Study to assess 2 RoHS new exemption requests:

#1 for cadmium in video cameras designed for use in environments exposed to ionising radiation

#2 for lead and cadmium in PVC profiles of electric windows and doors

Final report

March 2017

Europe Direct is a service to help you find answers to your questions about the European Union.

Freephone number (*)**:**

00 800 6 7 8 9 10 11

(*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Luxembourg: Publications Office of the European Union, 2017

ISBN 978-92-79-68781-5
doi:10.2779/349459

European Commission - DG ENV, Brussels

Study to assess 2 RoHS new exemption requests: #1 for cadmium in video cameras designed for use in environments exposed to ionising radiation; #2 for lead and cadmium in PVC profiles of electric windows and doors

Study request under the multiple Framework contract with reopening of competition "Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation"

Reference: ENV.A.2/FRA/2015/0008

Final Report

24 March 2017

bipro

Part of Ramboll Environ

Contents

Acronyms and definitions

CA	Cellulose acetate
CAB	Cellulose acetate butyrate
CaZn	Calcium Zinc
CCD	Charge coupled devices
CCTV	Closed-circuit television
Cd	Cadmium
CdSe	Cadmium Selenide
CdSeO3	Cadmium Selenite
CMOS	Complementary metal-oxide-semiconductor
ECVM	European Council of Vinyl Manufacturers
EEE	Electrical and electronic equipment
EPD	Environmental Product Declarations
EPPA	European PVC Window Profile and Related Building Products Association
Gy	Gray
JBCE	Japan Business Council in Europe
KGy	Kilogray
LCA	Life-cycle-assessment
LDPE	Low-density polyethylene
MF	melamine-formaldehyde
MGy	Megagray
Pb	Lead
PBB	polybrominated biphenyls
PBDE	polybrominated diphenyl ethers
PBT	Polybutylene terephthalate
PET	Polyethylene terephthalate [3907 60]
PP	Polypropylene
PVC	Polyvinylchloride
PVC-U	Unplasticized/rigid polyvinylchloride
Sb_2S_3	Antimony sulfide / diantimony trisulfide
SNEP	Syndicat National de l'Extrusion Plastique
SVHC	Substances of Very High Concern
UF	Urea-formaldehyde
UP	Unsaturated polyesters
VKG	Vereiniging Kunststof Gefelelementenindustrie
VPE	Cross-linked polyethylene
α	Alpha radiation
β	Beta radiation
γ	Gamma radiation

CLIENT	European Commission Directorate-General Environment Unit ENV.A.2 BU9 5/171 B-1049 Brussels Belgium
Report title	Final Report
Date	6 April 2017
PROJECT	**Study to assess 2 RoHS new exemption requests: #1 for cadmium in video cameras designed for use in environments exposed to ionising radiation; #2 for lead and cadmium in PVC profiles of electric windows and doors (ENV.A.2/FRA/2015/0008)** *Study request under the multiple Framework contract with reopening of competition "Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation"*
CONSULTANT	BiPRO GmbH, Munich, Germany
CONTACT	**Ferdinand Zotz / Marie Dollhofer** BiPRO GmbH Grauertstrasse 12 81545 Munich, Germany
Telephone	+49-89-18979050
Telefax	+49-89-18979052
E-mail	Ferdinand.zotz@bipro.de
Website	www.bipro.de
Disclaimer	This report has been prepared for the European Commission in accordance with the associated contract. It must be stressed that the views expressed in this report which are not otherwise assigned are those of the authors and are not necessarily shared by the European Commission.

Executive summary

Background and objectives

BiPRO GmbH has been assigned with providing technical and scientific support for the evaluation of two exemption requests under the RoHS 2 Directive, as a Service Request 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" (ENV.A.2/FRA/2015/0008).

On 21 July 2011, RoHS 2 Directive 2011/65/EU entered into force, replacing and repealing Directive 2002/95/EC. The main instrument of the Directive is to restrict certain hazardous substances in electrical and electronic equipment with a view to contribute to the protection of human health and the environment as well as to the environmentally sound recovery and disposal of WEEE.

- The **scope** of the RoHS Directive (Annex I in the Directive) includes several EEE categories including inter alia large and small household appliances; IT and telecommunications equipment; monitoring and control instruments including industrial monitoring and control instruments; automatic dispensers as well as other EEE not covered by any of the categories above.
- The **relevant substances** to be restricted under the Directive (Annex II) are Mercury (Hg), Cadmium (Cd), Lead (Pb), Hexavalent Chromium (Cr-VI), Polybrominated biphenyls (PBB) and Polybrominated diphenyl ethers (PBDE).

RoHS 2 Directive foresees the possibility of very specific exemptions for the continued use of the restricted substances in EEE. Annexes III and IV of the Directive contain a list of exemptions. The Annexes are adapted to scientific and technical progress, whereby the following procedure and substantial preconditions apply:

- Pursuant to Article 5(1) of RoHS 2, the inclusion in Annexes III or IV of materials and components of EEE shall be adopted by the Commission by means of individual delegated acts (cf. Articles 20-22 of RoHS 2).
- Article 5(1) lit. (a) provides for the exemption of materials and components if this does not weaken the environmental and health protection afforded by REACH Regulation (EC) 1907/2006 where **any of the following conditions** is fulfilled:
    - The elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to the list 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 decision on inclusion of exemptions and the duration of possible exemptions shall take into account the availability of substitutes and the socio-economic impact of substitution. Decisions on the duration of possible exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant.
- The decision on inclusion of materials and components of EEE in Annexes III or IV on exemptions and the duration of possible exemptions shall take into account the availability of substitutes and the socio-economic impact of substitution. Decisions on the duration of possible exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant.
- Pursuant to Article 5(2) of RoHS 2, all exemptions have expiry dates and can only be renewed after an application for renewal. For applications for renewal of exemptions the same criteria apply as for applications for new exemptions.
- On the basis of these provisions, the Commission is receiving requests for (granting, renewing, but possibly also for deleting) exemptions that need to be evaluated in order to assess whether they fulfil the requirements of Article 5(1) of RoHS 2. Where the requirements of Article 5(1) are fulfilled, the Commission shall under the set procedure adopt a measure amending the Annexes to the RoHS Directive.

Within this scope the consultants have undertaken evaluation of two new exemptions request under the requirements of the RoHS 2 Directive.

Overview of the evaluation results

A visual summary of the assessment of the two exemption requests and our final recommendations such as proposed expiry dates can be seen below in Table 1. The reader is then referred to the corresponding section of this final report for additional details. The initial exemption requests provided by the applicants have been published at the EU CIRCABC website including also all contributions received during the stakeholder consultation.[1]

Please note that the role of BiPRO GmbH within this study was to collect and evaluate information provided by stakeholders with a goal to provide the Commission with a recommendation on an exemption's justification. The recommendations for the exemption requests A-2016 and B-2016 elaborated by BiPRO GmbH in this report are not legally binding, any decision making is the sole responsibility of EU institutions. The recommendations should not be interpreted as a political or legal signal that the Commission intends to take a given action.

Table 1: Overview of the two exemption requests assessed within this project

Exemption request No.	Requested wording of the exemption	Applicant	Recommendation	Recommended duration of exemption
A-2016	Cadmium in video cameras designed for use in environments exposed to ionising radiation with a dose rate in excess of 100Gy/hour and a total dose in excess of 100KGy with a centre resolution greater than 450 TV Lines	Mirion Technologies Ltd.	Exemption (different wording proposed)	7 years
B-2016	Use of recycled PVC for profiles (windows and doors)	EuroWindoor AISBL et al	Exemption (different wording proposed)	3 years

[1] https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp **Browse:** CIRCABC > env > RoHS Evaluations(BiPRO)

Résumé

Contexte et objectifs

BiPRO GmbH a été commandé de fournir soutien technique et scientifique pour l'évaluation de deux demandes d'exemption en vertu de la directive RoHS 2, dans le cadre du contrat "*Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation"* (ENV.A.2/FRA/2015/0008).

Le 21 juillet 2011, RoHS 2 Directive 2011/65/UE est entrée en vigueur, remplaçant et abrogeant la directive 2002/95/CE. L'instrument principal de la directive est de limiter certaines substances dangereuses dans les équipements électriques et électroniques en vue de contribuer à la protection de la santé humaine et de l'environnement ainsi qu'à la récupération et à l'élimination écologiquement rationnelles des DEEE.

La champ d'application de la directive comprend plusieurs catégories d'EEE, y compris, entre autres, gros appareils ménagers; Petits appareils ménagers; Équipements informatiques et de télécommunications; Dispositifs médicaux; Instruments de contrôle et de surveillance, y compris instruments de contrôle et de surveillance industriels; Distributeurs automatiques; et autres EEE n'entrant pas dans les catégories ci-dessus.

Les substances pertinentes à limiter en vertu de la directive (Annexe II) sont mercure (Hg), cadmium (Cd), plomb (Pb), chrome hexavalent (Cr-VI), Polybromobiphényles (PBB) et Polybromodiphényléthers (PBDE)).

La directive RoHS 2 prévoit la possibilité d'exemptions spécifiques pour l'utilisation continue des ces substances. Les annexes III et IV de la directive contiennent une liste des exemptions. Les annexes sont adaptées au progrès scientifique et technique, selon laquelle la procédure et les conditions préalables suivantes s'appliquent:

- Conformément à l'article 5(1) de RoHS 2, l'inclusion dans les annexes III ou IV des matériaux et composants de l'EEE est adoptée par la Commission au moyen d'actes délégués individuels (voir articles 20-22 de RoHS 2).
- Article 5(1) lit. a) prévoit l'exemption des matériaux et des composants si cela ne diminue pas la protection de l'environnement et de la santé conférée par le règlement REACH et lorsque l'une des conditions suivantes est remplie:
    - L'élimination ou le remplacement sur la base de modifications de la conception, ou par des matériaux et composants ne nécessitant aucun des matériaux ou substances énumérés à l'annexe II, est scientifiquement ou techniquement impraticable,
    - la fiabilité des produits de substitution n'est pas garantie,
    - il est probable que l'ensemble des incidences négatives sur l'environnement, sur la santé et sur la sécurité du consommateur liées à la substitution l'emportent sur l'ensemble des bénéfices qui en découlent pour l'environnement, la santé et la sécurité du consommateur.

- La décision d'inclusion des exemptions et la durée des éventuelles exemptions tiennent compte de la disponibilité des produits de substitution et de l'incidence socio-économique de la substitution. Les décisions relatives à la durée d'une exemption doivent prendre en considération tous les effets potentiellement négatifs sur l'innovation. Le cas échéant, une réflexion axée sur le cycle de vie est menée concernant les incidences globales de l'exemption.
- Conformément à l'article 5(2) de RoHS 2, toutes les exemptions ont des dates d'expiration et ne peuvent être renouvelées qu'après une demande de renouvellement. Pour les demandes de renouvellement des exemptions, les mêmes critères s'appliquent que pour les demandes de nouvelles exemptions.
- Sur la base de ces dispositions, la Commission reçoit des demandes de dérogations qui doivent être évaluées afin d'évaluer si elles remplissent les conditions de l'article 5(1) de RoHS 2. Lorsque les exigences de l'article 5(1) sont remplies, la Commission procède, dans le cadre de la procédure établie, à une mesure modifiant les annexes de la directive RoHS.

Dans ce cadre, les consultants ont procédé à l'évaluation de deux nouvelles demandes d'exemption conformément aux exigences de la directive RoHS 2.

Aperçu des résultats de l'évaluation

Un résumé visuel de l'évaluation des deux demandes d'exemption et de nos recommandations finales telles que les dates d'expiration proposées figure ci-dessous dans le Table 1 au-dessus. Le lecteur est ensuite renvoyé à la section correspondante de ce rapport final pour plus de détails. Les demandes initiales d'exemption fournies par les demandeurs ont été publiées sur le site Web de l'UE CIRCABC, y compris toutes les contributions reçues lors de la consultation des parties prenantes.

Veuillez noter que le rôle de BiPRO GmbH dans cette étude était de recueillir et d'évaluer les informations fournies par les parties prenantes dans le but de fournir à la Commission Européenne une recommandation sur la justification d'une exemption. Les recommandations pour les demandes d'exemption A-2016 et B-2016 élaborées par BiPRO GmbH dans ce rapport ne sont pas juridiquement contraignantes, toute décision est la seule responsabilité des institutions de l'UE. Les recommandations ne doivent pas être interprétées comme un signal politique ou juridique que la Commission envisage de prendre une mesure donnée.

1 Introduction

BiPRO GmbH has been assigned with providing technical and scientific support for the evaluation of two exemption requests under the RoHS 2 Directive, as a Service Request 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" (ENV.A.2/FRA/2015/0008).

1.1 Background

On 21 July 2011, RoHS 2 Directive 2011/65/EU ("RoHS 2", "the Directive") entered into force, replacing and repealing Directive 2002/95/EC. The main instrument of the Directive is to restrict certain hazardous substances in electrical and electronic equipment with a view to contribute to the protection of human health and the environment as well as to the environmentally sound recovery and disposal of WEEE.

- The **scope** of the RoHS Directive (Annex I in the Directive) includes several EEE categories including inter alia large and small household appliances; IT and telecommunications equipment; monitoring and control instruments including industrial monitoring and control instruments; automatic dispensers as well as other EEE not covered by any of the categories above.
- The **relevant substances** to be restricted under the Directive (Annex II) are Mercury (Hg), Cadmium (Cd), Lead (Pb), Hexavalent Chromium (Cr-VI), Polybrominated biphenyls (PBB) and Polybrominated diphenyl ethers (PBDE).

RoHS 2 Directive foresees the possibility of very specific exemptions for the continued use of the restricted substances in EEE. Annexes III and IV of the Directive contain a list of exemptions. The Annexes are adapted to scientific and technical progress, whereby the following procedure and substantial preconditions apply:

- Pursuant to Article 5(1) of RoHS 2, the inclusion in Annexes III or IV of materials and components of EEE shall be adopted by the Commission by means of individual delegated acts (cf. Articles 20-22 of RoHS 2).
- Article 5(1) lit. (a) provides for the exemption of materials and components if this does not weaken the environmental and health protection afforded by REACH Regulation (EC) 1907/2006 where **any of the following conditions** is fulfilled:
    - The elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to the list 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 decision on inclusion of exemptions and the duration of possible exemptions shall take into account the availability of substitutes and the socio-economic impact of substitution. Decisions on the duration of possible exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant.
- Pursuant to Article 5(2), all exemptions have expiry dates and can only be renewed after an application for renewal.
- An application for granting, renewing or revoking an exemption must include the mandatory content and shall be made to the Commission in accordance with Annex V.

1.2 Objective

The objective and scope of this project is the assessment of two new exemption requests based on clear technical and scientific evidence that the Commission has obtained in December 2015. The first exemption was received on 3 December 2015 for Cadmium (Cd) in video cameras designed for use in environments exposed to ionising radiation (several categories of EEE according to the applicant) and the second one was received on 15 December 2015 for Pb and Cd in PVC profiles of electric windows and doors (Category 11). Both applications for exemption aim for inclusion in Annex III of RoHS.

1.3 Project tasks

The project was divided into two major tasks:

1. Assessment and evaluation of the two requested exemptions respectively, and
2. Conduct a stakeholder consultation.

The stakeholder consultation was carried out according to the requirements set by the European Commission. It was launched on 28 October 2016; the deadline for contributions was 22 December 2016. In order to keep stakeholders informed of the progress of the project, a specific project website has been established: http://rohs.exemptions.bipro.de. The website includes a general guidance document, the initial applicants' documents for both of the exemption requests, and a specific questionnaire. Also a link to the project specific group on the EU CIRCA website has been provided where all aforementioned documents and the contributions received to the consultation are available.[2] An overview which stakeholders have submitted contributions is included in sections 3.4 (No. A-2016) and 4.4 (No. B-2016) respectively.

[2] https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp **Browse:** CIRCABC > env > RoHS Evaluations(BiPRO)

1.4 Approach for critical review

Within the critical review, the respective applicant's factual and legal positions are critically reviewed. The benchmark for the critical review are the relevant criteria laid down in Article 5(1) of RoHS 2 Directive, thus we have focused on:

- scope of the exemption request, and relevant category (as per Annex I of RoHS Directive);
- compliance with REACH Regulation;
- feasibility of substitution;
- environmental, health and consumer safety impacts;
- socio-economic impact of substitution as applicable.

To this end, we have carefully considered:

- the applicant's initial request;
- further arguments and information the applicant has provided in the course of the project;
- stakeholder's substantial arguments and information;
- additional own research as applicable.

The critical review is included in sections 3.5 (No. A-2016) and 4.5 (No. B-2016).

Note that the wording of applicants' and stakeholders' explanations and arguments have been occasionally re-phrased as far as required and reasonable in the context of the evaluation to maintain the readability and comprehensibility of the text. Wherever information has been used which was independently researched by us, it is duly cited.

For each exemption request, we have prepared a conclusion and a recommendation.

2 REACH compliance: connection between the RoHS 2 Directive and REACH

As pointed out above, one of the preconditions for any inclusion of materials and components of EEE for specific applications in Annexes III and IV is that such inclusion does not weaken the environmental and health protection afforded by REACH Regulation. This section describes the background of REACH, its relation to RoHS Directive, and the approach of the project team how to develop criteria for that the environmental and health protection is not weakened.

2.1 Background

REACH is the EU's central legal document on chemicals, its main instruments being registration, evaluation, authorisation and restriction. REACH aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

Of particular interest in the context of connection between RoHS and REACH are authorisation and restriction.

2.2 Authorisation

The authorisation regime is designed to ensure that the risks of substances of very high concern (SVHC) are adequately controlled, such SVHC being understood by REACH as having one of the following properties:

- Substances which meet the "criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Commission Regulation (EC) No 1272/2008" - Carcinogenic, mutagenic, reprotoxic (CMR) substances.
- Substances which are classified as "persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII)."
- Substances which are "identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances".

The process of authorisation starts with listing a substance on the so-called 'candidate list' (that is, identifying it as a substance of very high concern. Subsequently, substances may be included in Annex XIV of REACH and thus becoming subject to authorisation, meaning that they can only be placed on the market or used after a specific date (called sunset date) in case an authorisation or exemption have been granted for that specific use.

2.3 Restriction

The restriction regime, which already existed in EU legislation before REACH, aims to address "unacceptable risks to human health or the environment" requiring action at EU level.

A restriction may be used to limit or ban the manufacture, placing on the market or use of a substance (on its own, in a mixture or in an article). Restrictions are laid down in the Annex XVII of the REACH Regulation.

2.4 Approach for assessing REACH compliance

For assessing whether that applied exemptions for the uses under the provision of the RoHS would weaken the environmental and health protection provided by REACH, we checked Annexes XIV and XVII of REACH for any relevant entry. Further, we checked whether the relevant substances were present in any of the lists related to the REACH Regulation which are presented in the Annex to this report, using the European Chemicals Agency's (ECHA's) website as reference.

Table 2: REACH related lists of substances consulted

Document	Available at
Registry of Intentions regarding the list of substances proposed for inclusion in the candidate list	https://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions
Candidate list (list of SVHC)	https://echa.europa.eu/web/guest/candidate-list-table
List of substances recommended for inclusion in the Annex XIV	https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

Finally, we followed the current and upcoming initiatives by ECHA as announced on their website.

3 Exemption Request No. A-2016

Exemption Request no. A-2016 has been filed by Mirion Technologies Ltd. ("the applicant"), which is based in the United Kingdom. The application for exemption aims at inclusion into the appropriate Annexes of the RoHS Directive of the following:

> ***"Cadmium in video cameras designed for use in environments exposed to ionising radiation with a dose rate in excess of 100Gy/hour and a total dose in excess of 100KGy with a centre resolution greater than 450 TV Lines"***

Abbreviations and Definitions:

CCD	Charge coupled devices
CA	Cellulose acetate
CAB	Cellulose acetate butyrate
CCTV	Closed-circuit television
Cd	Cadmium
CdSe	Cadmium Selenide
CdSeO3	Cadmium Selenite
CMOS	Complementary metal-oxide-semiconductor
EEE	Electrical and electronic equipment
Gy	Gray
JBCE	Japan Business Council in Europe
KGy	Kilogray
LDPE	Low-density polyethylene
MF	melamine-formaldehyde
MGy	Megagray
Pb	Lead
PBT	Polybutylene terephthalate
PET	Polyethylene terephthalate [3907 60]
PP	Polypropylene
Sb_2S_3	Antimony sulfide / diantimony trisulfide
UF	Urea-formaldehyde
UP	Unsaturated polyesters
VPE	Cross-linked polyethylene
α	Alpha radiation
β	Beta radiation
γ	Gamma radiation
CCD	Charge coupled devices

3.1 Summary of exemption request

The applicant requests an exemption for Cd (cadmium) used as a photo detector in ionising radiation tolerant video camera tubes. These video cameras are reportedly designed to be used inside high radiation exposure environments such as in nuclear power plants and radioactive waste management facilities [Mirion 2015].

[Mirion 2015] states that such cameras are used in nuclear facilities to remotely observe operations and inspect various parts of a nuclear reactor and its dependent systems. The applicant states that such inspections search for fabrication defects and that they are exposed to high doses of gamma and other radiation that rapidly damage all other available types of video cameras. The applicant also notes that the Cd-based photo-detector has optimal optical performance to enable clear images to be obtained. Most video cameras today use CCD (charged coupled devices) or CMOS (Complementary metal-oxide-semiconductor) silicon detectors that cannot be used in high radiation environments whereas the few remaining "vidicon" camera tube types[3] that are commercially available contain RoHS substances (Pb or Cd). Of these remaining types, Plumbicon, which uses Pb is less sensitive to light and is not tolerant to gamma radiation.

[Mirion 2015] states that Manufacturers of Chalnicon camera tubes do not provide data on the Cd content, therefore an exact amount of Cd entering the EU for the use/application described in this request are not precisely known. The applicant has however provided an estimate, based off of scientific literature that they provided: the cadmium selenide layer is probably 0.5 to 2 µm thick [Shreekanthan et al. 2003] and an illustrative example tube has a target active area of 15 mm diameter = 176mm2 [JSC 2017]. In this example, the CdSe (cadmium selenide) volume is 0.09 to 0.35 mm3. As the density of CdSe is 5.82 g/cm3, the mass is 0.5 to 2 milligrams of CdSe per tube. The cadmium content of CdSe is 59% Cd so each tube contains 0.3 to 1.2 milligrams of Cd. Further the applicant estimate that less than 100 cameras with Chalnicon camera tubes which are in scope of the RoHS directive are placed on the EU market annually so the total amount of cadmium is about 0.03 to 0.12 grams of Cd per year.

[3] **Additional note to supplement the information provided by the applicant:** A vidicon tube is a video camera tube design in which the target material is a photoconductor.

3.2 Description of the requested exemption

3.2.1 Scope/wording

The applicant summarizes their exemption request:

> *"This exemption is requested to allow the use of cadmium as a photo-detector in ionising radiation tolerant video camera tubes. These cameras are used in nuclear facilities to remotely observe operations and inspect various parts of a nuclear reactor for fabrication defects. They are exposed to high doses of gamma and other radiation that will rapidly damage all other available types of video camera. The cadmium-based photo-detector has optimal optical performance to enable clear images to be obtained. Most video cameras today use CCD or CMOS silicon detectors that cannot be used in high radiation environments whereas the few remaining "vidicon" camera tube types that are commercially available contain RoHS substances (lead or cadmium) and the type with lead (Plumbicon) is less light sensitive and is not gamma radiation tolerant."*

3.2.2 Proposed Annex I category

The applicant requests an exemption for the categories 3, 4, 9, and 11 as of Annex I to RoHS Directive, with a focus on Category 9 ("monitoring and control instruments in industry").

Category 11 ("other EEE not covered by any of the categories") has been indicated by the applicant, whereas three other categories have been selected in addition. The applicant explained that four categories have been identified due to the uncertainty and differing opinion on which is appropriate for professional video cameras. The applicant argues that video cameras are usually regarded as being consumer products, however the Chalnicon camera tubes covered by this exemption are designed for exclusively professional use and so depending on interpretation if they are not in Category 4 ("Consumer equipment"), then they would be in Category 11 ("other EEE not covered by any of the categories"). The applicant also states that some market surveillance authorities may regard CCTV (closed-circuit television) as falling into Category 9, but when the main purpose is real time imaging, Category 4 is usually regarded as being the correct category, and the applicant states that this classification is unclear to them [Mirion 2016].

3.3 Applicant's justification for exemption

In this application, the applicant claims that there is not substitution for Cd used as a photo detector in ionising radiation tolerant video camera tubes.

3.3.1 Background

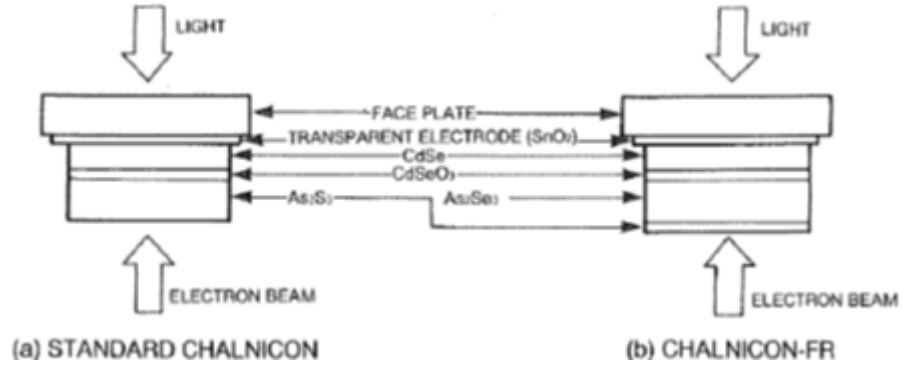
In relation to the function of the component, the applicant explains that the nuclear industry has always had a requirement for cameras that are radiation tolerant to 1-2MGy (megagray) against gamma radiation. The applicant states that these cameras are used for inspection and general surveillance activities in nuclear power stations while they are also used to monitor various operations in waste processing plants such as those found at the Sellafield nuclear fuel waste processing facility in the UK.

The applicant explains that the radiation tolerant cameras fundamentally achieve their high radiation tolerance by using a thermionic image sensor (camera tube), which was the image sensor used in all types of camera in the 1960's. These sensors used a light sensitive semiconductor layer on the faceplate of the tube referred to as the target layer. The applicant states that originally there were a number of different target layers manufactured, however over the years, this image sensor has been replaced by CCD and CMOS sensors in other industries leading to the demise of the thermionic image sensor. Currently there is only one suitable type of thermionic image sensor that is in production called Chalnicon, which comprise of camera tubes whose target layer contains 58.7% Cd [Mirion 2015].

CCD and in particular, CMOS radiation tolerant technologies had advanced over the past ten years driven primarily by the medical and space industries. The applicant explains that these sensors have not yet reached the radiation tolerance levels of the Chalnicon camera tubes or those required by the nuclear industry. As a result it is necessary for the applicant to apply for an exemption to allow the use of Cd in the Chalnicon camera tubes for ROHS 2 compliance [Mirion 2015].

The applicant details that the CdSe layer in the Chalnicon camera tubes contains 58.7% Cd in CdSe (by weight), and to be 0.5 to 2 microns in thickness, which is illustrated below in Figure 4-1. The applicant further explains that commercial abrasive materials with a grit sizes between 0.25 to 1 microns are available and could be used to separate the CdSe from the substrate. Therefore, according to the applicant, the CdSe layer itself, and not the entire tube, is considered to be a homogeneous material consistent with the RoHS Directive's definition of homogenous materials ("one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes").

Figure 3-1: provided schematic representation of the target structure [Mirion 2016].



In addition, the applicant describes that preparation for reuse or recycling of waste from this EEE is not possible. The applicant claims that the video camera is likely to become radioactive during use, and therefore must be treated as a radioactive waste. The applicant continues to justify this by stating that radioactive waste is strongly regulated in the EU by Council Directive 2011/70/Euratom[4] and due to this, radioactive waste will not enter waste streams with other electrical equipment.

3.3.2 Availability of substitution

The applicant informs that Chalnicon had been developed in the 1970s and since has been widely used inside nuclear reactors and nuclear reprocessing facilities because of its unique combination of optical performance and radiation resistance.

The choice of photoconductor materials for Vidicon cameras is very limited. Important characteristic for cameras used for observations in nuclear facilities particularly include:

- sensitivity to visible light,
- low dark current – signal generated in complete darkness,
- stability with temperature,
- image burn-in – this can occur after a long period with a static image and can appear to remain after the objects are moved,
- flare due to reflected light from the detector surface - very high light adsorption properties prevent this effect,
- radiation tolerance and image not affected by radiation.

[4] The applicant provided the following link: https://ec.europa.eu/energy/en/topics/nuclear-energy/radioactive-waste-and-spent-fuel

The applicant's main requirement for the video cameras is resistance to very high exposure to ionising radiation, which occurs in nuclear environments including α, β and γ radiations. The applicant acknowledges that shielding can protect the electrical circuitry but reminds us that visible light has to reach the light detector and so it is not possible to block the ionising radiation which will damage most light sensitive materials [Mirion 2015]. The applicant provided a list of several types of camera tubes that have been developed, although only a few are still manufactured, including Vidicon camera tube types [Mirion 2015]:

- *Chalnicon which use Cd selenide detectors and were first developed in the early 1970s and cameras using these tubes are available from several suppliers, but the tubes are made by only one manufacturer that we are aware of.*
- *Tubes with antimony trisulphide photodetector, but are no longer manufactured.*
- *Several designs use a Pb oxide detector (e.g. Plumbicon). Some designs are intended for X-ray imaging using fluoroscopy (this converts X-rays to a visible image that is imaged by the camera).The number of manufacturers is uncertain (for example, Matsushita has ceased production) and there may be none. Plumbicon are not radiation tolerant and so are not suitable as substitutes for Chalnicon.*
- *Saticon camera tubes use selenium / tellurium / arsenic photoconductor detectors with a layer of antimony trisulphide. These are no longer produced. One supplier advertises Plumbicon tubes (which contain Pb) as alternatives[5] to Saticon.*
- *Silicon diode photoconductor are described by* [Burle 1987]*, but no known manufacturers exist. However, they are not designed to be exposed to intense ionising radiation.*
- *Newvicon camera tubes use zinc selenide but also contains Cd. Apparently available from at least two suppliers[6], but are no longer manufactured and so cannot be used as a substitute. Some types are designed to have sensitive near infrared response.*

The applicant states that there are many types of video cameras that have been developed but none of these (and in particular not CCD and CMOS detectors) were are able to withstand the high radiation levels in the most demanding environments, such as in nuclear reactors. In this respect, the applicant explains that obtaining a clear image at locations exposed to high levels of ionising radiation is not readily achievable because of the radiation induced noise (snow effect). The radiation also quickly damages the camera causing rapid failure. The applicant views this is a serious problem in nuclear facilities, as it is dangerous for workers to enter radioactive environments to replace them. The applicant has provided statements that indicate Vidicon-type camera tubes are significantly more radiation resistant than CCD and CMOS types. The applicant believes that shorter lifetimes are not acceptable as plant operators need to view their facilities remotely as operators will be severely

[5] http://www.nimaging.com/products/tubes/
[6] http://www.nimaging.com/products/tubes/ and http://frank.pocnet.net/other/Matsushita/Matsushita_Vidicon-Tubes.pdf

harmed if exposed to these environments; therefore they are not easily able to replace cameras that fail [Mirion 2015].

The applicant explains that several of the Vidicon-type camera tubes cannot be considered as alternatives which do not require any of the materials or substances listed in Annex II to RoHS Directive, because they also contain RoHS substances, i.e. those that have Pb oxide (e.g. Plumbicon) and zinc cadmium selenide (Newvicon) photodetectors [Mirion 2015]. The applicant has provided a comparative table of some, and notes that Chalnicon camera tubes have the highest visible light sensitivity, lowest dark current and best temperature stability and are not susceptible to image burn-in or flare. Typical comparative data from [Burle 1987] was provided by the applicant in the following table:

Table 3: Vidicon type camera tubes properties [Mirion 2015].

Type	Signal current nA/µW at 450nm	Signal current nA/µW at 600nm	Dark current at 30˚C (nA)	Dark current at 50˚C (nA)
Chalnicon	340	430	1	6
Sb_2S_3	120	70	20	>50
Plumbicon (lead oxide)	270	80	2 (from Naraganset XQ2182 data sheet)	
Silicon diode	270	460	10	40
Newvicon	250	430	7 (from Naraganset XQ1440X data sheet)	

The applicant believes that in practice, the only commercially available camera tubes with sufficient radiation tolerance are the Chalnicon camera tubes, all other types are either no longer produced (and would have been inferior) or are not sufficiently radiation tolerant for nuclear applications. The applicant further states that several suppliers advertise radiation tolerant cameras which contain Chalnicon camera tubes and there are also a few suppliers of Chalnicon camera tubes, but there appears to be only one Chalnicon camera tubes manufacturer (others have ceased production) [Mirion 2015]. According to the applicant, the most important concern with light sensitivity is to be close to the unity quantum yield, in which the entire range of light visible to the human eye, for which the applicant again cites [Burle 1987], and explains that this behaviour is closest for Chalnicon camera tubes.

The applicant describes that resistance to ionising radiation can be achieved by using physical barriers such as thick layers of heavy metals such as Pb or tungsten but these cannot be used at the viewing position where optically transparent materials must be used. The applicant notes that lenses that do not discolour (go brown) have been developed and glass with a high Pb content is an effective barrier to alpha and beta-radiation, but is less effective with gamma-radiation. Therefore, the applicant explains the only remaining option is to use a photoconductive material that is resistant to gamma and other ionising radiation.

3.4 Stakeholder contribution

The Japan Business Council in Europe (JBCE) was the only contributor during the stakeholder consultation concerning the exemption request, focusing on the scope of the application for exemption (see Section 3.5.1, directly below).

The original stakeholder documents can be found on the EU CIRCA website (Browse categories > European Commission > Environment > RoHS Evaluations (BiPRO).

3.5 Critical review

3.5.1 Scope and relevant EEE category (RoHS Annex I)

3.5.1.1 Scope

Regarding the scope of the application for exemption, [JBCE 2016] considers "video cameras designed for use in environments exposed to ionising radiation" to be excluded from the RoHS Directive because they are "specifically designed" for use in nuclear facilities in systems which in JBCE's opinion should be considered as "large-scale fixed installations".

This raises the question whether the conditions of

- Article 2(4) lit. (e), or as applicable
- Article 2(4) lit. (e) read in conjunction with lit. (c)

of RoHS Directive are met which reads in its relevant parts:

> *"This Directive does not apply to:*
> *(c) equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment (…)*
> *(e) large-scale fixed installations"*

In consideration of this comment, we asked the applicant for clarification regarding the uses of radiation tolerant video camera tubes. The applicant clarified that there are two types of cameras using these tubes fulfilling different purposes:

- the first type being portable cameras used for inspection/maintenance purposes at nuclear facilities such as the inspection of a nuclear reactor core
- the second type being permanently installed in various locations within the nuclear facility for surveillance,

and further confirmed that the used tubes are identical for both applications.

Regarding portable cameras, in our opinion the exclusion as of Article 2(4) lit. (e) RoHS Directive, or Article 2(4) lit (e) read in conjunction with lit. (c) RoHS Directive does not apply since they are not part of a fixed installation, nor do they fall under any other potential exclusion. Thus, even in case the use in permanently installed cameras would fall under the exemption of Article 2(4) lit. (e), or as applicable Article 2(4) lit. (e) read in conjunction with lit. (c), the RoHS approach in terms of dual use would apply following which EEE that is intended to have at least one use within the scope of RoHS 2 has to comply with the provisions of the directive. [EC 2012].

Thus, in our opinion the use of Chalnicon tubes overall could be subject to an exemption under RoHS.

3.5.1.2 Relevant EEE category

While the original exemption request from the applicant listed the relevant EEE categories 3, 4, 9 and 11, we are of the opinion that **the exemption request falls under EEE Category 9** ("monitoring and control instruments including industrial monitoring and control instruments") as *of* Annex I of RoHS 2 applies. The other categories listed by the applicant are:

- Category 3 (IT and telecommunications equipment) – The video cameras are described by the applicant as being used for inspection and maintenance purposes, which thus is the main function of the equipment rather than any communication or broadcasting purpose.
- Category 4 (Consumer equipment) – The applicant clarified that the cameras using these specific tubes are not intended for any other use except in nuclear applications, which are performed by specialists. Therefore, it is obvious to us that radiation tolerant video camera tubes are not consumer equipment.
- Category 11 (Other EEE not covered by any of the other categories above) – because the tubes fall under Category 9 (see above), this category is logically eliminated.

3.5.2 REACH compliance

One of the prerequisites of Article 5(1) RoHS for granting an exemption is that the exemption does not weaken the environmental and health protection determined by REACH Regulation (EC) 1907/2006.

Consequently, we have assessed whether the possible exemption would be in line with the REACH Regulation environmental and health protection requirements. Possible problems such as conflicting or overlapping provisions have been investigated to prevent inconsistencies or double regulation. With regard to REACH compliance we have checked whether Cd or its substitutes are:

1. listed in REACH Annex XIV (List of substances subject to authorisation),
2. listed in REACH Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles),
3. in the recommendations of substances for Annex XIV,
4. on the list of substances proposed for the adoption to the Candidate List, or
5. on the list of substances of very high concern (SVHC).

For Cd that is currently restricted according to RoHS Annex II some relevant entries are listed in Annex XVII of the REACH Regulation, see Appendix A.

- Entry 23 of Annex XVII of the REACH Regulation restricts the use of Cd and its compounds. This entry restricts the use of Cd in various materials and articles, including in paints and painted articles as well as in mixtures and articles produced from a number of synthetic organic polymers referred to as plastic materials. Appendix A of this report lists entry 23 in its entirety.
- Further, entry 28 to 30 of Annex XVII of the REACH Regulation sets that various Cd compounds shall not be placed on the market, or used as substances, constituents of other substances, or in mixtures for supply to the general public.

In our opinion, the restrictions of Cd and its compounds listed under entry 23 or entries 28 to 30 **do not apply** to the material/component of EEEE in the scope of this exemption request, since neither the specific material addressed by the application for exemption is addressed by Entry 23 nor is the article intended to be supplied to the general public.

Further, by February 2017 no other entries, relevant for the use of Cd in the exemption request could be identified in Annex XIV and Annex XVII. Thus, on the basis of 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 a criterion of Art. 5(1)(a) applies.

3.5.3 Review of criteria for inclusion into Annexes III and/or IV

We recall that Article 5 of RoHS Directive sets as one further condition of granting an exemption that:

> *(…) 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, or*
> *— the reliability of substitutes is not ensured*

The applicant provided relevant information regarding potential substitutes and alternatives to camera tubes. In the application, it is made plausible that none of the alternatives was able to meet the critical criteria of having a centre resolution greater than 450 TV lines and tolerance to ionising radiation exposure exceeding 100Gy/hour and a total dose in excess of 100KGy. Further, several alternatives contain itself substances regulated under Annex II of RoHS.

The applicant also provided information regarding the development, particularly for design changes, such as the use of radiation resistant non-browning leaded glass as a barrier to protect the camera sensor. While such leaded glass is used, it is not effective against gamma radiation. The applicant also states in regards to substitute development and research that in the last 50 years, all potential materials for camera sensors has been evaluated, and that it is unlikely that any substitute will become available.

The applicant was asked to provide further details/sources such as test results or other studies, they stated that info was not available [Mirion 2016].

The applicant's assessment has not been challenged during stakeholder's consultation.

We independently searched for additional potential suppliers with alternatives, including outside the EU. While many radiation resistant cameras are available (some containing RoHS substances), we also found no evidence contradicting the applicant's assessment regarding the applicant's assessment, and in particular the assessment regarding the lack of alternatives are comparably tolerant to the high levels of ionising radiation.

3.5.4 Conclusion and recommendation

3.5.4.1 Granting the exemption against the criteria of Article 5(1)

Overall, it is the result of our assessment that

(1) For the scope as described and clarified (section 3.5.1),

an inclusion into the Annexes III or IV of RoHS Directive

(2) Would not weaken the environmental and health protection afforded by REACH Regulation (section 3.5.2)

and

(3) The 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, as well as the reliability of substitutes is not ensured (section 3.5.3).

Thus, we recommend granting the exemption in line with the wording proposed below.

3.5.4.2 Duration of the exemption

Article 5(2) of RoHS Directive reads:

> *"Measures adopted in accordance with point (a) of paragraph 1 shall, for categories 1 to 7, 10 and 11 of Annex I, have a validity period of up to 5 years and, for categories 8 and 9 of Annex I, a validity period of up to 7 years. The validity periods are to be decided on a case-by-case basis and may be renewed.*
> *(…)"*

Decisions on the duration of any exemptions shall according to Article 5(1) RoHS Directive take into account the availability of substitutes and the socioeconomic impact of substitution, as well as any potential adverse impacts on innovation.

The applicant's original exemption request was for *"Cadmium in video cameras designed for use in environments exposed to ionising radiation with a dose rate in excess of 100Gy/hour and a total dose in excess of 100KGy with a centre resolution greater than 450 TV Lines*" [Mirion 2015] to be added as an exemption to Annex III. The request was for the maximum validity period.

Due to the equipment falling under Category 9 of EEE (see section 3.5.1) and thus being subject for inclusion into Annex IV, the validity period is according to Article 5(2) of RoHS Directive up to 7 years. Given that there are currently no substitutes available, and no promising research activities with a view on alternatives could be identified thus we do not expect adverse impacts on innovation, **we recommend an exemption with a validity period of 7 years.**

3.5.4.3 Wording of the exemption

We recommend granting the requested exemption with a validity period of 7 years for the below wording be added to Annex IV of the RoHS 2 Directive:

> **Cadmium in radiation tolerant video camera tubes designed for cameras with a centre resolution greater than 450 TV lines which are used in in environments with ionising radiation exposure exceeding 100Gy/hour and a total dose in excess of 100KGy.**

3.6 References for exemption request No. A-2016

[Burle 1987] "Photosensitive camera tubes and devices handbook" – Burle (1987). http://www.r-type.org/pdfs/pctdh.pdf

[EC 2012] "RoHS 2 FAQ" – European Commission (2012). http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf

[Gnatenko, et. Al 2014] "Study of the correlation between structural and photoluminescence properties of CdSe thin films" - Yu.P. Gnatenko, A.S. Opanasyuk, M.M. Ivashchenko, P.M. Bukivskij , I.O. Faryna (2014). http://www.researchgate.net/profile/Yuriy_Gnatenko2/publication/263363816_Study_of_the_correlation_between_stru ctural_and_photoluminescence_properties_of_CdSe_thin_films_deposited_by_closespaced_vacuum_sublimation/links/00b4953aaaf2501ca2000000.pdf

[JBCE 2016] "JBCE comment on public consultation of 'Cadmium in video cameras designed for use in environments exposed to ionising radiation' in Exemption request A-2016" – Japan Business Council in Europe (2016). https://circabc.europa.eu/sd/a/d038a6ca-07a2-42e2-8b6a-6b102fa46223/20161222_JBCE_Contribution_RoHS_Exemption_A-2016.pdf

[JSC 2017] "Radiant-Resistant Vidicon LI501-1MK" - JSC 'Ruselectronics' National Resource Institute Electron (Accessed Feb. 2017). http://www.electron.spb.ru/data_eng/LI501.pdf

[Kwak, et. al 2011] "Identification of Induced-Radioactivity in Medical LINAC Using a NaI(Tl)Crystal Detector" - Kwak et. al (2011). http://www.aesj.or.jp/publication/pnst001/data/525.pdf

[Mirion 2015] "Mirion Exemption Request Form" - Mirion Technologies (2015). http://rohs.exemptions.bipro.de/exemption-consultations/2016-2/

[Mirion 2016] "Applicant Consultation Q&A"- Mirion (2016). http://rohs.exemptions.bipro.de/exemption-consultations/2016-2/

[Mirion 2017] " email from Mirion for further clarification" - Mirion Technologies (2017). http://rohs.exemptions.bipro.de/exemption-consultations/2016-2/

[Shreekanthan et al. 2003] "Growth and characterization of semiconducting cadmium selenide thin films" by K. N. Shreekanthan, B. V. Rajendra, V. B. Kasturi, and G. K. Shivakumar, Cryst. Res. (2003) Technol. 38, No. 1, 30 – 33

[Shreekanthan, et. al 2003] "Growth and characterization of semiconducting cadmium selenide thin films" by K. N. Shreekanthan, B. V. Rajendra, V. B. Kasturi, and G. K. Shivakumar, Cryst. Res. Technol. 38, No. 1, 30 – 33 (2003)

[U.S.NRC 2017] "Induced radioactivity" – United States Nuclear Regulatory Commission (Accessed Feb. 2017). https://www.nrc.gov/reading-rm/basic-ref/glossary/induced-radioactivity.html

[Weeks 1998] "Production of radioisotopes by direct electron activation" – Weeks KJ, O'Shea PG (1998). https://www.ncbi.nlm.nih.gov/pubmed/9571615

4 Exemption request No. B-2016

Exemption Request no. B-2016 has been filed by EuroWindoor AISBL, in co-operation with EPPA ivzw, both established in Belgium ("the applicant"). The application aims at inclusion into Annex III of the RoHS Directive as a new exemption with the following wording:

> **"for windows and doors, being manufactured out of plastic window profiles containing recovered PVC, in case these windows and doors may be equipped or retrofitted with electric and/or electronic devices."** [EuroWindoor 2016].

Abbreviations and Definitions:

CaZn	Calcium Zinc
Cd	Cadmium
ECVM	European Council of Vinyl Manufacturers
EEE	Electrical and electronic equipment
EPD	Environmental Product Declarations
EPPA	European PVC Window Profile and Related Building Products Association
LCA	Life-cycle-assessment
Pb	Lead
PVC	Polyvinylchloride
PVC-U	Un-plasticized/rigid polyvinylchloride
SNEP	Syndicat National de l'Extrusion Plastique
VKG	Vereiniging Kunststof Gefelelementenindustrie

4.1 Summary of exemption request

The applicant requests a new exemption to use recycled PVC for profiles (windows and doors). Cd (cadmium) and Pb (lead) are used in the PVC-U frame material for windows and door-sets with the particular characteristic specified as being a stabilizer for PVC-U used in profiles [EuroWindoor 2015].

[EuroWindoor 2015] reports that the content of Pb and Cd in the homogeneous material is 2% and 0.1% respectively.

4.2 Description of the requested exemption

4.2.1 Scope/wording

The original version of the application aimed at inclusion into Annexes III of RoHS Directive of a new exemption regarding *"use of recycled PVC for profiles (windows and doors)"* [EuroWindoor 2015].

When asked for clarification, the applicant revised the wording for the exemption request to be:

> ***"A derogation from the directive shall be granted for windows and doors, being manufactured out of plastic window profiles containing recovered PVC, in case these windows and doors may be equipped or retrofitted with electric and/or electronic devices."***

4.2.2 Proposed Annex I category

The relevant category as per Annex I of RoHS Directive is identified by the applicant as being Category 11 ("*other EEE (electrical and electronic equipment) not covered by any of the categories*").

4.3 Applicant's justification for exemption

4.3.1 Background

The applicant explains that the RoHS-regulated substances are used in PVC-U frame material for windows and door sets. The function of these substances is the stabilisation of PVC-U for profiles. The particular characteristics and functions of the RoHS-regulated substances that require their use in this material is polymer stabilisation [EuroWindoor 2015].

The subject of the request is an exemption for Cd and Pb in recycled PVC-U profiles of electronic doors and windows. However, information and data included in the application form is mostly related to recycle PVC profiles without distinguishing whether they are used in electrical / electronical equipment. The applicant explained that when PVC window and door profiles as well as their related building products are manufactured it is not known whether the final product (windows and doors) will be equipped with EEE [EuroWindoor 2016].

With regard to the low rate of EEE PVC windows and doors (estimate less than 1% of PVC windows and doors are electronically equipped), all life cycle assessments and hence Environmental Product Declarations for PVC windows refer products containing recovered PVC whether they are equipped with or without electric and/or electronic devices [EuroWindoor 2016].

The applicant indicated that a closed loop system exists for the EEE waste of application, the closed loop system for PVC-U profiles for post-consumer windows and door sets (e.g. Rewindo). The article is collected and dismantled where PVC-U, glazing, and metal are being subsequently recycled [EuroWindoor 2015]. This functioning post-consumer recycling system for PVC windows and doors has been installed in 2002 and is continuously growing in volume. The system is managed by well-

established clearinghouses, for instance REWINDO GmbH. The scheme essentially consists of a controlled loop recycling which refers to both, post-industrial and post-consumer waste streams. Even quite seldom, used PVC windows equipped with EEE can enter into the post-consumer waste stream. This equipment will be dismantled and separated like pane and hard-ware and hence will enter an own material specific recycling process. The applicant further estimates that post-consumer collection rate of electric windows and doors with PVC-U profiles containing Cd/Pb is below 1% [EuroWindoor 2016].

Regarding the amount (weight) of RoHS substance present in EEE waste accumulates per annum EuroWindoor provided information that in 2014 around 60,000 tonnes post-consumer PVC containing approx. 600 tonnes of post-consumer PVC in EEE waste with up to approx. 3 tonnes RoHS substances [EuroWindoor 2015].

4.3.2 Availability of substitution

The application states that substitution is feasible, and that there are no problems with the availability of substitutes. Indeed, following the application, Pb and Cd are already substituted in newly manufactured “virgin” rigid PVC formulations by CaZn. Using CaZn as a stabilizer for PVC-U profiles for windows and doors instead of Pb and/or Cd is state of the art and fulfils the requirements of the European standard EN 12608 “Un-plasticized polyvinylchloride (PVC-U) profiles for the fabrication of windows and doors – Classification, requirements and test method”, such as the quality standards RAL-GZ 716/1 and NF 126 [EuroWindoor 2015].

Only the use of PVC recyclate may result in exceeding the maximum concentration values tolerated by weight in homogeneous materials under Annex I to RoHS Directive (0.1 % for Pb; 0.01 % for Cd).

4.3.3 Environmental and socio-economic considerations

EuroWindoor explains that recycling PVC-U reduces the amount of energy and natural resources (such as water, petroleum and natural salt) needed to create virgin PVC. Recycling PVC-U-profiles of windows and doors also keeps them out of landfills and allows the PVC to be reused in manufacturing new profiles for new windows and doors (Life Cycle and socio-economic advantages). In the applicant’s view, this is intended by the EU Commission, as expressed within the documents Communication COM (2014) 398 “Towards a circular economy: A zero waste programme for Europe”, and the Communication COM (2014) 445final on resource efficiency opportunities in the building sector. Further, EuroWindoor describes that medical test results of workers involved verify that the use of recovered PVC does not pose any risk to health, safety and environment. Since neither Pb nor Cd could be mechanically disjointed from PVC-U profiles, and as a result, an approved exemption would not weaken the environment and health protection afforded by REACH [EuroWindoor 2016].

In addition, the applicant states that the reuse of PVC waste had a proven socio-economic benefit in particular with regard to decarbonisation, circular economy, competitiveness and raw material availability. For instance, the today´s ratio of around 16% recovered PVC used in PVC profiles would reduce primary energy demand by approximately 8% (source: “Environmental Product Declaration

for double-glazed PVC Windows", § 6.3 Sensitivity concerning the use of recycled PVC[7]. The applicant explains that all these benefits would be lost should post-consumer PVC waste be disposed of instead of closing the loop towards a circular economy through recycling [EuroWindoor 2016].

Finally, EuroWindoor concludes that the use of recycled PVC has a strong positive environmental impact by closing the loop towards a circular economy: by reducing the use of raw materials and by reducing the primary energy demand in the extrusion process and thus aims to achieve low carbon manufacturing. They provide a sensitivity analysis as a result of a life cycle assessment for environmental product declarations sourced from [IBU 2016], see the figure below. [EuroWindoor 2016].

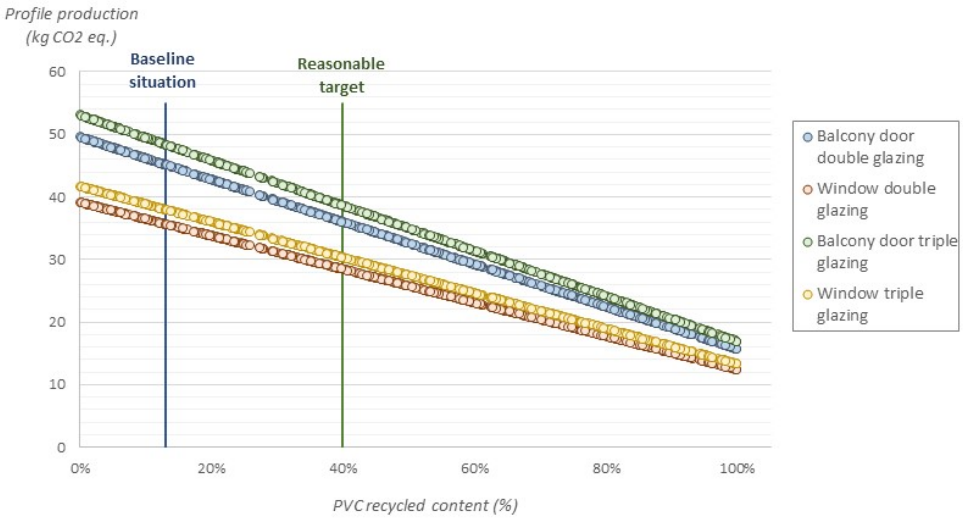


Figure 4-1: Sensitivity analysis LCA recycled PVC [EuroWindoor 2016]

[7] https://epd-online.com/PublishedEpd/Detail/9185

4.4 Stakeholder contribution

There were a total of 18 contributions to Exemption Request No. B-2016. Among these, 16 were supportive and 2 were non-supportive contributions to the requested exemption. The 16 supportive contributions agreed with the scope of the exemption as proposed by the applicant. Due to the volume of similar supportive contributions, the supportive contributions are grouped by response rather than by stakeholder. The two non-supportive contributions are individually described. The original communication documents from the stakeholders are available at the EU CIRCA website (Browse categories > European Commission > Environment > RoHS Evaluations (BiPRO), at top left, click on "Library").

Kemikalieninspektionen (Swedish Chemicals Agency) does not agree with the scope proposed by the applicant for the reasons below [KEMI 2016]:

- The RoHS Directive regulates that EEE placed on the market does not contain certain hazardous substances. The applicant asks for an exemption of a material with a certain history, namely recycled from waste. When equipment is placed on the market we are not able to see if its content material has been recycled or not. There are no provisions in RoHS that requires the supplier to keep track of the origin of the input material. Thus the same provisions have to be given both virgin and recycled materials when RoHS is implemented. Virgin PVC can be produced without the addition of cadmium and Pb, and thus we cannot justify those elements as necessary in the manufacturing of doors and windows equipped with electric parts.
- It is not clear from the wording in which parts of the windows or doors the Pb and Cd may occur. With the proposed wording the recycled material could theoretically be used in any part, also in the electronic equipment mounted on a door or window.
- It is not clear that it is meant that Cd and Pb are added to the EEE as part of the recycled PVC. The wording does not include *such information, which opens for separate addition of Pb and cadmium.*
- There *is no information on the maximum expected concentration for Pb and Cd in any homogenous material.*

The Norwegian Environment Agency does not agree with the scope proposed by the applicant due to the following [NEA 2016]:

- The scope is too broad.
- There is no information on the maximum expected concentration for Pb and cadmium in any homogenous material. In the original request the applicant stating that amounts of hazardous substances in recovered PVC pose up to 2% Pb and up to 0.1% Cd in homogeneous material. This is 20 times above limit for Pb and 10 times above limit for cadmium given in RoHS Directive.
- It is not clear in which part of the door or window Pb and Cd may occur.
- There are alternatives to recovered PVC for use in these kinds of articles.

- The application does not seem to be in line with conditions stated in article 5 in the RoHS-directive.

On the other side, supportive contributions for the requested exemption were made by the following stakeholders:

- **Deceuninck nv** [DECUENINCK 2016]
- **European Council of Vinyl Manufacturers** [ECVM 2016]
- **EuroWindoor AISBL** [EuroWindoor 2016]
- **FCIO Fachverband der Chemischen Industrie Österreichs** [FCIO 2016]
- **Internorm International GmbH** [INTERNORM 2016]
- **Profine GmbH - International Profile Group (2)** [PROFINE 2016]
- **PVC Forum Italia** [PVC-FI 2016]
- **Rehau AG+Co.** [REHAU 2016]
- **Salamander Industrie-Produkte GmbH** [SALAMANDER 2016]
- **Schüco Polymer Technologies KG** [SCHÜCO 2016]
- **SNEP - Syndicat National de l'Extrusion Plastique** [SNEP 2016]
- **VEKA AG (2)** [VEKA 2016]
- **VEKA Umwelttechnik GmbH** [VEKA-U 2016]
- **VKG - Vereiniging Kunststof Gefelelementenindustrie** [VKG 2016]

In the below summaries, all of the supportive contributors are implied as they had very similar contributions, unless otherwise stated. All supportive stakeholders listed agree with the scope of the exemption as proposed by the applicant.

All stakeholders in the above list agreed with the wording as proposed by the applicant except *Deceuninck nv* which suggests to*:* enlarge the scope to "window & door frames and related building products." Being louvre and roller shutters/boxes [DECUENINCK 2016].

The only positive stakeholder to comment regarding environmental, health and consumer safety issues was *Rehau AG+Co*., stating that "The articles are co-extruded which means that the consumer doesn't have a chance to get in contact with the post-consumer recyclate material." [REHAU 2016].

All of the positive stakeholders responded that they are unaware of possible health effects of Cd/Pb contained in recycled PVC. The *European Council of Vinyl Manufacturers (ECVM)*, along with *Rehau AG+Co.* and EuroWindoor AISBL made brief additional statements in favour of the safety of recycled PVC, including the study "Health Risk of Occupational Pb Exposure in Conventional PVC Recycling and Converting Operation" (2016) which states there is no occupational health risk [ECVM 2016], [REHAU 2016], [EuroWindoor 2016].

Two of the supportive stakeholders (*Deceuninck nv* and *The European Council of Vinyl Manufacturers*) commented referring to Commission Regulation 494/2011 modifying Annex XVII of REACH which addresses cadmium in polymers and specific aspects of recycling. [ECVM 2016]. The

rest of the positive stakeholders either had no comment, or referred to cadmium derogation as a similar case.

The stakeholders listed above provided some estimates regarding Cd content in recycled PVC-U profiles of electronic doors and windows in the EU annually. One such stakeholder also provided no estimate for Pb [INTERNORM 2016]. One stakeholder stated that Pb content in recyclates will be 1% or less. However, 13 positive stakeholders stated that they assume the Pb content in recyclates intended to be used in PVC windows being around 1% w/w or lower, and in specific single cases the amount reaching 2% w/w [SNEP 2016]. Meanwhile, *Deceuninck nv* provided no estimate, but instead suggested that rather than looking at the Cd/Pb of individual components, the content of the final product as a whole could be the correct approach [DECUENINCK 2016]. *Veka AG* provided an estimate that included Cd, stating that new PVC profiles typically use less than 50% recycled PVC, which would indicate profiles made with recyclates would contain less than 1% Cd/Pb or lower [VEKA 2016].

All of the supportive stakeholders agreed with the applicant's conclusion that "The use of recycled PVC has a strong positive environmental impact by closing the loop towards a circular economy, by reducing the use of raw materials and by reducing the primary energy demand in the extrusion process and thus aims to achieve low carbon manufacturing" [EuroWindoor 2015]. Most of the positive stakeholders stated that today´s existing controlled loop scheme to collect and to recycle used PVC windows amounts to around 10% all over Europe. It means that new PVC windows contain - as an average - around 10% recycled PVC, which in the EU results in 1.4 million tonnes of carbon emissions prevented by recycling.

Of the supportive stakeholders, 13 cited Environmental Product Declarations for PVC windows sensitivity analysis to lower the impact of the global warming potential through recycling. Others stated either nothing or very similar statements when asked to quantify any environmental impact.

All but one of the supportive stakeholders either provided no comment, or stated that they see no adverse impacts to the granting of the exemption. *Deceuninck nv* commented that in case of no derogation, the industry will cease development of innovative materials/products that contain recyclates needed for a circular economy, and that without such innovation the EU market could be flooded with PB or Cd containing windows/doors/shutters imported from outside the EU [DECUENINCK 2016].

4.5 Critical review

4.5.1 Scope and relevant EEE category (RoHS Annex I)

4.5.1.1 Scope/wording

KEMI has commented on the proposed scope and wording of the exemption that

- It is not clear that it is meant that the cadmium and lead substances are added to the EEE as part of the recycled PVC. The wording does not include *such information, which opens for separate addition of lead and cadmium.*
- It is not clear from the wording in which parts of the windows or doors the lead and cadmium may occur. With the proposed wording the recycled material could theoretically be used in any part, also in the electronic equipment mounted on a door or window.

While we believe that the revised proposal of the applicant already addresses this concern to some extent, we feel that it will in any case be necessary aligning any exemption entry into Annex III of RoHS Directive with the wording of the relevant restriction entry as of Annex XVII REACH, to avoid any obvious ambiguities and different standards.

Further, we feel that the wording chosen by the applicant

> *" … in case these windows and doors may be equipped or retrofitted with electric and/or electronic devices"*

may be misunderstood as covering also windows and doors which are already built into existing edifices. An alignment of the wording with the one used by REACH Annex XVII entry would avoid such potential for misunderstanding.

4.5.1.2 Relevant RoHS category

The allocation to Category 11 of Annex I RoHS by the applicant has not been challenged by any stakeholder. Indeed, there seems to be a consensus that this is correct allocation in line with previous study [Öko-I 2015].

4.5.2 REACH compliance

4.5.2.1 REACH regulation compliance- current regulations and upcoming initiatives under REACH

One of the prerequisites of Article 5(1) RoHS for granting an exemption is that the exemption does not weaken the environmental and health protection determined by REACH Regulation.

Consequently, the project team has assessed whether the possible exemption would be in line with the REACH Regulation environmental and health protection requirements. Possible problems like conflicting or overlapping provisions have been investigated to prevent inconsistencies or double regulation. With regard to REACH compliance we have checked whether Pb and Cd are:

1. listed in REACH Annex XIV (The Authorization List),
2. listed in REACH Annex XVII (the List of Restrictions),
3. in the recommendations of substances for Annex XIV,
4. on the list of substances proposed for the adoption to the Candidate List; or
5. on the list of substances of very high concern (SVHC).

4.5.2.2 Current regulations

As regards the currents regulations for Cadmium and Lead that are currently restricted according to RoHS Annex II some relevant entries are listed in Annex XVII of the REACH Regulation, see Annex A: Table 6.

Entry 23 of Annex XVII REACH

Entry 23 of Annex XVII of the REACH Regulation, as amended inter alia by Commission Regulation No 494/2011, restricts the use of cadmium and its compounds. This entry restricts the use of Cadmium in various materials and articles, including in paints and painted articles as well as in mixtures and articles produced from a number of synthetic organic polymers referred to as plastic materials.

Appendix A of this report lists entry 23 that is restricting the use of cadmium and its compounds (CAS No 7440-43-9) in Annex XVII of the REACH Regulation. This entry restricts the use of cadmium in various materials and products; its relevant parts are depicted in the table below:

Table 4: REACH Annex XVII relevant restrictions for the use of cadmium in materials and products

Paragraph	Descriptiion of restriction
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 master batch [3901 10] — cellulose acetate (CA) [3912 11] — cellulose acetate butyrate (CAB) [3912 11]

Paragraph	Descriptiion of restriction
	— 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. (…)**
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**

In the consultants opinion, the restrictions of cadmium and its compounds listed under entry 23 does apply to the application in the scope of this exemption request.

Paragraph 1 of entry no 23 defines that Cadmium shall not be used in mixtures and articles produced from polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21]. It further specifies that mixtures and articles produced from plastic material […] 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.

However, paragraph 4 of entry no 23 provides for a derogation, paragraph 1 […] shall not apply to 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.

Entries 10 to 12 Annex XIV REACH

If granted, the exemption would allow the use of lead in windows and doors, being manufactured out of plastic window profiles containing recovered PVC, in case these windows and doors may be equipped or retrofitted with electric and/or electronic devices.

Currently, Annex XIV of the REACH Regulation contains several entries for lead compounds, use of which requires authorisation:

- 10. Lead chromate;
- 11. Lead sulfochromate;
- 12. Lead chromate molybdate sulphate red.

In our opinion, none of the above listed compounds is relevant for this requested exemption, neither as directly added substance nor as substance that can reasonably be assumed to be generated in the course of the manufacturing process.

Entries 16, 17, and 63 of Annex XVII REACH

Appendix A of this report lists entries 16, 17, and 63 restricting the use of lead carbonates, lead sulphate, and lead and its compounds in Annex XVII of the REACH Regulation respectively. These entries restrict the use of Lead in various materials and products as summarised in the table below:

Table 5: REACH Annex XVII restrictions for the use of Lead in materials and products

Entry	Paragraph	Descriptiion of restriction
16. Lead carbonates: (a) Neutral anhydrous carbonate (PbCO3) CAS No 598-63-0 EC No 209-943-4 (b) Trilead-bis(carbonate)-dihydroxide 2Pb CO3-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. M20 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.

Entry	Paragraph	Descriptiion of restriction
17. Lead sulphates: (a) PbSO4 CAS No 7446-14-2 EC No 231-198-9 (b) Pbx SO4 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. M20 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.
63. Lead and its compounds **CAS No 7439-92-1** **EC No 231-100-4**	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.

In our opinion, the restrictions of Lead to be used in paints and jewellery listed under these entries do not apply to the application in the scope of this exemption request.

4.5.2.3 Upcoming initiatives under REACH

Review clause for entry 23 of Annex XVII REACH

In accordance with Article 69 of REACH regulation, the paragraph 4 of entry 23 on **cadmium** does include a review of the granted exemption "**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".** Thus it can be assumed, that a revision of the limit value for cadmium of 0.1% by weight of the plastic material in the following rigid PVC applications is possible in the near future, notably within this year.

Initiative for a restriction of Pb compounds

In addition, ECHA has submitted a proposal to restrict the placing on the market and use of lead compounds (EC 231-100-4) in PVC and of the placing on the market of PVC articles stabilised with lead compounds: "Restriction of lead compounds in PVC articles in concentrations equal to or greater than 0.1% (w/w) with a 15-year derogation for certain building and construction articles produced from recycled PVC (with a higher restriction limit of 1% w/w) and a 10 year derogation for PVC silica separators in lead acid batteries." [ECHA ANNEX XV Lead 2016]

The Agency's committees are currently performing a conformity check on the dossier. The dossier is available on the ECHA website to increase transparency and to help stakeholders prepare for the six month public consultation on the dossier. If the dossier passes conformity, the public consultation is expected in February 2017.[8] The following table summarises the proposed restriction entry for lead in Annex XV of REACH.

Table 6: Proposed lead restriction wording [ECHA ANNEX XV Lead 2016]

Lead compounds	1. Shall not be placed on the market or used in articles or parts thereof produced from polymers or copolymers of vinyl chloride (PVC) if the concentration of lead (expressed as metal) is equal to or greater than **0.1% by weight of the PVC material**. 2. Paragraph 1 shall apply 24 months from the entry into force of the restriction. 3. By way of **derogation**, paragraph 1 shall not apply to: a. the following article types containing recycled PVC **for a period of 15 years from entry into force**, **if the concentration of lead** (expressed as metal) **does not exceed 1% by weight of the PVC material**: **i. profiles and rigid sheets for building applications;** **ii. doors, windows, shutters, walls, blinds, fences, and roof gutters;** iii. cable ducts; iv. fittings for tubes, furniture etc.; v. pipes for non-drinking water, if the recycled PVC is used in a multilayer pipe and is entirely enclosed with a layer of virgin PVC in compliance with paragraph 1. Suppliers shall ensure before the first placing on the market of mixtures and articles containing recovered PVC that these are visibly, legibly and indelibly marked as follows: 'Contains recycled PVC' or with the following pictogram: (same as for entry 23.) b. PVC-silica separators in lead acid batteries for a period of 10 years. c. Articles that can be placed in the mouth covered by paragraph 7 of Entry 63 of Annex XVII. d. Articles covered under existing legislation: i. food contact materials covered by Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011 on plastic materials; ii. articles covered under 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 (RoHS Directive); iii. Directive 94/62/EC on packaging and packaging waste; iv. Directive 2009/48/EC on the safety of toy. 4. By way of derogation, paragraph 1 shall not apply to articles placed on the market for the first time before xxxxx (based on the transition period of 24

[8] https://echa.europa.eu/-/echa-weekly-21-december-2016

	months).

In this dossier, the ECHA concludes that [ECHA ANNEX XV Lead 2016]:

> *"there are risks from lead in PVC that are not adequately controlled and therefore regulatory action on a Union-wide basis is justified. The proposed restriction is the most appropriate Union-wide measure because it targets the risks for humans exposed to lead emissions from PVC articles, by restricting the use of lead stabilisers in all PVC applications. It is also capable of addressing these risks within a reasonable timeframe, i.e., from 2020 onwards. As suggested by studies, the proposed restriction might also lead to other human health and environmental benefits, which although have not been quantified, they could be significant."*

4.5.2.4 Discussion on REACH compliance

Compliance regarding entry 23 of Annex VII REACH (Cadmium)

We understand that

(a) Entry 23 of Annex XVII to REACH covers all relevant PVC profiles for windows and door including all profiles which are equipped with electrical equipment and for which the current RoHS exemption is applied;

(b) Where Cd is found in recycled PVC used for door and window profiles, the environmental and health impacts are identical irrespective whether the windows and doors are electric (and thus subject to RoHS) or not.

Against this understanding, our conclusion is that if any granted exemption under RoHS, as required by Article 5(1) of the Directive, must not weaken the environmental and health protection afforded by REACH Regulation, this does mean that an exemption granted for PVC profiles needs to be aligned with what entry 23 of REACH Regulation requires. Thus any article containing recovered PVC must not exceed 0.1% Cd by weight of the plastic material, and must meet any further requirements set by REACH Regulation. We believe it is advisable that in case an exemption under RoHS Directive is granted the entry for Annex III should explicitly feature the threshold as per Annex XVII REACH.

On the other hand, we also opine that REACH compliance is ensured if the applicable thresholds from the REACH restriction entry are applied, and that already for the sake of coherence of EU legislation, an exemption under RoHS should not be rejected for PVC profiles for electric windows and doors, while the identical material can currently legally be used under the terms of REACH for non-electric windows and doors.

Compliance regarding upcoming relevant initiatives at EU level (Review of entry 23 (Cadmium)); Regulation of Lead)

Regarding the foreseen review of entry 23 by 31 December 2017, and regarding the initiative of regulating the Pb content in PVC rigid applications at EU level, we are of the opinion that the RoHS exemption process should not anticipate decisions of the relevant EU institutions. We understand compliance as compliance with current EU acquis, not with developments the outcome of which is currently not clear.

On the other hand, we believe

- it is advisable to take into account scientific evidence gathered in the regulatory process and
- be aware of the upcoming initiatives in the framework of EU chemicals law, and take into consideration all relevant new or updated regulations of REACH once adopted

Our proposal how to take this into account is presented in section 4.5.4.

4.5.3 Review of criteria for inclusion into Annexes III and/or IV

Article 5(1) (a) of RoHS has three points for potential inclusion into Annexes III and IV, in the case that any of the three conditions applies to the situation, the first two being:

- 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, or
- the reliability of substitutes is not ensured,

These first two points are clearly not applicable to this exemption request. As is easily identified, and as stated by the applicant, a substitution meeting the technical requirements, which is reliably available is already in use today. As noted by the applicant, the substitute CaZn as a stabilizer for PVC-U profiles and doors fulfils EU quality standards including EN 12608, RAL-GZ716/1 and NF 126 [EuroWindoor 2015]. Therefore, these two potential points for exemption are not reviewed further.

Therefore the primary and only potential justification for inclusion is the third criteria point, which is:

- 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 total negative environmental, health and consumer safety impacts caused by substitution thus need to be compared to the total environmental, health and consumer safety benefits of substitution, as the primary justification for the applicant's application for an exemption.

As described in section 4.3.3, the applicant states that test results verify the use of recovered PVC does not post any risk to the health, safety or the environment when considering the environment and health protection afforded by REACH. This statement has been supported by some stakeholder positions during the stakeholder consultation and contested by others (see section 4.4). As a starting point, we are of the opinion that the justification of the applicant is comprehensibly, in that the use of recovered PVC is in line with the goal of a circular economy when considering the life-cycle of these substances and containing products, and that it reduces waste, emissions and energy use, and by this is in line with the general direction of EU papers cited in the application. However, it is obvious on the other hand that these benefits have to be balanced against the impacts of unwanted substance such as Cadmium and Lead being further present in PVC profiles, and more generally in the material chain. We believe that considering the existing, and discussed future, regulations of Cadmium and Lead in the context of relevant REACH restriction is crucial in this respect.

Cadmium

We recall as a starting point again that

(a) Entry 23 of Annex XVII to REACH covers all relevant PVC profiles for windows and door including all profiles which are equipped with electrical equipment and for which the current RoHS exemption is applied;

(b) Where Cd is found in recycled PVC used for door and window profiles, the environmental and health impacts are identical irrespective whether the windows and doors are electric (and thus subject to RoHS) or not.

We further believe that the standard for acceptance of the risks of Cadmium under the restriction process of REACH, and under an exemption under RoHS, are identical.

Against this, we are of the opinion that the environmental, health and consumer safety impacts in terms of presence of Cadmium in PVC profiles for windows and doors, on the basis of the scientific evidence available at time of adoption in 2011, have been balanced by the legislature when introducing entry 23 in Annex XVII of REACH which is part of the binding EU acquis.

Entry 23 will be reviewed by December 2017, in accordance with Article 69 of REACH. This process, and the decision, will take into account the entire market for PVC profiles, going far beyond the windows and doors equipped with electric devices. We expect that the PVC recycling industry will be invited to further investigate the presence of pollutants in the relevant profiles. While we feel on the one hand that it is important to take any development under REACH into account once adopted, on the other hand we deem it appropriate to not anticipating this decision at REACH level, leading to our conclusion as presented at the end of this section, and our overall proposal as presented in section.

Lead

A result of the stakeholder consultation is that most agree with the applicant's statement that Lead, just as Cadmium, is embedded in the polymer matrix, not volatile, and therefore emissions are not occurring and exposure to humans or the environment would be negligible. Most stakeholders reference the 2016 study titled "*Health Risk of Occupational Lead (Pb) Exposure in Conventional PVC Recycling and Converting Operation"* which concludes there is no occupational health risk. The same is true regarding the alleged environmental benefits of use of recycled PVC in terms of reducing the amount of waste produced, and reducing the energy needed (and therefore CO_2 emissions). Many stakeholders echo the same example: that with an annual production of 700,000 tons of PVC window profiles in the EU, 10% of this being recycled would be result in the saving of 140,000 tons of carbon emissions [EuroWindoor 2016]. Further, as pointed out, a number of stakeholders stated that they assume the Pb content in recyclates intended to be used in PVC windows being around 1% w/w or lower. Applicant and stakeholders have been explicitly requested to provide any further scientific information for supporting their position.

No specific data detailing the potential negatives in such a situation was provided to the consultant, and indeed, such a decision to allow the use of recycled PVC is already afforded under REACH, though the thresholds are likely to be decreased in the future. As the applicant states, it is not known if the recycled PVC door and window frames will be fitted with electronic components or not, and under REACH the practice of recycling PVC for use in such frames is already allowed when the percentages of substances in the product are below a certain threshold, therefore a comparison of specifically those frames outfitted with electronics is not possible with the data available to the consultant, and instead the broader allowance for all frames, which would include those fitted with electronics, is possible under REACH when keeping within the required tolerances.

Note that from the assessment of available information, [ECHA 2016] concludes that approximately 90% of the estimated lead emissions during 2016 are expected to be released from PVC articles imported into the EU, and thus that there are risks from lead in PVC that are not adequately controlled and therefore regulatory action on a Union-wide basis is justified. ECHA comes to the conclusion that a restriction as proposed is the most appropriate Union-wide measure because it targets the risks for humans exposed to lead emissions from PVC articles, by restricting the use of lead stabilisers in all PVC applications within a reasonable timeframe, i.e., from 2020 onwards. ECHA concludes that the proposed restriction might also lead to other human health and environmental benefits, which although have not been quantified, they could be significant.

Whereas ECHA's proposal will be subject to the relevant institution's decision, we further believe that it is important to take into account stakeholder's information about the Pb content as a means of addressing adequately any environmental, health and consumer safety impacts, thus leading to the proposed threshold for Lead of 1% w/w (see section 4.5.4).

Therefore

- on the basis of available information,
- embracing current relevant restriction regarding Cadmium as set by REACH restriction entry 23 of Annex XVII,
- with the introduction of a separate threshold for the Lead content,
- taking into consideration the upcoming decisions on relevant restrictions regarding Cadmium and Lead in the framework of REACH restriction process, and introducing to this end a clear interconnection to the REACH restriction process into the recitals of the relevant delegated directive amending the Annexes of RoHS, and
- given the limited period of time for an exemption under RoHS

we are of the opinion that the negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits.

Socio-economic impacts of substitution

Article 5 of RoHS further stipulates that decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the socioeconomic impact of substitution. The applicant has stated that at the time of manufacturing, there is currently no perspective whether the door or window frames will be equipped with electric equipment, thus any restriction on manufacturing would obviously heavily affect the production of, and the market for, entire profiles made of recycled PVC. This is in particular the case for any market restriction imposed by means of refusing RoHS exemption which would go beyond what is currently required by REACH, which in effect could cause manufacturers to be unwilling to utilize recycled PVC even when allowed under REACH, to avoid risk of non-compliance with RoHS due to the unknown destination and use of the frames, a development which could ultimately lead to the ceasing of the PVC recycling scheme, despite its allowance under REACH within certain parameters.

We feel that socio-economic impacts of substitution are thus a further strong element for keeping decision on exemptions under RoHS in this specific case aligned with the situation under REACH.

4.5.4 Conclusion and recommendation

4.5.4.1 Granting the exemption against the criteria of Article 5(1)

Overall, it is the result of our assessment that

(1) For the scope as described and clarified (Section 4.5.1),

an inclusion into the Annexes III or IV of RoHS Directive

(2) Would not weaken the environmental and health protection afforded by REACH Regulation (Section 4.5.2)

and

(3) 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 (Section 4.5.3).

Thus, we recommend granting the exemption in line with the wording proposed below.

4.5.4.2 Duration of the exemption

Article 5(2) of RoHS Directive reads:

> *"Measures adopted in accordance with point (a) of paragraph 1 shall, for categories 1 to 7, 10 and 11 of Annex I, have a validity period of up to 5 years and, for categories 8 and 9 of Annex I, a validity period of up to 7 years. The validity periods are to be decided on a case-by-case basis and may be renewed. (…)"*

Decisions on the duration of any exemptions shall according to Article 5(1) RoHS Directive take into account the availability of substitutes and the socioeconomic impact of substitution, as well as any potential adverse impacts on innovation.

Due to the equipment falling under Category 11 of EEE (see Section 4.5.1) and thus being subject for inclusion into Annex III, the validity period is according to Article 5(2) of RoHS Directive up to 5 years. Given the ongoing initiatives at level of REACH restrictions to further investigate risks from presence of Lead and Cadmium in recovered PVC profiles, and given that it is part of our justification that embracing any upcoming decision on relevant restrictions regarding Cadmium and Lead in the framework of REACH restriction process should be taken into account and lead to a further development of the exemption, we believe that a duration of **three years** is appropriate rather than the maximum five years, so that the exemption may be reviewed after the presumed finalization of the restriction process for both Cadmium and Lead as appropriate. We further recommend introducing in the recitals of the relevant delegated directive under RoHS an explicit interconnection to these restriction processes.

4.5.4.3 Wording of the exemption

We recommend granting the requested exemption with a validity period of 3 years for the below wording be added to Annex III of the RoHS 2 Directive:

> **Cadmium and lead in plastic profiles containing mixtures produced from PVC waste (hereinafter referred to as 'recovered PVC'), used for electric and/or electronic windows and doors, where the concentration in the plastic homogeneous material does not exceed by weight 0.1 % cadmium (expressed as Cd metal) and 1 % lead (expressed as Pb metal), provided that the components concerned are visibly, legibly and indelibly marked with the statement 'Contains recovered PVC' or with the following pictogram:**

4.6 References for exemption request No. B-2016

[DECUENINCK 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Deceuninck nv (2016). https://circabc.europa.eu/sd/a/3499d4a6-9906-414c-8390-af44565809bc/20161128_DECEUNINCK_Contribution_RoHS_Exemption_B-2016.pdf

[EC CD 2010] "Socio-economic impact of a potential update of the restrictions on the marketing and use of cadmium." – European Commission (2010).

[EC 2014a] "Com 398 - Towards a circular economy: A zero waste programme for Europe" - European Commission (2014). http://cor.europa.eu/en/activities/stakeholders/Documents/COM(2014)%20398%20final.pdf

[EC 2014b] "Com 445 – On Resource Efficiency Opportunities in the Building Sector" - European Commission (2014). http://cor.europa.eu/en/activities/stakeholders/Documents/COM(2014)%20398%20final.pdf

[ECHA ANNEX XV Lead 2016] "Annex XV Restriction Report – Proposal for a Restriction" – European Chemicals Agency (2016). https://echa.europa.eu/documents/10162/92e35a66-3381-b7ad-3a6d-d7090ff65f11 (Retrieved 20.02.2017).

[EC 2016] "Request to the European Chemicals Agency" - European Commission (2016). https://echa.europa.eu/documents/10162/13641/echa_rest_proposals_rubber_granules_en.pdf

[ECVM 2014/15] Information exchange with an industry group coordinated by ECVM in the course of the project in 2014 and 2015 (contact person: Arjen Sevenster).

[ECVM 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – European Council of Vinyl Manufacturers (2016). https://circabc.europa.eu/sd/a/447ebc0c-30b4-4897-84e3-7c54420f360f/20161112_ECVM_Contribution_RoHS_Exemption_B-2016.pdf

[EuroWindoor 2015] "EuroWindoor RoHS Application Form for exemption of use of recycled PVC for profiles (windows and doors)" – EuroWindoor AISBL (2015). http://rohs.exemptions.bipro.de/exemption-consultations/2016-2/

[EuroWindoor 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – EuroWindoor AISBL (2016). https://circabc.europa.eu/sd/a/5fbce31a-9f75-4d94-b7ed-28e7f2ab1219/20161209_EUROWINDOOR%20AISBL_Contribution_RoHS_Exemption_B-2016.pdf

[EuroWindoor 2016] "Applicant Consultation" – EuroWindoor AISBL (2016).

[EuroWindoor Meeting 2016] "EuroWindoor Consultant Meeting 2016" – EuroWindoor (2016). http://rohs.exemptions.bipro.de/exemption-consultations/2016-2/

[FCIO 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Fachverband der Chemischen Industrie Österreichs (2016).

https://circabc.europa.eu/sd/a/1480e8b4-5d92-4a79-8a54-6e4a70c2e4a3/20161213_FCIO__Contribution_RoHS_Exemption_B-2016.pdf

[IBU 2017] "Environmental Product Declaration for double-glazed PVC Windows: 6.3 Sensitivity concerning the use of recycled PVC " – Intitut Bauen und Umwelte e.V. (Accessed Feb. 2017). https://epd-online.com/PublishedEpd/Detail/9185

[INTERNORM 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Internorm International GmbH (2016). https://circabc.europa.eu/sd/a/edc61e0a-90e9-450e-8d07-912b060ba754/20161206_INTERNORM_Contribution_RoHS_Exemption_B-2016.pdf

[KEMI 2016] "Contribution to Stakeholder Consultation B-2016 Request for exemption of Lead and cadmium in PVC profiles of electric windows and doors" – Kemikalieinspektionen / Swedish Chemicals Agency (2016). https://circabc.europa.eu/sd/a/16a159ac-e835-447b-a45a-925e2aa2a1e1/20161222_KEMI_Contribution_RoHS_Exemption_B-2016.pdf

[NEA 2016] "RoHS Directive 2011/65/EU – Contributions on Stakeholder Consultation B-2016" – Norwegian Environment Agency (2016). https://circabc.europa.eu/sd/a/c71ca08b-4010-4984-a410-ffc8839bb731/20161221_NORWEGIAN%20ENVIRONMENT%20AGENCY_Contribution_RoHS_Exemption_B-2016.pdf

[PROFINE 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Profine GmbH – International Profile Group (2016). https://circabc.europa.eu/sd/a/d5d05329-3caf-40f3-989e-a1e98dbb257c/20161207_PROFINE_Contribution_RoHS_Exemption_B-2016.pdf

[PVC-FI 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – PVC Forum Italia (2016). https://circabc.europa.eu/sd/a/a8cb0584-973a-48da-9a70-c7cf8b894980/20161213_PVC%20FORUM%20ITALIA_Contribution_RoHS_Exemption_B-2016.pdf

[ÖkoI 2015] Study for the analysis of impacts from RoHS2 on non-road mobile machinery without an on-board power source, on windows and doors with electric functions, and on the refurbishment of medical devices. Report for the European Commission DG Environment under Framework Contract No ENV.C.2/FRA/2011/0020.

[REHAU 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Rehau AG+Co. (2016). https://circabc.europa.eu/sd/a/3d526cbe-2b7c-42a6-b906-2a07c8d8f657/20161216_REHAU_Contribution_RoHS_Exemption_B-2016.pdf

[SALAMANDER 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Salamander Industrie-Produkte GmbH (2016). https://circabc.europa.eu/sd/a/22b82ace-9073-405d-95e9-e7bfe2dd8d56/20161212_SALAMANDER_Contribution_RoHS_Exemption_B-2016.pdf

[SCHÜCO 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Schüco Polymer Technologies KG (2016). https://circabc.europa.eu/sd/a/283d21c8-4e05-4c0e-97bd-7403eee022be/20170112_SCH%25c3%259cCO_Contribution_RoHS_Exemption_B-2016.pdf

[SNEP 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Syndicat National de l'Extrusion Plastique (2016). https://circabc.europa.eu/sd/a/a1d1ac7c-48f0-4aa8-9c67-e5ce43680849/20161222_SNEP_Contribution_RoHS_Exemption_B-2016.pdf

[TAUW 2013]: Impact of lead restriction on the recycling of PVC. Tauw, 2013

[VEKA 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Veka AG (2016). https://circabc.europa.eu/sd/a/742d012a-26eb-48dd-9a09-be00293b1ebd/20161207_VEKA_Contribution_RoHS_Exemption_B-2016.pdf

[VEKA-U 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Veka Umwelttecknik GmbH (2016). https://circabc.europa.eu/sd/a/520598c2-3c05-4890-abd0-ff52aa4a5904/20161212_VEKA_Umwelttechnik_Contribution_RoHS_Exemption_B-2016.pdf

[VEKA 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Veka AG (2016). https://circabc.europa.eu/sd/a/0e60ff78-1dbf-439c-8d01-ea8e8da7b8f8/20161219_VEKA_Anwendungstechnik_Contribution_RoHS_Exemption_B-2016.pdf

[VKG 2016] "Stakeholder Consultation on Exemption Review under Directive 2011/65/EU, B-2016" – Vereiniging Kunststof Gevelelementenindustrie (2016). https://circabc.europa.eu/sd/a/ac7955a3-e58b-4ec0-8af5-178c17d7c29e/20161220_VKG_Contribution_RoHS_Exemption_B-2016.pdf

Appendix A: Relevant REACH Regulation Entries

The REACH regulation entries which are considered to be relevant to assess the exemption request have been checked in order to clarify the possibility that a granted exemption could "weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006" (Article 5(1)(a), pg.1)". Moreover, the review of the REACH annexes and processes also aims to track possible future trends and impacts on exemption requests.

The last consolidated version of the REACH regulation which has been published on 14 July 2016 has been consulted and the relevant content has been included here with short clarifications when necessary.

The Table 7 lists the RoHS-2 substances which are included in the Annex XIV (subject to Authorisation).

Table 7: RoHS-2 substances in the Annex XIV

Entry Nr.	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses
			Latest Application date[9]	Sunset date[10]	
4	Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	Toxic for reproduction (category 1B)	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.

[9] As defined in the Article 58 (1) (c) of the REACH Regulation: "a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken [referred to as application date]"

[10] As defined in the Article 58 (1) (c) of the REACH Regulation: "the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as the sunset date) which should take into account, where appropriate, the production cycle specified for that use"

Entry Nr.	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses
			Latest Application date[9]	Sunset date[10]	
5	Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7	Toxic for reproduction (category 1B)	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.
6	Dibutyl phthalate (DBP) EC No: 201-557-4 CAS No: 84-74-2	Toxic for reproduction (category 1B)	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.
7	Diisobutyl phthalate (DIBP) EC No: 201-553-2 CAS No: 84-69-5	Toxic for reproduction (category 1B)	21 August 2013	21 February 2015	-
10	Lead chromate EC No: 231-846-0 CAS No: 7758-97-6	Carcinogenic (category 1B) Toxic for reproduction (category 1A)	21 November 2013	21 May 2015	-

Entry Nr.	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses
			Latest Application date[9]	Sunset date[10]	
11	Lead sulfochromate yellow (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2	Carcinogenic (category 1B) Toxic for reproduction (category 1A)	21 November 2013	21 May 2015	-
12	Lead chromate molybdate sulphate red (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8	Carcinogenic (category 1B) Toxic for reproduction (category 1A)	21 November 2013	21 May 2015	-
16	Chromium trioxide EC No: 215-607-8 CAS No: 1333-82-0	Carcinogenic (category 1A) Mutagenic (category 1B)	21 March 2016	21 September 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	Carcinogenic (category 1B)	21 March 2016	21 September 2017	-

Entry Nr.	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses
			Latest Application date[9]	Sunset date[10]	
18	Sodium dichromate EC No: 234-190-3 CAS No: 7789-12-0 10588-01-9	Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21 March 2016	21 September 2017	-
19	Potassium dichromate EC No: 231-906-6 CAS No: 7778-50-9	Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21 March 2016	21 September 2017	-
20	Ammonium dichromate EC No: 232-143-1 CAS No: 7789-09-5	Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21 March 2016	21 September 2017	-
21	Potassium chromate EC No: 232-140-5 CAS No: 7789-00-6	Carcinogenic (category 1B) Mutagenic (category 1B)	21 March 2016	21 September 2017	-

Entry Nr.	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses
			Latest Application date[9]	Sunset date[10]	
22	Sodium chromate EC No: 231-889-5 CAS No: 7775-11-3	Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21 March 2016	21 September 2017	-
28	Dichromium tris(chromate) EC No: 246-356-2 CAS No: 24613-89-6	Carcinogenic (category 1B)	22 July 2017	22 January 2019	-
29	Strontium chromate EC No: 232-142-6 CAS No: 7789-06-2	Carcinogenic (category 1B)	22 July 2017	22 January 2019	-
30	Potassium hydroxyoctaoxodizincatedic hromate EC No: 234-329-8 CAS No: 11103-86-9	Carcinogenic (category 1A)	22 July 2017	22 January 2019	-
31	Pentazinc chromate octahydroxide EC No: 256-418-0 CAS No: 49663-84-5	Carcinogenic (category 1A)	22 July 2017	22 January 2019	-

Regarding the substances which are restricted as listed in the RoHS Annex II (i.e. cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls, polybrominated diphenyl ethers, Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP) and their compounds), relevant entries as listed in Annex XVII of the REACH Regulation have been found. The conditions of restriction for the RoHS-2 substances included in the Annex XVII are presented below in the Table 8. Moreover, amendments to the Annex XVII which have not been included in the last concise document of the REACH regulation are disclosed in the

Table 9.

Table 8: Annex XVII - Conditions of restriction of RoHS-2 substances

Designation of the substance, of the group of substances or of the 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 (PbCO3)** **CAS No 598-63-0** **EC No 209-943-4** **(b) Trilead-bis(carbonate)-dihydroxide 2Pb CO3-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. ►M20 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) PbSO4** **CAS No 7446-14-2** **EC No 231-198-9** **(b) Pbx SO4** **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. ►M20 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. ◄

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
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. ►M19 _____ ◄ ►M19 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;

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	(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. ◄
23. Cadmium and its compounds CAS No 7440-43-9 EC No 231-152-8	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 (*). ►M13 ►M17 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

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	[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. ◄ ►C5 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 (**) and acts adopted on its basis. ►M17 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. ◄ ►M34 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:

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	— 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. ◄ 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:

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	— 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: — 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. ►M13 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.

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	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. ►C5 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. ◄ ◄ _____ (*) OJ L 256, 7.9.1987, p. 42. (**) OJ L 365, 31.12.1994, p. 10
28. Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as carcinogen category 1A or 1B (Table 3.1) or carcinogen category 1 or 2 (Table 3.2) and listed as follows: — Carcinogen category 1A (Table 3.1)/ carcinogen category 1 (Table 3.2) listed in Appendix 1 — Carcinogen category 1B (Table 3.1)/ carcinogen category 2 (Table 3.2) listed in Appendix 2: **Chromium (VI) trioxide** **Zinc chromates including zinc potassium chromate** **Nickel chromate** **Nickel dichromate** **Potassium dichromate**	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, ►M3 — the relevant generic concentration limit specified in Part 3 of Annex I of 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

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
Ammonium dichromate **Sodium dichromate** **Chromyl dichloride; chromic oxychloride** **Potassium chromate** **Calcium chromate** **Strontium chromate** **Chromium (VI) compounds, with the exception of barium chromate and of compounds specified elsewhere in Annex VI to Regulation (EC) No 1272/2008** **Chromium III chromate; chromic chromate** **Sodium chromate** **Cadmium oxide** **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Cadmium sulphide** **Cadmium (pyrophoric)** **Chromium (VI) trioxide** **Lead Chromate** **Lead hydrogen arsenate** **Silicic acid, lead nickel salt Lead sulfochromate yellow; C.I. Pigment Yellow 34;** **Lead chromate molybdate sulfate red; C.I. Pigment Red 104;** 29. Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as germ cell mutagen category 1A or 1B (Table 3.1) or mutagen	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); ►M3 (d) artists' paints covered by Regulation (EC) No 1272/2008; ◄ ►M14 (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, of the group of substances or of the mixture	Conditions of restriction
category 1 or 2 (Table 3.2) and listed as follows: — Mutagen category 1A (Table 3.1)/ mutagen category 1 (Table 3.2) listed in Appendix 3 — Mutagen category 1B (Table 3.1)/ mutagen category 2 (Table 3.2) listed in Appendix 4: **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Chromium (VI) trioxide** **Potassium dichromate** **Ammonium dichromate** **Sodium dichromate** **Chromyl dichloride; chromic oxychloride** **Potassium chromate** **Sodium chromate**	
29. Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as germ cell mutagen category 1A or 1B (Table 3.1) or mutagen category 1 or 2 (Table 3.2) and listed as follows: — Mutagen category 1A (Table 3.1)/ mutagen category 1 (Table 3.2) listed in Appendix 3 — Mutagen category 1B (Table 3.1)/ mutagen category 2 (Table 3.2) listed in Appendix 4: **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Chromium (VI) trioxide** **Potassium dichromate**	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, ►M3 — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. ◄ Without prejudice to the implementation of other Community provisions relating to the classification,

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
Ammonium dichromate **Sodium dichromate** **Chromyl dichloride; chromic oxychloride** **Potassium chromate** **Sodium chromate**	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); ►M3 (d) artists' paints covered by Regulation (EC) No 1272/2008; ◄ ►M14 (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date. ◄
30. Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as toxic to reproduction category 1A or 1B (Table 3.1) or toxic to reproduction category 1 or 2 (Table 3.2) and listed as follows: — Reproductive toxicant category 1A adverse effects on sexual function and fertility or on development (Table 3.1) or reproductive toxicant category 1 with	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, ►M3 — the relevant generic concentration

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
R60 (May impair fertility) or R61 (May cause harm to the unborn child) (Table 3.2) listed in Appendix 5 — Reproductive toxicant category 1B adverse effects on sexual function and fertility or on development (Table 3.1) or reproductive toxicant category 2 with R60 (May impair fertility) or R61 (May cause harm to the unborn child) (Table 3.2) listed in Appendix 6: **Bis(2-ethylhexyl) phthalate; di-(2-ethylhexyl) phthalate; DEHP** **Benzyl butyl phthalate; BBP** **Dibutyl phthalate; DBP** **Diisobutyl phthalate** **Cadmium chloride** **Cadmium fluoride** **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 hydrogen arsenate** **Lead acetate** **Lead alkyls**	limit specified in Part 3 of Annex I of 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); ►M3 (d) artists' paints covered by Regulation (EC) No 1272/2008; ◄ ►M14 (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, of the group of substances or of the mixture	Conditions of restriction
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. 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. ►M20 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. ◄ ►M24 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.

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	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. ►M29 _____ ◄ 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.
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 (*);

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	(b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961. ►M30 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. ◄ ►M30 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/cm2 per hour (equivalent to 0.05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. 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;

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	(e) keys and locks, including padlocks; (f) musical instruments; (g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0.5 % by weight; (h) the tips of writing instruments; (i) religious articles; (j) portable zinc-carbon batteries and button cell batteries; (k) articles within the scope of: (i) Directive 94/62/EC; (ii) Regulation (EC) No 1935/2004; (iii) Directive 2009/48/EC of the European Parliament and of the Council (**); (iv) Directive 2011/65/EU of the European Parliament and of the Council (***) 9. By 1 July 2019, the Commission shall re-evaluate paragraphs 7 and 8(e), (f), (i) and (j) of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 7, including the requirement on coating integrity, and, if appropriate, modify this entry accordingly. 10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016. ◄ _____ ►M18 (*) OJ L 326, 29.12.1969, p. 36. ◄ ►M30 (**) 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). ◄

Table 9: Amendment to Annexes XVII Not included in the Last Concise Version of the REACH Regulation

Substance, group of substances or mixture	Conditions of restriction	Amendment to Annex XVII
Addition of Entry 62 concerning: **(a) Phenylmercury acetate** **EC No: 200-532-5** **CAS No: 62-38-4** **(b) Phenylmercury propionate** **EC No: 203-094-3** **CAS No: 103-27-5** **(c) Phenylmercury 2-ethylhexanoate** **EC No: 236-326-7** **CAS No: 13302-00-6** **(d) Phenylmercury octanoate** **EC No: -** **CAS No: 13864-38-5** **(e) Phenylmercury neodecanoate EC No: 247-783-7** **CAS No: 26545-49-3**	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.'	Entry 62, amendment from 20 September 2012

The Table 10 includes the RoHS substances which are included in the REACH candidate list of SVHCs for Authorisation as of January 2017.

Table 10: Relevant Substances Currently on the REACH Candidate List[11]

Substance	Date of Inclusion	Reason for inclusion
Cadmium fluoride **EC No.: 232-222-0** **CAS No.: 7790-79-6**	17 December 2014	Carcinogenic (Article 57 a); Mutagenic (Article 57 b); Toxic for reproduction (Article 57 c); Equivalent level of concern having probable serious effects to human health (Article 57 f)

[11] Adapted from https://echa.europa.eu/candidate-list-table?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=2&p_p_col_count=3&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

Substance	Date of Inclusion	Reason for inclusion
Cadmium sulphate **EC No.: 233-331-6** **CAS No.:** **10124-36-4** **31119-53-6**	17 December 2014	Carcinogenic (Article 57 a); Mutagenic (Article 57 b); Toxic for reproduction (Article 57 c); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Cadmium chloride **EC No.: 233-296-7** **CAS No.: 10108-64-2**	16 June 2014	Carcinogenic (Article 57a);
Cadmium sulphide **EC No.: 215-147-8** **CAS No.: 1306-23-6**	16 December 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Lead di(acetate) **EC No.: 206-104-4** **CAS No.: 301-04-2**	16 December 2013	Toxic for reproduction (Article 57 c);
Cadmium **EC No.: 231-152-8** **CAS No.: 7440-43-9**	20 June 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Cadmium oxide **EC No.: 215-146-2** **CAS No.: 1306-19-0**	20 June 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Pyrochlore, antimony lead yellow **EC No.: 232-382-1** **CAS No.: 8012-00-8**	19 December 2012	Toxic for reproduction (Article 57 c)
Lead bis(tetrafluoroborate) **EC No.: 237-486-0** **CAS No.: 13814-96-5**	19 December 2012	Toxic for reproduction (Article 57 c)
Lead dinitrate **EC No.: 233-245-9** **CAS No.: 10099-74-8**	19 December 2012	Toxic for reproduction (Article 57 c)
Silicic acid, lead salt **EC No.: 234-363-3** **CAS No.: 11120-22-2**	19 December 2012	Toxic for reproduction (Article 57 c)
Lead titanium zirconium oxide **EC No.: 235-727-4** **CAS No.: 12626-81-2**	19 December 2012	Toxic for reproduction (Article 57 c)
Lead monoxide (lead oxide) **EC No.: 215-267-0** **CAS No.: 1317-36-8**	19 December 2012	Toxic for reproduction (Article 57 c)
Cadmium fluoride **EC No.: 232-222-0** **CAS No.: 7790-79-19**	19 December 2012	Toxic for reproduction (Article 57 c)

Substance	Date of Inclusion	Reason for inclusion
Cadmium fluoride **EC No.: 232-222-0** **CAS No.: 7790-79-20**	19 December 2012	Toxic for reproduction (Article 57 c)
Cadmium fluoride **EC No.: 232-222-0** **CAS No.: 7790-79-21**	19 December 2012	Toxic for reproduction (Article 57 c)
Cadmium fluoride **EC No.: 232-222-0** **CAS No.: 7790-79-22**	19 December 2012	Toxic for reproduction (Article 57 c)
Silicic acid (H2Si2O5), barium salt (1:1), lead-doped [with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008] **EC No.: 272-271-5** **CAS No.: 68784-75-8**	19 December 2012	Toxic for reproduction (Article 57 c)
Trilead bis(carbonate)dihydroxide **EC No.:215-290-6** **CAS No.: 1319-46-6**	19 December 2012	Toxic for reproduction (Article 57 c)
Lead oxide sulfate **EC No.: 234-853-7** **CAS No.: 12036-76-9**	19 December 2012	Toxic for reproduction (Article 57 c)
Cadmium fluoride **EC No.: 232-222-0** **CAS No.: 7790-79-26**	19 December 2012	Toxic for reproduction (Article 57 c)
Lead titanium trioxide **EC No.: 235-038-9** **CAS No.: 12060-00-3**	19 December 2012	Toxic for reproduction (Article 57 c)
Acetic acid, lead salt, basic **EC No.: 257-175-3** **CAS No.: 51404-69-4**	19 December 2012	Toxic for reproduction (Article 57 c)
[Phthalato(2-)]dioxotrilead **EC No.: 273-688-5** **CAS No.: 69011-06-9**	19 December 2012	Toxic for reproduction (Article 57 c)
Tetralead trioxide sulphate **EC No.: 235-380-9** **CAS No.: 12202-17-4**	19 December 2012	Toxic for reproduction (Article 57 c)

Substance	Date of Inclusion	Reason for inclusion
Dioxobis(stearato)trilead **EC No.: 235-702-8** **CAS No.: 12578-12-0**	19 December 2012	Toxic for reproduction (Article 57 c)
Tetraethyllead **EC No.: 201-075-4** **CAS No.: 78-00-2**	19 December 2012	Toxic for reproduction (Article 57 c)
Pentalead tetraoxide sulphate **EC No.: 235-067-7** **CAS No.: 12065-90-6**	19 December 2012	Toxic for reproduction (Article 57 c)
Trilead dioxide phosphonate **EC No.: 235-252-2** **CAS No.: 12141-20-7**	19 December 2012	Toxic for reproduction (Article 57 c)
Orange lead (lead tetroxide) **EC No.: 215-235-6** **CAS No.: 1314-41-6**	19 December 2012	Toxic for reproduction (Article 57 c)
Sulfurous acid, lead salt, dibasic **EC No.: 263-467-1** **CAS No.: 62229-08-7**	19 December 2012	Toxic for reproduction (Article 57 c)
Lead cyanamidate **EC No.: 244-073-9** **CAS No.: 20837-86-9**	19 December 2012	Toxic for reproduction (Article 57 c)
Lead(II) bis(methanesulfonate) **EC No.: 401-750-5** **CAS No.: 17570-76-2**	19 December 2012	Toxic for reproduction (Article 57 c)
Lead diazide, Lead azide **EC No.: 236-542-1** **CAS No.: 13424-46-9**	19 December 2011	Toxic for reproduction (Article 57 c)
Lead dipicrate **EC No.: 229-335-2** **CAS No.: 6477-64-1**	19 December 2011	Toxic for reproduction (Article 57 c)
Dichromium tris(chromate) **EC No.: 246-356-2** **CAS No.: 24613-89-6**	19 December 2011	Carcinogenic (article 57 a)
Pentazinc chromate octahydroxide **EC No.: 249663-84-5**	19 December 2011	Carcinogenic (article 57 a)
Potassium hydroxyoctaoxodizincatedichromate **EC No.: 234-329-8** **CAS No.: 11103-86-9**	19 December 2011	Carcinogenic (article 57 a)
Lead styphnate **EC No.: 239-290-0** **CAS No.: 15245-44-0**	19 December 2011	Toxic for reproduction (article 57 c)

Substance	Date of Inclusion	Reason for inclusion
Trilead diarsenate **EC No.: 222-979-5** **CAS No.: 3687-31-8**	19 December 2011	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Strontium chromate **EC No.: 232-142-6** **CAS No.: 7789-06-2**	20 June 2011	Carcinogenic (article 57a)
Acids generated from chromium trioxide and their oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid. **EC No.: 231-801-5, 236-881-5** **CAS No.: 7738-94-5, 13530-68-2**	15 December 2010	Carcinogenic (article 57a)
Chromium trioxide **EC No.: 215-607-8** **CAS No.: 1333-82-0**	15 December 2010	Carcinogenic and mutagenic (articles 57 a and 57 b)
Potassium dichromate **EC No.: 231-906-6** **CAS No.: 7778-50-9**	18 June 2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Ammonium dichromate **EC No.: 232-143-1** **CAS No.: 7789-09-5**	18 June 2010	Carcinogenic, mutagenic and toxic for reproducetion (articles 57 a, 57 b and 57 c)
Sodium chromate **EC No.:231-889-5** **CAS No.: 7775-11-3**	18 June 2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Potassium chromate **EC No.: 232-140-5** **CAS No.: 7789-00-6**	18 June 2010	Carcinogenic and mutagenic (articles 57 a and 57 b).
Lead sulfochromate yellow (C.I. Pigment Yellow 34) **EC No.: 215-693-7** **CAS No.: 1344-37-2**	13 January 2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c))
Lead chromate molybdate sulphate red (C.I. Pigment Red 104) **EC No.: 235-759-9** **CAS No.: 12656-85-8**	13 January 2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead chromate **EC No.: 231-846-0** **CAS No.: 7758-97-6**	13 January 2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead hydrogen arsenate **EC No.: 232-064-2** **CAS No.: 7784-40-9**	28 October 2008	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)

Substance	Date of Inclusion	Reason for inclusion
Sodium dichromate **EC No.: 234-190-3** **CAS No.: 7789-12-0, 10588-01-9**	28 October 2008	Carcinogenic, mutagenic and toxic for reproduction (articles 57a, 57b and 57c)

The intention to propose restrictions or to classify a substance as SVHC can be registered by Member States by submitting a dossier. Such intention dossier is afterwards reviewed and the process can continue or be withdrawn.

Currently there are two registries of intentions proposing restrictions applicable to RoHs regulated substances, see Table 11.

Table 11: Current registries of intentions proposing restrictions of RoHs regulated substances[12]

Name	EC Number	CAS Number	Details on the scope of the restriction	Expected date of submission
Lead and its compounds	231-100-4	7439-92-1	Restriction on the use of lead shots over wetlands. The harmonisation of the conditions of use of lead in shot in wetlands is a priority at EU level, as national legislation has already been enacted by some Member States (or regions in some Member States) further to international action through the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) under the auspices of the UN Environment Programme (UNEP) to which the EU is a Party.	12 April 2017

Submitted SVHC and restriction proposals regarding RoHS regulated substances have been summarized in the Table 12.

Table 12: submitted SVHC and restriction proposals regarding RoHs regulated substances[13]

Restriction / SVHC Classification	Substance Name	Details on the scope	Submitted by	Date of submission

[12] European Chemicals Agency (ECHA), Registry of intentions to propose restrictions https://echa.europa.eu/registry-of-current-restriction-proposal-intentions (accessed 10.02.17)

[13] Adapted from https://echa.europa.eu/registry-of-submitted-restriction-proposal-intentions

Restriction / SVHC Classification	Substance Name	Details on the scope	Submitted by	Date of submission
Restriction	Lead and lead compounds	Restriction on the placing on the market and use of lead compounds in PVC and of the placing on the market of PVC articles stabilised with lead compounds. Depending on the outcome of the assessment, the scope of the restriction might be broad or targeted specifically to articles or article groups that are the main contributors to the risks targeted by this proposal.	ECHA	16 December 2016
	Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP)	Restriction under Article 69(2) on the four classified phthalates in articles. Depending on the outcome of the assessment, the scope of the restriction might be broad or targeted specifically to articles or article groups that are the main contributors to exposure of the general population.	ECHA	01 April 2016
	Cadmium and its compounds	Artist paints	Sweden	17 January 2014
	Cadmium and its compounds	Amendment of the current restriction (entry 23) on use of paints with TARIC codes [3208] & [3209] containing cadmium and cadmium compounds to include placing on the market of such paints and a concentration limit.	ECHA	17 October 2013
	Chromium VI	Placing on the market of leather articles	Denmark	20 January 2012

Restriction / SVHC Classification	Substance Name	Details on the scope	Submitted by	Date of submission
		containing Chromium VI		
	Phenylmercuric octanoate; Phenylmercury propionate; Phenylmercury 2-ethylhexanoate; Phenylmercury acetate; Phenylmercury	Mercury compounds	Norway	15 June 2010
	Mercury in measuring devices	Mercury compounds	ECHA	15 June 2010
	Lead and its compounds in jewellery	Substances containing lead	France	15 April 2010
SVHC Classification	Benzyl butyl phthalate (BBP)	Endocrine disruptor	Denmark	04 August 2014
	Bis (2-ethylhexyl)phthalate (DEHP)	Endocrine disruptor	Denmark	04 August 2014
	Cadmium fluoride	CMR	Sweden	04 August 2014
	Cadmium sulphate	CMR	Sweden	04 August 2014
	Dibutyl phthalate	Endocrine disruptor	Denmark	04 August 2014
	Diisobutyl phthalate	Endocrine disruptor	Denmark	04 August 2014
	Cadmium chloride	CMR; other;	Sweden	03 February 2014
	Cadmium sulphide	CMR; other;	Sweden	05 August 2013
	Lead di(acetate)	CMR	Netherlands	05 August 2013
	Cadmium	CMR; other;	Sweden	04 February 2013
	Cadmium oxide	CMR; other;	Sweden	04 February 2013

Restriction / SVHC Classification	Substance Name	Details on the scope	Submitted by	Date of submission
	Trilead dioxide Phosphonate; Lead Monoxide (Lead Oxide); Trilead bis(carbonate)dihydroxide; Lead Dinitrate; Lead Oxide Sulphate; Acetic acid, lead salt, basic; Dioxobis(stearato)trilead; Lead bis(tetrafluoroborate); Tetraethyllead; Pentalead tetraoxide sulphate; Lead cyanamidate; Lead titanium trioxide; Silicic acid (H2Si2O5), barium salt (1:1), lead-doped; Silicic acid, lead salt; Sulfurous acid, lead salt, dibasic; Tetralead trioxide sulphate; [Phthalato(2-)]dioxotrilead; Orange lead (lead tetroxide); Fatty acids, C16-18, lead salts; Lead titanium zirconium oxide	CMR; substances Containing Lead	ECHA	30 August 2012
	Lead(II) bis(methanesulfonate)	CMR; Amides	Netherlands	30 January 2012
	Lead styphnate; Lead diazide; Lead azide; Lead dipicrate	CMR; Substances containing lead	ECHA	01 August 2011
	Trilead diarsenate	CMR; Arsenic compounds		
	Strontium Chromate	CMR; Substances containing chromate	France	24 January 2011
	Acids generated from chromium trioxide and their oligomers: Chromic acid; Dichromic acid; Oligomers of chromic acid and dichromic acid	CMR; Substances containing chromate	Germany	27 August 2010
	Chromium Trioxide	CMR; Substances containing chromate	Germany	02 August 2010
	Sodium chromate; Potassium chromate; Potassium Dichromate	CMR; Substances containing chromate	France	10 February 2010
	Lead chromate molybdate sulfate red (C.I. Pigment Red 104); Lead sulfochromate yellow (C.I. Pigment Yellow 34)	CMR; substances Containing Lead	France	03 August 2009

Restriction / SVHC Classification	Substance Name	Details on the scope	Submitted by	Date of submission
	Lead Chromate	CMR; Substances containing chromate	France	03 August 2009
	Lead hydrogen arsenate	CMR; Arsenic compounds	Norway	27 June 2008
	Sodium dichromate	CMR; Substances containing chromate	France	26 June 2008

Some of the proposals above have turned into new restrictions or identification of substances as SVHCs. For some of them, which have not been withdrawn, it is not possible to foresee if, or when, they might be implemented. The implications of future restrictions or future classification of substances as SVHCs have not been considered in the present assessment of exemption requests. In the future, however, the development of such processes will be followed and considered if relevant for upcoming exemption requests.

Contact details:

BiPRO GmbH

Grauertstr. 12

81545 Munich, Germany

Phone: +49-89-18979050

Fax: +49-89-18979052

URL: www.bipro.de

HOW TO OBTAIN EU PUBLICATIONS

Free publications:

- one copy:
  via EU Bookshop (http://bookshop.europa.eu);

- more than one copy or posters/maps:
  from the European Union's representations (http://ec.europa.eu/represent_en.htm);
  from the delegations in non-EU countries
  (http://eeas.europa.eu/delegations/index_en.htm);
  by contacting the Europe Direct service (http://europa.eu/europedirect/index_en.htm)
  or calling 00 800 6 7 8 9 10 11 (freephone number from anywhere in the EU) (*).

  (*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Priced publications:

- via EU Bookshop (http://bookshop.europa.eu).

Priced subscriptions:

- via one of the sales agents of the Publications Office of the European Union
  (http://publications.europa.eu/others/agents/index_en.htm).

KH-01-17-453-EN-N

Publications Office

doi:10.2779/349459