Study to assess one (1) request for renewal of exemption 12 of Annex IV to Directive 2011/65/EU (Pack 19) – Final Report

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

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Disclaimer

Oeko-Institut 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

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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 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 one exemption request in this study.

1.2. Key findings – Overview of the evaluation results

The exemption request covered in this project and the applicant concerned, as well as the final recommendation and proposed expiry date are depicted in Table 1-1. The reader is referred to the corresponding section of this report for more details on the evaluation result.

Table 1-1: Overview of the exemption requests, associated recommendations and expiry dates

Ex. Req. No.	Current exemption wording	Applicant	Recommendation	Expiry date and scope
Existing exemptions				
Annex IV, 12	Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors.	Japan Superconductor Technology, Inc. (JASTEC)	Lead in metallic bonds creating superconducting electric circuits in SQUID detectors.	7 years
			In case exemption 11 is not renewed, or if the scope of exemption 11 will not be changed to include NMR and MRI: Lead in metallic bonds creating superconducting electric circuits in MRI and NMR (Nuclear Magnetic Resonance), and in SQUID detectors.	

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.

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

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

La demande d'exemption couvertes par ce projet et le demandeur concerné, ainsi que la recommandation finale et la date d'expiration proposée sont résumées dans le tableau 1 1. Une demande de renouvellement d'une exemption existante a été incluse dans le champ d'application de ce projet. Le lecteur est invité à se reporter à la section correspondante 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. Cette dernière fait foi.

Dem. ex. n°	Terme de l'exemption	Demandeur	Recommandation	Date d'expiration et champ d'application
Exemptions en vigueur				
Annexe IV, Ex. 12	Le plomb et le cadmium dans les liaisons métalliques permettant de créer des circuits magnétiques supraconducteurs dans les détecteurs IRM, SQUID, RMN (résonance magnétique nucléaire) ou FTMS (spectromètre de masse à transformée de Fourier).	Japan Superconductor Technology, Inc. (JASTEC)	Le plomb dans les liaisons métalliques permettant de créer des circuits magnétiques supraconducteurs dans les détecteurs SQUID.	7 ans
			Au cas où l'exemption 11 ne serait pas renouvelée, ou si le champ d'application de la dérogation 11 ne sera pas modifié pour inclure la RMN et l'IRM : Le plomb dans les liaisons métalliques permettant de créer des circuits magnétiques supraconducteurs dans les détecteurs IRM et RMN (résonance magnétique nucléaire) et SQUID.	

3. Introduction

3.1. Project scope and methodology

The scope of the project covers the evaluation of one request for exemption renewal, listed in Annex IV, 12 under the current exemption 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.” This request was submitted by Japan Superconductor Technology, Inc. (JASTEC). The European Commission has received a further application for RoHS exemption 12 of Annex IV by Megin Oy and has requested to consider the application as a contribution to the evaluation.

In the course of the project, a stakeholder consultation was conducted. The stakeholder consultation was launched on the 10th of January 2020 and ended on the 20th of February 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. The comments that have been received on the request for exemption in question have been made available at the project website.

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

The evaluation of the exemption appears in sections 5 and 6 of this report. The information provided by the applicants and by stakeholders is summarised in the first sections of the respective sections. 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.[1]

3.2. Project set-up

Assignment of project tasks to Oeko-Institut, started in 11 November 2019. The overall project has been led by Carl-Otto Gensch. At Fraunhofer IZM the contact person is Otmar Deubzer.

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

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,[2] and in the following for the evaluation of a range of requests assessed through previous projects in respect of RoHS 2.[3] 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.[4]

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.

[2] 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

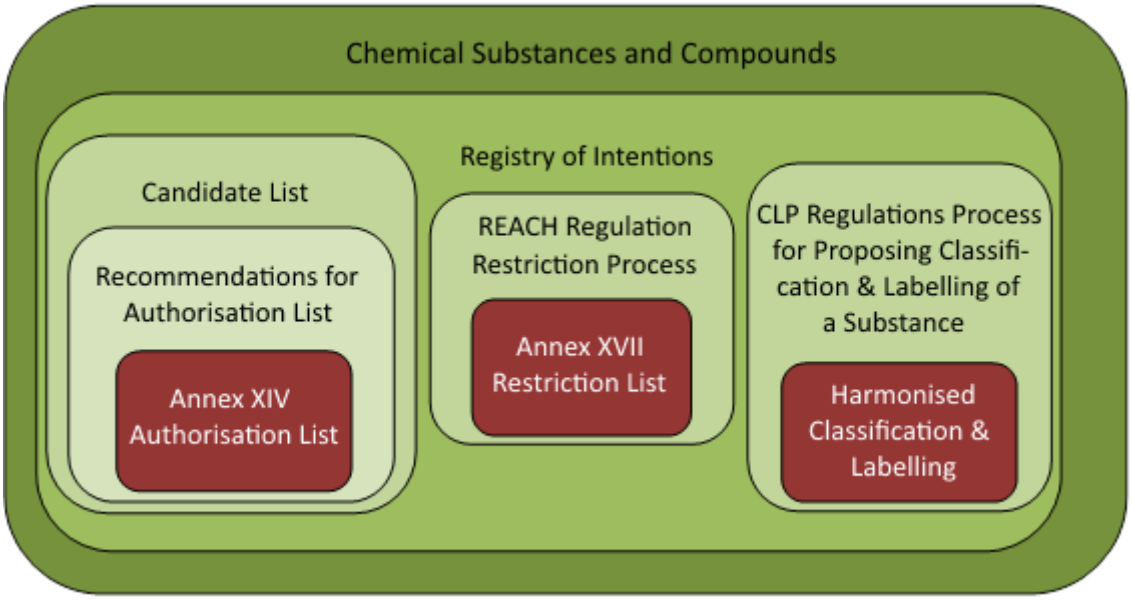
[3] Gensch, C., Baron, Y., Blepp, M., Deubzer, O., Manhart, A. & Moch, K. (2012) Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive), Final Report, Oeko-Institut 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

[4] 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.[5] 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).[6] 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

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

[6] 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 June 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).[7]

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) under the relevant section titled “REACH compliance – Relation to the REACH Regulation” (Section 5.5.1).

[7] 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. Annex IV, Ex. 12

"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

Declaration

In the sections that precede the "Critical review" the phrasings and wordings of applicants' and stakeholders' explanations and arguments have been adopted from the documents provided by them 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

Critical current	Electrical current above which a superconductor is no longer superconducting
Critical magnetic field	Magnetic field strength above which a superconductor is no longer superconducting
EEE	Electrical and electronic equipment
fMRI	functional Magnetic Resonance Imaging
JASTEC	Japan Superconducting Technology Inc. (applicant)
K	Kelvin, temperature, 0 K is equivalent to around 273.15 °C
MEG	Magnetoencephalography
MEGIN	Megin Oy (applicant)
MRI	Magnet resonance imaging
MRI	Magnetic Resonance Imaging
Nb3Sn	Niobium-tin (superconducting material)
NbTi	Niobium titanium (superconducting material)
NMR	Nuclear Magnetic Resonance
OPM	Optically-pumped magnetometers
PET	Positron Emission Tomography
SQUID	Superconducting Quantum Interference Device
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
T_c	critical temperature, temperature below which a material is a superconductor
TRL	Technology Readiness Level

5.1. Background of the Exemption and of the Request

5.1.1. History of Exemption 12 of Annex IV

Exemption 12 was listed on Annex IV with the below wording already when the European Union (2011) published the recast RoHS Directive (RoHS 2) with expiry in July 2021:

> *Lead and cadmium in metallic bonds to superconducting materials in MRI and SQUID detectors*

In 2012, the Test and Measurement Coalition (TMC[8]) applied to include NMR devices into the scope of exemption 12. The Commission followed the recommendation of Gensch et al. 2012 to expand the exemption scope of exemption 12 with a slightly different 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.*

The exemption expires on 30 June 2021. JASTEC and MEGIN request the renewal of the exemption.

5.1.2. Overview and summary of renewal requests and stakeholder contributions

JASTEC (2019 a) applied for the renewal of the exemption with a narrower scope excluding FTMS and SQUID detectors, and a validity of 7 years:

> *Lead in metallic bonds creating superconducting circuits in MRI (Magnetic Resonance Imaging) or NMR (Nuclear Magnetic Resonance)*

Megin (2019) requested the renewal of the exemption with the current wording for seven years until 30 June 2028. Megin produces superconducting quantum interference devices (SQUIDs).

COCIR (2020 a) contributed to the stakeholder consultation stating that they "[…] have submitted a separate exemption renewal request for exemption 11 '*Lead and its*

[8] C.f. TMC's exemption request: https://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_13/13_Lead_and_cadmium_in_metallic_bonds_to_superconducting_magnetic_circuits.pdf

alloys as a superconductor and thermal conductor in MRI'[9] which is similar in scope. Only one of exemption 11 or exemption 12 would appear to be needed to cover lead in superconducting bonds."

According to JASTEC (2019 a), MRI and NMR manufacturers used an alloy that contains both lead and cadmium (Woods metal alloy) when exemption 12 was originally added to Annex IV of the RoHS Directive. Research since then has found that lead alloys without cadmium are also suitable, and that lead-bismuth alloys provide superior performance. Cadmium is therefore no longer used and so does not need to be included in the renewed exemption 12. Since JASTEC (2019 a) is concerned only with NMR and MRI, it proposes the above revised wording. JASTEC (2019 a) explain that NMR spectrometers, used for chemical analysis, and MRI scanners, used for medical imaging, use powerful electromagnets made with superconducting wires that are connected to each other and to the power supplies using superconducting solder bonds. Soldering has been found to be the only consistent and reliable method for making electrical connections. Solders based on lead are the only materials that have a sufficiently high critical field value (the maximum allowable field where superconductivity persists) of over 1 Tesla to be used within the electromagnet cryostat. All lead-free solder materials have much lower critical field values that are too small for use in this application. JASTEC (2019 a) have carried out trials using lead-free solders as substitutes, but the measured critical current values (at which non-dissipative current flows) were too low and were smaller than the currents typically used for NMR and MRI. Research into alternative bonding methods is at an early stage and will take many more years and may prove to be unsuitable.

Megin (2019) use lead in their SQUIDs. Like JASTEC, they do not use cadmium anymore. They sum up their request explaining that superconducting quantum interference devices (SQUIDs) are used to measure extremely weak magnetic fields. Megin (2019) use SQUID detectors in magnetoencephalography (MEG) systems, i.e. in devices that non-invasively measure brain activity. Their application does not refer to NMR, MRI, or FTMS. SQUIDs are, for example, applied MEGs in pre-surgical mapping of brain tumors or epilepsy in medical diagnostics as well as brain research. SQUID detectors require the use of lead containing bonds as part of the superconducting loop which are immersed in liquid helium at 4.2 K. The bonds are required to be superconducting to allow the operation of the SQUID detector. They must exhibit a high degree of durability to withstand immersion in liquid helium, and reliability as it is not possible to build in redundancy into the system to compensate for bond failures. Megin (2019) put forward that potential alternative solutions to substitute or eliminate lead are either not superconducting at the temperatures required or have reduced reliability either due to the inadequately robust bond formation or potentially due to the formation of tin pest. Megin (2019) research via the "macQsimal" project, an EU-funded Horizon 2020 research project, alternative technologies which do not rely on lead. There are, however, a number of technical challenges which will take a number of years to complete in order to demonstrate that Optically-Pumped Magnetometers

(OPM) are a viable alternative. It also currently seems unlikely that OPM-based devices will be able to replace all uses due to their smaller bandwidth. Applications that require > 100 Hz detection will continue to require SQUID based systems.

5.1.3. Amount of lead used under the exemption

JASTEC (2019 a) use a lead-bismuth alloy. They estimate the amount of lead used under the requested exemption to be around 1.2 tonnes per year in the EU. They base this estimate on the below deliberations:

- NMR devices
- JASTEC estimate that 200 NMR superconducting magnets (120 of 400 MHz, 40 of 500 MHz and 40 of 600 MHz) are sold in the EU annually and contain 0.3 kg lead (400 MHz), 0.7 kg lead (500 MHz) or 1.3 kg lead (600 MHz). This results in 116 kg of lead for the EU.
- MRI devices
- Based on OECD data, BMI research "Worldwide medical devices market forecasts to 2021", annual sales of superconducting magnets for MRI sold in the EU are 600 per year. JASTEC estimate that the average amount of lead metal per MRI is 1.8 kg. This sums up to 1080 kg of lead in the EU.

The total lead uses amount to around 1.2 tonnes per year in the EU.

Megin (2019) use tin-lead and tin-lead-indium solders with around 37 % to 88 % of lead in superconducting connections of detector circuits in superconducting quantum interference device (SQUID) for magnetoencephalography (MEG). They estimate that 68 mg of lead will be used in the EU under the requested exemption, without providing further details due to confidentiality reasons.

5.2. Technical description of the requested exemption for SQUIDs (Megin)

Superconducting quantum interference devices (SQUIDs) according to Megin (2019) are used to measure extremely weak magnetic fields. The sensitivities of the present SQUID detectors are of the order of a couple of femtotesla (10^{-15} T). Megin (2019) use SQUID detectors in magnetoencephalography (MEG) systems, i.e. in devices that measure non-invasively brain activity. Their application does not refer to NMR, MRI, or FTMS. They use tin-lead and lead-indium alloys for superconducting solder connections in these SQUID detector circuits.

The magnetic field density generated by the brain activity is in the order of 10^{-13} T when measured outside the head. The magnetic field arises directly from the neurons activated during, for example, physical processes like e.g. moving an arm. Unlike the other functional imaging techniques (fMRI[10] or PET[11]), where the capability to measure brain activity is based on the relatively slow changes of blood flow in the brain, magnetoencephalography (MEG) and electroencephalography (EEG) measure directly

[10] fMRI = functional Magnetic Resonance Imaging
[11] PET = Positron Emission Tomography

the activation of neurons, offering millisecond-scale time resolution. The MEG signals, however, in comparison with EEG, are not distorted by the skull or tissue surrounding the brain, allowing superior localization capability of the active brain areas. The combination of high temporal and spatial resolution offered by MEG is unique among the functional brain imaging techniques. Therefore, the SQUID detectors employed in MEG are crucial for medical diagnostics and basic brain research. Megin (2019) provide some examples of their current and future applications:

- MEG is increasingly being used in the pre-surgical mapping of patients with, e.g. brain tumors or epilepsy, due to its high spatial and temporal resolution. It is used for the accurate localization of visual, somatosensory and auditory cortices as well as complex cognitive functions like language processing;
- MEG is used in epilepsy diagnostics. It is able to detect epileptic “spikes” (very fast waves in brain activity) in about 75 % of patients whereas EEG detects them in about 60 %. When combined, the two technologies can detect almost all spikes;
- MEG has been utilised to identify biomarkers of auditory and speech deficits in autism spectrum disorders and Alzheimer’s. The technology can also be used in other applications such as for the measurement of muscular activity of heart with magnetocardiography (MCG). MCG offers advantages over Electrocardiogram (ECG) which include vector field measurement including all three components in comparison with scalar field surface-restricted measurements and the ability to undertake fetal MCG. Although MCG is not as well established as MEG, it is a growing field with examples in the literature where the technology is proving to be critical for certain applications.

The MEG system manufactured by Megin (2019) uses an array of 306 individual SQUID detectors located in 102 sensor modules to map precisely the pattern of the electromagnetic fields generated by brain activity, and, by the analysis, to precisely determine the parts of the brain which are functionally active. The measurements are taken with millisecond time resolution. The locations of the functionally active parts of the brain as a function of time can be accurately superimposed onto an MRI or computer tomography (CT) images to provide information about the anatomy and function of the brain. MEG allows insights into sensory processing, motor planning and action, cognition, language perception and production, social interaction, and various brain disorders which otherwise would not be possible. It can localize active brain areas inside the brain with a few mm accuracy.

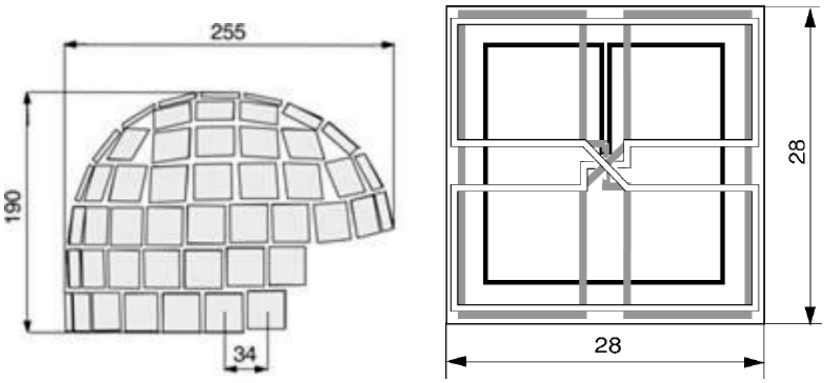
Figure 5-1: MEG system

Source: Megin (2019)

Megin (2019) describe that SQUID detectors use Josephson junctions to detect a change of magnetic field as much as 100 billion times weaker than the magnetic field of the earth that moves a compass needle. The Josephson junction consists of two superconductors separated by a thin insulating layer which allows superconducting electron pairs to pass through.

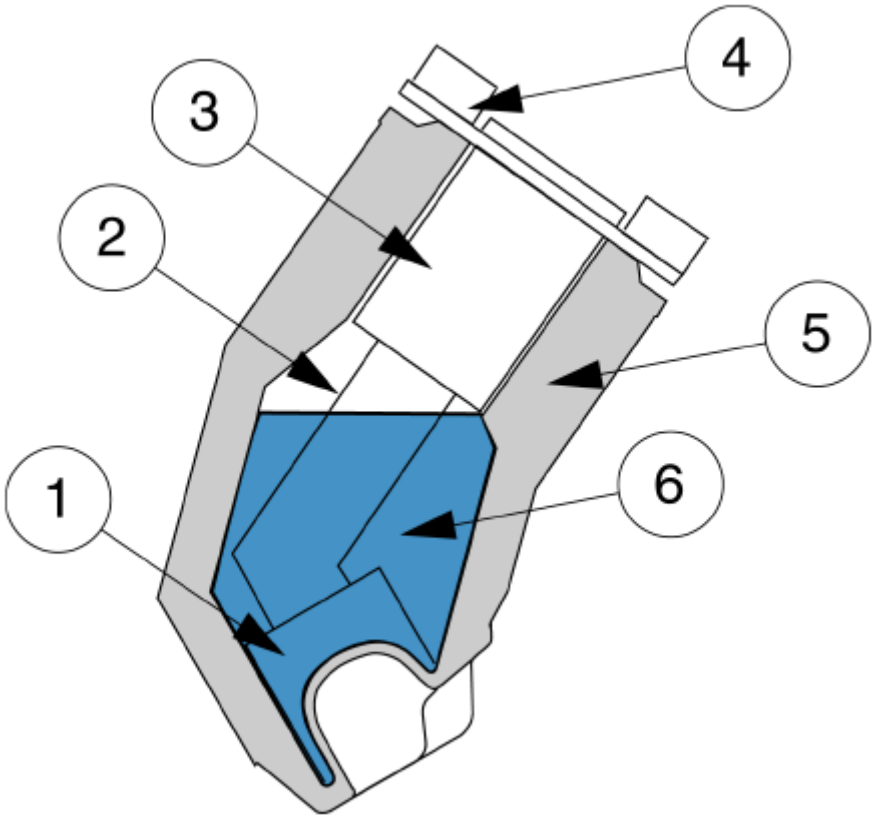
Megin (2019) further on explicate that the SQUID detectors employed in MEG are made on silicon wafers using semiconductor fabrication techniques. Each detector comprises a superconducting sensing coil and a SQUID connected. The sensor array comprising 102 three-channel sensor modules is cooled to 4.2 K by immersion in liquid helium in a vacuum-insulated vessel such that the sensing coils and SQUIDs are superconducting. The sensors (Figure 5-2) containing the lead solder are mounted in the helmet of the MEG (Part 1: wiring unit with sensor elements, in Figure 5-3).

Figure 5-2: Sensor elements installed in the “helmet” (Part 1 in Figure 5-3)



Left: detector array, side view.
Right: Triple sensor detector unit.
All dimensions in millimetres
Note: the sensor coils are shown schematically, not to scale.

Figure 5-3: Construction of the probe



1: Wiring unit with sensor elements
2: Wiring,
3: Neck plug
4: Preamplifiers
5: Dewar with vacuum insulation
6: Liquid helium

Sources: Megin (2019), Megin (2020 b), for Figure 5-2 and Figure 5-3

According to Megin (2019), the array built from 102 sensor modules to map brain activity in three dimensions contains several tin-lead alloy bonds per SQUID detector, all of which play a critical role in the technology and so have to be reliable.

5.3. Technical description of the requested exemption for MRI and NMR (JASTEC)

JASTEC (2019 a) says that MRI are used in hospitals for the generation of 3-dimensional images of the insides of human patients as well as of animals for veterinary examinations. MRI can image soft tissues such as the internal organs, muscles and blood vessels. MRI with powerful magnetic fields (1.5 and 3 Tesla are commonly used) require superconducting magnets. NMR spectroscopy instruments are used for chemical analysis. Various designs are produced with a wide range of electromagnetic field strengths. NMR with less powerful magnetic fields are simpler and therefore cheaper to buy and use, and are suitable for analysis of relatively simple compounds. These might be used by students as well as professional researchers. NMR with powerful superconducting magnets can analyse more complex substances, mixtures of substances and substances present at low concentrations, but due to the greater skill and experience needed to use them, these tend to be used only by professionals.

JASTEC (2019 a) explains that NMR and MRI both use superconducting electromagnet coils, although the designs are different. The coils are made from niobium-titanium (NbTi) and niobium-tin (Nb_3Sn) alloy wires which are superconducting at temperatures below about 9 to 18 K. NbTi has a critical temperature Tc of 10 K, and Nb_3Sn of 18.3 K. While MRI uses NbTi superconductor wires only, NMR spectrometers combine NbTi in an outer coil with Nb_3Sn in an inner coil to achieve the highest possible magnetic field strength inside the bore, especially those with high field strength of 10 Tesla. Nb3Sn has a higher critical field, so can achieve more powerful magnetic fields than NbTi alone, although it is more difficult to make very low resistance bonds to Nb3Sn wire. The Nb_3Sn coil wires of NMR have to be bonded to the NbTi coil's wires using a superconducting material to ensure that the entire conductor coil remains superconducting. NMR electromagnets will have multiple joints. JASTEC (2019 a) reports of one published example with10 joints in a 9.4 Tesla NMR and 100 A electrical current.[12]

According to JASTEC (2019 a), MRI are usually made using single lengths of copper clad NbTi superconductor with electrical connections at each end, but more powerful magnets may have two or more lengths of NbTi connected by superconducting bonds.

JASTEC (2019 a) says that, in order to maintain a sufficiently low temperature to ensure that the electromagnet wires are superconducting, these are cooled with liquid helium which boils at 4.2 K. The MRI and NMR coils are used to create a very powerful magnetic field which is used with MRI for imaging parts of the human body and with NMR for chemical analysis. The more powerful the magnetic field, the better the MRI image quality and the more detailed the NMR spectrum. To obtain a powerful

[12] Persistent current joints between technological superconductors, Greg Brittles, et. al., article in Superconductor Science and Technology · September 2015; source as referenced by JASTEC 2019 a.

magnetic field, a large current is passed through the coil, typically of many hundreds of Amperes. With this size of current, any electrical resistance would result in resistance heating that could raise the temperature of the bonds and the coil to temperatures where the materials are not superconducting and the temperature rise can destroy the coils. According to JASTEC (2019 a), the heat generated is calculated from:

Power = current squared x resistance ($I^2 \cdot R$)

JASTEC (2019 a) adds that a magnetic field decay due to resistance in the superconducting circuit is a problem since NMR and MRI require a highly stable magnetic field. If a superconducting bond has a small electrical resistance, it causes current consumption in the superconducting circuit and consequently reduces the current flow in the circuit.

As a result, JASTEC (2019 a) concludes, it is essential that the materials used to make electrical connections to the superconducting coils are also superconducting materials; lead alloys are used because of the overall performance they provide. Superconducting solders for connecting magnet conductors need to stay superconducting at the operating temperature and magnetic field. At a reasonable distance from the magnet, the magnetic field decays to less than the critical field of lead-bismuth alloy. This makes lead-bismuth alloy suitable as a superconducting bonding material, whereas no other solder materials have a sufficiently high critical field to place them within a magnet cryostat.

JASTEC (2019 a) states that the superconducting alloys NbTi and Nb_3Sn are hard brittle materials that are difficult to make electrical connections. In MRI and NMR, these alloy wires are embedded in copper with many superconductor wires encased in copper which is then drawn down to the required thickness so that the NbTi and Nb_3Sn wires are present inside the copper cable as very thin wires. The simplest and most reliable method of making electrical connections to the ends of the coil is by soldering. In the soldering process, the copper matrix is removed and then the superconductor filaments are soldered tightly. Lead alloys such as lead-bismuth solders are ductile at low temperatures, are superconductors at liquid helium temperature in the presence of the strong magnetic field which arise when passing very large currents, and are sufficiently robust to withstand the severe vibrations that occur in the superconductors in the presence of the high magnetic fields of NMR and MRI.

MRI (and NMR) coils can experience severe vibration due to the effect of “gradient coils” that are placed around the parts of patient’s being scanned, or around samples to be analyzed. To prevent damage from vibration as well as the stresses that occur when coils are cooled from ambient temperature to 4 K, the coils are impregnated with resins that prevent movement that would otherwise damage the superconducting coils. When exemption 12 was originally added to Annex IV of the RoHS Directive, MRI and NMR manufacturers used an alloy that contained both lead and cadmium (Woods alloy). Cadmium is no longer used and so does not need to be included in the renewed exemption 12.

5.1. Justification for the requested exemption (MEGIN)

Megin (2019) use tin-lead lead-indium solders for connections in SQUID detectors as these alloys have the following technical properties:

- Superconducting below its T_c of 7.3 K.
  Few other metals are superconducting at or above this temperature that are also suitable for soldering, other than lead and its alloys. The whole detector loop is required to be superconducting with zero electrical resistance, or at worst down to the nano-Ohm level resistance as any higher values negatively affect the measurements of the SQUID detector;
- Ideally, the critical superconducting temperature (Tc) of the bonding material should be as high as possible as this would allow designs with less liquid helium to be used;
- Resistance to oxidation both in service and during manufacturing is critical to ensure low/zero electrical resistance and the formation of clean metal-to-metal contacts;
- The bonds must have a high degree of proven reliability as it is not possible to build in redundancy into the system to compensate for bond failure. Therefore, there is the requirement for 100 % bond reliability. If any bonds were to fail, they would not be able to be repaired at operating temperature, but the whole detector array would need to be warmed up to room temperature for repair. Bond failure would negatively impact image quality in a section of the brain, as well as increase the likelihood of other bonds failing due to the large temperature changes that occur during warming and cool-down required by the repair, potentially causing further bond failures. If bonds cannot be made reliably and more fail during the repair process, it will be impossible to build a properly functional MEG;
- Lead is the most effective additive that inhibits tin pest phase transformation occurring with tin and its alloys at low temperature;
- If repair is required, this will cause the MEG to be unavailable for medical diagnostics for patients and research activities, and patients cannot be measured for 1 – 2 weeks who will suffer as a result;
- Durability of the bonds is crucial as the SQUID detector is cycled from room temperature to 4.2 K during the annual servicing of the MEG system. The bonds have to be ductile and flexible as well as being reasonably strong to ensure they are not damaged in service or when boiling liquid helium is introduced which creates an extremely turbulent environment around the SQUID detector circuits;
- Manufacturability requires various specific conditions to be fulfilled:
  - The process of application of the connectors to the sensors needs to be able to be applied at less than 200 °C to avoid damaging other electrical components of the circuit; and
  - The ability to be soldered without the use of flux which would impact the conductivity and therefore the signal measured by the detector; and
  - The bond between the connector and the surfaces of the circuits needs to have sufficient material compatibility to ensure that a good bond is formed. Parameters such as differential thermal expansion between various construction materials (e.g. silicon, lead, niobium wire, printed circuit board

made of fibre glass) need to be considered to minimise mechanical stresses which could lead to failures.

Megin (2019) state that the normal lifetime of SQUID detectors is between 10 to 15 years, with known examples of products being used for over 20 years.

Megin (2019) point out that MEG systems are a very expensive diagnostic tool which limits its availability and so manufacturers are carrying out research into alternative designs that avoid the need for liquid helium cooling. These alternatives may also avoid the need for superconducting bonds made of tin-lead.

Megin (2019) want any alternative substance or technology in addition to meeting the required functionality and requirements to maintain or increase the operational temperature in order not to increase the need of liquid helium. Helium is a very scarce element on the Earth with the demand for the element expected to rise dramatically over the coming years. Anything which reduces the requirement for helium will ensure that capabilities such as SQUID detectors, and other applications not covered in this application (such as MRI) are able to be supported, and the environmental impact arising from the extraction, processing and use of this very scarce element is reduced.

5.1.1. Substitution or elimination of lead

Potential candidate metals and alloys for substituting lead solders

Megin (2019) claim to have considered alternatives to lead in SQUID detectors. Table 5-1 below lists metallic elements that are low temperature superconductors with comments on their suitability as substitutes with view to the required properties explained in section 5.1 above.

Table 5-1: Properties of potential alternative metals for SQUID sensor bonding

Metal	Critical temperature, T_c (K)	Properties
Niobium	9.46	Hard inflexible metal, readily oxidises (this oxide is very inert and can be removed only with hydrofluoric acid), unsuitable as a solder
Lead	7.2	Ductile and flexible. Resistant to oxidation and corrosion
Lanthanum	6.0	Hard inflexible metal, readily oxidises. Unsuitable as a solder
Vanadium	5.38	Hard inflexible metal, readily oxidises, Unsuitable as a solder
Tantalum	4.47	Hard inflexible metal, readily oxidises. Unsuitable as a solder
Tin	3.72	Ductile and flexible, but T_c is too low. Suitable as an alloy with lead as these alloys have a suitable T_c and are ductile and easy to solder and achieve 100% good and reliable bonds. Some other tin alloys also have T_c >4.2K but have disadvantages including the risk of tin pest phase transformation, which occurs at low temperatures.
Indium	3.41	Ductile and flexible, but T_c is too low. Susceptible to oxidation and corrosion. Suitable when alloyed with lead, but alloys with high indium content form inert oxide coatings that make soldering difficult.
Aluminium	1.2	Ductile and flexible, resistance to oxidation and used for wire bonding ICs but T_c is much too low
Cadmium	0.56	Ductile and flexible. Resistance to oxidation but T_c is much too low. Previously used as a constituent of Woods alloy, but this is no longer used as a superconductor. RoHS restricted substance
Gold	Not a superconductor at any temperature	Most elements in the periodic table are not superconductors and gold is just one example.

T_c = Critical temperature, this is the temperature below which the metal conducts electricity with zero resistance.

Source: Megin (2019)

Megin (2019) states that there are no other naturally occurring superconducting elements with critical temperatures above 5 K other than those listed in the table

above. Technetium has a critical superconducting temperature (T_c) of 7.7 K but is a radioactive man-made element. It cannot be used for this reason, and it would also be too hard.

Bismuth-tin-indium (BiSnIn) alloys

Megin (2019) mention that alloys can have higher or lower T_c than the elements. Megin currently considers Bismuth-tin-indium alloys, which are being investigated for MRI applications as a potential substitute for future systems. Solders based on indium are susceptible to oxidation and corrosion and so are difficult to solder unless a corrosive flux is used. The use of corrosive fluxes is not acceptable as these can cause corrosion which causes failures to the very small bonds. Lead-free tin alloys are also potentially susceptible to “tin pest” (described below).

Megin (2019) explicate that the addition of bismuth makes the alloy brittle and hard which is a significant disadvantage during the rapid cool down in liquid helium. Cool down and heat up will cause stresses due to thermal expansion mismatch as well as stresses from the churning, boiling liquid helium that could cause fracture of brittle bonds. According to Megin (2020 h), even though InSn is the most promising lead-free alloy, bismuth is added nevertheless, among other reasons, to improve the critical current. Megin (2019) sees tin pest as a potential a problem with indium tin whereas addition of bismuth should reduce its susceptibility.

Megin (2019) is aware of confidential information yet to be published indicating that bonds trialed with BiInSn and SnBi have demonstrated a small, but still too large amount of electrical resistance in liquid helium which will need further investigation as it would make the alloy unsuitable for MEG applications.[13]

Megin (2019) explains the role of the tin pest, which has been known for many decades, with most research having been carried out at temperatures between -50 and -30 °C, which is the temperature range where the transformation occurs most rapidly. Megin (2020 h) considers tin pest as a serious reliability concern in MEG, as in a single Megin MEG system there are 612 bond wires with 1224 bonds, all of which have to tolerate numerous coolings and warm-ups from the room temperature to 4.2 K during the system lifetime of more than 10 years. According to Megin (2019), testing at liquid helium temperatures is very difficult to carry out. The rate of tin pest transformation is highly complex and dependant on a variety of complex factors but Megin (2019) describes them as depending on two distinct processes occurring:

- First nucleation where minute α-phase particles are formed within the β -phase. The driving force for nucleation is the difference in temperature between 13 °C and the actual temperature and so the driving force for nucleation increases as the temperature drops. Nucleation usually requires a defect such as a grain boundary or a particle of impurity but the time for nucleation to occur varies considerably.
- The second process is phase transformation where the α-phase grows from the initial nucleation sites. The rate at which this occurs also varies considerably

[13] This information has been confirmed by JASTEC, c.f. section 5.2.1

depending on the alloy composition and its history as this affects crystal structure, as well as the temperature.

Megin (2019) claims that research therefore needs to be carried out for periods that are similar to the lifetime of the Megin products and to temperature histories during the use phase, which can be up to ten or more years. Tin/lead alloys have been used for several decades at liquid helium temperatures in MEG and in MRI without tin pest failures. Therefore the reliable lifetime is uncertain for all other tin alloys, especially if they have been shown to suffer from tin pest more rapidly than tin/lead. Testing of lead-free solders has been published and one researcher[14] found that they suffer from tin pest significantly sooner than tin/lead although this work is with bulk samples and there is evidence that very small solder bonds may behave differently. Testing of very small solder bonds made with lead-free solders (for >10 years) has not been published and has probably not been carried out as most University research projects are limited to about 3 years.

Elimination of lead via niobium wire bonds

Megin (2019) reports ultrasonic niobium wire bonding research by Megin's subsidiary as part of their in-house testing of alternatives. The niobium bonding was tested on the MEG system without helium submersion of the sensors to investigate the reliability of the bonds using this alternative material and bonding method. Niobium wire was used because it is a superconductor and is used for the SQUID magnetic field detector loops. The testing revealed that the reliability of the bond for the niobium wire between the niobium loop and the chip pads was inadequate with only 70-80 % achieving the required properties, i.e. good very low resistance bonds. More than 20 % of the bonds were unsatisfactory, differently from the lead-tin to lead-indium alloys where 100 % of bonds can be manufactured to the required standard. The ultrasonic niobium bonding method could not be considered as an alternative to lead alloy bonding.

Further on, Megin (2019) observed that some sensors employing niobium wire bonds exhibited a small electrical resistance in the sensor coil-SQUID connection. This was demonstrated by a low-frequency drift in the output signal from the superconducting loop after a change of ambient magnetic field due to, e.g. shielded room door closure, rather than a stable measurement which is required to be achieved. MEG must be used in a shielded room because the brain signals being measured are much smaller than the earth's magnetic field and the electromagnetic interference originating from other electrical equipment. Opening and closing the room door should not affect the SQUID detector's output.

[14] W. J. Plumbridge, "Further Observations on tin pest formation in solder alloys", J. Electronic Materials, Vol 39(4), p 433, 2010; source as referenced by Megin 2019.

Elimination of lead via replacing superconductor technology by optically-pumped magnetometers (OPMs)

Megin (2019)[15] are part of the macQsimal project; an EU-funded Horizon 2020 research project[16] which has two of the total of three years remaining at the time of submission of this exemption request end of 2019. The objective of the project is, among others, to design, develop, and validate OPMs for measuring low frequency magnetic fields in biomagnetic, scientific, and medical applications. The project will be a sensor technology demonstration, equating to a technology readiness level (TRL) of 4-5 and, therefore, will require considerable further development once it is completed. OPMs are being developed as a potential alternative to cryogenic, superconducting MEG systems. They do not require cooling, and, therefore, potentially allowing sensors to be placed closer to the head increasing the sensitivity in comparison with SQUID detectors. There would also be the significant advantage of lower costs, which would allow this technique to be more widely adopted by EU hospitals than at present. Optical pumping refers to the use of a light source such as a laser or discharge lamp to cause absorption or emission of energy by a sample at a precisely defined frequency, changing the sample's quantum state. Although this technology showed, in late 1950s and early 1960s, that optical pumping can be used for inducing a magnetically sensitive state in an atomic system and, therefore, allow for the measurement of weak magnetic fields, the technology still faces significant technical challenges before it can be deployed. Megin (2019) list the following outstanding technical considerations which need resolution:

- One of the most significant issues, which may not be able to be resolved with this technology, is the reduction in bandwidth of OPM in comparison with SQUID detectors. The present OPM sensors have sufficient sensitivity up to around 100 Hz, while SQUID-based detectors are capable of measuring signals at several kHz, with an example from Megin offering 1.6 kHz as standard. A large bandwidth is particularly important for some applications such as brain stem measurements. The bandwidth of the brain signals spans typically from 0.1Hz up to 600-800Hz, some of which would be unable to be measured by OPM.
- Clinically relevant high frequency oscillation at about 200Hz relating to epilepsy would also be unable to be conducted with the OPM bandwidth currently available; brain research undertaken with SQUID detectors often require the broadest range of bandwidth, which would be unable to be supported with the OPM bandwidth currently offered. Currently around 50 % of Megin's SQUID detector MEGs are sold for research applications, and, therefore, the limited bandwidth of the OPM sensors would negatively affect multiple research applications.
- Related to limited bandwidth, the sensitivity over the bandwidth for OPM is not constant, which requires compensation. Although this issue in time could be resolved, this will require the use of negative feedback technology which has not been used so far with OPM-based sensors.

[15] Megin originally joined the macQsimal project under the legal entity name as Elekta Oy. However, the legal entity name was recently changed to Megin Oy.

[16] For details see https://www.macqsimal.eu/

- The OPM sensors that are sensitive enough for MEG applications have the requirement for zero field operation as they are absolute field sensors, requiring extremely good shielding from the earth's magnetic field and disturbance from electrical sources. To be able to achieve the required level of shielding, active field compensation is required, which is still in development. In comparison, SQUID-based sensors require a constant but not a zero field which is achieved inside a shielded room.
- The signal is currently affected by higher noise generation, which could be compensated by a closer proximity to the patient. However, the high power demands currently required by the technology generate large amounts of heat in the system, which impacts the allowable proximity to the patient;
- There are also current limitations on the proximity of sensors to each other due to cross talk issues, meaning that the sensors interact if placed too close to each other. This interaction affects the signal and, therefore, reduces the useful signal produced by the detector.

These technological challenges are addressed in the macQsimal project. Once this project has ended, Megin (2019) expect considerable further work for developing a system level solution[17] (technology readiness level (TRL) 8-9) and establishing sufficient system level data on reliability to gain global regulatory approvals before launching the new technology. It currently seems unlikely that OPM-based MEG systems can replace all SQUID-based MEG systems due to their smaller bandwidth. Therefore, SQUID-based MEG systems will probably also be needed for the medical and research applications that require more than 100 Hz detection.

Overall, Megin (2019), the technological demands of finding an alternative to lead as a connective material in SQUID detectors are high. Megin is committed to only using RoHS exemption requests when necessary and has ensured that the number utilised is minimised. Megin has modified all their electronics to be RoHS compliant and has developed alternative pin connections such that it no longer relies on Exemption 25 of Annex IV. Megin has also monitored the supply chain removal of lead in cryocoolers (exemption 29 of Annex IV). According to Megin (2020 g), MEGIN has started using a cryocooler model that is RoHS compliant without exemption 29.

Megin (2019) claims that these applications have removed much larger quantities of lead from the MEG system than is used in SQUID detectors. Megin is carrying out extensive research to replace lead but this involves many very significant technology challenges that need to be resolved.

5.1.2. Roadmap towards substitution or elimination of lead

Megin (2019) points out that magnetic field sensors are the core technology of the MEG due to the high sensitivity requirement. Changes that might have an impact on the reliability require extensive testing. Changes in the key technologies, specifications

[17] For details concerning the technology readiness levels (TRLs) see https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf

and operating principles (e.g., change from SQUIDs to OPMs) require clinical trials before regulatory approvals can be submitted.

Table 5-2: Steps towards elimination of lead by OPMs

Phase	Elapsed time
MacQsimal project, resulting in TRL4-5 sensor	2 more years (from 2019)
Development of the sensor to TRL level 8-9	[redacted]
System development, resolving screening issues, design of sensor array, ancillary controls development, etc.	[redacted]
Clinical trials and regulatory approval	[redacted]
Total Cumulative Time	[redacted]

Source: Megin (2019); Note of the consultants: the blackened fields cover confidential information

Megin (2020 f) states that the overall time required for the development of lead-free alternatives will be more than seven years.

5.1.3. Environmental arguments

Megin (2019) put forward that helium is a very scarce element on the Earth with the demand for the element expected to rise dramatically over the coming years. Anything which reduces the requirement for helium will ensure that capabilities such as SQUID detectors, and other applications not covered in this application (such as MRI) are able to be supported, and the environmental impact arising from the extraction, processing and use of this very scarce element is reduced.

5.1.4. Socioeconomic impacts

Megin (2019) is afraid that without this exemption, reliable SQUID-based MEG systems could not be sold in the EU, which would be a significant disadvantage to EU hospitals and research institutions as a key diagnostic ability would be lost and research efforts would also be impeded. The annual cost to society of brain disorders in Europe has been estimated at 800 billion Euros[18]. Much of the cost is due to inadequate diagnostics and lack of early intervention, e.g. in epilepsy or neurodegenerative pathologies, leading to institutionalisation and/or inability to work. In Europe there are 6 million children suffering from brain disorders, and the cost of their care is 21 billion Euros.[19] Due to the ionising radiation used for the most common brain function imaging tool, PET, this is of limited use with children. PET requires that patients consume radioactive isotopes that are used for imaging.

[18] The economic cost of brain disorders in Europe. European Journal of Neurology, 2012, 19:155-162
[19] Cost of disorders of the brain in Europe 2010. European Neuropsychopharmacology, 2012, 21:718-779

According to Megin (2019), many if not most brain disorders involve dynamic aspects and connectivity dysfunction;[20] these cannot be studied with conventional means such as CT, MRI, or PET. MEG, with its exceptional spatial and temporal accuracy, offers a solution to this problem but is reliant on the use of lead in superconducting connections. If manufacturers were forced to replace lead without a fully developed alternative including time for reliability testing, three scenarios could result:

1. They would not gain Notified Body approval so MEG could not be sold in the EU;
2. If an alternative technology were used, but reliability is found in the future to be inferior, unexpected failures would cause inferior data quality and delays in medical diagnosis with resultant negative health impacts and unexpected delays in research programs. Repairs of detectors take 1 – 2 weeks in which time, the MEG cannot be used; or
3. If lifetimes were very much shortened by detector failures, this would very significantly increase costs incurred by EU hospitals and research institutions due to the need for more regular maintenance and replacement. The estimated cost to fix 2-3 channels due to the failure of a connection would be thousands of euros each time.

5.2. Justification for the requested exemption (JASTEC)

5.2.1. Substitution of lead

JASTEC (2019 a) explains that superconducting electrical connections to the superconducting electromagnet coils must have a high critical current (i.e. they must be able to pass a high current without losing superconductivity) at an operating temperature lower than their critical temperature (Tc) and at an operating magnetic field lower than the bonding material's critical field. Only a few metallic elements and alloys have Tc values that are significantly higher than the boiling temperature of liquid helium (4.2 K), sufficiently high critical field strengths, and melting points below 400 °C so that they can be used as solders. Table 5-2 shows illustrative examples.

[20] Dynamical diseases. Nature, 1978, 272:673–674

Table 5-3: Comparison of properties of elements and binary solder alloys

Metal / alloy	Tc critical temperature	Critical field strength	Comments
Lead	7.19 K	80 mT	Suitable, but has lower critical field than PbBi alloy
Indium	3.41 K	28.15 mT	Tc and critical field are too low as below boiling temperature of He*
Tin	3.72 K	30.6 mT	Tc and critical field are too low*. Also, tin will undergo a phase transformation at low temperature and disintegrate (tin pest)
Zinc	0.86 K	5.4 mT	Tc is much too low*
Lead–bismuth ($Pb_{60}Bi_{40}$)	8.4 K	1770 mT	Suitable for MRI and NMR
Indium-tin ($In_{50}Sn_{50}$)	6.5 K	650 mT	Inferior performance to PbBi, but is the most promising lead-free substitute
Indium-bismuth ($In_{43}Bi_{57}$)	2.3 K	40 mT	Tc is too low*
Tin-lead ($Sn_{60}Pb_{40}$)	7.05 K	83.2 mT	Critical field is too low (and lead based)
Tin bismuth ($Sn_{43}Bi_{57}$)	2.25 K	38.3 mT	Both Tc and critical field are too low*

** The boiling temperature of Helium is 4.2 K.*
Source: Persistent current joints between technological superconductors, Greg Brittles, et. al., article in Superconductor Science and Technology · September 2015; source as referenced in JASTEC (2019 a)

JASTEC (2019 a) reports trials with InSnBi and SnBi solders as superconducting bonding materials which JASTEC had carried out. They were, however, unsuccessful as the bonds were found to have a small electrical resistance at liquid helium temperatures and the measured critical current was too low at only 30 – 40 A to be practical for use in MRI and NMR, which typically use 100 – 1000 A. Further research is needed to determine the cause of the small resistance as the cause is not clear, but the insufficiently high critical current will be difficult or impossible to overcome.

JASTEC (2019 a) further explain that pure bismuth was recently discovered to be superconductive at 0.00053 K, which is much too low to be of any use in MRI or NMR, which operate at about 4 K. Cadmium has a Tc of 0.52 K and gallium of 1.08 K, so are also both unsuitable as metallic elements for bonding.

Lead, according to JASTEC (2019 a) has a critical temperature of 7.2 K and some additive elements such as arsenic, bismuth and antimony increase Tc, although arsenic is very toxic and antimony will make the alloy very hard and brittle, especially at low temperatures. Arsenic increases Tc to 8.4 K at 10 atomic %.

What JASTEC (2019 a) deems most important for MRI and NMR however is the critical magnetic field of materials. At about 4 K, niobium has a thermodynamic critical field of 0.165 T, lead of 0.07 T, tin of less than 0.01 T, and indium is 0 T. Lead is therefore the most suitable solderable material in powerful magnetic fields for bonding. Niobium cannot be used for bonding as its melting point is higher than that of copper and the superconducting niobium alloys.

The critical current, JASTEC (2019 a) continues to explain, decreases as the critical magnetic field decreases. The performance of NMR and MRI increases as magnetic field strength increases and so it is important that a very large current can be used to generate a very powerful magnetic field, and this depends on the choice of superconducting bond material. Some research on ternary alloys has also been published. These tend to be multiphase alloys where each phase has different Tc and critical field values. In-Sn-Bi alloys have much smaller critical field values than Pb-Bi alloys.

JASTEC (2019 a) puts forward that another limitation of bonding alloys is that they must be ductile at very low temperatures. This is because bonds are made between the solder and copper/niobium superconductor wire at about 200 °C and then are cooled to the operating temperature of about 4 K (minus 269 °C). Copper and lead alloy solders will not have the same thermal expansion coefficient. For example, copper is 17 x 10-6 K-1, bismuth is 13 x 10-6 K-1 and lead is 29 x 10-6 K-1, although these values vary with temperature. As the bonds cool through ca. 470 °C, any mismatch in contraction on cooling will induce a stress on the bond. Unless relieved by the ductility of the solder, this could cause bond delamination and so failure would result as copper/ NbTi is much less ductile than PbBi. Lead and its alloys with bismuth are relatively ductile at low temperatures and so are suitable bonding materials.

5.2.2. Elimination of lead

Diffusion bonding

According to JASTEC (2019 a), diffusion bonding can be used to connect pairs of mechanically soft NbTi wires together, but it is not suitable for bonding to hard and brittle Nb3Sn. Diffusion bonding occurs when two oxide-free metal surfaces are placed in contact, usually with a large contact force that deforms the material to create intimate metal to metal contact. Higher melting point metals bond more easily if heated as long as this does not cause excessive oxidation. Diffusion bonding is relatively easy with soft metals such as indium which can easily be bonded at room

temperature with a fairly small force. NbTi is much harder than indium and has a thin but very stable surface oxide that prevents diffusion bonding from occurring. Nb_3Sn also has a thin and stable oxide but being hard it requires a very high force to achieve an intimate metal to metal bond. Copper from the supporting sheath is first removed such as by dissolution in nitric acid or in a bath of liquid tin. Next, to enable diffusion bonding the surface oxide and any residual copper must be removed and this is possible only with hydrofluoric acid (HF). HF is very hazardous and is used under strictly controlled conditions by the semiconductor industry, but manufacturers always avoid using it wherever possible because skin contact has caused worker deaths and serious injuries.

JASTEC (2019 a) concludes that bonding requires a controlled contact force and very low electrical resistance values have been obtained, although results were found to be inconsistent, probably because very little diffusion bonding occurred. No successful diffusion bonding has been reported with Nb_3Sn.

Welding

JASTEC (2019 a) informs that with welding, bonds have been achieved with NbTi, but due to chemical reactions that occur at high temperature, this was not suitable for Nb_3Sn. Bonding between NbTi filaments is possible but only after removal of copper to expose the filaments. Filaments can be bonded to niobium foil or twisted together before bonding. Results with twisted wires showed that the critical current ratio (CCR) was only 10 % of unbonded wires, which is unsuitable. Results showed that when copper sheet is used for thermomechanical support for the NbTi wires, copper infiltrates the NbTi and some oxidation also occurs but much higher CCRs were achieved. High temperatures can, however, negatively affect the nanostructure of the NbTi wires and detrimentally affect the superconducting properties.

JASTEC (2019 a) concludes that welding is a promising technique, but it will be difficult to use consistently in a production line to produce reliable bonds. Spot welding is therefore currently not used commercially for NMR or MRI.

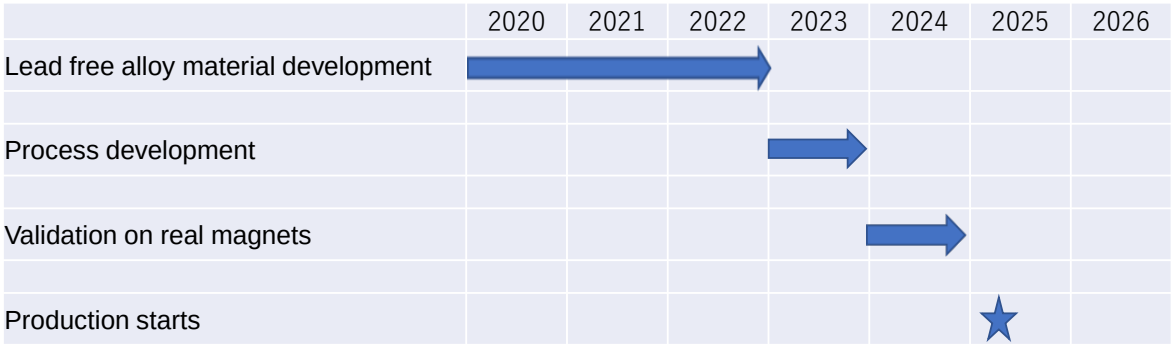
5.2.3. Roadmap towards substitution or elimination of lead

JASTEC (2019 a) put forward that it seems to be very unlikely that a substitute solder will be identified because all low melting point metals and alloys that are suitable for solder bonding and which will create ductile bonds have been considered. Only alloys containing lead give sufficiently high magnetic field strength for use in NMR and MRI. All potential substitute materials have significantly lower Tc and critical field values compared with lead alloys, so it appears that a substitute material does not exist.

Alternative bonding methods such as spot welding may eventually be possible, but this is far from certain. The influence of the magnetic behaviour of the superconductor on the shape of the magnetic field from the superconducting magnet is critical for achieving optimal performance of NMR and MRI. Any distortion of the magnetic field will impair MRI imaging and NMR analysis sensitivity and accuracy. Therefore, even if better consistency can be achieved and the process scaled up for manufacturing the impact of the high temperature on the flux pinning nanostructure of the NbTi filaments

needs to be resolved before commercialisation. Also, bonding of NbTi to Nb_3Sn by welding is not technically possible. JASTEC estimate that this research will take at least five years and may not be feasible. JASTEC (2020 c) presents the below steps and timelines.

Figure 5-4: Steps and timelines towards lead-free alternatives



Source: JASTEC (2020 c)

According to JASTEC (2020 c), the technology development for lead-free superconducting bonds to electromagnets used for MRI and NMR would follow the same timeline. If JASTEC develops the technology making superconducting joints without lead, that would be applicable for both NMR and MRI. The above timeline of five years covers the bond technology alone. JASTEC (2020 c) is a producer of NbTi and Nb_3Sn superconducting wire, NMR and MRI magnets, and of component parts and accessory for superconducting magnets, but does not produce MRI and NMR equipment. Additional time will be needed for NMR and MRI equipment manufacturers to adapt the technology in their MRI and NMR devices. JASTEC (2020 c) does not know how long NMR and MRI manufacturers will need to develop new designs of NMR and MRI using a new lead-free technology, but it estimates that this could require at least a further 5 years. Finally, not all NMR or MRI manufacturers may be able to use this technology since each company has its own superconducting joint technology and almost all technology is strictly confidential.

5.2.4. Environmental arguments and socioeconomic impacts

JASTEC did not raise environmental arguments in the context of its exemption request.

JASTEC (2019 a) apprehends that if this exemption is not renewed, hospitals will not be able to buy new MRI scanners and universities and research institutes would not be able to buy new high-performance NMR spectrometers.

As to MRI, currently 7,500 are estimated to be in use in the EU[21] according to JASTEC (2019 a), to diagnose and treat the EU's population of over 500 million people. OECD data indicates that about 14 million MRI scans are carried out annually in the EU. As the currently used MRI become older and begin to fail and cannot be repaired, so

[21] https://data.oecd.org/healthcare/magnetic-resonance-imaging-mri-exams.htm; source as referenced by the applicant

become unusable, this number of scans will inevitably decrease as the number of usable MRI decreases, so that eventually, many millions of EU citizens will not have their illnesses diagnosed as early as possible or at all. As a result, some will die e.g. due to detecting cancer later than is possible with MRI and the treatment times for some patients will be longer as they become more serious due to later diagnosis using less appropriate techniques. Longer treatment times will result in increased costs for hospitals which EU governments will not fund and also patients' outcomes may be inferior.

For NMR, JASTEC (2019 a) estimates that there are about 3000 NMR spectrometers in the EU with superconducting magnets. These are used by research establishments such as for pharmaceuticals, food, chemistry and industrial product research. Many thousands of researchers at R&D laboratories and at universities will be at a very significant disadvantage compared with those at non-EU establishments and many will as a result lose their jobs. It is also inevitable that many company research laboratories will be forced to relocate outside of the EU in order to be able to use the best performing NMR and this will negatively impact on EU competitiveness and there would be a significant loss of jobs. R&D accounts for over 2 % of GDP in the EU and employed 1.2 % of the EU labour force[22] in 2016, equivalent to 2.7 million jobs.[23] A significant proportion of these jobs would be at risk if exemption 12 is not renewed.

Further on, JASTEC (2019 a) puts forward that as possible social impacts external to the EU, EU citizens may need to travel to non-EU countries to use MRI for medical treatment. Researchers and EU research facilities may relocate to non-EU countries.

5.3. Stakeholder contributions

COCIR (2020 a) stated in the stakeholder consultation that it "[…] submitted a separate exemption renewal request for exemption 11 *'Lead and its alloys as a superconductor and thermal conductor in MRI'* which is similar in scope. Only one of exemption 11 or exemption 12 would appear to be needed to cover lead in superconducting bonds."

Further on, COCIR (2020 a) supports JASTEC's exemption request claiming that "[…] lead containing alloys are essential to create reliable bonds for MRIs. […] COCIR represents multiple MRI device manufacturers, all of whom require an exemption for lead in superconducting bonds to MRI magnets."

COCIR (2020 a) also states that lead-free solutions that might be available for FTMS and for SQUID detectors could not be used for MRI as the requirements are very different. COCIR (2020 a) say that they cannot comment on NMR.

[22] GDP = Gross Domestic, data from Product from https://ec.europa.eu/eurostat/statisticsexplained/index.php/Europe_2020_indicators_-_R%26D_and_innovation; source as referenced by the applicant

[23] EU employment is estimated to be 228.7 million employees, https://www.statista.com/topics/4095/employment-in-europe/; source as referenced by the applicant

5.4. Critical review

5.4.1. 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 a few substances, the use of which would require an authorisation in the European Economic Area:

- Lead chromate – used in printing inks, paints and to colour vinyl, rubber and paper[24];
- Lead sulfochromate yellow –used as a pigment, a dye and as a paint and coating additive[25];
- 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;

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

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

- 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, the above entries of Annex XVII of the REACH Regulation would not apply.

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.

5.4.2. Megin - Lacking stakeholder support for the exemption request

No stakeholders contributed to the online consultation to either contradict or support Megin's exemption request. The absence of supporting contributions which raises the question whether other manufacturers of SQUID-based MEGs may have lead-free solutions that would render exemption 12 obsolete for this application. When asked for other MEG manufacturers that make MEGs with SQUIDs available on the European Economic Area, Megin (2020 b) explained that "*[…] the present situation is unclear. To our knowledge, at the moment there are no other MEG-device manufacturers that would sell new whole-head MEG instruments based on SQUID technology in the European Economic Area (EEA) due to lacking the CE-mark.*" Megin (2020 c) do not know whether other manufacturers' MEGs will obtain the CE-mark in the foreseeable future so that they can place MEGs on the EEA market. According to Megin (2020 d) "*[…] there are at least Compumedics (Australia) and Ricoh (Japan) that sell new SQUID-based MEG-devices. However, based on the public tenders, it seems that they are concentrating to the US and East Asian markets. […] There is a third company, CTF (Canada), but we are not certain if they really manufacture new systems, or only re-furbish & upgrade their older systems. CTF went out of business in 2006, and sold all the manufacturing equipment.*" Megin (2020 c) notes that "*[…] Compumedics has started developing and manufacturing MEG only recently and has sold 1 system so far (USA). Megin (previously under names Elekta and Neuromag) has manufactured more than 100 systems since 1994.*"

The consultants contacted Compumedics and Ricoh via e-mail and phone, but could not reach out to the competent departments and persons in those enterprises. Questions sent by e-mail to the respective departments were not answered. COCIR (2020 c) has no knowledge either of the EU MEG market or of any companies planning to sell MEG in the EU since none of its members produce MEG devices. No further clarification of the situation was possible within the available time frame.

The lacking comments from other manufacturers for Megin's exemption request thus cannot be interpreted that the substitution or elimination of lead in applications in the scope of exemption 12 are practicable and that the exemption may be obsolete since it cannot be excluded that they do not serve the EU/EEA market.

5.4.3. Scientific and technical practicability of substitution or elimination of lead in SQUID detectors (MEGIN)

Substitution of lead

The SQUID detectors in MEGs are operated immersed in liquid helium of 4.2 K as part of the superconducting loop. Table 5-1 on page 31 presents potential candidates to substitute lead. Their critical temperature is, however, either too low so that they are not superconductive at 4.2 K, or they are not appropriate to be used as solders. The information is congruent with the arguments provided by JASTEC as justification for their exemption. It is plausible that with these substances, substitution of lead is scientifically and technically impracticable.

Further on, Megin (2019) mention that it is currently working on bismuth-tin-indium alloys under investigation for MRI devices as potential candidates replacing lead solders in SQUID-based MEGs. JASTEC (2019 a), too, mentions this alloy as the most promising lead-free alternative for NMR and MRI. Among other obstacles to overcome, both applicants point out recent findings showing that these alloys are not completely superconductive under the operation conditions in SQUID detectors, MRI and NMR, which limits or even disqualifies them for th uses in the scope of exemption 12.

At the time being, the argument can be followed that substitution of lead in SQUID detectors is not feasible in the foreseeable future.

Elimination of lead

Lead can be evaluated via bonding technologies other than soldering, i.e. via ultrasonic niobium wire bonding, and by an alternative sensor technology which does not depend on superconductor elements.

As to alternative bonding technologies, Megin's tests of niobium wires revealed that more than 20 % of the bonds were unsatisfactory, differently from the lead-tin to lead-indium alloys where 100 % of bonds can be manufactured to the required standard. The consultants can therefore follow the argument that ultrasonic niobium bonding method cannot be considered as an alternative to lead alloy soldering since the reliability is insufficient.

JASTEC reports spot welding as a further tested alternative, which possibly could also be an alternative to lead solders in SQUID detectors. The results of JASTEC's tests are, however, negative and further development is needed so that, given the similar technological background of the exemption requests for MRI and SQUIDs, the same can be concluded for the use of spot welding in MEGs.

Finally, optically pumped magnetometers are a potential alternative which would eliminate the use of lead in the scope of exemption 12. As described in the section

"Elimination of lead via replacing superconductor technology by optically-pumped magnetometers (OPMs)" of chapter 5.1.1 on page 34, this technology is still under development and not yet mature to replace SQUIDS in MEGs.

The consultants found one publication about mini sensors for MEGs which can be operated at room temperature.[26] Megin (2020 c), when asked to comment on this, explained that these mini sensors are one example of an OPM with the before-mentioned shortcomings which still have to be overcome before they can be used in MEGs.

Overall, the situation shows that currently and in the foreseeable future, the elimination of lead in SQUID detectors is scientifically and technically impracticable.

5.4.4. Substitution and Elimination of lead in MRI and NMR devices (JASTEC)

Lacking stakeholder support for use of lead in NMR devices

While COCIR representing, among others, MRI manufacturers, supports JASTEC's exemption request for MRI devices, there is no such support for NMR equipment. JASTEC (2020 d) says that JASTEC manufactures not only superconductors but also superconducting magnet used for NMR and MRI. JASTEC makes superconducting magnets for NMR using homemade superconductor. JASTEC supplies these magnets to JEOL, and JEOL sells JEOL sells NMR spectrometer. Bruker is doing similar thing. They make superconducting magnets which they use for their NMR superconductors which they integrate into their NMR spectrometers. JASTEC (2020 d) thinks that Bruker is the largest superconductor supplier for NMR and MRI.

An internet investigation showed that Agilent also offers NMR devices. The consultants contacted Bruker and Agilent via e-mail and phone asking whether they actually use exemption 12 in their NMR devices but did not receive any feedback. The consultants also contacted the Test and Measurement Coalition (TMC), which in 2012 has requested the inclusion of NMR devices into the scope of exemption 12. TMC (2020) replied stating that their members do not produce equipment utilizing NMR devices. It is thus actually not clear whether all NMR manufacturers actually require the exemption which JASTEC asks to be continued.

Looking at the situation that, based on the available information, MRI device manufacturers depend on this exemption, and the congruent scientific and technical background of the exemption for NMR and MRI, it is not plausible to assume that the exemption would only be required in MRI, but not in NMR equipment. The consultants can therefore not exclude that lead-free solutions might be available but deem it improbable that this might actually be the case. It might nevertheless be considered that for future exemption requests, applicants are required to organize a broader

[26] NIST: NIST Mini-sensor Measures Magnetic Activity in Human Brain, 2012, c.f. https://www.nist.gov/newsevents/news/2012/04/nist-mini-sensor-measures-magnetic-activity-human-brain

stakeholder support for their requests at the time of the application already as clearer evidence that the exemption is actually required.

Substitution of lead

If appropriate lead-free solders were found, they could substitute lead. JASTEC discusses several potential alternatives, which, however, exhibit too low critical temperatures and critical currents. Trials with InSnBi and SnBi solders were unsuccessful since the solders were found to develop small electrical resistances at the operating temperatures of around 4 K used in MRI and NMR.

The consultants can therefore follow the applicant's argument that substitution of lead is scientifically and technically not yet practicable.

Elimination of lead

In its exemption request, JASTEC discusses diffusion bonding and spot welding as potential alternative bonding technologies to eliminate lead. Spot welding may be feasible in principle for bonding to NbTi, however, to date, this technique has not given consistent results and the process is possible only under controlled laboratory conditions. Due to the material properties, spot welding cannot be used for contacting Nb_3Sn, which is used in NMR.

Taking into account the overall situation, the consultants conclude that substitution of lead in the applications in the scope of exemption 12 in MRI and NMR is scientifically and technically not yet practicable.

5.4.5. Overlapping scopes of exemptions 11 and 12

COCIR raised concerns about overlapping scopes between exemption 11 and 12 of Annex IV for applications in MRI devices.[27] The consultants share these concerns and therefore proposed changes to separate the scopes.

COCIR (2020 c) and JASTEC (2020 b) agreed to exclude MRI from the scope of exemption 12 so that the lead applications in MRI are only covered by exemption 11 provided this exemption would be renewed as COCIR has already requested. JASTEC can then contribute to the upcoming stakeholder consultation for exemption 11 to be involved in the review process.

The consultants further on propose to integrate NMR into the scope of exemption 11 as well. MRI devices use NbTi coils only, while NMR equipment additionally uses Nb3Sn coils, and MRI scanners produce images of human bodies while NMR devices record spectra of atomic nuclei allowing the identification of elements. Otherwise, however, both NMR and MRI are built on the same superconductor technologies, which is in the focus of JASTEC's exemption request for MRI and NMR, and both devices experience, differently from MEGs, severe vibrations during their operation. JASTEC (2020 b) agrees to this change provided NMR will actually be adequately included into

[27] Current wording of exemption 11 of Annex IV: *Lead in alloys as a superconductor and thermal conductor in MRI*

the scope of exemption 11. Exemption 12 would thus in future cover SQUID detectors only resulting in a clear demarcation of the scopes of these two exemptions.

5.4.6. Environmental arguments and socioeconomic impacts

As long as the substitution or elimination of lead is scientifically and technically impracticable, manufacturers of MRI, MEGs and NMR devices could no longer place their equipment on the EEA market. The applicants arguments is comprehensible that this would cause severe impacts in the health sector as well as in those research and development activities which depend on the use of NMR devices.

5.4.7. 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 applicants MEGIN and JASTEC plausibly explain the scientific and technical impracticability of lead use in the scope of exemption 12. COCIR, representing several MRI equipment manufacturers, supports the exemption request, while no stakeholder comments were received as to the applications NMR devices and SQUID detectors. For the latter, it is well possible that MEGIN currently is the only producer serving the EU/EEA market with SQUID-based MEGs, which would explain the lacking stakeholder comments. For NMR, it is technically plausible that the exemption is essential for NMR devices if it is indispensable for MRI equipment since both are based on a very similar superconductor technology.

Taking into account the overall situation, including the technical aspects as well as the potential severe impacts on health care and research in the EU/EEA should the exemption not be granted, the consultants recommend renewing the exemption.

To avoid overlapping scopes of exemptions 11 and 12, it was agreed with JASTEC and COCIR to recommend shifting MRI and NMR appliances from exemption 12 into the scope of exemption 11, provided the Commission will renew this exemption. Exemption 11 specifies the function of lead as superconductor and thermal conductor and therefore is more specific for MRI and NMR than exemption 12. COCIR has submitted an exemption request for its renewal already so that the review of exemption 11 is to be expected in the near future. NMR devices should then be

integrated adequately[28] into the scope of exemption 11 with JASTEC participating as stakeholder in the evaluation process.

SQUID detectors should remain in the scope of exemption 12 with the following recommended wording:

Lead in metallic bonds creating superconducting electric circuits in SQUID detectors.

This is a slight deviation from the current wording since "magnetic circuits" is replaced by "electric circuits" as suggested by COCIR and agreed with MEGIN. The reformulation better reflects the actual situation, which is that lead bonds are applied to create superconducting electric circuits which produce magnetic fields.

In case exemption 11 is not renewed, or if the Commission should not agree to shifting NMR and MRI devices into the scope of exemption 11, the consultants recommend renewing exemption 12 with the following wording:

Lead in metallic bonds creating superconducting electric circuits in MRI and NMR, and in SQUID detectors.

A comma was inserted after "NMR", since the exemption could otherwise be interpreted as covering detectors in MRI, NMR and SQUIDs, whereas only the SQUIDs can be understood as detectors.

Since the available information suggests that neither substitution nor elimination of lead in the applications in scope of exemption 12 are foreseeable in the near future, the consultants recommend granting the renewed exemption 12 for the maximum seven years.

5.5. Recommendation

The consultants recommend renewing the exemption. The scientific and technical information submitted by the applicants allows concluding that substitution or elimination of lead in the applications in scope of exemption 12 are currently and in the foreseeable future scientifically and technically impracticable. The renewal of the exemption would therefore be in line with the requirements for exemptions stipulated in Art. 5(1)(a).

In alignment with the involved stakeholders, the consultants propose excluding MRI equipment from the scope of exemption 12 since it is included in exemption 11 whose renewal is already requested. Otherwise, the scopes of both exemptions are overlapping for MRI equipment. Since NMR and MRI are based on a very similar

[28] JASTEC 2020 b actually agreed to the shift provided the wording of exemption 11 would be *"Lead in alloys as a superconductor and thermal conductor in MRI and NMR".* The future wording of exemption 11 will, however, have to be assessed reflecting the current state of science and technology taking into account the findings of this review process.

superconductor technique and the technical requirements on which the exemption is based are almost identical, all stakeholders agreed to recommend shifting NMR equipment into the scope of the future exemption 11.

The following wording for exemption 12 was agreed with the stakeholders:

Lead in metallic bonds creating superconducting electric circuits in SQUID detectors.

In case exemption 11 is not renewed, or if the Commission does not agree to shifting NMR and MRI devices into the scope of exemption 11, the consultants recommend renewing exemption 12 with the following wording:

Lead in metallic bonds creating superconducting electric circuits in MRI and NMR, and in SQUID detectors.

The available information suggests that neither substitution nor elimination of lead in the applications in scope of exemption 12 are foreseeable in the near future. The consultants therefore recommend a validity of seven years for the future exemption 12.

5.6. References

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COCIR (2020 c): Answers to questionnaire 3, received from Riccardo Corridori, COCIR, by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail on 7 May 2020, document "Ex12_AnnexIV_Questionnaire-3_COCIR v2.docx". Answers to questionnaire 2.

European Union (2011): 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 (recast). RoHS 2. European Union. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065, zuletzt aktualisiert am 01.07.2011, zuletzt geprüft am 05.10.2012.

Gensch et al. 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 RoHS 5. Unter Mitarbeit von Carl-Otto Gensch, Yifaat Baron, Markus Blepp, Andreas Manhart, Katja (Öko-Institut) Moch und Otmar (Fraunhofer IZM) Deubzer. Carl-Otto GenschYifaat BaronMarkus BleppAndreas ManhartKatja Moch. Online verfügbar unter https://circabc.europa.eu/sd/a/42ccb088-4c26-4e3a-8a0c-218ea738964c/RoHS_V_Final_report_12_Dec_2012_Final.pdf.

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JASTEC (2020 c): Answers to questionnaire 4, received from Saito Kazuyoshi, JASTEC/Kobelco, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM, on 14 May 2020, document "Ex12_AnnexIV_Questionnaire-4_JASTEC.DOCX". Answers to questionnaire 4.

JASTEC (2020 d): Answers to questionnaire 5, received from Saito Kazuyoshi, JASTEC/Kobelco, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM, on 15 May 2020, document "Ex12_AnnexIV_Questionnaire-5_JASTEC.DOCX". Answers to questionnaire 4.

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Megin (2020 f): Answers to questionnaire 6, received from Petteri Laine, Megin Oy, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM, on 11 May 2020, document "Ex12_AnnexIV_Questionnaire-6_Megin.pdf". Answers to questionnaire 6.

Megin (2020 g): Answers to questionnaire 7, received from Petteri Laine, Megin Oy, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM, on 14 May 2020, document "Ex12_AnnexIV_Questionnaire-6_Megin.pdf". Answers to questionnaire 7.

Megin (2020 h): Answers to questionnaire 8, received from Petteri Laine, Megin Oy, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM, on 14 May 2020, document "Ex12_AnnexIV_Questionnaire-6_Megin.pdf". Answers to questionnaire 8.

TMC (2020): Answers to questionnaire 1, received from Meglena Mihova, EPPA, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM, on 11 May 2020. Answers to questionnaire 1.

Appendix

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

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

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

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

(*) 1 September 2019 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without that spare part, and for the use of the substance (on its own or in a mixture) for the repair of such articles where that substance on its own or in a mixture was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.
(**) 1 March 2021 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without those spare parts, and for the use of the substance (on its own or in a mixture) for the repair of such articles, where that substance was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.

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

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

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

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

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

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

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

Designation of the substance, group of substances, or mixture	Conditions of restriction
	— articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. 8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons. 10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. 11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.
28. Substances which are classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively: 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)).