase from about 110 K to about 116 K. This increased Tc gives an advantage over other ceramic superconductors that are capable of being made into superconducting magnet coils as well as low temperature superconductors such as NbSn and NbTi. This is especially important in alternate current (AC) applications. When a current passes through a wire this creates a magnetic field. As the size of the current being passed changes either because AC is used or when power is switched on, i.e. from zero to the maximum and off, this creates a "hysteresis loss", which occurs when the magnetic field strength increases and decreases. These losses are converted into heat which causes the superconductor's temperature to rise. Eddy currents are also generated and can create energy losses which result in heat due to field gradients. The higher Tc of LBi2223 is a big advantage over other materials with lower Tc in preventing catastrophic failure due to temperature rise to above Tc causing thermal runaways.

[30] High-Tc Phase Promoted and Stabilized in the Bi, Pb-Sr-Ca-Cu-O System, M. Takano, et.al., Japanese Journal of Applied Physics, Vol 27 (6), 1988, pp1041-1043; reference as cited by the applicant

[31] Yamada et.al., US Patent 5,317,007 "High Tc oxide superconductor and method for producing the same, granted May 1994; reference as cited by the applicant

[32] P. J. Majewski, „Phase Equilibria and Crystal Chemistry, Bismuth-based High-temperature superconductors", from Bismuth-Based High-Temperature Superconductors, Edited By Hiroshi Maeda, CRC Press, 1996, pp139-145

- One limitation of all ceramic superconductors is that they are anisotropic, which means that their properties are orientation dependent. The electromagnetic anisotropy parameter γ is relatively large for undoped Bi2223. This is less important if the crystals of the superconductor can be oriented so that the axis with the highest performance is parallel to the direction of the passing current. However lower γ values are beneficial if < 100 % of crystals are optimally orientated. Lead doping of Bi2223 has the benefit of significantly lowering the γ value.
- Lead doping significantly increases the critical current density of undoped Bi2223.
- Porous structures are formed when Bi2223 is sintered. This porosity is removed by rolling and sintering in oxygen at higher pressure. This orientates grains into the optimum direction and ensures that the material is homogeneous along the full length of wires and cables. It is also non-porous so that crystal to crystal conduction can occur. Lead doping makes Bi2223 grains larger and thus enhances the critical current density Jc.

7.3.2. Elimination of lead - comparison of LBSCCO with other superconducting materials

Using lead-free low and high temperature superconducting materials (LTS and HTS) could be an option to eliminate the use of lead provided these alternative superconductors can provide the same or similar performance and advantages like the LBi2223-based superconductors.

Alternative low-temperature superconducting materials

Sumitomo (2019 a) say the aim of manufacturers is to advance the performance of electrical equipment such as NMR and MRI and the materials which give the best overall performance will be used. At present, the optimum material overall is LBi2223. It is envisaged that if other materials can be made into superconducting wires and coils, these will be evaluated and if superior performance is achieved and the equipment is reliable, then this will be used. It is not currently possible to predict when development of designs using lead-free superconductors will be possible. LBi2223 was originally discovered in 1988, but commercial wire was not available until 2004, 15 years later. Commercial equipment such as NMR is only now being realised, >14 years after commercial wire was available. Commercialisation of any new superconductors is likely to take a similar length of time once a material is found to be suitable and meets all essential requirements, i.e. a total of about 30 years.

Sumitomo (2019 a) state that many metals are superconductors but these all have fairly low critical temperatures (Tc). Niobium-titanium (NbTi) and niobium-tin (NbSn) are used as superconductors in MRI scanners and NMR spectrometers. Such supercon-ductors with low Tc values known as low temperature superconductors (LTS) need to be cooled with liquid helium (boiling point 4.2 K), which is a big disadvantage as helium is a very scarce element and the cooling equipment required is complex and consumes large amounts of energy. As a result, scientists have searched for many decades to find superconductors with much higher Tc with an ideal material being a superconductor that can be used at room temperature. While this has not yet been achieved, a large number of ceramic formulations have been developed that have higher critical temperatures than niobium including many that are superconductors at temperatures above the boiling point of liquid nitrogen (77 K). These are referred to as "high temperature superconductors" (HTS) of which Bi2223 is one example.

Alternative high temperature superconducting materials

Although many such high temperature superconductors (HTS) have been developed[33], very few can be fabricated into cables and wires that have properties such as high critical current so that they are commercially useful. One reason that many ceramic materials are unsuitable is that they are too brittle and so cannot be used in flexible wire.[34] The only substitute HTS to LBi2223 that have been made into useful lengths of wire or tape and which can be made in into magnets are:

- Undoped Bi2223 and Bi2212 oxide phases;
- REBCO (rare earth elements, barium and copper as mixed oxides:
  - GdBCO or Gd123 (gadolinium BCO);
  - YGdBCO (yttrium gadolinium BCO);
  - YBCO (yttrium BCO);
- Magnesium boride.

Sumitomo (2019 a) explicate that although the HTS materials are superconducting at liquid nitrogen temperature, many of the current applications are operated at liquid helium temperatures as critical current values are significantly higher at the lower temperature. This enables significantly more powerful electromagnets as their critical current densities are higher than those of low temperature superconductors (LTS) such as NbSn and NbTi. These HTS additionally have the big advantage over LTS that if the temperature were to rise by up to 100 K, the material remains as a superconductor and so catastrophic failure due to thermal runaway is less likely to occur.

Sumitomo (2019 a) put forward that the LTS currently used in commercial NMR and MRI have a further significant disadvantage if the magnets have to be switched off, for example if a magnetic metal part accidentally comes into contact with the bore. Ramping up[35] of LTS magnets to the operating field strength takes considerably longer than ramping up LBi2223 superconducting magnets. A commercial MRI can take as long as three days to bring it back into full operation including recalibration[36], which will cause potentially harmful delays in treating patients. Table 7-1 illustrates the magnetic field ramp rates of LTS and LBi2223 as used for NMR.

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[33] For example, those listed at http://superconductors.org/Type2.htm; reference as cited by the applicant

[34] US Patent 4,880,771, R. J. Cava, "Bismuth Lead Strontium Calcium Cuprate Superconductors", Nov 1989; reference as cited by the applicant

[35] Starting a superconducting device like an MRI device for the first time, or restarting it after e.g. repairs with interruption of the magnetic field, to achieve full operation

[36] http://mriquestions.com/how-to-ramp.html; reference as cited by the applicant

Table 7-1: Magnetic field ramp rates for LBi2223 magnets and an LTS

Change in magnetic field strength	Pb-Bi2223 magnet with 88 mm bore	LTS magnet with 100 mm bore
0 to 6 T	30 seconds	6 minutes
0 to 8 T	30 seconds	8 minutes
0 to 10 T	4 minutes	12 minutes

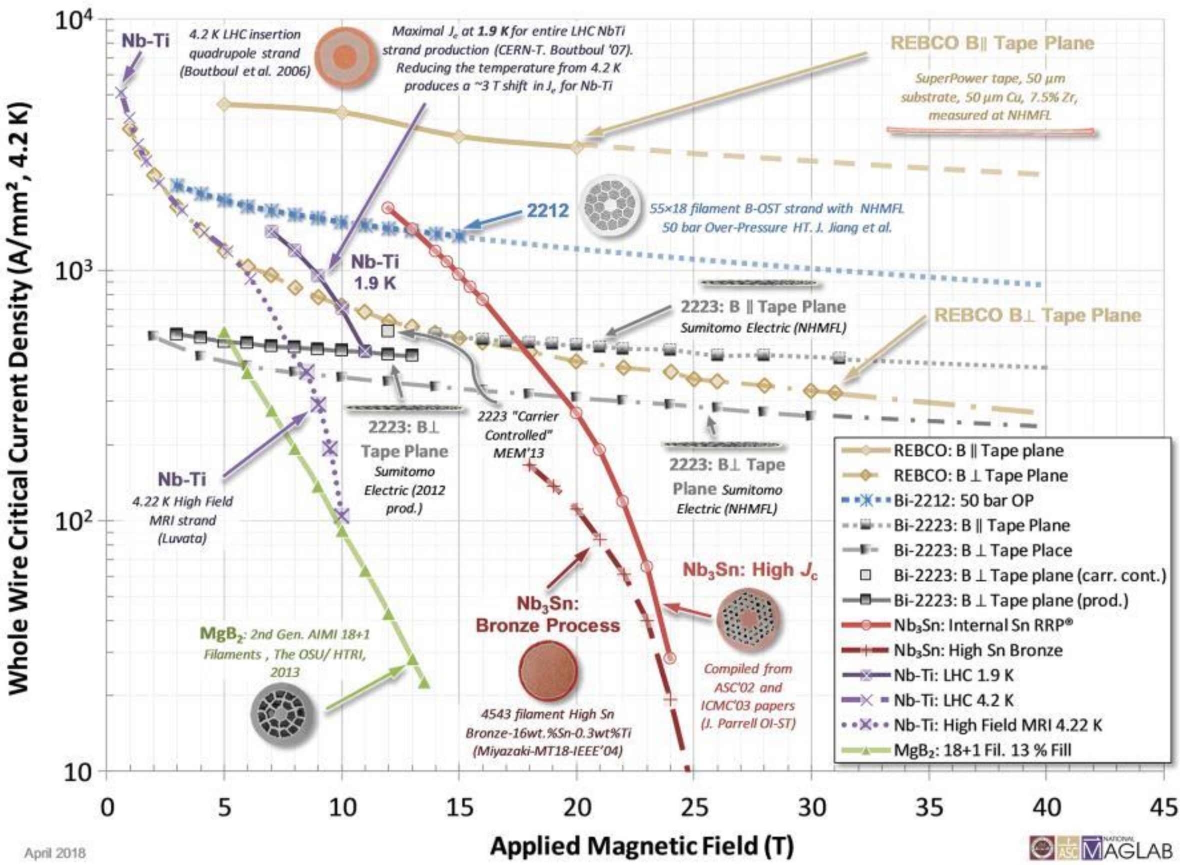
Source: Superconducting electromagnet manufacturer in Sumitomo (2019 a)

Sumitomo (2019 a) are afraid that longer ramp up times may cause harmful delays in treating patients.

Comparison of LBSCCO with magnesium boride

Magnesium boride (MgB_2) has a T_C of 39 K which is much lower than that of LBi2223. Although this is higher than the T_C values for LTS such as NbTi, it is more likely to fail than LBi2223 if a temperature rise occurs. Two further disadvantages of MgB_2 over LBi2223, Sumitomo (2020 b) explain, are its much lower critical current density and a lower critical magnetic field value than BSCCO as illustrated in Figure 7-1.

Figure 7-1: Critical current density versus applied magnetic field of different superconducting materials

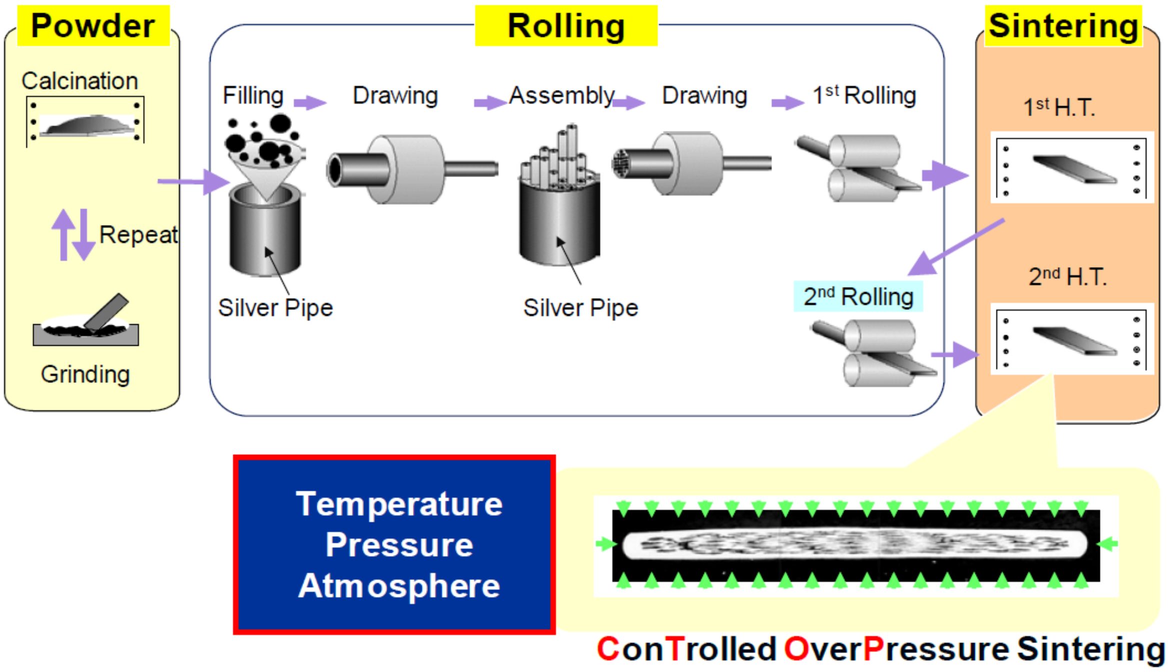


Source: National High Magnetic Field Laboratory, Florida University: https://nationalmaglab.org/images/magnet_development/asc/plots/Je_vs_B-041118_1920x1393_PAL.png, *and https://nationalmaglab.org/magnet-development/applied-superconductivity-center/plots; reference cited by Sumitomo (2020 b)*

Comparison of LBSCCO with REBCO in general

Sumitomo (2019 a) puts forward the significant disadvantage of REBCO superconductors that they can be formed only as thin films deposited onto tape containing less than 2 % of superconductor, whereas LBi2223 can be made as silver wire with 40 % of its volume as the superconducting phase. Bi2223 can be formed into multi-filamentary wires using the powder in tube method depicted in Figure 7-2.

Figure 7-2: Manufacturing of multi-filamentary BSCCO wires



Source: Sumitomo (2019 a)

According to Sumitomo (2019 a), this structure can realize smaller screening currents (see next section). Moreover, it has high strength against peeling forces caused by electromagnetic forces and thermal stress. The ability to make multi-filamentary wires enables Bi2223 to be used to make powerful electromagnets with superior performance.

Limitations of all superconducting electromagnets are that they can exhibit:

1. Screening of magnetic fields;
2. Degradation of coil performance due to excessive mechanical stress;
3. Difficulties protecting electromagnets from thermal runaway.

Screening magnetic fields can cause distortion of the magnetic field, which distorts MRI images, impairs NMR analysis and causes "field drift" due to screening currents being generated. This was originally an issue with low temperature superconductors such as NbTi, but was resolved by using twisted multi-filamentary wires for MRI and NMR superconducting magnets.

LBi2223 can be used as untwisted multi-filamentary wire. REBCO wire can only be used as monolithic (thin-film) REBCO layer in tape. Both LBi2223 wire and REBCO tape suffer from field drift and hysteresis, but LBi2223 to a significantly lesser extent. Experiments have shown that the hysteresis from LBi2223 is only one fifth of REBCO. Hysteresis and the resultant distortion of MRI images and NMR spectra and drift are reduced by use of multi-filamentary wire compared with flat tape and may be reduced further if the filaments can be twisted. Hysteresis also generates heat which can cause or contribute to thermal runaways.

Sumitomo (2019 a) report that several organisations have successfully constructed and operated NMR and MRI using LBi2223 superconductors. One organisation, RIKEN, has built prototype NMR with both LBi2223 and REBCO. Both experience a drift in magnetic field which can be suppressed using a current sweep method, but the drift with REBCO was 20 times larger than that with LBi2223.

Sumitomo (2019 a) further on cite the experiences of Yanagisawa[37] who have successfully built an NMR spectrometer using a LBi2223 electromagnet. Bi2223 was chosen instead of REBCO because REBCO has the following limitations:

- Substantial field drift due to REBCO being a thin-film on tape;
- Reduced central magnetic field intensity resulting in reduced performance;
- Large field error harmonics. These are oscillations in the strength of the magnetic field. These seriously degrade performance if they cannot be eliminated using shim and field coils;
- Degradation of performance of superconducting shim coils and field correction coils. Shim coils are used with current commercial NMR and MRI to eliminate unwanted harmonics in the magnetic field.

LBi2223 was used for the NMR coil as it has insignificant screening currents and so does not suffer from the above limitations. The only potential limitation of Bi2223 is a lower tensile strength, but this was overcome by use of nickel-alloy reinforcement tapes to increase the coil’s tolerance to hoop stress.

Sumitomo (2019 a) also explain the **degradation of coil performance due to excessive mechanical** stress. This occurs when stresses damage the ceramic superconductor material. Such stresses are generated when superconducting wires in coils used for NMR and MRI electromagnets are cooled with liquid nitrogen or liquid helium, or by conduction cooling using a cryo-cooler. This limits the choice of superconductor materials that can be used. LBi2223 wires are not damaged by rapid cooling.

Thermal runaway according to Sumitomo (2019 a) can happen when large currents as used in NMR an MRI devices pass through a superconducting wire when the latter ceases to be superconducting. This can occur if the critical temperature, critical field strength or critical current are exceeded, as explained earlier. Heat is generated in the

[37] Combination of high hoop stress tolerance and a small screening current-induced field for an advanced B-2223 conductor coil at 4.2K in an external field, Yanagisawa, et.al., Supercond. Sci. Technol. 28 (2015)125005; reference as cited by the applicant

resistive wire according to I^2R (I=current and R= resistance), temperatures rise quickly and damage bonding resins which fix the wires to avoid damages from vibration. Therefore, it is essential to ensure that critical temperatures, critical magnetic fields and critical currents are not exceeded to maintain the superconduct-tivity which is easiest at a stable temperature, magnetic field and current. LBi2223 has considerably smaller drifts in magnetic fields and screening currents than REBCO, and the T_C of LBi2223 (~110K) is also higher than that of REBCO (YBCO is 92K, GdBCO is 94K). Several publications describe catastrophic failures of prototype REBCO electromagnets.

Sato[38] reports that superconductors containing barium can be degraded by moisture and carbon dioxide. Superconductivity of ceramic materials relies on grain-to-grain conduction. This is hindered if electrically insulating phases form at grain boundaries when barium oxide readily reacts with moisture and carbon dioxide to form electrically insulating barium carbonate as an impurity that forms between grains. Elimination of moisture and carbon dioxide in commercial scale production is difficult but less critical with LBi2223 as this superconductor does not contain barium and so does not as readily form electrically insulating carbonates.

Comparison of LBSCCO with different types of REBCO

Sumitomo (2019 a) compare LBSCCO with gadolinium barium copper oxide ($GdBa_2Cu_3O_7$, **GdBCO** or Gd123, a type of REBCO (RE123) superconductor with a T_c of 94 K. This has been used to make powerful superconducting electromagnets that have been compared with similar performance electromagnets made of LBi222321. The coils consisted of a low temperature superconductor coil combined with a high temperature superconductor coil of either Gd123 or of LBi2223.

Sumitomo (2019 a) report that Gd123 superconductivity was quenched (lost superconductivity) at the upper magnetic field strength of 23.6 T. There was a difference of 0.4 T between the calculated and measured magnetic field which was due to hysteresis effects. The LBi2223 coil achieved a magnetic field of 24.5 T without being quenched. The difference between calculated and measured magnetic fields was much smaller (0.07 T) than for Gd123 due to the smaller hysteresis effects so that less heat is generated.

Sumitomo (2019 a) mention Y123 (YBa2Cu3O7, YBCO, a type of REBCO) with a TC of 92 K as one of the first high temperature superconductors with a TC over the boiling temperature of nitrogen. It has been used much less in research and for commercial applications. Generally, the process of YBCO is less tolerant compared with other REBCO materials, so it is not used for commercial applications. Nevertheless, Sumitomo (2020 b) report that MIT has carried out research[39] into powerful electro-

38 “Research, Fabrication and Applications of Bi-2223 HTS Wires”, edited by K. Sato, World Scientific Series in Applications of Superconductivity and Related Phenomena, Vol I. Published by World Scientific Publishing Co. Pte. Ltd, 2016, ISBN 978-981-4749-25-1; reference as cited by Sumitomo 2019 a.

39 C.f. Figure 4 in: “Research, Fabrication and Applications of Bi-2223 HTS Wires”, edited by K. Sato, World Scientific Series in Applications of Superconductivity and Related Phenomena, Vol I. Published by World Scientific Publishing Co. Pte. Ltd, 2016, ISBN 978-981-4749-25-1; reference as cited by the applicant

magnets using a combination of an YBCO magnet and an LTS magnet made with NbTi and Nb3Sn, which achieved 21.1 T. According to Sumitomo (2020 c), the highest published field strength for Bi2223 is 24.5 Tesla[40], which was achieved without failure, and so higher field strengths may be achievable.

Finally, Sumitomo (2019 a) compare LBSCCO with another type of REBCO that has been researched, yttrium gadolinium barium copper oxide ($(Y_{0.5}Gd_{0.5})Ba_2Cu_3O_7$, **YGdBaCO**) with a Tc of 97 K. The critical current performance of wires was measured and compared with LBi2223, yttrium barium copper oxide (YBCO), and published data on YGdBCO were compared.[41] Measurements were made at relatively low field (up to 0.4 T) but this is relevant to currently available commercial NMR and MRI equipment. This clearly showed effects due to anisotropy of materials, including of LBi2223. The tests showed that the critical current decreases with increasing magnetic field strength, as would be expected. However, the performance was different depending on whether the conductors were perpendicular or parallel to the magnetic field. When oriented perpendicularly to the magnetic field, LBi2223 was inferior to YBCO and YGdBCO, but in orientation parallel to the magnetic field, LBi2223 was superior to both of the other materials achieving significantly higher critical current values and being less affected by magnetic field strength. As the production process can orient crystals of LBi2223 in one specific direction, this can be used to ensure that LBi2223 is used in its optimum orientation to achieve superior performance compared to YBCO and YGdBCO.

Sumitomo (2019 a) explain that overall, lead-doped BSCCOin its optimal superconducting phase Bi2223, is a superconductor which can generate very strong magnetc fields in high quality for MRI and NMR devices with a critical temperature (T_C) of 110 K to 116 K depending on lead content. The material has zero electrical resistance at temperatures below the critical temperature. A T_C of 110 K and more is sufficiently high to avoid the use of liquid helium as a coolant since liquid helium boils at 4 K. Instead, liquid nitrogen cooling (boils at 77 K) could be used. There is also research[42] into refrigerant-free superconducting electromagnets and at least one commercial product[43] has been developed. Sumitomo (2020 a) describe it is a cryogen-free superconducting magnet which uses NbTi superconductors for field strengths under 10 T, and NbTi and Nb3Sn are expected to be used for 10 T or more. These can be used for NMR. The bore is too small for MRI, and the performance of these magnets are inferior to lead-doped BSCCO magnets.

Sumitomo (2019 a) believe that the main advantages of Bi2223 over low temperature superconductors requiring liquid helium cooling such as niobium-tin is that its overall performance is superior. It is envisaged that finished Bi2223-based equipment will operate at liquid helium temperatures to achieve the optimum performance. For

[40] "First performance test of a 25 T cryogen-free superconducting magnet", S. Awaji, et.al., Supercond. Sci. Technol. 30 (2017) 065001; reference as cited by Sumitomo 2019 a.

[41] Comparative study on the critical current performance of Bi-2223/Ag and YBCO wires in low magnetic fields at liquid nitrogen temperature, F. Feng, et.al., Physica C 471 (2011) 293–296; reference as cited by the applicant

[42] S. Awaji, et. al., "First performance test of a 25 T cryogen-free superconducting magnet", Supercond. Sci. Technol. 30 (2017) 065001, referenced as cited by the applicant

[43] http://www.jastec-inc.com/products_nmr/detail5.html; reference as cited by the applicant

example, the critical current and critical field strength[44] of lead-doped Bi2223 are much higher at 4 K than at 77 K.

7.3.3. Substitution or elimination of lead in solder

According to Sumitomo (2019 a), research[45] has shown that if SAC solder is used for bonding, the SAC coating on the superconducting wire melts and delaminates and this weakens the wire. Therefore, a lower melting point solder must be used for bonding. The electronics industry has many decades of experience with SnPb solder including when used at low temperatures such as in cold environments and it has proven to be reliable. There are only a few low melting point solders that are both lead-free and cadmium-free and these are all based on bismuth or indium, for example:

- In52%Sn48%, melting point 118 °C
- 58%Bi42%Sn, melting point 138 °C
- 97%In3%Ag, melting point 143 °C

Bismuth makes the alloys hard and brittle and this is exacerbated at very low temperatures. Indium alloys tend to be very soft and ductile, but indium is a relatively reactive metal so that it corrodes and oxidises much more readily than other types of solders. Also, due to its softness, bonds are easily deformed when force is applied such as when the magnetic field strength changes and this can cause bond failure. The following summarises the main reasons why lead-free and cadmium-free low melting point solders cannot be used instead of SnPb:

- Brittle bonds, especially bismuth-based alloys;
- Inferior wetting properties compared with SnPb;
- Bad anti-shock properties;
- Voids within bonds readily form, larger size voids will weaken bonds;
- Bad mechanical properties (bismuth too hard, indium too soft);
- Deformation by heat cycles (especially indium solders);
- Unknown long-term reliability in this application;
- When soldering to nickel alloy or stainless lamination, the indium or bismuth solder will not make strong bonds with nickel or nickel in stainless steel as the intermetallic phases that form result in weak bonding whose strength is insufficient.
- Inferior corrosion resistance - indium solders require aggressive fluxes in the soldering process as indium oxidises more readily than SnPb. These fluxes can cause corrosion;
- Very little published research or experience at low temperature;

[44] See figure 12 of US Patent 4,880,771, R. J. Cava, "Bismuth Lead Strontium Calcium Cuprate Superconductors", Nov 1989. This shows that magnetic field performance for this superconductor increases as the temperature decreases; reference as cited by the applicant

[45] High-Temperature Superconducting Magnets for NMR and MRI: R&D Activities at the MIT Francis Bitter Magnet Laboratory, Yukikazu Iwasa, et al., IEEE, available from https://dspace.mit.edu/handle/1721.1/69163;. Reference as cited by the applicant

- Less information on cold brittleness than for SnPb.

Sumitomo (2019 a) put forward that NMR, MRI and other electromagnet applications will experience cyclic stresses due to the powerful magnetic fields that are generated. Bond ductility is therefore highly beneficial. SnPb solder is known to be more ductile than lead-free solder alloys, bismuth-based solders and also braze alloys and so SnPb is likely to be more reliable than these bonding options.

According to Sumitomo (2019 a), conductive adhesives have not been evaluated because these are not specified for use at very low temperatures. Also, they would become very hard and brittle at low temperature, and high resistivity bonds may develop due to oxidation of the conductive base metals in the adhesives occurs.

7.3.4. Roadmap for substitution or elimination of lead

Sumitomo (2019 a) want to investigate alternative solders once long-term reliability of BSCCO based products is proven. However, it will take many years to determine whether lead-free bonding will give long term reliability as testing needs to be carried out under realistic use conditions, which are at low temperatures, so accelerating failure modes significantly is not possible as behaviour at higher temperatures will not be representative.

7.3.5. Environmental arguments

Sumitomo (2019 a) say that the superconducting wire will be sold to manufacturers of NMR, MRI, etc. who will use it in their products which are all used by industry or by professionals. The equipment will be fairly large and complex and so will have a positive value in terms of metal content at end of life, making recycling for materials recovery highly likely. Although some of the equipment may be returned to the original manufacturer, the superconducting wire is not envisaged to be returned to the wire manufacturer and so an auditable closed loop will not exist.

Sumitomo (2019 a) estimate that eventually the annual amount of lead in products for reuse or recovery will increase from 1 to 15.5 kg per year if the exemption is granted. However, for at least 15 years, no waste products containing lead will become available due to the long lifetime of these types of equipment.

7.3.6. Socioeconomic impacts

Sumitomo (2019 a) claim that lead-doped Bi2223 is used solely because it gives superior performance and reliability compared to alternative superconductors. This exemption would allow EU organisations to buy and use NMR and MRI that use this material and this will give benefits to researchers (NMR, etc.) and the health of EU citizens (MRI). Without this exemption, this cannot be realised as substitutes are inferior.

Sumitomo (2019 a) fear that there could be a possible loss of jobs if EU organisations could not use types of equipment (such as NMR) that use LBSCCO, if this exemption is not granted. These will be available to non-EU organisations in countries without the same RoHS restrictions as the EU. There may also be possible health impact as described above.

7.4. Stakeholder contributions

No stakeholder contributions were received.

7.5. Critical review

7.5.1. REACH compliance – Relation to the REACH Regulation

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

Lead is a substance of very high concern, but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV as an element. The fact that lead is a candidate substance therefore at the time being does not weaken the "*environmental and health protection afforded by*" the REACH Regulation.

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

- Lead chromate – used in printing inks, paints and to colour vinyl, rubber and paper[46];
- Lead sulfochromate yellow – used as a pigment, a dye and as a paint and coating additive[47];
- Lead chromate molybdate sulphate red – understood to be used as a pigment;

As the exemption for lead in solders and in superconducting BSCCO materials used within the scope of the requested exemption does not regard pigments nor substances used in paints and dyes, it is concluded that a renewal of the exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

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

- Entry 16 restricts the use of lead carbonates in paints;
- Entry 17 restricts the use of lead sulphates in paints;

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

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

- Entry 19 refers to arsenic compounds but includes a few lead compounds and restricts their use as a fouling agent, for treatment of industrial water or for treatment of wood;
- Entry 63 restricts the use of lead and its compounds in jewellery and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children;
- Entry 28 and entry 30 stipulate that various lead compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;
- Entry 72 stipulates that various lead compounds shall not be used in clothing.

The exemption for lead in solders and in superconducting BSCCO materials used within the scope of the requested exemption does not regard paints or jewelry, nor components that could be expected to be placed in the mouth by children under normal or foreseeable use. Furthermore, the use of lead in solders in the scope of the requested exemption is not a supply of lead compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of articles and as such, entry 28 and entry 30 of Annex XVII of the REACH Regulation would not apply. It is concluded that a renewal of the exemption would not weaken the protection afforded by REACH through entries 16, 17, 19, 28, 29, 63 and 72.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status March 2020). Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

7.5.2. Scientific and technical practicability of substitution

Substitution of lead in LBSCCO

The information which the applicant made available shows clear advantages for the LBSCCO/LBi2223 material. The addition of lead to the BSCCO material promotes the formation of the LBi2223-phase of the BSCCO material. The LBi2223-phase shows the best superconducting and magnetic properties:

- Increase of the critical temperature TC from 110 K to about 116 K, which reduces the risks of thermal runaways
- The addition of lead enables a higher critical temperature than the addition of other substances, e.g. aluminium.
- The addition of lead increases the critical current density of LBiSCCO compared to undoped Bi2223.
- It significantly reduces the anisotropy of the material making the properties of the material less dependent on the orientation of the grains in the superconducting material, which is a benefit.

The information provided by the applicant is plausible. Based on this information, and in the absence of any stakeholder comments objecting the applicant's views, the consultants conclude that the addition of lead to BSCCO provides technical and functional advantages which cannot be reached without lead.

Elimination of lead by use of low temperature superconducting materials

The applicant mentions the low temperature superconductors (LTS) niobium-titanium and niobium-tin, which are used in MRI scanners and NMR spectrometers. They are cooled with liquid helium (boiling point 4.2 K). Besides the danger of thermal runaways due to the low critical temperature, the European Union CRMs (2017) list helium as a critical raw material. The applicant says, however, that in many cases high temperature superconductor (HTS) devices like the LBi2223-superconducting magnets will be operated at the temperatures of LTS to benefit from higher critical current densities. This enables generating much more powerful magnetic fields compared to LTS devices. The BSCCO-based devices will therefore still use helium even though they may also be operated at higher temperatures e.g. with liquid nitrogen which boils at 77 K. Remaining as advantages over the LTS devices are, however, the reduced risk of thermal runaways and the possibility to generate more powerful magnetic fields with the LBi2223 superconducting material.

The applicant shows that the start-up phase of MRI devices with LBi2223 superconductors is significantly shorter[48] than with LTS-based MRIs. This advantage of a few minutes is, however, hardly relevant in the clinical daily practice since according to Sumitomo (2019 b), such restarts happen only once every few years.

The available arguments in the consultant's view plausibly explain that eliminating lead by using LTS cannot be achieved without losing preferable technical properties which the LBi2223 material provides. These are in particular the stronger magnetic fields and higher critical temperature, which reduces the risk of thermal runaways. In principle LBi223 superconductors and cables can be cooled with liquid nitrogen instead of helium, which is a critical raw material, however with performance losses so that this possibility might only become relevant in cases where helium might not be sufficiently available.

Elimination of lead by alternative high temperature superconducting materials

The applicant compares the LBi2223 HTS with various alternative HTS which do not require the use of lead.

- Magnesium boride

The superconducting material has a lower Tc (39 K) and critical magnetic field value than LBi2223 (110 K to 116 K), as well as a lower critical current density.

48 C.f. Table 7-1 on page 47

- REBCO-type HTS (GdBCO, YGdBCO and YBCO)

Compared to LBi2223 they are more prone to screening magnetic fields and hysteresis effects which both adversely affect the image quality of MRI and NMR devices. Hysteresis also generates heat that can contribute to thermal runaways. Further disadvantages of these materials are field drifts, a reduced central magnetic field intensity, large field error harmonics, and the degradation of superconducting shim coil performances used to eliminate the harmonics in the magnetic field.

- Use of Bi2212 as lead-free alternative

According to Sumitomo (2020 c), Bi2212 does not use lead. The applicant had explained that the material was too brittle to reliably withstand the mechanical stress occurring in superconducting magnets and therefore cannot replace Bi2223.
In Figure 7-1 on page 52, the material, however, exhibits a higher critical current density and critical magnetic field strength than Bi2223. The consultants assumed that, in order to test this, a superconducting magnet was constructed and operated with a strong magnetic field which generates high mechanical stresses while the applicant had claimed that the material is too brittle to be reliable under such conditions. Sumitomo (2020 d) explain that the Bi2212 round wire in Figure1 is provided from testing straight wires in a magnetic field and not in the form of a magnet coil. Therefore, although higher critical currents can be achieved with Bi2212 as a straight wire than with Bi2223, this material is not able to provide the same technical performance when used as a superconducting magnet.

Sumitomo (2020 d) claim that Bi2212 round wires are more brittle than Bi2223 tape and are more strain-sensitive than tape shaped wire. Usually a "Wind&React"process is used for Bi2212 coils. As the Bi2212 phase that is generated in wire is brittle in nature, a specialised very high temperature heat treatment processing is required to make magnet coils. Due to these high temperatures, the normal resin-based insulation used with Bi2223 cannot be applied and so usually glass-fibre braided tube insulation is required, which decreases the maximum current density. In addition to this, internal co-wound reinforcement is required, which needs another reinforcing metal to allow the coil to be wound.
According to Sumitomo (2020 d), the Florida State University are developing the technology with Bi2212, but have achieved only 16 T using this approach. Furthermore, the long-term reliability of Bi2212 magnets in end-products such as NMR and MRI, which experience severe vibration, is not yet known for Bi2212 magnets.

In the consultant's view, the available information shows that the LBi2223 material offers clear technical advantages over lead-free HTS materials. The elimination of lead is thus scientifically and technically not practicable without performance losses.

Use of Bi2223 in low-strength magnetic fields

Sumitomo states that Bi2223 magnets will be used for higher field strengths, which raises the question whether the exemption could be restricted to higher magnetic fields.

Sumitomo (2020 c) state that Bi2223 can be used at lower magnetic field strength, but is very unlikely to be used if NbTi (niobium alloys) can be used as they are much cheaper. Niobium alloys can be used at up to about 10 Tesla. For magnets from around 10 T, both Nb_3Sn (niobium intermetallic compounds) and NbTi are usually used. For magnets over around 20 T, it is difficult to generate the magnetic field by only Nb_3Sn and NbTi because of the critical magnetic field of Nb_3Sn, and so, HTS wires (Bi2223 and/or REBCO) have to be used.

However, Sumitomo (2020 c) continue, another technical advantage considered to be important for Bi2223 over NbTi magnets is the possibility to use it for lower magnetic fields. For example, to potentially reduce or eliminate the consumption of helium, reducing the size of the magnet when space is restricted, etc. In case of up-to 10 T magnets, very high ramp-rate magnets (c.f. Table 7-1 on page 52) can be realized by Bi2223 because of its large margin between Tc and operating temperature. In case of 10-20 T magnets, Bi2223 wires will facilitate smaller magnets compared with the magnet using Nb_3Sn and NbTi because the critical current density of Bi2223 is larger than ones of Nb_3Sn and NbTi.

So, even if the main application field of Bi2223 supcerconducting magnets and wires are strong magnetic fields, it can be applied to achieve specific benefits in the lower and middle field strength ranges. Since, as Sumitomo (2020 c) state, the B2223-material is more expensive than the lead-free superconducting ones, it can be assumed that it will only be used where its advantages are beneficial. Misuse to replace lead-free superconducting materials are unlikely. In this situation, given the benefits which the material can offer also for low and middle magnetic field strengths, restricting the exemption to higher field strengths would, in the consultants' opinion, neither be adequate nor compellingly required by Art. 5(1)(a).

Substitution and elimination of lead in solders

The applicant reports that SAC solder melts and delaminates the SAC layer on the BSCCO wire which weakens the mechanical stability. The applicant therefore uses SnPb (tin-lead) solder whose melting point is around 35 °C lower than that of SAC solder, and industry has decades of experiences with it including it's use in very cold environments.

Lead- and cadmium-free low-melting point solders are based on bismuth and indium. Bismuth-containing solders are too brittle, while indium-based solders are too soft to withstand the mechanical stress and are more prone to corrosion. It is thus plausible that lead-free solders cannot yet be used in this environment with the necessary reliability.

Conductive adhesives, according to the applicant, are not specified for use at very low temperatures. They would become very hard and brittle at low temperature and high resistivity bonds may develop if oxidation of the conductive base metals in the adhesives occurs.

The applicant was asked how such oxidation could occur in an atmosphere of liquid helium or nitrogen in which superconductors are operated. Sumitomo (2020 b) replied that the magnets are not only operated in liquid helium or nitrogen. After manufacture, the magnets may spend a long time at room temperature before installation and also room temperature maintenance will be needed. Sumitomo (2020 b) added that oxidation may not be the main limitation of these adhesives, but the fact that no commercially available conductive adhesives have been qualified for such low temperatures so far.

The consultants follow the applicant's argumentation and, in the absence of other contradicting information, conclude that substitution and elimination of lead in the solders are scientifically and technically not yet practicable.

7.5.3. Overlapping scope with exemptions 12 and 27 of Annex IV

Exemption 27 of Annex IV (c.f. renewal request in chapter 5 on page 23 et sqq.) also allows the use of lead in solders of NMR and MRI devices. In case the Commission renews the exemption 27 as applied for, it will have the following wording:

"Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere."

To avoid overlapping scopes of exemptions, the applicant was asked whether exemption 27 in case of its renewal does not cover the use of lead in solders for the MRI equipment. Sumitomo (2020 b) replied that lead solders would have to be used also outside the 1 m radius around the magnets' isocenters which exemption 27 does not cover. LBi2223 wires will be used for large-size superconducting magnets. Large size magnets are more powerful and are easier to insulate due to the smaller surface area to volume ratio. These magnets will have a radius of more than 1 m so solder bonds to superconducting wires will be located more than 1 meter from the magnet's isocentre.

Exemption 27 would therefore not cover all applications in the scope of the requested exemption.

Exemption 12 of Annex IV also covers the use of lead in solders of MRI and NMR equipment in its current wording:

Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors. Expires on 30 June 2021

There are two requests for renewal of exemption 12, which, if granted, might still cover Sumitomo's use of lead in solders of MRI and NMR equipment. The applicant was asked to explain why the above exemption does not cover the use of lead in solders of the LBSCCO superconductors. Sumitomo (2020 b) replied that exemption 12 would not be sufficient as the solder bonds used in lead doped Bi2223 magnets will not always be superconducting joints but will be resistive (normal) joints although with very low electrical resistance.

This situation is reflected in section 7.2.2 on page 45. Adding to the applicant's above argument, exemption 12 would not allow the use of lead in LBi2223-material itself so that at least this application would need a new exemption. Furthermore, the requested exemption is specific for BSCCO-type superconductors while exemption 12 is applicable to all metallic superconducting bonds regardless of the superconductor material. Should exemption 12 be repealed, manufacturers cannot use the requested exemption instead. It is therefore recommended to exclude the applications in the scope of the requested exemption from the scope of exemption 12 in order to avoid partially overlapping exemption scopes, provided exemption 12 will be renewed.

7.5.4. Roadmap for substitution or elimination of lead in LBSCCO and related solders

The applicant did not provide much information on the steps and timelines towards substitution or elimination of lead in LBSSCCO and the related solder. Sumitomo (2019 a) want to investigate alternative solders once the long term reliability of BSCCO based products is proven, which they claim to take many years to determine whether lead-free bonding will give long term reliability as testing needs to be carried out under realistic use conditions, which are at low temperatures, so accelerating failure modes significantly is not possible as behaviour at higher temperatures will not be representative.

Upon request, Sumitomo (2020 d) explain that some equipment, such as analytical equipment to measure magnetic materials, are already on the market in non-EU countries and therefore the long-term reliability of lead doped Bi2223 in these products is known.

Substitution and elimination of lead in solders

Sumitomo (2020 d) put forward that research into alternative methods of bonding high temperature superconductor wires is being carried out. Research on several novel methods has been published by G D Brittles et al. on persistent current joints between technological superconductors (published 2015), but all attempts to make reliable bonds with very low electrical resistance were unsuccessful. Brittles et al. evaluated various methods for several types of superconductor, not only Bi2223 which included various solders, diffusion bonding and welding. JASTEC also state in the exemption 12 renewal request[49] (which has been submitted) that they had evaluated two low melting point lead-free solders - InSnBi and SnBi, but both produced bonds with a small, but significant electrical resistance and they had too low critical current values. Research published by S. Spellman shows that critical current and critical field strength of these two alloys will always be inferior to lead-based alloys.[50]

In the opinion of Sumitomo (2020 d) , the most promising results obtained by Brittles were using spot welding, but this was with niobium alloys and so may not be suitable for SAC solder bonded Bi2223 as the high temperature is likely to cause delamination.

49 For details see https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_19/Application_JASTEC_RoHS_Exemption_Request_Exemption_12.pdf

50 C. f. slide 13 of paper at https://stfc.ukri.org/files/superconducting-joints-for-magnet-applications/

In view of the above results, there are no promising options to be investigated and so further fundamental research is needed, which could take at least 5 years.

If a successful lead-free boding method is found, Sumitomo (2020 d) think that prototype magnets using the alternative bonds will be constructed and tested for reliability under realistic use conditions. Based on the difficulties experienced so far and the complexity of magnet design, it is expected that this will require at least 5 years. Further time will then be needed to build and test prototype NMR, MRI, etc., which could take at least 3 more years and if successful, commercial NMR may be available after another 3 years. Commercialisation in MRI will take longer as data is needed to obtain Notified Body approval.

Sumitomo (2020 d) summarize the timeline as below:

- Identification of substitute bonding method — Unknown, at least 5 years
- Construction and testing of prototype magnets — At least 3 years
- Commercialisation (NMR, etc.) — At least 3 years
- Approvals (MRI) — 2 years

Sumitomo (2020 d) indicate the total time required with at least 13 years for MRI equipment and a minimum of 11 years for NMR devices.

Substitution and elimination of lead in the superconducting material

Sumitomo (2020 d) claim that currently there are no known alternatives to lead-doped Bi2223 which can provide the same technical performance and reliable superconducting magnets. Based on the timeline of development of Bi2223, the commercialisation of any new superconductor, including lead free superconductors, is likely to take 15 years to find a suitable commercial material, if at all possible. Work has already been undertaken to investigate alternative dopants and different high temperature superconductors and only a few materials are being investigated further by researchers. For example, research with Bi2212 is still being carried out in order to improve its performance.[51]

Sumitomo (2020 d) are monitoring this research and if or when a suitable lead-free material is discovered, will assess it for commercialisation. Once Sumitomo (2020 d) will have completed this assessment, all essential requirements would have to be tested. As these tests would need to be carried out under realistic use conditions, which are at low temperatures and exposure to vibration, accelerated testing is not possible as the behaviour at higher temperatures (usually used to accelerate failure modes) will not be representative of very low temperatures as material properties are temperature dependent.

Consequentially, Sumitomo (2020 d) estimate a timeframe of 15 years for this work. Therefore, a total of over 30 years would not be unexpected and could be longer if substitute materials prove to be unreliable.

[51] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5473663/; reference as cited by the applicant

7.5.5. Environmental arguments and socioeconomic impacts

Due to the high price, the size and composition of NMR and MRI devices, the applicant assumes that they will be reused or undergo recycling processes when in around 15 years the first LBi2223-superconducting devices will reach their end of life. This will increase the amount of lead in such type of waste from currently 1 to around 15.5 kg per year.

The applicant does not raise the claim that the use of lead in this case is likely to outweigh environmental, health and consumer safety benefits of a potential substitution according to Art. 5 (1)(a)(III) since lead-free alternatives are not yet available. Reuse and sound recycling of such waste devices are important and beneficial, but per se would not justify an exemption if lead-free alternatives are available.

The applicant argues that researchers (NMR) and the health sector (MRI) would not benefit from the superior performance of the LBi2223 material in case this exemption is not granted. Since the applicant's arguments supporting this superiority thesis are plausible, and no stakeholders objected this view, the consultants agree that granting the exemption would be beneficial for the EU as long as no lead-free alternatives are available.

7.5.6. 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 applicant requests an exemption for a lead-doped bismuth strontium calcium copper oxide (BSCCO) material for superconducting wires and cables for NMR and MRI devices.

Based on the available and in the absence of contradicting information, it is concluded that the substitution and/or elimination of lead in this material are scientifically and technically not practicable in the foreseeable future. The addition of lead to BSCCO is required to promote the most advantageous Bi2223-phase of the material. The available information also suggests that lead is also required to form reliable electrical connections to lead-doped BSCCO-wires. Substitution or elimination are not scientifically and technically impracticable in the foreseeable future.

In its Bi2223-phase, the lead-doped BSCCO-material (LBSCCO) exhibits performance and technical advantages over other superconducting materials that have been in use for MRI and NMR devices in the EU.

The material's physical properties have the potential to enable stronger magnetic fields in high quality compared to niobium-titanium and niobium-tin superconductors. Strong high-quality magnetic fields produce higher resolution images with MRI and in particular with NMR devices, where the LBi2223 material's capability to generate very strong magnetic fields can be exploited to its physical limits since no patients are exposed to these very strong magnetic fields.

Higher resolution images allow better diagnoses of patients (MRI devices) and therefor offer clinical health advantages for humans. In NMR devices, higher resolution images enable deeper insights into structures of molecules etc., which provides advantages for research and innovation.

In theory, LBSCCO superconductors could be operated at higher temperatures, e.g. the temperature of liquid nitrogen (around 77 K) since its critical temperature is around 100 K higher than that of NbSn and NbTi superconductors, who have to be operated at low temperatures, i.e. the liquid helium temperature of around 4 K. This would avoid the use of the critical material helium and save energy. In practice, LBSCCO superconductors will, like other high temperature superconductors, be operated at liquid helium temperature nevertheless as critical current values are then higher enabling significantly stronger magnetic fields.

In this 4 K low temperature operation mode, the LBSCCO reduces, however, the risk of thermal runaways. In case the temperature in superconductors exceeds the critical temperature, they lose their superconducting properties and develop electrical resistance which heats up the device and due to the strong currents in the superconducting wires and cables may destroy the device and cause accidents. The LBSCCO provides a safety margin of around 110 K to thermal runaways, while NbSn and NbTi superconductors offer only a margin of around six and 14 K.

The applicant puts forward the further advantage that LBSCCO-superconductors take less time to bring them into operational mode when the magnetic field had to be switched off, e.g. at the first start or after repair and maintenance works (short ramp-up times). This reduces downtimes of the MRI and in particular of NMR devices. Since such interruptions of the operations does not occur often in practice, this advantage is minor.

The above advantages of the LBSCCO-material have the potential to promote improvements and innovation in medical diagnostics and in research. Substitution or elimination of lead in the LBSCCO material are scientifically and technically impracticable in the foreseeable future. Granting the exemption in the consultants' opinion would be in line with Art. 5(1)(a).

7.6. Recommendation

Based on the information submitted by the applicant and in the absence of contradicting information, the consultants recommend granting the exemption. The addition of lead to the BSCCO-material promotes the LBi2223-phase of the material which exhibits superior properties which at the current state of science and technology cannot be verified without lead in the superconducting LBi2223-material and without lead-solders. Granting an exemption would therefore be justified by Art. 5(1)(a).

The consultants recommend the following wording for the exemption in agreement with the applicant:

> *Lead in bismuth lead strontium calcium copper oxide superconductor cables and wires and lead in electrical connections to these wires*
>
> *Expires on 30 June 2027*

Substitution or elimination of lead in the superconducting material and the related solders are neither currently nor for the foreseeable future expected to be scientifically and technically practicable. The consultants therefore recommend granting the exemption for the maximum possible seven years.

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A Appendix

A.1 Aspects relevant to the REACH Regulation

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), pg. 1)
- Where processes related to the REACH regulation should be followed to understand where such cases may become relevant in the future;

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

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

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

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

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

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

(*) 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 $2PbCO_3$-$Pb(OH)_2$ 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_xSO_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: Cadmium carbonate Cadmium chloride Cadmium dihydroxide Cadmium dinitrate Cadmium fluoride	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: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,

Designation of the substance, group of substances, or mixture	Conditions of restriction
Cadmium hydroxide Cadmium (pyrophoric) Cadmium nitrate Cadmium oxide Cadmium Sulphate Cadmium sulphide Chromium (VI) trioxide Zinc chromates including zinc potassium chromate Nickel Chromate Nickel dichromate Potassium dichromate Ammonium dichromate Sodium dichromate Chromyl dichloride; chromic oxychloride Potassium chromate Calcium chromate Strontium chromate Chromium III chromate; chromic chromate Sodium chromate Lead Chromate Lead hydrogen arsenate Lead Nickel Salt Lead sulfochromate yellow; C.I. Pigment Yellow 34; Lead chromate molybdate sulfate red; C.I. Pigment Red 104;	— 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.

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: Cadmium carbonate Cadmium chloride Cadmium dihydroxide Cadmium dinitrate Cadmium fluoride Cadmium hydroxide Cadmium nitrate Cadmium Sulphate Chromium (VI) trioxide Potassium dichromate Ammonium dichromate Sodium dichromate Chromyl dichloride; chromic oxychloride Potassium chromate Sodium chromate	
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.'Toxic to reproduction: category 1A or 1B or toxic to reproduction category 1 or 2 According to Appendices 5 and 6: Cadmium chloride Cadmium fluoride	

Designation of the substance, group of substances, or mixture	Conditions of restriction
Cadmium Sulphate Potassium dichromate Ammonium dichromate Sodium dichromate Sodium chromate Nickel dichromate Lead compounds with the exception of those specified elsewhere in this Annex Lead Arsenate Lead acetate Lead alkyls Lead azide Lead Chromate Lead di(acetate) Lead hydrogen arsenate Lead 2,4,6-trinitroresorcinoxide, lead styphnate Lead(II) methane- sulphonate Trilead bis- (orthophosphate) Lead hexa-fluorosilicate Mercury Silicic acid, lead nickel salt	
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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	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. 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.
51. The following phthalates (or other CAS and EC numbers covering the substance): (a) Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0 (b) Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4 (c) Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7	1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles. 2. Toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market. 4. For the purpose of this entry 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.
62. (a) Phenylmercury acetate EC No: 200-532-5 CAS No: 62-38-4 (b) Phenylmercury propionate EC No: 203-094-3	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: 103-27-5 (c) Phenylmercury 2-ethylhexanoate EC No: 236-326-7 CAS No: 13302-00-6 (d) Phenylmercury octanoate EC No: - 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate paragraphs 1 to 5 of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly. 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 (***)

Designation of the substance, group of substances, or mixture	Conditions of restriction
	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. --- (*) 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	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. (*) 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 June 2020, 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)).

A.2 Update of the data provided by the analysis model developed in the course of the "Study to assess socio-economic impact of substitution of certain mercury-based lamps currently benefiting of RoHS 2 exemptions in Annex III"

Öko-Institut e.V.
Institut für angewandte Ökologie
Institute for Applied Ecology

Update of the data provided by the analysis model developed in the course of the "Study to assess socio-economic impact of substitution of certain mercury-based lamps currently benefiting of RoHS 2 exemptions in Annex III"

Performed under the study request No.07.0201/2019/811056/ENV.B.3

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List of Abbreviations

BAU	Business as usual scenario
CFLni	Compact fluorescent lamps without integrated ballast
LED	light-emitting diode
LFL	Linear fluorescent lamps
MELISA	VHK (2016) Model for European LIght Sources Analysis (MELISA) VHK (2019) MELISA update for Single Lighting Regulation
Plug&Play	A lamp that can be used as a “drop-in” replacement, through its insertion into a luminaire (plugging in, screwing in), without requiring the performance of any technical changes to the luminaire aimed at establishing the compatibility of the luminaire with the replacement lamp.
SEA	Socio-economic analysis
SUB	Substitution scenario
T5	Linear fluorescent lamps with a tube diameter ≥ 9 mm and ≤ 17 mm
T8	Linear fluorescent lamps with a tube diameter > 17 mm and ≤ 28 mm
VHK	Van Holsteijn en Kemna B.V.

1 Introduction and scope of the study

In July 2019, Oeko-Institut published the final report for *the "Study to assess socio-economic impact of substitution of certain mercury based lamps currently benefiting of RoHS 2 exemptions in Annex III*" (Baron et al. 2019) (hereafter referred to as "2019 SEA study"). This study had been contracted in 2017 by the European Commission as a follow up to the "*Study to assess renewal requests for 29 RoHS 2 Annex III exemptions [no. l(a to e -lighting purpose), no. l(f - special purpose), no. 2(a), no. 2(b)(3), no. 2(b)(4), no. 3, no. 4(a), no. 4(b), no. 4(c), no. 4(e), no. 4(f), no. 5(b), no. 6(a), no. 6(b), no. 6(c), no. 7(a), no. 7(c) - I, no. 7(c) - II, no. 7(c) - IV, no. 8(b), no. 9, no. 15, no. 18b, no. 21, no. 24, no. 29, no. 32, no. 34, no. 37]*" carried out by the Oeko-Institut in 2016 which recommended inter alia a phase-out of exemptions for certain mercury-based lamps. The goal of the 2019 SEA study was to assess possible socioeconomic impacts related to the substitution of these mercury-based lamps.

The 2019 SEA study was prepared based on data from the VHK (2016) Model for European LIght Sources Analysis (MELISA), data provided by Lighting Europe in 2015 as part of its applications for exemption, as well as data provided by Lighting Europe in 2017 through direct consultation related to the study. A first version of the study was submitted to the European Commission in 2017 but underwent several technical corrections until final publication in 2019. In this sense, despite the study's relatively recent publication in 2019, the results of the assessments contained therein are based on data representing the years 2013-2017.

In particular the data for the availability of substitutes, which has a significant impact on the costs of substitution, is considered outdated. This is due to the fast development and dynamic nature of the LED market segment. The European Commission has received new evidence from stakeholders as to the share of substitutes available and has thus requested a review of the assessment results for a number of lamp types: compact fluorescent lamps with non-integrated ballast (CFLni), linear fluorescent lamps (LFL) with a tube diameter ≥ 9 mm and ≤ 17 mm (T5) and LFL with a tube diameter > 17 mm and ≤ 28 mm (T8).

This document presents the results of a review of the 2019 SEA study as regards the elements specified below, based on three different data sets described in detail in the next section.

Regarding CFLni, T5 and T8, impacts have been calculated for the period 2021-2035, as regards:

- Purchase costs of substitution of such lamps with LED alternatives (considers costs of lamps and of luminaires as well as labour costs for luminaire rewiring and for luminaire replacement, where relevant);
- Energy savings expected through substitution of such lamps with LED alternatives;
- The amount of mercury avoided on the market through substitution of such lamps with LED alternatives;
- The amount of e-waste to be generated prematurely, where substitution with LED alternatives results in replacement of lighting components (e.g., driver, dimmer) or of the luminaire in its entirety.

The following scenarios were considered:

- Business as usual scenario (BAU): current RoHS exemptions for CFLni, T5 and T8 remain valid, however, as a result of the application of the new Ecodesign Regulation on light sources, some conventional lamp types will not be allowed to be placed on the market from respective dates[1].
- Substitution scenario (SUB): RoHS exemptions for CFLni, T5 and T8 expire, resulting in a regulatory driven phase-out of such lamps as of 2021.

[1] From 1 September 2021, the Ecodesign regulations (EC) No 244/2009, (EC) No 245/2009 and (EU) No 1194/2012 will be repealed and replaced by Commission Regulation (EU) 2019/2020 of 1 October 2019 laying down ecodesign requirements for light sources and separate control gears pursuant to Directive 2009/125/EC of the European Parliament and of the Council. With the new regulation, most traditional fluorescent tube lighting T8, which are common in offices, will be phased-out from September 2023 onwards. Likewise, most CFL with integrated ballast will not be able to fulfil the requirements set by the Regulation from September 2021.

2 Data used for the current review

The current estimations have been calculated applying the 'VHK-Oeko-Institut Combined Model for RoHS'. For assessing the impacts of possible new RoHS measures for the above mentioned three lamp types, the 'VHK-Oeko Institut Combined Model for RoHS' uses as reference the sales, efficiency, power, and light source price data from the ECO-scenario of the Model for European LIght Sources Analysis (VHK 2019), which was developed by VHK for scenario analysis in the Ecodesign and Energy Labelling context. The Eco-scenario in this model integrates the differences in sales for LFL T8 lamps that are expected due to the new lighting regulations CR 2019/2020 (ecodesign) and CDR 2019/2015 (energy labelling). For LFL T5 and CFLni the sales specified in this scenario are identical to those used in the initial 2019 SEA study. Additional differences in data applied from this source are specified in Annex I.

Further input for the Combined Model comes from the 2019 SEA study. In the combined model, VHK performed the energy and cost modelling and Oeko-Institut added modelling regarding the impacts on mercury and e-waste. For assessments regarding mercury impacts, the values specified in the 2019 SEA study (Baron et al. 2019), table 15 (for CFLni) and table 34 (for T5 and T8) have been used for revised calculations. Regarding assessments made for e-waste impacts, values used for the revised calculation are based on an average of best and worst case values applied in the 2019 study (Baron et al. 2019). In both cases, the values used in the 2019 SEA study were consulted with LightingEurope in 2017.

In the 2019 SEA study, assumptions were made for each lamp type as to the following aspects:

- the share of lamps that would be substituted with Plug&Play LED alternatives,
- the share of lamps to be substituted with LED alternatives requiring a rewiring or conversion of the luminaire, and
- the share of lamps the replacement of which would require a replacement of the luminaire.

Following the market developments of the last few years, further evidence as to the current shares related to these substitution routes in the market situation of 2020 was submitted to the European Commission. For LFL, the following estimations (Table 2-1) were provided to the European Commission by CLASP (Scholand 2020), based on a study performed jointly with the Swedish Energy Agency (Bennich, P. & Scholand, M. 2020)[2] (hereafter referred to as CLASP/SwEA report), which provides an overview of the current availability of LED alternatives for the relevant lamp types. Estimations for CFLni (also under Table 2-1) were provided separately (Bass, F. & Scholand, M. 2020) for the purpose of this review and are based on the market study performed for the CLASP/SwEA report. These market share estimations shall be referred to throughout this study as the **CLASP/SwEA data set**.

The second data set used in this review is based on the market share estimates for the availability of LED alternatives for T5, T8 and CFLni initially used in the 2019 SEA study and shall be referred to throughout this study as the **2019 SEA study data set**. In the consultants' view, documents submitted to the European Commission in the period of January-May 2020 by LightingEurope

[2] For T8, CLASP also provided data based on an estimation by Seaborough, a company developing LED technologies, which represents the availability of LED alternatives as estimated by this company. This estimate was slightly higher than that of the CLASP and Swedish Energy Agency report. Due to its similarity, the Seaborough estimations were not used for a separate assessment.

indicate that the lighting industry still considers data underlying the 2019 SEA study to correctly reflect the market situation in 2020.

The consultants base this conclusion on the following assessment of documents provided by LightingEurope: In January 2020, LightingEurope submitted renewed applications for exemptions to the European Commission. The renewal of exemptions 1(a, b, c, e) (LightingEurope 2020a) and exemptions 2(a)(2), 2(a)3, and 2(b)3 (LightingEurope 2020b) was requested. The applications refer to the difficulties expected regarding the substitution of various lamp types, including CFLni, LFL T5 and LFL T8. LightingEurope also refers to the three substitution routes mentioned above.

LightingEurope (2020a) states that replacement lamps for **CFLni** are available only for a limited number of lamp bases and includes a diagram showing nineteen different lamp bases, six of which are specified to exist as LED retrofits (accounting for ca. 30%). LightingEurope states that according to the MELISA model, the penetration for LED retrofit lamps substituting CFLni lamps is estimated to be 7% in 2019 and 10% in 2021. The substitution by LED indoor luminaires is estimated at 29% in 2019 and 37% in 2021. The consultants assume that these statements represent the share of lamps replaced with Plug&Play alternatives (7-10%) and with luminaire replacements (29-37%) under a BAU scenario where new CFLni can still be purchased as replacements. In the consultants' assessment, these shares are compatible with the 2019 SEA study data set shares for the CFLni SUB-scenario, where the availability of Plug&Play replacements is between 0-20%, of rewiring replacements between 24-30% and of luminaire replacement between 56-70%, depending on the lamp power sub-category (see Table 2-1).

For LFL T8, it is explained (LightingEurope 2020b) that due to the new Ecodesign Regulation, suitable LED alternatives will be available for T8 lamps with a length of 2, 4, or 5 feet for general lighting purposes. For such lamps, "*the most common colour temperatures are not available in very cool (12000K) and warm (2700K) colours*". In the consultants' view, assuming the above numbers refer to Plug&Play availability of T8 being between 10-30%, this would be in line with the 2019 SEA study estimate of 12% Plug&Play availability.

LightingEurope (2020b) state that there is currently no substantial amount of LED based lamps available for direct LFL T5 replacement in existing applications. In the consultants' assessment, this also fits with the 2019 SEA study data set shares which assume 1% availability of Plug&Play alternatives.

The shares applied under CLASP/SwEA data set and 2019 SEA study data set are presented inTable 2-1:

Table 2-1: Lamp share estimates applied in the model

Lamp Type		CLASP/ SwEA Plug&Play*	CLASP/ SwEA: LED + Rewiring*	CLASP/ SwEA: Luminaire replacement*	2019 SEA study** Plug&Play	2019 SEA study**: LED + Rewiring	2019 SEA study**: Luminaire replacement
CFLni	P <12 W	100%	0%	0%	0%	30%	70%
	12 W ≤ P < 30 W	85%	4.5%	10.5%	20%	24%	56%
	30 W ≤ P < 50 W	75%	7.5%	17.5%	0%	30%	70%
	P ≥ 50 W	75%	7.5%	17.5%	0%	30%	70%
T5		76%	0.7%	23.3%	1%	3%	96%
T8		96%	0.45%	3.55%	12%	10%	78%

Source: *Estimations presented for P&P by CLASP at Stakeholder meeting of 12.2.2020 and confirmed per email by Michael Scholand on 25.3.2020 and by (Bass, F. & Scholand, M. 2020). Estimations for LED+Rewiring and for Luminaire replacement calculated for remainder by Oeko-Institut. **Estimations from the 2019 SEA study are reproduced from the study for all categories.
Note: The CLASP estimation for T8 is a combined estimation for EM/CGG (100% coverage representing 70% of the market share) and HF/ECC (88% coverage representing 30% of the market share);

Considerations regarding CLASP/SwEA and 2019 SEA study data sets

As an explanation for the low shares of Plug&Play availability ascertained in their documents, LightingEurope mentions various limitations and technical aspects of the discharge lamps in question. In this respect, LightingEurope (2020a) mentions the wide variety of lamps in terms of types, shapes, sizes, wattages and colours, only for a few of which one-to-one replacements are available on the market. Standards such as EN60901, EN60969, EN60968 and EN61199, for CFL compatibility are also mentioned, whereas LED standardisation is said not to exist for these aspects. Additional aspects mentioned include the light distribution of the lamp itself and within the luminaire, the often-higher weight and sometimes higher prices (higher wattages) of LED alternatives, their compatibility with existing drivers and dimmers, and possible problems with flicker. Regarding the options to replace luminaires it is mentioned that luminaires are often built into the wall or ceiling, also resulting in the need for adjustments to introduce replacement luminaires. Lamps installed in emergency lighting luminaires are also addressed where standards specify which replacement lamps they can accept, ruling out LED retrofits.

Though it can be followed that there may be various limitations to the applicability of available Plug&Play alternatives, estimating the range of these is not straightforward. However, the assumptions for the 2019 SEA study were determined at the beginning of 2017. The range of LED lamp substitutes available on the market for each of the mentioned lamp types has increased in the period between 2017 and now (2020) and is also expected to increase further due to the dynamic character of this sector. Consequently, it stands to reason that the Plug&Play coverage of such lamps has also increased beyond the numbers applied in the 2019 SEA study. The CLASP/SwEA data set represents higher shares and assumes a very high coverage of Plug&Play lamps. It is not completely clear to which degree the CLASP/SwEA Plug&Play shares take into account some of the potential problems signalled by LightingEurope, such as the share of users having an FL control gear that is listed as incompatible by the manufacturers, the share of users having an FL control gear that does not appear on the compatibility lists, the share of users potentially facing difficulties with flicker, EMC, or certification after rewiring or light distribution issues. As mentioned above, these compatibility issues are generally difficult to quantify.

Against this background, a third data set has been applied in the model calculations to check the impacts in case the shares are more moderate than the two data sets addressed in Table 2-1. This third data set is considered as a sensitivity analysis and thus titled the **Sensitivity data set**. It is based on shares applied by VHK in a calculation of impacts presented at a stakeholder meeting organised by the European Commission on 12 February 2020. The Sensitivity data set assumes an availability of Plug&Play alternatives which leads to: 50% of lamps requiring a replacement; 10% requiring rewiring; and in the rest of the cases, luminaire replacement. These shares are presented in Table 2-2.

It has been considered necessary to add the Sensitivity dataset to the report also in view of the chain of comments from LightingEurope (2020c). In its comments on the 12 February 2020 meeting, LightingEurope stated: '*In the view of LightingEurope, VHK assumed and presented a realistic share of replacement options during the stakeholder meeting*', while in later communications to the Commission they clarified that this should be interpreted as '*the VHK approach seemed to be the most realistic compared to the CLASP and Seaborough comments*'. In a subsequent presentation of calculations, LightingEurope (2020d) stated that '*About 50% of retrofit solutions are not compatible with installed luminaires*', thus suggesting that a 50% Plug&Play share, as used in the Sensitivity dataset, could at least be considered plausible. In later communications to the Commission they clarified that '*the 50% is a generalization based on a more specific breakdown by application and by product group*', but without specifying the details of this breakdown, and without supporting the 50%/10%/40% substitution shares. Taking these comments into account, the Sensitivity dataset was considered sufficiently relevant to be added to the report.

Table 2-2: Lamp share estimates applied in the model for the Sensitivity data set

Lamp type	Plug&Play	Rewiring	Luminaire replacement
All types (CFL, LFL)	50%	10%	40%

Source: Based on shares presented by VHK at expert meeting held by the European Commission on 12.2.2020

Finally, the 2019 SEA study estimated impacts for the period between 2016 and 2025. Effectively, this meant impacts to incur between 2019 and 2025, as it was assumed in the study that following a delegated act regarding the exemptions listed in Annex III of RoHS, a certain time period would be granted before discharge lamps for which an exemption would have expired would no longer be placed on the market. The current model looks at impacts over a longer period, between 2021 and 2035. 2021 was chosen in consultation with the European Commission. Although it is not clear at the time of this report when the decision on the relevant exemptions will be adopted, in practice, any amendments to the relevant exemptions are unlikely to become applicable before July 2021. The current investigation thus looks at impacts starting in 2021. A longer observation period until 2035 has been chosen to provide a more representative impact that covers most lamps to be substituted as well as a more significant share of energy savings to be obtained through the shift to LED. As setting this final date is also not straightforward, the presentation of results includes cumulative cost savings for all years, allowing readers to also see results were the observed period is set to end at an earlier date.

Detailed explanations as to how market flows and certain impacts have been calculated are specified in the 2019 SEA study report. Additional input variables used appear in Annex I. The following sections provide a summary of the results of the revision, calculated on the basis of the data sets specified above.

3 Revised estimated impacts for CFLni

Table 3-1 presents data and estimations identical for all three data sets. It includes the number of CFLni that need replacement in each year (distribution to residential and non-residential), the energy (cost) savings related to substitution with LED alternatives and the total avoided mercury on the market.

Table 3-1: Number of CFLni to be replaced, related energy (cost) savings and mercury avoided on the market

All data sets	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
CFLni projected sales, all sectors (mln)	44.8	41.9	38.1	33.5	28.6	23.5	19.1	15.0	11.3	8.3	6.5	5.1	3.9	3.0	2.2
CFLni replaced by LED, residential (mln)	13.3	13.2	12.9	12.3	10.9	9.3	7.6	5.8	4.4	3.4	2.8	2.4	2.1	1.7	1.4
CFLni replaced by LED, non-resident. (mln)	31.4	28.6	25.2	21.2	17.6	14.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total energy savings in SUB, GWh	-693	-1354	-1966	-2506	-2974	-3363	-2972	-2581	-2209	-1874	-1587	-1349	-1152	-991	-866
Total energy cost savings in SUB, M euros	**-124**	**-245**	**-359**	**-463**	**-555**	**-634**	**-569**	**-502**	**-437**	**-378**	**-323**	**-278**	**-240**	**-210**	**-186**
Total avoided mercury in SUB in kg	**134**	**126**	**114**	**101**	**86**	**71**	**57**	**45**	**34**	**25**	**20**	**15**	**12**	**9**	**7**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

The first line in Table 3-1 presents the projected sales of CFLni, decreasing with the years, which would take place in the BAU scenario, where RoHS exemptions remain applicable for CFLni. Practically all these sales are replacement sales, i.e., of CFLni replacing CFLni that have reached the end-of-life. In the SUB scenario, once the RoHS exemptions are revoked, it is assumed that CFLni could no longer be sold and could no longer be used for replacement of such lamps at end-of-life. Thus, all such replacements would need to be performed with LEDs through Plug&Play replacements, through such replacements with additional rewiring work or through replacement of the luminaire. In the residential sector, where CFLni lifetime is 14 years, LED replacements take place based on these sales until 2035 (second line in table). In the non-residential sector however, where the average CFLni lifetime is 6 years, in the BAU scenario, CFLni sold in for example 2027 would replace CFLni sold in 2021. In contrast, in the SUB Scenario, CFLni replaced in 2021 by LEDs, which have a much longer lifetime, will not need to be replaced again in 2027, nor later within the observed period. Therefore, from 2027 onwards, non-residential CFLni replaced by LED are set to zero (third line in table).

Energy savings are computed as the difference between electricity consumption by LEDs replacing CFLni in the SUB scenario and electricity consumption that CFLni would otherwise have generated in the BAU scenario. The difference is multiplied by the electricity rate (€/kWh) to derive the corresponding cost savings. Energy savings (negative values in the table) increase in early years but decrease from 2027. In that year the CFLni bought in 2021 reach their end-of-life and the stock considered in the analysis starts to decrease.

In the period between 2021 and 2035, given that alternatives do not contain mercury, a total amount of 856 kg of mercury is avoided from being placed on the EU market.

The revised calculations for impacts of the regulatory driven substitution of CFLni lamps, performed on the basis of the CLASP/SwEA data set, are presented in Table 3-2.

Table 3-2: Revised estimated impacts calculated for CFLni (using CLASP/SwEA data set)

CLASP/SwEA data set	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Avoided purchase cost in SUB for CFLni, M euros	-208	-195	-179	-158	-135	-111	-91	-71	-54	-39	-31	-24	-19	-15	-11
Additional purchase cost for LED in SUB plug&play, M euros	471	403	345	285	229	186	38	28	21	16	13	11	9	8	7
Additional cost for LED+rewiring in SUB, M euros	68	62	56	48	40	33	8	6	5	4	3	3	2	2	2
Additional cost for LED+luminaire in SUB, M euros	292	274	249	219	187	153	50	38	29	22	19	16	13	11	9
Total additional purchase costs in SUB, M euros	**624**	**544**	**471**	**394**	**321**	**261**	**6**	**2**	**0**	**2**	**3**	**5**	**6**	**6**	**6**
Total additional cost in SUB, M euros (add. purchase cost minus energy cost savings)	500	299	112	-68	-234	-373	-563	-500	-437	-376	-320	-273	-234	-203	-180
Cumulative from period start in SUB, M euros	**500**	**800**	**912**	**843**	**609**	**236**	**-327**	**-828**	**-1264**	**-1640**	**-1960**	**-2232**	**-2467**	**-2670**	**-2849**
Total additional E-waste in SUB in million kg	**4,1**	**3,8**	**3,5**	**3,0**	**2,6**	**2,1**	**0,7**	**0,5**	**0,4**	**0,3**	**0,3**	**0,2**	**0,2**	**0,2**	**0,1**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

The additional purchase costs are computed as the sum of (additional) costs in the SUB scenario for LED Plug&Play, LED + rewiring, and LED + luminaire replacement, minus the (avoided) purchase costs for CFLni of the BAU scenario. The additional purchase costs decrease with the years because the number of CFLni lamps substituted by LEDs decreases and because LED prices progressively decrease. From 2027, the additional costs are close to zero because only few residential CFLni are still to be replaced by LED.

Combining the additional purchase costs with the energy cost savings of Table 3-1 leads to an annual net benefit already from 2024, whereas cumulatively, the total purchase costs are set-off by total energy savings starting from 2027. The regulatory-driven substitution would result in a total net benefit of 2849 million euros for the period between 2021 and 2035. Considering a total number of 242 million CFLni substituted by LEDs, this translates into a net benefit of 11.78 euros per lamp. As the table provides cumulative results for each year, it can also be observed for example, that in the years between 2021 and 2030, benefits accumulate in an order of 1640 million euros.

The regulatory-driven phase-out results in some cases in the need to rewire existing luminaires or to replace them, which generates a total amount of 22,000 tonnes of e-waste prematurely (accelerated impact). It is noted that this calculation does not consider that fluorescent lamps or luminaires may weigh more than the LED lamps or luminaires replacing them, which in the long term could lead to a decrease in generated e-waste.

Results change significantly when applying the 2019 SEA study data set estimate on the availability of between 0 to 20% Plug&Play substitutes to the calculation model. The revised calculations for impacts, performed on the basis of the 2019 SEA study data set, are presented in Table 3-3. In total, the regulatory-driven substitution results for this data set in a total net cost of 9,044 million euros for the period between 2021 and 2035 due to the high costs of luminaire replacements. This translates into a cost of 37.39 euros per lamp. Here too, cumulative costs can be observed for each year in the table below.

In this period, a larger amount of e-waste, 180 thousand tonnes, is generated prematurely (accelerated impact) when applying the 2019 SEA study data set as a larger number of lamps replaced require rewiring (24-30%) or luminaire replacement (56-70%).

Table 3-3: Revised estimated impacts calculated for CFLni (using 2019 SEA study data set)

2019 SEA study data set	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Avoided purchase cost in SUB for CFLni, M euros	-208	-195	-179	-158	-135	-111	-91	-71	-54	-39	-31	-24	-19	-15	-11
Additional purchase cost for LED in SUB plug&play, M euros	46	39	33	28	22	18	4	3	2	2	1	1	1	1	1
Additional cost for LED+rewiring in SUB, M euros	559	509	454	391	328	268	68	51	38	30	25	21	18	15	12
Additional cost for LED+luminaire in SUB, M euros	2386	2232	2031	1785	1523	1251	406	311	234	180	151	128	110	92	76
Total additional purchase costs in SUB, M euros	**2782**	**2585**	**2340**	**2046**	**1738**	**1426**	**387**	**295**	**221**	**172**	**146**	**126**	**110**	**93**	**78**
Total additional cost in SUB, M euros (add. purchase cost minus energy cost savings)	2659	2341	1981	1583	1183	792	-182	-207	-216	-206	-177	-152	-130	-116	-108
Cumulative from period start in SUB, M euros	**2659**	**4999**	**6981**	**8563**	**9746**	**10538**	**10356**	**10149**	**9933**	**9727**	**9550**	**9399**	**9268**	**9152**	**9044**
Total additional E-waste in SUB in million kg	**33.2**	**31.1**	**28.3**	**24.9**	**21.2**	**17.4**	**5.7**	**4.3**	**3.3**	**2.5**	**2.1**	**1.8**	**1.5**	**1.3**	**1.1**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

3.1 Sensitivity analysis

The 2019 SEA study dataset and the CLASP/SwEA dataset represent the upper and lower ranges of possible impacts of a phase-out of CFLni lamps to begin in 2021. To show how impacts are affected when an intermediate number of lamps is assumed to be replaced with Plug&Play substitutes, the Sensitivity data set was applied. Results for this data set are presented in Table 3-4.

Annually, the total additional costs under the Sensitivity data set assumptions lead to benefits as of 2027. However, cumulatively, the costs of the phase-out that amount to 3,404 million euros are not completely set-off within the period between 2021 and 2035. The costs of this transition amount to 14.05 euro per lamp. In total, within this period ca. 106 thousand tonnes of E-waste are generated prematurely.

Table 3-4: Revised estimated impacts calculated for CFLni (using Sensitivity data set)

Sensitivity data set	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Avoided purchase cost in SUB for CFLni, M euros	-208	-195	-179	-158	-135	-111	-91	-71	-54	-39	-31	-24	-19	-15	-11
Additional purchase cost for LED in SUB plug&play, M euros	265	227	194	161	129	105	22	16	12	9	7	6	5	4	4
Additional cost for LED+rewiring in SUB, M euros	204	186	166	143	120	98	25	19	14	11	9	8	7	5	5
Additional cost for LED+luminaire in SUB, M euros	1492	1396	1270	1116	952	782	254	195	146	113	94	80	69	58	47
Total additional purchase costs in SUB, M euros	**1753**	**1613**	**1451**	**1261**	**1066**	**874**	**210**	**158**	**118**	**93**	**80**	**70**	**62**	**53**	**45**
Total additional cost in SUB, M euros (add. purchase cost minus energy cost savings)	1629	1369	1092	799	511	239	-359	-344	-319	-285	-243	-208	-179	-157	-141
Cumulative from period start in SUB, M euros	**1629**	**2998**	**4090**	**4888**	**5399**	**5638**	**5279**	**4935**	**4617**	**4332**	**4089**	**3881**	**3702**	**3546**	**3404**
Total additional E-waste in SUB in million kg	**19.6**	**18.3**	**16.7**	**14.6**	**12.5**	**10.3**	**3.3**	**2.6**	**1.9**	**1.5**	**1.2**	**1.1**	**0.9**	**0.8**	**0.6**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

4 Revised estimated impacts for LFL T5

Table 4-1 presents data and estimations identical for all three data sets. It includes the number of LFL T5 that need replacement in each year (distribution to residential and non-residential), the energy (cost) savings related to substitution with LED alternatives and the total avoided mercury on the market.

Table 4-1: Number of LFL T5 to be replaced, related energy (cost) savings and mercury avoided on the market

All data sets	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
LFL T5 projected sales, all sectors (mln)	61.2	57.3	52.7	47.7	42.7	39.3	36.1	33.0	29.9	26.8	25.0	23.1	21.1	19.0	16.9
LFL T5 replaced by LED, residential (mln)	0.4	0.3	0.3	0.3	0.3	0.3	0.2	0.2	0.2	0.2	0.3	0.4	0.6	0.7	0.8
LFL T5 replaced by LED, non-resid. (mln)	60.8	56.9	52.3	47.4	42.5	39.1	35.9	32.8	29.7	26.6	0.0	0.0	0.0	0.0	0.0
Total energy savings in SUB, GWh	-1477	-2984	-4501	-5980	-7389	-8754	-10033	-11223	-12321	-13321	-12192	-11121	-10128	-9222	-8403
Total energy cost savings in SUB, M euros	**-260**	**-531**	**-808**	**-1085**	**-1354**	**-1620**	**-1875**	**-2118**	**-2349**	**-2565**	**-2348**	**-2142**	**-1951**	**-1776**	**-1619**
Total avoided mercury in SUB, in kg	**122**	**115**	**105**	**95**	**85**	**79**	**72**	**66**	**60**	**54**	**50**	**46**	**42**	**38**	**34**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

The first line in the table presents the projected sales of LFL T5, decreasing with the years, which would take place in the BAU scenario, where RoHS exemptions remain applicable for such lamps. Most of these sales are replacement sales, i.e. LFL T5 replacing LFL T5 that have reached end-of-life. In the SUB scenario, once the RoHS exemptions are revoked, it is assumed that LFL T5 could no longer be sold and could no longer be used for replacement of such lamps at end-of-life. Thus, all such replacements would need to be performed with LEDs through Plug&Play replacements, through such replacements with additional rewiring work or through replacement of the luminaire. In the residential sector, where LFL T5 lifetime is 28 years, LED replacements take place based on these sales until 2035 (second line in table). However, in the non-residential sector, where average LFL T5 lifetime is 10 years, in the BAU scenario, LFL T5 sold in for example 2031 would be replacements for LFL T5 sold in 2021. Whereas in the SUB Scenario, LFL T5s replaced by LEDs in 2021, which have a longer lifetime, no longer need to be replaced again in 2031. Therefore from 2031 onwards, non-residential LFL T5 replaced by LED are set to zero (third line in table).

Energy savings are computed as the difference between electricity consumption by LEDs substituting LFL T5 in the SUB scenario and electricity consumption that LFL T5 would otherwise have had in the BAU scenario. The difference is multiplied by the electricity rate (€/kWh) to get the corresponding cost savings. Energy savings (negative values in the table) increase in early years but decrease from 2031. In 2031 the LFL bought in 2021 reach their end-of-life and the stock considered in the analysis decreases significantly.

In the period between 2021 and 2035, a total amount of 1064 kg of mercury is avoided from being placed on the EU market.

The revised calculations for impacts of the regulatory driven substitution of LFL T5 lamps, performed on the basis of the CLASP/SwEA data set, are presented in Table 4-2.

Table 4-2: Revised estimated impacts calculated for T5 lamps (using CLASP/SwEA data set)

CLASP/SwEA data set	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Avoided purchase cost for LFLT5 in SUB, M euros	-485	-454	-418	-378	-339	-312	-286	-262	-237	-213	-199	-184	-168	-151	-135
Additional purchase cost for LED plug&play in SUB, M euros	1430	1218	1056	908	767	701	616	541	482	424	4	6	7	9	10
Additional cost for LED+rewiring in SUB, M euros	23	20	18	16	14	12	11	10	9	8	0	0	0	0	0
Additional cost for LED+luminaire in SUB, M euros	1566	1467	1348	1221	1094	1007	924	845	766	687	8	11	15	17	20
Total additional purchase costs in SUB, M euros	**2533**	**2250**	**2004**	**1767**	**1536**	**1408**	**1265**	**1134**	**1019**	**906**	**-186**	**-167**	**-146**	**-125**	**-105**
Total additional cost in SUB, M euros (add. purchase cost minus energy cost savings)	2273	1720	1196	682	182	-211	-610	-984	-1329	-1659	-2534	-2308	-2096	-1901	-1724
Cumulative from period start in SUB, M euros	**2273**	**3993**	**5189**	**5871**	**6053**	**5842**	**5232**	**4247**	**2918**	**1259**	**-1275**	**-3583**	**-5679**	**-7581**	**-9304**
Total additional E-waste in SUB, in million kg	**22.2**	**20.8**	**19.1**	**17.3**	**15.5**	**14.3**	**13.1**	**12.0**	**10.9**	**9.7**	**0.1**	**0.2**	**0.2**	**0.2**	**0.3**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

The additional purchase costs are computed as the sum of (additional) costs in the SUB scenario for LED Plug&Play, LED + rewiring, and LED + luminaire replacement, minus the (avoided) purchase costs for LFL T5 of the BAU scenario. The additional purchase costs decrease with the years because the number of LFL T5 substituted by LEDs decreases and because LED prices progressively decrease. From 2031, the additional costs are even negative because the avoided costs for LFL T5 are higher than the additional costs for the few residential LFL T5 that are still to be replaced by LED.

Combining the additional purchase costs the energy cost savings of Table 4-1 leads to an annual net benefit already from 2026, whereas cumulatively the total purchase costs are set-off by the total energy cost savings starting from 2031. The regulatory-driven substitution results in a total net benefit of 9304 million euros for the period between 2021 and 2035. Considering a total of 430 million LFL T5 substituted by LEDs, this translates into a net benefit of 21.66 € per lamp.

The regulatory driven phase-out leads in some cases to the need to rewire existing luminaires or to replace them, which generates a total amount of 156,000 tonnes of e-waste prematurely (accelerated impact). It is noted that this calculation does not consider that fluorescent lamps or luminaires may weigh more than the LED lamps or luminaires replacing them, which in the long term could lead to a decrease in generated e-waste.

These results change significantly when applying the 2019 SEA study data set on the availability of 1% Plug&Play substitutes to the calculation model. The results can be viewed in Table 4-3. In total, the regulatory-driven substitution results for this data set in a total net cost of 17,426 million euros for the period between 2021 and 2035 due to the high costs of luminaire replacements. This translates into a cost of 40.57 euros per lamp. Cumulative results can be observed in the table for each year. This shows for example that 2030 is the "peak" year in terms of the cumulative costs, after which the energy cost savings are dominant and reduce the sum.

In this period a larger amount of e-waste, 643 thousand tonnes, is generated prematurely (accelerated impact) when applying the 2019 SEA study data set as a larger number of lamps replaced require rewiring (3%) or luminaire replacement (96%).

Table 4-3: Revised estimated impacts calculated for T5 lamps (using 2019 SEA study data set)

2019 SEA study data set	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Avoided purchase cost for LFLT5 in SUB, M euros	-485	-454	-418	-378	-339	-312	-286	-262	-237	-213	-199	-184	-168	-151	-135
Additional purchase cost for LED plug&play in SUB, M euros	19	16	14	12	10	9	8	7	6	6	0	0	0	0	0
Additional cost for LED+rewiring in SUB, M euros	93	82	73	64	56	51	46	41	37	33	0	0	1	1	1
Additional cost for LED+luminaire in SUB, M euros	6459	6050	5561	5037	4512	4152	3812	3485	3160	2834	34	47	61	72	83
Total additional purchase costs in SUB, M euros	6086	5694	5230	4735	4239	3901	3580	3271	2966	2659	-165	-136	-107	-79	-51
Total additional cost in SUB, M euros (add. purchase cost minus energy cost savings)	5826	5163	4422	3650	2885	2281	1705	1153	617	95	-2512	-2278	-2057	-1855	-1670
Cumulative from period start in SUB, M euros	**5826**	**10990**	**15412**	**19062**	**21947**	**24229**	**25934**	**27087**	**27704**	**27799**	**25287**	**23009**	**20951**	**19096**	**17426**
Total additional E-waste in SUB, in million kg	**91.6**	**85.8**	**78.8**	**71.4**	**64.0**	**58.9**	**54.0**	**49.4**	**44.8**	**40.2**	**0.5**	**0.7**	**0.9**	**1.0**	**1.2**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

4.1 Sensitivity analysis

The 2019 SEA study dataset and the CLASP/SwEA dataset represent the upper and lower ranges of possible impacts of a phase-out of LFL T5 lamps to begin in 2021. To show how impacts are affected when an intermediate number of lamps is assumed to be replaced with Plug&Play substitutes, the Sensitivity data set was applied. Results for this data set are presented in Table 4-4.

Annually, the total additional costs under the Sensitivity data set assumptions lead to benefits as of 2027. However, cumulatively, the costs are only set off in 2034. The total cumulative benefits amount to 2,405 million euros for the period between 2021 and 2035. The benefits of this transition amount to 5.60 euro per lamp. In total, within this period ca. 279 thousand tonnes of E-waste are generated prematurely.

Table 4-4: Revised estimated impacts calculated for LFL T5 (using Sensitivity data set)

Sensitivity data set	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Avoided purchase cost in SUB for CFLni, M euros	-485	-454	-418	-378	-339	-312	-286	-262	-237	-213	-199	-184	-168	-151	-135
Additional purchase cost for LED in SUB plug&play, M euros	941	801	695	598	505	461	405	356	317	279	3	4	5	6	7
Additional cost for LED+rewiring in SUB, M euros	310	275	244	215	186	171	153	137	123	109	1	2	2	3	3
Additional cost for LED+luminaire in SUB, M euros	2691	2521	2317	2099	1880	1730	1588	1452	1317	1181	14	20	25	30	35
Total additional purchase costs in SUB, M euros	**3458**	**3142**	**2838**	**2533**	**2232**	**2051**	**1861**	**1683**	**1519**	**1356**	**-181**	**-159**	**-136**	**-113**	**-91**
Total additional cost in SUB, M euros (add. purchase cost minus energy cost savings)	3198	2612	2030	1448	879	431	-14	-435	-829	-1209	-2528	-2300	-2086	-1890	-1710
Cumulative from period start in SUB, M euros	**3198**	**5809**	**7839**	**9288**	**10166**	**10597**	**10583**	**10148**	**9319**	**8110**	**5581**	**3281**	**1195**	**-695**	**-2405**
Total additional E-waste in SUB in million kg	**39.8**	**37.3**	**34.3**	**31.0**	**27.8**	**25.6**	**23.5**	**21.5**	**19.5**	**17.5**	**0.2**	**0.3**	**0.4**	**0.4**	**0.5**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

5 Revised estimated impacts for LFL T8

Table 5-1 presents data and estimations identical for all three data sets. It includes the number of LFL T8 that need replacement in each year (distribution to residential and non-residential), the energy (cost) savings related to substitution with LED alternatives and the total avoided mercury on the market.

Table 5-1: Number of LFL T8 to be replaced, related energy (cost) savings and mercury avoided on the market

All data sets	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
LFL T8 projected sales in SUB, all sectors (mln)	123.9	99.9	60.7	28.4	17.8	12.5	7.8	7.0	6.2	5.2	4.4	3.7	3.0	2.3	1.8
LFL T8 replaced by LED in SUB, residential (mln)	10.2	7.1	3.9	1.9	1.2	0.9	0.6	0.7	0.7	0.7	0.7	0.6	0.6	0.6	0.5
LFL T8 replaced by LED in SUB, non-resid. (mln)	113.7	92.8	56.8	26.5	16.5	11.5	7.2	6.3	5.4	4.5	0.0	0.0	0.0	0.0	0.0
Total energy savings in SUB, GWh	-4645	-8695	-11355	-12674	-13539	-14171	-14571	-14931	-15246	-15511	-10611	-6610	-4187	-3088	-2414
Total energy cost savings in SUB, M euros	-820	-1550	-2045	-2305	-2487	-2629	-2730	-2826	-2915	-2995	-2052	-1283	-816	-605	-475
Total avoided mercury in SUB, in kg	**310**	**250**	**152**	**71**	**44**	**31**	**20**	**18**	**15**	**13**	**11**	**9**	**7**	**6**	**4**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

The first line in Table 5-1 presents the projected sales of LFL T8, decreasing with the years, which would take place in the BAU scenario, where RoHS exemptions remain valid for LFL T8. This projection reflects the Ecodesign scenario with phase-out of most LFL T8 for energy efficiency reasons starting from 2023. Most of these sales are replacement sales, i.e. LFL T8 replacing LFL T8 that have reached end-of-life. In the SUB scenario, once the RoHS exemptions are revoked, it is assumed that LFL T8 could no longer be sold and could no longer be used for replacement of such lamps at end-of-life. Thus, all such replacements would need to be performed with LEDs through Plug&Play replacements, through such replacements with additional rewiring work or through replacement of the luminaire. In the residential sector, where LFL T8 lifetime is 18 years, LED replacements take place based on these sales until 2035 (second line in table). However, in the non-residential sector, where average LFL T8 lifetime is 10 years, LFL T8 sold in for example 2031 in the BAU scenario would be replacements for LFL T8 sold in 2021. Whereas in the SUB scenario, LFL T8 replaced in 2021 by LEDs, which have a longer lifetime, will not need to be replaced again in 2031. Therefore from 2031 onwards, non-residential LFL T8 replaced by LED are set to zero (third line in table).

Energy savings are computed as the difference between electricity consumption by LEDs substituting LFL T8 in the SUB scenario and electricity consumption that LFL T8 would otherwise have had in the BAU scenario. The difference is multiplied by the electricity rate (€/kWh) to get the corresponding cost savings. Energy savings (negative values in the table) increase in early years but decrease from 2031. In that year the LFL bought in 2021 reach their end-of-life and the stock considered in the analysis starts to decrease.

In the period between 2021 and 2035, a total amount of 962 kg of mercury is avoided from being placed on the EU market.

The revised calculations for impacts of the regulatory driven substitution of LFL T8 lamps, performed on the basis of the CLASP/SwEA data set, are presented in Table 5-2.

Table 5-2: Revised estimated impacts calculated for T8 lamps (using CLASP/SwEA data set)

CLASP/SwEA data set	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Avoided purchase cost for LFLT8 in SUB, M euros	-1060	-854	-518	-242	-152	-106	-67	-60	-53	-45	-38	-32	-26	-21	-16
Additional purchase cost for LED plug&play in SUB, M euros	4509	3338	1923	855	504	351	210	180	154	127	12	11	11	10	9
Additional cost for LED+rewiring in SUB, M euros	34	26	15	7	4	3	2	2	1	1	0	0	0	0	0
Additional cost for LED+luminaire in SUB, M euros	604	487	296	138	87	61	38	34	30	25	3	3	3	3	3
Total additional purchase costs in SUB, M euros	4087	2998	1716	758	443	308	183	156	132	108	-23	-18	-12	-8	-5
Total additional cost in SUB, M euros (add. purchase cost minus energy cost savings)	3267	1448	-329	-1547	-2044	-2321	-2547	-2670	-2782	-2887	-2076	-1300	-829	-613	-480
Cumulative from period start in SUB, M euros	**3267**	**4714**	**4386**	**2838**	**794**	**-1527**	**-4074**	**-6745**	**-9527**	**-12414**	**-14490**	**-15790**	**-16619**	**-17232**	**-17712**
Total additional E-waste in SUB, in million kg	**10.6**	**8.6**	**5.2**	**2.4**	**1.5**	**1.1**	**0.7**	**0.6**	**0.5**	**0.4**	**0.1**	**0.1**	**0.1**	**0.0**	**0.0**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

The additional purchase costs are computed as the sum of (additional) costs in the SUB scenario for LED Plug&Play, LED + rewiring, and LED + luminaire replacement, minus the (avoided) purchase costs for LFL T8 of the BAU scenario. The additional purchase costs decrease with the years because the number of LFL T8 substituted by LEDs decreases and because LED prices progressively decrease. From 2031, the additional costs are even slightly negative because the avoided costs for LFL T8 are higher than the additional costs for the few residential LFL T8 that are still to be replaced by LED.

Combining the additional purchase costs the energy cost savings of Table 5-1 leads to an annual net benefit already in 2023, whereas the cumulative total purchase costs are set-off by the cumulative total energy savings starting from 2026. The table shows cumulative costs for each year and as such it is observed for example that in 2030 the cumulative benefits have reached 12,414 million euro. In total, the regulatory driven substitution results in a total net benefit of over 17,721 million euros for the period between 2021 and 2035. Considering a total of 372 million LFL T8 substituted by LEDs, this translates into a net benefit per lamp of 47.56 euros.

The regulatory driven phase-out leads in some cases to the need to rewire existing luminaires or to replace them, which generates a total amount of 32,000 tonnes of e-waste prematurely (accelerated impact). It is noted that this calculation does not consider that fluorescent lamps or luminaires may weigh more than the LED lamps or luminaires replacing them, which in the long term could lead to a decrease in generated e-waste.

These results change significantly when applying the 2019 SEA study data set on the availability of 12% Plug&Play substitutes to the calculation model. In total, the regulatory-driven substitution results in a total net cost of 11,749 million euros for the period between 2021 and 2035 due to the high costs of luminaire replacements. This translates into a cost of 31.55 euros per lamp. This is despite the fact that on an annual basis, benefits can already be seen from 2025 and on. In the cumulative costs, specified in the table for each year, it is observed that total costs start to decrease here as well, however as the number of lamps to be replaced in the first years is significantly higher, though the energy savings have decreased the total costs on the cumulative basis in 2035 to less than half the amount of 2025, they are not set-off completely within the observed period.

In this period, the amount of mercury avoided on the EU market remains the same under both the CLASP/SwEA and 2019 SEA study data sets as the number of lamps to be replaced has not changed, but a larger amount of e-waste, 704 thousand tonnes, is generated prematurely (accelerated impact) applying the 2019 SEA study data set as a larger number of lamps replaced require rewiring (10%) or luminaire replacement (78%).

Table 5-3: Revised estimated impacts calculated for T8 lamps (using 2019 SEA study data set)

2019 SEA study data set	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Avoided purchase cost for LFLT8 in SUB, M euros	-1060	-854	-518	-242	-152	-106	-67	-60	-53	-45	-38	-32	-26	-21	-16
Additional purchase cost for LED plug&play in SUB, M euros	564	417	240	107	63	44	26	22	19	16	1	1	1	1	1
Additional cost for LED+rewiring in SUB, M euros	748	573	337	153	92	65	39	35	30	25	3	3	3	2	2
Additional cost for LED+luminaire in SUB, M euros	13285	10719	6515	3046	1906	1336	839	752	660	559	72	68	66	60	55
Total additional purchase costs in SUB, M euros	13537	10856	6574	3063	1909	1338	837	749	656	554	38	40	44	43	43
Total additional cost in SUB, M euros (add. purchase cost minus energy cost savings)	12717	9305	4530	758	-578	-1291	-1893	-2077	-2258	-2441	-2014	-1242	-772	-562	-433
Cumulative from period start in SUB, M euros	**12717**	**22022**	**26552**	**27310**	**26732**	**25441**	**23548**	**21471**	**19213**	**16773**	**14758**	**13516**	**12743**	**12182**	**11749**
Total additional E-waste in SUB, in million kg	**234.1**	**188.9**	**114.8**	**53.7**	**33.6**	**23.6**	**14.8**	**13.3**	**11.6**	**9.8**	**1.3**	**1.2**	**1.2**	**1.1**	**1.0**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

5.1 Sensitivity analysis

The 2019 SEA study dataset and the CLASP/SwEA dataset represent the upper and lower ranges of possible impacts of a phase-out of LFL T8 lamps to begin in 2021. To show how impacts are affected when an intermediate number of lamps is assumed to be replaced with Plug&Play substitutes, the Sensitivity data set was applied. Results for this data set are presented in Table 5-4.

Annually, the total additional costs under the Sensitivity data set assumptions lead to benefits as early as 2024. However, cumulatively, the costs are only set off in 2032. The total cumulative benefits amount to 2,879 million euros for the period between 2021 and 2035. The benefits of this transition amount to 7.73 euro per lamp. In total, within this period ca. 367 thousand tonnes of E-waste are generated prematurely.

Table 5-4: Revised estimated impacts calculated for LFL T8 (using Sensitivity data set)

Sensitivity data set	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Avoided purchase cost in SUB for CFLni, M euros	-1060	-854	-518	-242	-152	-106	-67	-60	-53	-45	-38	-32	-26	-21	-16
Additional purchase cost for LED in SUB plug&play, M euros	2349	1739	1001	445	262	183	109	94	80	66	6	6	6	5	5
Additional cost for LED+rewiring in SUB, M euros	748	573	337	153	92	65	39	35	30	25	3	3	3	2	2
Additional cost for LED+luminaire in SUB, M euros	6813	5497	3341	1562	977	685	430	386	339	287	37	35	34	31	28
Total additional purchase costs in SUB, M euros	**8850**	**6955**	**4161**	**1918**	**1180**	**826**	**512**	**454**	**396**	**332**	**7**	**11**	**16**	**18**	**19**
Total additional cost in SUB, M euros (add. purchase cost minus energy cost savings)	8029	5405	2117	-387	-1307	-1803	-2219	-2372	-2519	-2663	-2045	-1271	-800	-587	-456
Cumulative from period start in SUB, M euros	**8029**	**13434**	**15551**	**15163**	**13857**	**12054**	**9835**	**7463**	**4944**	**2281**	**236**	**-1035**	**-1835**	**-2423**	**-2879**
Total additional E-waste in SUB in million kg	**122.3**	**98.7**	**60.0**	**28.0**	**17.5**	**12.3**	**7.7**	**6.9**	**6.1**	**5.1**	**0.7**	**0.6**	**0.6**	**0.6**	**0.5**

Source: Calculated with the VHK-Oeko-Institut Combined Model for RoHS; Note: Values are rounded; Negative values represent benefits

6 Conclusions

For all lamp types (CFLni, LFL T5 and LFL T8), the total costs resulting from not granting the exemption renewals requested (a “substitution scenario”) largely depend on the share of Plug&Play lamps that would be available on the market as replacements at the time from when the exemptions expire. This is related to the costs of the rewiring and, in particular, to the costs of the luminaire replacement (where no Plug&Play lamps are available) being much higher for the end-user than a simple replacement of the lamp. Where Plug&Play alternatives are available, this relatively quickly leads to benefits through related energy savings and enables an average benefit of the substitution per lamp. Where such alternatives are lacking, the costs are high, as a result of the additional labour costs for rewiring and luminaire replacement and, particularly, of the luminaire replacement costs for which relatively high unit costs have been assumed in this study (100 euro per CFLni luminaire and 250 euro per LFL luminaire).

Common to all three data sets under the substitution scenario are the calculated energy savings and mercury emission avoidance. For all lamp types concerned, in the period of 2021-2035, energy savings would cumulatively amount to 309 TWh. Accordingly, mercury avoided in lamps being placed on the market would amount to 2 882 kg (this figure does not include reductions in mercury emissions from reduced electricity generation). It is to be noted that the environmental benefits from these energy savings (e.g. in terms of climate protection) and mercury emission avoidance (e.g. in terms of pollution prevention and human health benefits) could not be considered in the 2019 SEA study or this review.

The two main data sets examined here, one using estimations from CLASP/SwEA and the other from the 2019 SEA study, differ considerably in the estimations of the share of Plug&Play lamps available, as the market availability of these lamps increased significantly in the past three years. In consequence, there are considerable differences in the expected costs and benefits between the results generated by the calculation model for these data sets. The Sensitivity data set is more moderate relative to the two main data sets, the 2019 SEA study and CLASP/SwEA respectively, and its results are placed between them. It is also noted that although the 2019 SEA study considered multiple lamps per luminaire in its sensitivity analysis, the main scenario assumed a single lamp per luminaire. In the present model, depending on the lamp type, more than one lamp is assumed to be applied per luminaire replaced (1.5, 2 and 2.5 for CFLni, LFL T8 and LFL T5 respectively) and this affects the total estimated costs where luminaire replacement is concerned.

Regarding **CFLni** lamps, applying the CLASP/SwEA data set results in a total net benefit in the order of 2 849 million euros for the period between 2021 and 2035 (benefit of 11.78 euros per lamp). The 2019 SEA study data set results in total costs in the order of 9 044 million euros (cost of 37.39 euros per lamp). The process of substitution is accompanied with a premature generation of e-waste from rewiring and lamp replacement of between 22 and 180 thousand tonnes of e-waste (CLASP/SwEA and 2019 SEA study data sets respectively), though it is possible that lower weight of LED luminaires will in the long run generate a general decrease in e-waste amounts. Both cases avoid 856 kg of mercury in lamps being placed on the EU market. Under the Sensitivity data set, the cumulative costs of the phase-out amount to 3 404 million euros for the period between 2021 and 2035 or 14.07 euro per lamp. In parallel ca. 106 000 tonnes of e-waste are generated prematurely; mercury amounts not entering the market remain the same in all data sets (856 kg).

In relation to **LFL T5** lamps, applying the CLASP/SwEA data set results in a total net benefit in the order of 9 304 million euros to be incurred between 2021 and 2035 (benefit of 21.66 euros per lamp).

The 2019 SEA study data set results in total costs in the order of 17 426 million euros (costs of 40.57 euro per lamp). The process of substitution is accompanied by a premature generation of e-waste of between 156 and 643 thousand tonnes (CLASP/SwEA and 2019 SEA study data sets respectively), possibly to be offset in the future in light of lower weight of LED luminaires and tubes which could decrease general e-waste amounts. Both cases avoid 1 064 kg of mercury in lamps being placed on the EU market. Under the Sensitivity data set, the phase-out leads to cumulative benefits in the order of 2 405 million euros for the period between 2021 and 2035 or 5.60 euro per lamp. 279 000 tonnes of e-waste are generated prematurely; mercury amounts not entering the market remain the same in all data sets (1 064 kg).

In relation to **LFL T8** lamps, the CLASP/SwEA data set results in a total net benefit in the order of 17,712 million euros between 2021 and 2035 (benefit of 47.56 euros per lamp). The 2019 SEA study data set results in total costs in the order of 11,749 million euros (costs of 31.55 euro per lamp). The substitution is accompanied with a premature generation of e-waste from rewiring and lamp replacement of between 32 and 704 thousand tonnes of e-waste (CLASP/SwEA and 2019 SEA study data sets respectively), though possibly also with a general decrease in e-waste amounts in light of lower weight of LED luminaires and tubes. Both cases avoid 962 kg of mercury in lamps being placed on the EU market. Under the Sensitivity data set, the phase-out leads to cumulative benefits in the order of 2,879 million euros for the period between 2021 and 2035 or a benefit of 7.73 euro per lamp. 368 000tonnes of e-waste are generated prematurely; mercury amounts not entering the market remain the same in all data sets (962 kg).

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Annex I. Variables used in VHK-Oeko-Institut Combined Model for RoHS

Table 6-1: General input parameters

General input parameters			
Prices / costs	2015 euros		
Working hours per day	8		
Working days per year	220		
Labour cost (€/hour)	50		
VAT for residential users	20%		
	2020	2025	2030
Electricity rate, residential (2015 €/kWh) (incl. VAT)	0,21	0,22	0,23
Electricity rate, non-residential - tertiary (2015 €/kWh)	0,17	0,18	0,19
	LFL T8	LFL T5	All CFLni
N lamps per luminaire	2	2,5	1,5
Hours rewiring per luminaire	0,5	0,5	0,5
Hours installation per luminaire	0,5	0,5	0,5
FL unit price (excl. VAT, excl. install) (€)	8,42	7,92	4,39
CG unit price per light source, residential, incl. VAT (€)	10	10	10
CG unit price per light source, non-residential, excl. VAT (€)	10	10	20
LED luminaire price, residential, incl. light source and CG, incl. VAT (€)	250	250	100
LED luminaire price, non-residential, incl. light source and CG, excl. VAT (€)	250	250	100
Luminous flux, residential (lm) (FL and LED)	2400	2275	690
Luminous flux, non-residential (lm) (FL and LED)	3320	2600	1200
Annual burning hours, residential (h/a) (FL and LED)	700	700	700
Annual burning hours, non-residential (h/a) (FL and LED)	2200	2200	1600
Efficacy FL incl. CG, residential (lm/W)	72	82	55
Efficacy FL incl. CG, non-residential (lm/W)	77	85	55
Power FL incl. CG, residential (W)	33	28	12
Power FL incl. CG, non-residential (W)	43	31	22

Source: Source: Model for European LIght Sources (VHK 2019)

Table 6-2: Additional data for LEDs

LED input data	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
LED efficacy, res, lm/W [1]	110	118	126	134	142	150	152	155	157	160	160	160	160	160	160
LED efficacy, nres, lm/W [2]	132	139	148	157	166	175	179	183	186	190	190	190	190	190	190
LED price, res, euros/klm [1]	7.62	7.68	7.62	7.48	7.22	7.23	6.83	6.52	6.36	6.24	6.24	6.24	6.24	6.24	6.24
LED price, nres, euros/klm [2]	11.85	10.77	10.16	9.65	9.10	9.03	8.65	8.30	8.15	8.00	8.00	8.00	8.00	8.00	8.00
LEDs replacing LFL T8															
Power (W/unit) res	21.8	20.3	19.0	17.9	16.9	16.0	15.8	15.5	15.3	15.0	15.0	15.0	15.0	15.0	15.0
Power (W/unit) nres	25.2	23.9	22.4	21.1	20.0	19.0	18.6	18.2	17.8	17.5	17.5	17.5	17.5	17.5	17.5
LEDs replacing LFL T5															
Power (W/unit) res	20.7	19.3	18.1	17.0	16.0	15.2	15.0	14.7	14.5	14.2	14.2	14.2	14.2	14.2	14.2
Power (W/unit) nres	19.7	18.7	17.6	16.6	15.7	14.9	14.5	14.2	14.0	13.7	13.7	13.7	13.7	13.7	13.7
LEDs replacing CFLni															
Power (W/unit) res	6.3	5.8	5.5	5.1	4.9	4.6	4.5	4.5	4.4	4.3	4.3	4.3	4.3	4.3	4.3
Power (W/unit) nres	9.1	8.6	8.1	7.6	7.2	6.9	6.7	6.6	6.4	6.3	6.3	6.3	6.3	6.3	6.3

Notes:
1 – LED efficacy (incl. control gear) and price for residential, from MELISA 2019 for low-end LEDs with energy label effect (same as used in Impact Assessment accompanying 2019 single lighting regulation, SWD 2019/357 part 2, Annex 4, section 2.2)
2 – LED efficacy (incl. control gear) and price for non-residential, from MELISA 2019 for high-end LEDs with energy label effect (same as used in Impact Assessment accompanying 2019 single lighting regulation, SWD 2019/357 part 2, Annex 4, section 2.2)
Source: Model for European LIght Sources (VHK 2019)

Reference sales of fluorescent lamps

The MELISA model (VHK, 2019) projects the sales for LFL T8, and CFLni for an Ecodesign BAU scenario (without new ecodesign and energy labelling measures) and an Ecodesign ECO scenario (including also new measures). These sales are reported in Impact Assessment (IA) SWD 2019/357 Annex 4, accompanying the new lighting regulations CR 2019/2020 (ecodesign) and CDR 2019/2015 (energy labelling), but only the totals for all LFL and for all CFL are reported in the IA. The table below provides the subdivision of projected sales over LFL T8, T5 and CFLni.

For LFL T5 and CFLni, the new lighting regulations do not cause a phase-out of light sources and consequently the projected sales for BAU and ECO scenarios are the same. These sales can directly be used as fluorescent lamps to be replaced by LEDs in the RoHS SUB scenario.

For LFL T8, the new lighting regulations phase out models with 2/4/5 foot lengths. MELISA assumes that this covers ≈90% of all LFL T8 models. In the Impact Assessment the phase-out was proposed for 2021 (see sales of ECO 2021 IA in table below), but the final regulation implies a phase-out in 2023. The MELISA sales projection was adapted for the two year shift in phase-out between the IA and the final CR (see sales of ECO 2023 CR in table below).
In case of the RoHS BAU scenario (renewal of the exemptions, no forced substitution by LEDs), the ECO 2023 CR sales projection of MELISA remains valid. Hence, these ECO 2023 CR sales are the reference LFL T8 sales that would have to be substituted by LEDs in the RoHS SUB scenario.

The reference sales of MELISA are numbers of light sources. As the average FL luminaire contains more than one FL light source (see 'N lamps per luminaire' in table above), the number of luminaires to be substituted (when this substitution option is used) is lower.

In previous SEA analyses, regulation CR 2019/2020 was not finally decided yet, and thus the MELISA BAU sales were used as the reference for RoHS. As can be verified in the table below, this implied a much higher number of LFL T8 to be substituted. In addition, the previous analyses presented (maximum) purchase cost results assuming one light source per luminaire. This explains the large difference in results between the previous and the new analysis, even when the same substitution option shares are used.

Table 6-3: Sales data (mln units)

	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
LFL T8																	
MELISA BAU	162	151	136	122	111	103	97	91	85	79	73	65	60	54	49	43	38
MELISA ECO 2023 CR	162	151	124	100	61	28	18	12	8	7	6	5	4	4	3	2	2
MELISA ECO 2021 IA	147	124	74	34	20	14	9	8	7	6	5	4	4	3	2	2	1
LFL T5																	
MELISA BAU	65	64	61	57	53	48	43	39	36	33	30	27	25	23	21	19	17
MELISA ECO (IA, CR)	65	64	61	57	53	48	43	39	36	33	30	27	25	23	21	19	17
CFLni																	
MELISA BAU	52	47	45	42	38	33	29	23	19	15	11	8	7	5	4	3	2
MELISA ECO (IA, CR)	52	47	45	42	38	33	29	23	19	15	11	8	7	5	4	3	2

Source: Model for European LIght Sources Analysis (VHK 2019)

Values used for calculation of mercury contents of lamps and amounts of WEEE

The calculation of the amount of mercury to be placed on the market through discharge lamps (CLFni, LFL T5 and LFL T8) is based on values from the 2019 SEA study (Baron et al. 2019), table 15 (for CFLni) and table 34 (for T5 and T8).
The following values were applied in the current calculation:

Table 6-4: Hg average amount used for calculation of Hg per lamp, in mg

T8	T5	CFLni: P <12 W	CFLni: 12 W ≤ P < 30 W	CFLni: 30 W ≤ P < 50 W	CFLni: P ≥ 50 W
2.5	2	1.5	2.5	4	14

Source: 2019 SEA Study (Baron et al. 2019)

Regarding assessments made for e-waste impacts, the 2019 study (Baron et al. 2019) calculated the waste amounts in relation to a best case and a worst case estimation. For simplicity, an average of these two cases has been assumed in the current model. Values used in the model and the basis value for calculation appear in the following table.

Table 6-5: Values used in current model for calculating E-waste generated prematurely, in kg

	LFL T8	LFL T5	CFLni
Auxiliary components (rewiring) (in kg per light source)			
Best case (2019 SEA study)	0.25	0.24	0.25
Worst case (2019 SEA study)	0.5	0.37	0.5
Average applied in current model	**0.375**	**0.305**	**0.375**
Luminaire (replacement) (in kg per luminaire)			
Best case (2019 SEA study)	2.5	2.25	1
Worst case (2019 SEA study)	7	5.5	2
Average applied in current model	**4.75**	**3.875**	**1.5**

Source: Specified in table