Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

LEAD STABILISERS IN PVC

ECHA/RAC/RES-O-0000001412-86-173/F
ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Adopted

5 December 2017

5 December 2017

ECHA/RAC/RES-O-0000001412-86-173/F

30 November 2017

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**Lead compounds-PVC**
EC No.:	Not applicable
CAS No.:	Not applicable

This document presents the opinion adopted by RAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the public consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA on a request from the Commission or proposing restriction according to Article 69(2) has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/web/guest/restrictions-under-consideration on **22 March 2017**. Interested parties were invited to submit comments and contributions by **22 September 2017.**

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: *Stephen DUNGEY*

Co-rapporteur, appointed by RAC: *Michael NEUMANN*

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **5 December 2017*.***

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus.**

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: *Karen THIELE*

Co-rapporteur, appointed by SEAC: *Izabela RYDLEWSKA-LISZKOWSKA*

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **30 November 2017.**

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at http://echa.europa.eu/web/guest/restrictions-under-consideration on **20 December 2017.** Interested parties were invited to submit comments on the draft opinion by **20 February 2018.**

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***[date of adoption of the opinion]***. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by ***[number of days]*** by the ECHA decision ***[number and date]***]**[1]**.

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**]** **[**No comments were received from interested parties during the public consultation in accordance with Article[s 69(6) and][3]

[1] Delete the unnecessary part(s)

71(1)**]**[6].

The opinion of SEAC was adopted ***by*** **[*consensus*.][*a simple majority*]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[6].

Contents

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Brief title: Restriction of lead stabilisers in PVC articles.

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: - profiles and rigid sheets for building applications; - doors, windows, shutters, walls, blinds, fences, and roof gutters; - cable ducts; - fittings for tubes, furniture etc.; - 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: - food contact materials covered by Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011 on plastic materials; - 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); - Directive 94/62/EC on packaging and packaging waste; - Directive 2009/48/EC on the safety of toys.

	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 months).

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document.

RAC considers that the proposed restriction on lead compounds is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are:

– Lead compounds	Conditions of the restriction 1. Shall not be used in articles produced from polymers or copolymers of vinyl chloride (PVC). 2. Articles produced from polymers or copolymers of vinyl chloride (PVC) shall not be placed on the market if the concentration of lead (expressed as Pb metal) is equal to or greater than 0.1% by weight of the PVC material. 3. Paragraphs 1 and 2 shall apply 24 months from the entry into force of the restriction. 4. By way of derogation, paragraph 2 shall not apply to: (a) the following rigid PVC article types containing PVC recyclate for a period of 15 years from entry into force, if the concentration of lead (expressed as metal) does not exceed 2% by weight of the PVC material: - profiles and sheets for exterior applications in buildings and non-buildings (for example, gutters, fascia, shutters, blinds and wall cladding), excluding decks and terraces; - decks and terraces provided the recycled PVC is used in the middle layer and is entirely covered with a layer of virgin PVC; - profiles and sheets for use in concealed spaces or voids in buildings and non-buildings (where they are inaccessible during normal use, excluding maintenance, for example, cable ducts); - profiles and sheets for interior building applications provided the entire surface of the profile or sheet facing the occupied areas of a building after

	installation are produced using virgin PVC (for example, doors and windows fabricated from co-extruded/multi-layer PVC profiles or sheets); - multi-layer pipes if the recycled PVC is used in the middle layer and is entirely covered with a layer of virgin PVC (excluding pipes for drinking water); and - fittings, excluding fittings for pipes for drinking water, for example joints, elbows and flanges for pipes, furniture, coachwork, etc). All virgin PVC used in combination with recycle in the above applications shall comply with paragraph 2. Suppliers shall ensure before the first placing on the market of mixtures and articles specified above and containing recycled PVC that these are visibly, legibly and indelibly marked as follows: '*Contains recycled PVC'.* (b) the following PVC article types containing flexible (soft) PVC recyclate 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: - mats for stables and greenhouses; - noise insulation sheets; - the following applications provided the recycled PVC is entirely enclosed with a layer of virgin PVC: multi-layer hoses, roofing and waterproofing, road furniture and traffic management and professional footwear. All virgin PVC used in combination with recycle in the above applications shall comply with paragraph 2. Suppliers shall ensure before the first placing on the market of mixtures and articles specified above and containing recycled PVC that these are visibly, legibly and indelibly marked as follows: '*Contains recycled PVC'.* (c) PVC-silica separators in lead acid batteries for a period of 10 years from entry into force. (d) Articles covered by paragraph 7 of Entry 63 of Annex XVII. (e) Articles covered under existing legislation: - food contact materials covered by Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011 on plastic materials; - 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);

	- Directive 94/62/EC on packaging and packaging waste; - Directive 2009/48/EC on the safety of toys. 5. By way of derogation, paragraph 2 shall not apply to articles for which it can be demonstrated that they have been placed on the market for the first time before xxxxx (based on the transition period of 24 months). 6. By way of derogation, paragraphs 1 and 2 shall not apply to the use of the following pigments: • Lead sulfochromate yellow (EC No: 215-693-7) • Lead chromate molybdate sulfate red (EC No: 235-759-9)

RAC and the Dossier Submitter proposed various changes to the wording of the restriction proposal during the opinion making. These were mainly in relation to the proposed derogation for the use of post-consumer recycled PVC in articles, as follows:

1. The list of derogated article types was modified to explicitly separate rigid/un-plasticised (PVC-U) articles from flexible/plasticised (PVC-P) articles. This was because the initially proposed list was based on rigid PVC applications only (modified from the existing restriction on cadmium in recycled PVC – REACH Annex XVII entry number 23).

2. The article types listed in the derogation were further refined to reflect their different potential to result in human exposure to lead during their service lives, either via indirect (through the environment) or direct (through the potential to form dusts through polymer degradation and abrasion) pathways. As such, article types used for the exterior parts of buildings and non-building structures were separated from article types used in interior parts of buildings, further distinguishing between occupied and non-occupied interior parts of buildings.

3. For the purposes of this opinion "occupied" is intended to mean any part of a residential, commercial or industrial building that is intended to be occupied by humans. Non-building structures include bridges, dams, industrial, etc., that are not specifically designed for occupancy, but which could use PVC materials in their construction.

4. The use of recycled PVC in mono-extruded articles was derogated for uses in the interior of buildings (e.g. cable ducts), but only where these uses are limited to the concealed spaces or voids of a building (that are inaccessible during normal use, excluding maintenance). This was on the basis that there is limited potential for dust formation or for sensitive populations (e.g. children) to come into contact with them in these locations. Examples of concealed spaces or voids include joist or truss spaces that are part of floor-ceiling assembles; spaces above suspended ceilings; spaces inside stud walls; crawl spaces; vertical chases between floors for pipes and ducts. Areas that are occupied or used for storage would not be considered to be concealed spaces or voids.

5. 'Fittings' for a number of specified applications were derogated as they are not accessible under normal conditions of use (e.g. if they are present in internal parts of a more complex article) implying a limited potential for human exposure during their service life. The article types specified in the restriction text are listed on EU databases[2].

6. The use of rigid PVC articles produced using post-consumer recycled PVC were derogated for use in the occupied parts of buildings but only where these were produced using a co-extrusion process with recycled PVC encapsulated by virgin material. This was to prevent the potential for the formation of lead-containing dusts during article service life. Co-extrusion of rigid PVC profiles for the fabrication of doors and windows is already widely practiced (e.g. EN 12608-1).

7. Similarly, on the basis of comments submitted by industry during the public consultation, various article types produced using recycled flexible PVC have been included in the proposed derogation. However, as flexible PVC has greater potential for leaching lead than rigid PVC, RAC considers that some of the articles produced using flexible PVC recyclate should be co-extruded, with virgin PVC encapsulating the recycled PVC to prevent leaching during article service life.

8. The Forum advice raised that the use of 'stabiliser' in paragraph 1 of the proposal would be difficult to enforce, especially in relation to articles that had been produced from recycled PVC. Therefore the Dossier Submitter, supported by RAC, proposed not to include the term 'stabiliser' in the entry, but to specifically derogate the two lead chromate substances (lead sulfochromate yellow and lead chromate molybdate sulfate red) that are known to be used in PVC (including for authorised uses) and that would now be inadvertently included in the restriction. There was no intention to change the scope of the Dossier Submitter in changing the wording, simply to express the intention in a different way. However, it was agreed that the risks identified by the Dossier Submitter would equally apply to lead compounds that were not used as stabilisers (even if they were not specifically included in the original proposal) as they would result in additional lead emission to the environment. ECHA will consider a further restriction on the use of lead chromate pigments in PVC articles under article 69(2) of REACH. RAC notes that, with the exception of the two substances used as pigments identified above, no information was received in the PC to support a view that any other lead compounds are used in PVC for non-stabilising uses. This issue will be further explored in the SEAC draft opinion PC.

THE OPINION OF SEAC

See the opinion of SEAC.

[2] Fittings for pipes e.g. joints, elbows, flanges (EU CN commodity code 3917 40 / EUROSTAT 2016 Prodcom code 22.21.29.70); Plastic fittings for furniture, coachwork or the like (EU CN commodity code 3926 30 / EUROSTAT 2016 Prodcom category 22.29.26.10)

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope)

Summary of proposal:

Several human health hazards have been identified for lead and its compounds and EFSA has recommended that steps should be taken to reduce human exposure to lead in general within the EU. Based on this health concern, the proposal aims to restrict the placing on the market of PVC articles stabilised using lead compounds. The aim is to protect the general public from exposure to lead through direct contact with such articles and, more particularly, from environmental emissions both during the service life of the articles (including indoor dust) and from their treatment and disposal as waste.

Several lead compounds can be used to stabilise PVC. The proposal groups them together because the toxic moiety of concern is the lead cation. Lead compounds cannot stabilise PVC in a satisfactory way at concentrations below approximately 0.5 % (w/w). The proposed concentration limit of 0.1 % (w/w) would therefore ensure that the intentional addition of lead compounds as stabilisers during PVC compounding in the EU can no longer occur, and ensure that imported articles (quantities of which have been increasing in recent years) meet the same standards.

The proposal includes polymers and copolymers of PVC, since additional comonomers (other than vinyl chloride) are often used to derive PVC-based copolymers. For example, vinyl acetate is a common comonomer of PVC (used to increase heat resistance). PVC containing copolymers still require stabilisation, and their inclusion in the restriction prevents a loophole whereby addition of a small amount of a second monomer could be used to exclude an article from the scope of the proposed restriction.

A transitional period of 24 months after entry into force is proposed to allow the use of existing stocks and to ensure that effective supply chain communication on the details of the restriction can occur.

The Dossier Submitter's proposal included several derogations:

1) A 15-year derogation was proposed to allow the recycling of PVC, which was considered by the Dossier Submitter as an effective risk management measure to prevent end-of-life release of lead to the environment, to continue as a viable waste management practice. The derogation comprises a lead concentration limit of 1 % w/w for an exhaustive list of article types considered to have relatively low potential to result in human exposure to lead during their service life. The derogation was not intended to allow the continued use of lead compounds to stabilise recycled PVC, but recognises that PVC recyclate will typically contain residual lead from the legacy use of lead-based stabilisers (and potentially lead-containing pigments) when the PVC material was originally produced.

2) A 10-year derogation was proposed to allow the continued use of lead compounds to stabilise PVC-silica separators in lead-acid batteries in the absence of a suitable alternative.

3) To prevent double regulation, other derogations were proposed for PVC articles already covered under existing legislation.

4) For the second hand market (consistent with Entry 63 of Annex XVII concerning lead and its compounds in articles supplied to the general public that can be mouthed by children).

RAC conclusion(s):

RAC concludes that the purpose of the restriction and reasons for the proposed derogations are clear. It only applies to finished articles (not PVC recyclate itself). The restriction specifically relates to use of lead compounds as stabilisers in PVC since this is the application that has been considered in the proposal, but in principle any use of lead in PVC is relevant to the identified risk. The restriction text is clear that intentional addition of lead stabilisers during any part of the production process for PVC articles for supply to the EU is not permitted, but specifying stabiliser use in the restriction text would complicate enforcement. Use of two lead compounds as pigments[3] in PVC has been authorised in the EU under REACH[4]. As these specific uses were outside of the scope of the assessment performed by the Dossier Submitter they need to be excluded from the scope of the restriction by means of a derogation.

Key elements underpinning the RAC conclusion:

The grouping of all lead compounds is appropriate to prevent substitution with lead-containing substances that are not currently registered for this application (since they would pose a similar level of hazard) and to facilitate enforcement based on lead content.

During public consultation, Industry confirmed that no lead-based stabilisers need to be added in the production of articles made from PVC recyclate (levels of lead-based stabilisers in the recyclate may be sufficient and, if not, calcium-based alternatives can be used).

RAC notes that it is possible for lead to be present in PVC due to uses other than as stabilisers (e.g. use of two lead-chromate pigments have been granted a REACH authorisation). Restriction of any lead present in PVC (regardless of intended function) would contribute to addressing the risks identified in the proposal. In addition, it might not be readily apparent why lead is present in an article, so specifying a particular use might not be helpful from an enforcement perspective (the Forum for enforcement indicated in their advice that the restriction will be simpler to enforce if enforcement authorities do not have to demonstrate the function of any lead detected in PVC above the relevant concentration limit). Supply chain communication is likely to be important in this context, and several certification schemes exist in the EU that may be relevant. However, RAC recognises that a derogation from the restriction is needed for uses of lead pigments as these substances were not within the scope of the restriction proposal requested by the Commission or the analysis undertaken by the Dossier Submitter. ECHA plan to address the use of lead chromate pigments in imported

[3] Lead sulfochromate yellow (EC No: 215-693-7) and Lead chromate molybdate sulfate red (EC No: 235-759-9)
[4] A further lead pigment, lead chromate, has also been authorised but not for use in PVC.

articles in an Article 69(2) restriction proposal.

Description of the risk(s) addressed by the proposed restriction

Information on hazard(s)

Summary of proposal:

Lead compounds have a harmonised classification under the CLP Regulation as toxic to organs through prolonged or repeated exposure by inhalation or ingestion (H373). The most critical effects are developmental neurotoxicity, effects on blood pressure and chronic kidney disease. In particular, a safe blood lead concentration has yet to be established for negative impacts on IQ in children, and so lead is regarded as a non-threshold substance. This was the basis for the restriction on lead compounds in consumer articles that can be mouthed by children (Entry 63 of Annex XVII to REACH). EFSA also concluded that there is no evidence for a threshold for renal effects in adults. The Annex XV report therefore takes a qualitative approach to risk assessment.

Lead is also harmful to the environment. The Annex XV report presents information on environmental hazards, but these are not used in the risk characterisation so are not summarised here.

RAC conclusion(s):

RAC concludes that a threshold for neurodevelopmental effects in children as well as renal effects in adults has not been established, although this may need further review for future risk management purposes. Minimising the possibility that child brain development can be affected by lead exposure will also serve to reduce other effects (e.g. on blood pressure).

Key elements underpinning the RAC conclusion(s):

The proposed restriction is based on the same human health concern as previous restriction proposals for lead that RAC has already given an opinion on, so RAC has not re-evaluated the underlying data. A key difference is that whereas RAC previously derived a maximum lead exposure value (0.05 µg/kg bw per day, relating to a likely increase in blood lead level of 1.2 µg/L and potentially equivalent to an IQ reduction of 0.1 point), a tolerable level has not been assumed for this proposal.

No threshold has been scientifically established for the neurotoxic/neurodevelopmental properties of lead; previous RAC opinions indicate that lead causes IQ deficits in children at blood lead levels lower than 10 µg/L, which is below typical levels found in European children (15–20 µg/L in Western Europe, 30–50 µg/L in Central and Eastern Europe). RAC therefore agrees that current blood lead levels need to be lowered, and notes that this is not disputed by the REACH Registrants in their CSRs for lead compounds.

Comments submitted during public consultation (#1518, #1659) suggest that an expert review sponsored by the Australian Government highlighted that there is insufficient evidence to support a causal relationship between blood lead levels less than 10 µg/L and adverse neurological development in children. However, this analysis is not reflected in the report's conclusions. For example, the introduction of the review states "*it appears that no threshold*

can be identified for developmental neurotoxicity…" (NHMRC, 2015a). The existence of a threshold is not discussed further, but NHMRC (2015b) concludes:

- *"Minimising lead exposure remains a long-term goal for Australian governments….*
- *Reducing the amount of lead in our environment (e.g. in soil, dust, air and products) as much as possible will reduce the risk of harm to future generations, especially for young children and unborn babies."*

NHMRC analysed 14 additional studies to those included in the two extensive reviews by US NTP (2012) and US EPA (2013). Whilst these additional studies do not affect the report's conclusions, comment #1659 suggests that these conclusions reflect a policy position rather than a detailed evaluation of the available scientific evidence on causation or dose response, and asks RAC to re-evaluate all relevant evidence published since the 2010 EFSA evaluation. In contrast, other comments (e.g. #1609, #1672 and #1674) emphasise that lead is a potent toxic substance with a complex range of toxic effects at low doses, which might potentially include carcinogenicity and endocrine disruption.

The assumption of no safe threshold is important for both this and previous restrictions, as well as for future regulatory risk management measures under REACH (e.g. authorisation applications). It may also affect the way lead is regulated under other European legislation (e.g. in drinking water, food, sewage sludge and air). For example, permissible lead levels in sewage sludge for application to land were established more than two decades ago. Given the complexities of the evidence, the Commission may wish to consider a review of all relevant toxicological data published to ensure that a consistent set of regulatory trigger concentrations for relevant environmental media is available for lead, in the interests of human health protection.

Information on emissions and exposures

Summary of proposal:

The dossier considers two routes of exposure:

(1) Direct exposure to lead through contact with PVC articles

The Dossier Submitter does not consider that the use of lead compounds as stabilisers in PVC will lead to significant direct exposure of the general population to lead (through mouthing or via direct and prolonged contact with skin). However, the Dossier Submitter highlights that lead compounds used as stabilisers in certain PVC articles may have greater potential for direct exposure to lead. In particular, infants and young children could be considered to have greater potential for direct and prolonged contact with PVC flooring and interior wall coverings, or dusts that collect on surfaces (due to hand-to-mouth exposure).

For example, Norman et al. (1997) found that PVC mini-blinds (venetian blinds) were the predominant source of lead exposure for 8 out of 92 (9 %) children aged 6 – 72 months who had been selected for further investigation in the USA due to elevated blood lead concentrations (lead was measured in dust and was confirmed to have resulted from the degradation of PVC rather than other sources, such as lead paint).

Similarly, concentrations of lead recovered (by wiping) from the surface of 20 PVC window profile samples (manufactured in 1990 and 2006) were reported to range from 0.14 to 0.45

µg/cm^2 (Sleeuwenhoek and van Tongeren, 2006). These measurements were intended to replicate dermal transfer relevant to potential hand-to-mouth exposure. However, no specific information is available in the literature on the contribution of PVC articles in general to overall lead levels in indoor dusts.

The diffusion rates of lead from PVC water pipes into drinking water are acknowledged to be low and result in concentrations of lead below relevant drinking water standards.

(2) Indirect exposure to lead via the environment

The Dossier Submitter has estimated the magnitude of (total) environmental releases of lead from PVC articles during their service life and following their treatment and disposal as waste. The model is complex and built on a large number of assumptions. A key consideration is that releases may potentially occur at an unspecified time in the future (in some cases more than 50 years after entering service given the types of articles within scope) rather than during a specific year, depending on how the article is disposed of (similar to the approach previously taken in a REACH restriction proposal for the flame retardant decabromodiphenyl ether)[5].

Service life

In use, PVC articles may release lead compounds to the atmosphere (including indoor air), land and/or water due to abrasion, polymer degradation (caused by light and heat) and diffusion processes. The extent of release will vary depending on the type of article and the way it is used (e.g. indoors or outdoors).

The Dossier Submitter has used a default release factor of 0.01 % as cited in the OECD emission scenario document for plastics additives to represent losses during the service life of all PVC articles (no specific receiving compartment is mentioned). Additional service life release estimates based on empirical diffusion rates of lead from various article types, including flexible (soft) PVC articles, were submitted during public consultation (comment #1553 and #1663). In these comments it was assumed that there are no service life releases from some article types because of (for example) encapsulation of lead-containing PVC by virgin PVC material, or use in internal parts. The figures therefore represent current and future use of recycled PVC rather than legacy use, and do not account for losses that could occur in addition to diffusion, for example through degradation or abrasion of the polymer matrix.

In general, the data support the data reported in the Background Document that release factors for soft PVC applications are greater than those for rigid PVC applications. The greatest release factors are associated with flexible PVC articles used for 'roofing and waterproofing' due to a relatively high surface area to volume ratio combined with a relatively long estimated service life of 20 years. The Dossier Submitter estimates a release factor of up to 2 % for this application, compared to 0.4 % in traffic management, 0.03 % in mats for stables and greenhouses and 0.01 % in monolayer pipes).

In terms of overall releases, the amounts of lead predicted to arise from traffic management articles (e.g. base of cones) are similar to those from roof tiles / waterproofing, reflecting the

[5] Entry 67 of Annex XVII of REACH (amended by Commission Regulation (EU) 2017/227 of 9 February 2017): https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1897/term

greater amount of PVC used in the former application. However, the release rate was based on the assumption of a relatively thin layer of PVC, which is a worst case approach.

Waste disposal

Waste PVC articles can be disposed of in a number of ways and therefore cause different releases and emissions of lead to the environment:

- They can be exported from the EU for disposal or re-use elsewhere. For this pathway the releases of lead are not estimated.

- PVC articles disposed direct to landfill are considered to be relatively stable with limited potential for lead release from the PVC matrix, although some release is expected over time. The release factor for lead from municipal landfill is in the range 0.004 – 0.01 % to water (REACH registration data based on reviewed measured leachate data) and 0 – 0.16 % to soil (the lower value assumes that the landfill membrane is impermeable, and the upper value is a default from the ECHA R.18 guidance).

- Despite pollution abatement measures, PVC articles disposed to municipal waste incinerators may give rise to direct emissions. The release factor for lead from incinerators is in the range 0.03 – 0.06 % to air (based on a default from the ECHA R.18 guidance and a consultant's report included in the REACH CSRs that reviewed measured data), 0.007 % to water (wet-cleaning facilities only, based on a consultant's report included in the REACH CSRs that reviewed measured data) and 0.6 % to sludge that ends up in hazardous waste landfill (based on a consultant's report included in the REACH CSRs that reviewed measured data).

  However, the vast majority of the lead entering the incinerator will end up in two forms of ash: around 37 % in incinerator fly ash (also described as air pollution control residue) from air scrubbing systems, and around 63 % in incinerator bottom ash (the relative amounts are estimated in a consultant's report included in the REACH CSRs). Fly ash is acknowledged to be heavily contaminated with soluble (potentially mobile) metal compounds, which can be readily released through leaching. EU waste legislation requires that fly ash is carefully managed. Stabilisation of fly ash (e.g. solidification with binders such as cement, washing or various chemical or thermal treatments) prior to disposal in hazardous waste landfill can be successful in reducing the leaching potential of lead (and other heavy metals). However, acceptance criteria for hazardous waste landfill allow wastes that have some lead leaching potential (albeit at relatively low rates) to be disposed, implying that lead cannot be considered to be completely contained within stabilised hazardous waste over the expected lifetime of a hazardous waste landfill. In addition, 'end of waste' protocols in place for the re-use of fly ash as aggregate in the construction industry can also permit low rates of lead leaching. The Dossier Submitter assumes a release factor for lead from hazardous waste landfill in the range 0.01 – 3.2 % to water (based on the OECD ESD for service life emissions for plastic additives and a default from the ECHA R.18 guidance) and 0 – 0.16 % to soil (same as for municipal landfill).

- Incinerator bottom ash (IBA) may be disposed of to landfill, or can be re-used in some circumstances in the construction industry (e.g. in aggregates for roads). Releases to

groundwater from this re-use are assumed to arise from leaching, and are in the range 0.01 – 0.32 % (based on the OECD ESD for service life emissions for plastic additives and combined defaults for soil and water from the ECHA R.18 guidance). This is applied to the entire tonnage of lead in IBA.

Recycling of PVC articles can also give rise to emissions to air (from grinding and milling) and possibly surface waters (e.g. due to waste water arising from washing processes). The Dossier Submitter only considers a release of 0.02 % to air (based on an ECHA default release of dusts from plastic material of 10 % during shredding/milling, further corrected for the average concentration (1.5 %) of lead in PVC articles and the effectiveness of dust filters).

The total amount of lead estimated to be present in lead-stabilised PVC articles placed on the EU market in 2016 was 1 057 – 4 579 tonnes (of which imported articles account for at least 60 %). This range is a result of information provided by European producers of the lead stabilisers and import statistics for plastic articles. It involves a series of assumptions, including:

- the amount of manufactured PVC that is exported,
- the market share of companies who are not known to have already voluntarily phased out the use of lead stabilisers,
- excluding articles subject to other legislation,
- conversion of mass of stabiliser to mass of lead,
- the fraction of imported plastic articles that are made from PVC,
- the fraction of imported PVC articles that contain lead stabilisers, and
- the average lead content of imported PVC articles (1.5 %).

The release model uses this tonnage range along with the lower and upper bound release factors described above and assumptions about the proportion of PVC waste disposed via different routes in the future (based on industry predictions) as illustrated in Figure 1.

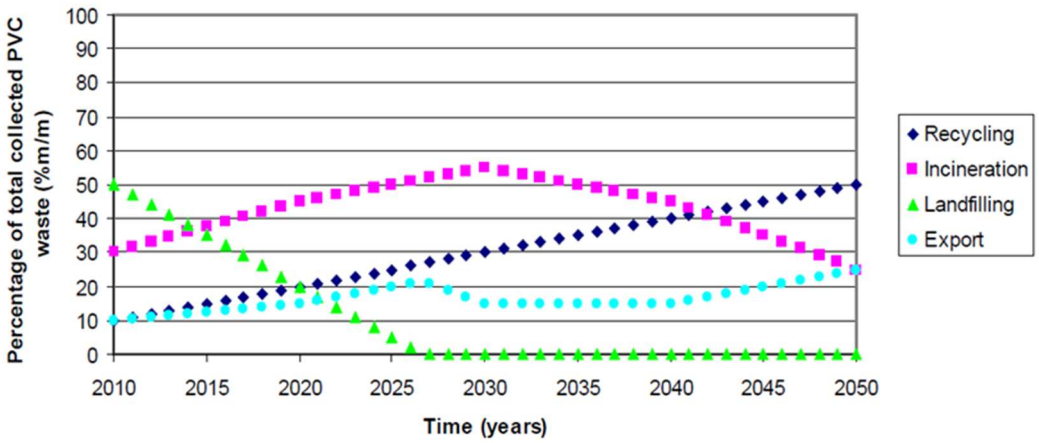

Figure 1: Contribution of waste management options to total waste (Tauw IA, 2013)

There are relatively large uncertainties in the input parameters, so a probabilistic modelling approach (using Monte Carlo simulation) was adopted to (a) integrate the variability in the input parameters and (b) estimate the most likely releases from within the theoretical minimum and maximum extremes of the model. The model was re-run 100 000 times with different values for the input parameters selected from within the lower and upper bound ranges on each occasion. On each model run, a year of disposal was selected from between 2025 to 2065, to take account of different proportional splits of PVC waste disposed of in landfill, incinerated and recycled. The model was weighted such that a year of disposal is ten times more likely to be from the later part of the range than the earlier part, recognising that PVC articles have a relatively long service life and are therefore more likely to be disposed in 50 years, than in 10.

The resulting estimated (total) lead releases are summarised in Table 1.

Table 1: Lead releases from PVC articles placed on the EU market in 2016 (estimated via Monte Carlo analysis) (tonnes)

Lifecycle stage	**25th percentile**	**Median**	**75th percentile**	**% of overall release (based on median values)**
Service life	0.19	0.26	0.34	4
Recycling of articles	0.16	0.23	0.30	3
Municipal landfill	0.07	0.14	0.22	2
Municipal incineration[a]	3.29	6.11	9.88	90
Total[b]	**4.3**	**6.8**	**10.3**	**100**

Note: a) Includes releases associated with long-term disposal of fly-ash and from the re-use of incinerator bottom ash in construction projects.
b) Due to the characteristics of the Monte Carlo simulation the sum of the estimates for the different life-stages at 25th percentile, median and 75th percentile are not necessarily consistent with corresponding estimates of total releases.
c) These release figures include an assumption of limited continuing use of lead stabilisers within the EU due to supply by a very small number of companies that were not part of the voluntary initiative. These companies have since confirmed to ECHA that they no longer supply lead compounds for this use in the EU, which will reduce the numbers very slightly.

The minimum total estimated release is 0.4 tonnes and the maximum is 34 tonnes. The disposal phase accounts for approximately 95 % of the estimated median emissions (the remainder being released during service life). Since the majority of the European PVC industry has already phased out the use of lead compounds as PVC stabilisers, around 90 % of the total estimated emissions are attributable to PVC articles imported into the EU during 2016.

Any lead released to the environment during use or disposal of PVC articles can potentially end up in air, soil (e.g. due to atmospheric deposition or sewage sludge application to land) and/or surface water. Consequently, it may be present in drinking water or human foodstuffs, which are the assumed primary routes of human exposure (EFSA has concluded that food and water are the most important sources of lead exposure for the general population).

Lead is regulated as a food and drinking water contaminant in the EU. According to EFSA (2010), the average consumption of lead (from all sources, not just PVC) for adults in the

European population was estimated to be 0.36 – 1.24 µg/kg bw per day. Drinking water was considered to account for 4 % of this exposure. The Dossier Submitter has not attempted to convert the estimated releases from PVC applications into likely human exposure concentrations via diet, air or drinking water. The argument is that this is not necessary given the non-threshold nature of the toxicological end point of concern.

The Dossier Submitter considers that occupational exposure is well-controlled, based on information from the CSRs. No estimate is provided of environmental releases from the manufacture of lead stabilisers or their use in PVC processing (N.B. only article production is in scope of the restriction) or article production. A specific exposure scenario for the use of PVC in lead-acid batteries has not been considered either, although the tonnage used in batteries is included in the total tonnage of stabiliser used for the preceding calculations (end-of-life handling of lead-acid batteries is also subject to specific legislation).

The Annex XV report lists further anthropogenic sources of lead that can be directly and indirectly released to the environment, including:

- metal production and processing,
- electricity / heat generation,
- (legacy) lead-based paint systems,
- use of lead ammunition,
- automotive applications (lead-acid batteries), and
- metallic lead-based water distribution systems.

The level of release from industrial point sources has been estimated to be approximately 500 tonnes/year across the EU based on pollution inventory data (with around 90 tonnes arising from waste and waste water management). Assessments by the lead industry suggest lead emissions of about 30 000 tonnes/year (85% of which is attributable to the use of lead shots). In addition, lead is a naturally occurring substance, but there is no comparison of how releases from PVC compare with natural sources.

RAC conclusion(s):

RAC concludes that the Dossier Submitter has taken a realistic worst case approach. Although limited information on actual human exposures arising from use and disposal of PVC is presented, RAC concludes that the direct exposure of the general population from the use of lead stabilisers in PVC can occur but is likely to be less significant than the indirect exposure route via the environment. Information from the USA demonstrates elevation of blood lead levels in young children arising from proximity to miniblinds. In certain worst case scenarios (e.g. a child's bedroom equipped with PVC venetian or mini-blinds and vinyl flooring/interior wall coverings), direct exposure of children and infants to "lead-rich" dusts could therefore occur. However, the Dossier Submitter has not estimated human exposure levels arising from dusts contaminated with lead derived from PVC.

RAC also considers that PVC is a minor source of indirect exposure to lead via the environment compared to other sources (e.g. use of lead shots). The maximum estimated emission from PVC of 34 tonnes/year is about 0.1 % of the total.

RAC notes that the Dossier Submitter's conclusion that waste disposal accounts for the majority of emissions may create an unintended perception that waste sites are associated with unacceptable releases, whereas in fact emissions from such sites are subject to specific controls under EU legislation (e.g. via permits).

Key elements underpinning the RAC conclusion(s):

RAC considers that the Dossier Submitter has selected the best available information to estimate releases, and has used an appropriate model to take account of the large uncertainty in the relatively high number of input parameters. Limited data provided during public consultation (#1544) provide some reassurance that potential emissions from incinerator fly ash are covered by the range of emission factors used. Nevertheless, the estimated emissions can be considered to be a relevant "order of magnitude" indication and should not be over-interpreted. In particular, the amount of lead actually placed on the EU market in PVC during 2016 is not known and some of the release factors are defaults, which may not be realistic when applied to the whole tonnage. This especially concerns article service life and some parts of the waste disposal phase. For example, the Dossier Submitter's analysis of the release estimates submitted by industry during public consultation (comment #1553 and #1663) indicates that release factors for some flexible PVC article types (such as roofing) are significantly higher than 0.01 %, and these may still underestimate releases over the entirety of an article's service life. It is therefore possible that the default assumption will under-estimate total service life losses to some extent.

Comments submitted during public consultation (#1609, #1671) highlight that the release estimates provided in the dossier for the use of lead stabiliser assume that PVC articles produced from PVC recyclate would not result in further lead emissions during their subsequent service life. This is an oversight, but service life emissions are relatively low compared to those at the end-of-life stage (approximately 5 % of overall emissions are estimated to occur during service life) so this is unlikely to be significant (especially if the recyclate is encapsulated).

A second important factor is that the approach assumes that all of the lead released from PVC is potentially available for human exposure at an unspecified point in the future (spanning several decades). So, whereas use in PVC during 2016 is estimated to give rise to potential emissions in the region of 4 – 10 tonnes (interquartile range), the potential for human exposure also depends on the partitioning (e.g. sedimentation) and transport of lead in the environment and its bioavailability. Lead in incinerator ash will be in the form of oxides and other compounds like sulfates, carbonates and phosphates. Within anaerobic landfills and sediments, other types of lead compounds may form (e.g. sulfides) which are much less water soluble and so less mobile.

Some relevant information on environmental fate and distribution is provided in the Annex XV report, but this is not carried through to the exposure assessment. RAC therefore considers that the annual amount of lead actually reaching the receptor (e.g. children) from PVC sources via the environment is likely to be much lower than the 4 – 10 tonnes estimated to be released, but acknowledges that it is not possible to estimate by how much due to the lack of appropriate modelling methodologies.

Service life emissions are not relevant for use of lead in separators for batteries. Comment #1610 received during public consultation highlights that such separators are not suitable for

recycling and are mostly incinerated in Europe, so this is accounted for in the emission estimates.

Characterisation of risk(s)

Summary of proposal:

Releases of lead from PVC articles into the environment are used as a proxy for risk, since lead is a non-threshold toxic substance and the risks to humans via the environment caused by its use in PVC cannot be adequately addressed in a quantitative way (e.g. by derivation of DNELs or PNECs). In addition, direct exposure through contact with PVC articles may also lead to a non-quantifiable risk to sensitive human receptors (e.g. children and infants) if the lead stabiliser can be emitted in a relevant form (such as in dusts). The Dossier Submitter has therefore followed the same approach that has been used in previous reports for other substances for which a threshold cannot be derived (e.g. PBT/vPvB substances such as decaBDE, and the neurotoxic phenylmercury compounds). The reduction of lead releases achieved by the proposed restriction is used as an estimate of risk reduction capacity of the proposed restriction.

Manufacturing of the stabiliser substance and formulation of the stabiliser mixtures is not proposed to be restricted by the Dossier Submitter. According to available information, the occupational exposures in manufacturing and use of lead stabilisers are well controlled below the EU binding airborne lead limit of 0.15 mg/m^3 and the biological exposure limit of 70 µg/dL. Taking this into account, the Dossier Submitter decided to target the proposal on the use of stabilisers in PVC articles. As manufacture is not restricted, the export of the stabiliser is also not restricted.

Risks to the environment may also be relevant, but this has not been addressed in the Annex XV report.

RAC conclusion(s):

RAC concludes that the proposed restriction will help to reduce anthropogenic releases of lead to the European environment. Environmental emissions are expected to arise from the use and especially the disposal of articles at the end of their service life. Releases at the end of service life are very difficult to manage and will make a (small) contribution to overall human exposure and therefore risk for this non-threshold substance.

RAC also concludes that the proposed restriction will help to reduce direct human exposure to lead through contact with PVC articles. RAC notes that there are specific article types (e.g. mini-blinds and potentially vinyl flooring/interior wall coverings) that may pose a relatively greater risk than other articles for this exposure route if the outer layer contains lead. Similarly, indirect exposure may be higher for some article types (especially those made from soft PVC, such as roofing tiles), particularly where the recycled PVC is not encapsulated or otherwise protected from weathering and abrasion. This should be taken into account when considering derogations from the proposed restriction.

Occupational exposure and risk are not the focus of the proposal (manufacture of lead stabilisers is out of the scope). Health risks for workers involved with PVC production, waste treatment and recycling are controlled by Occupational Health and Safety legislation. Production of PVC mixtures (e.g. as masterbatch) stabilised with lead would still be permitted, but as manufacture of lead-stabilised PVC articles would no longer be allowed and lead content

in PVC recyclate will decline with time, worker exposure to lead may reduce further in the long term.

There are potential risks to the environment from use of lead compounds as stabilisers in PVC (including at manufacturing and processing sites), but no assessment is presented so no opinion can be given.

Risks from use in separators for batteries have not been quantified but are likely to be very low.

Key elements underpinning the RAC conclusion(s):

The Dossier Submitter justifies their approach to qualitative assessment by citing the requirements of Annex I of REACH, paragraph 6.5. In principle, the lack of a relevant threshold for toxic effects creates difficulties in producing a reliable risk characterisation for the wide range of potential receptors (i.e. people or wildlife). This is why emissions are used as a proxy for risk for environmental end points in particular. In this case, children/infants are a sensitive receptor, and whilst it should be possible to make an estimate of their exposure from this source (i.e. PVC), the absence of reliable methodological approaches for modelling exposure to metals via the environment makes this problematic. In addition, the non-threshold nature of the health concern means that risks are difficult to quantify with certainty even where exposure is known.

In the absence of a detailed exposure assessment or comparative data for other lead sources, it is not possible to comment on the relative contribution that PVC makes to overall human exposure to lead, although it is likely to be relatively very small.

Industry submitted further information on releases to help justify derogation of additional article types. Service life releases are estimated to make a relatively small contribution to the overall environmental exposure of lead from PVC. However, from a risk perspective it may be inappropriate to derogate articles with a relatively high potential for release during service life (both direct and indirect), depending on the amounts of lead involved.

For example, based on industry information, overall service life releases from roof tiles and road furniture (such as road cones and cable ramps for traffic management) are likely to be of a similar order of magnitude, and relatively much greater than rigid monolayer pipes (used in sewerage networks or for technical applications e.g. improving ground stability).

Other article types (e.g. multi-layer hoses, noise insulation sheets, and mats for stables/greenhouses) have intermediate overall releases (though still generally low). Emissions have not been properly quantified for a range of other article types industry proposed for derogation (e.g. footwear/boots for professionals, rain gutter cladding, fascia, liners, waterproofing sheets and other rigid PVC applications such as wall and stable equipment, compounding, honeycombed thermoformed films for cooling towers, drainage elements, and bases and elements for brooms).

It is therefore very difficult for RAC to rank the various article types on the basis of risk. It is worth noting, however, that risks can be minimised by encapsulation of the recycled PVC by virgin PVC material, or enclosure within an article so that it is not exposed to weathering, abrasion, etc. Therefore in principle many types of article might be expected to pose a lower risk if the lead is not in the external layer.

Uncertainties in the risk characterisation

As described in the preceding sections, the assessment is based on a large number of assumptions, including the non-threshold nature of the hazard, the quantities of lead in PVC articles currently on the market (especially from imports) and release factors for various stages of the life cycle. In addition, environmental risks are not addressed.

Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

Whilst use of lead stabilisers within the EU has been voluntarily phased out, users are not prevented from switching back. Recycling keeps lead in the technosphere, but most PVC articles containing recyclate will presumably eventually be incinerated or landfilled, and article manufacturers/importers have limited control over this phase of the life cycle. In addition, PVC imports have steadily increased in the last decade. Lead emissions associated with imported PVC articles will therefore continue to add to the total lead stock of the EU environment. Exposure (particularly from the end-of-life stage) and therefore risk will therefore continue to occur in the absence of EU legislative action.

RAC conclusion(s):

RAC concludes that current risk management measures are insufficient to prevent ongoing lead releases from imported articles, and potentially also from some types of recycled PVC articles.

Key elements underpinning the RAC conclusion(s):

N/A

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

Lead and its compounds have been extensively regulated at national, Union and global level. This is reflected in the large number of sector-specific Union legislative acts that restrict the use of lead or its compounds in mixtures, articles and consumer products based on the risks posed to human health and the environment.

A detailed (but non-exhaustive) inventory of existing Union legal requirements and international agreements related to the use of lead, can be found in the Appendix to Annex B.9 in the Background Document, separating general legislative frameworks, human health legislation and environmental legislation.

Various studies and assessments agree that lead in PVC articles is bound within the plastic matrix at the time of manufacture and has low inherent extractability during the service life

of the main downstream uses. Overall, on the basis of the available data, it can be concluded that lead stabilised PVC articles release only small quantities of lead during their service life. However, it should be noted that since lead is a non-threshold toxic substance, a restriction on lead stabilisers in PVC would reduce additional exposure for consumers, including infants, young children and pregnant women.

The principal risk addressed in this restriction report was described in a scientific opinion on lead in food by the European Food Safety Authority (EFSA, 2010) and in previous REACH restriction reports (e.g. lead in consumer articles). Whilst it is acknowledged that human and environmental exposure to lead has decreased significantly over the last 20 to 30 years, exposure in the general population still exceeds the highest tolerable level with respect to the neurodevelopmental effects. Thus, any additional human exposure from food and non-food sources should be avoided (EFSA, 2010).

PVC articles can contribute to overall releases of lead to the atmosphere and water both during their service life (via degradation, abrasion and diffusion processes) and after disposal as waste.

RAC conclusion(s):

RAC concludes that there are no existing regulatory risk management instruments to limit and reduce releases of lead from PVC articles into the environment.

Key elements underpinning the RAC conclusion(s):

N/A

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of RAC and SEAC

Summary of proposal:

Action on a Union-wide basis would reduce both environmental exposure and human exposure via the environment to non-threshold hazardous substances, and therefore also reduce risks. The health concern as well as the marketing of PVC articles should be similar in all Member States, so regulating the risk at Union level is likely to offer the strongest protection.

SEAC and RAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with the use of lead-based stabilisers in PVC should be implemented in all MS.

Key elements underpinning the SEAC and RAC conclusion(s):

N/A

JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of RAC and SEAC

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

The preferred restriction option is to restrict lead compounds used as stabilisers 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), a 10-year derogation for PVC silica separators in lead acid batteries, and derogations for second-hand articles and articles covered under existing EU legislation.

A second restriction option considered comprised the 0.1 % (w/w) limit but no derogations. A third restriction option considered proposed a slightly higher concentration limit of 0.5 % w/w for all PVC articles (which was assumed to be low enough to prevent intentional use of lead stabilisers but high enough to avoid any need to derogate PVC recycling), and included the derogation for PVC silica separators in lead acid batteries.

RAC conclusion(s):

RAC concludes that the proposed restriction of lead stabilisers in articles made from virgin PVC confirms current (voluntary) practice within the EU, and will reduce the import of lead-containing PVC articles from outside the EU. It is therefore an appropriate measure.

The lead concentration limit in some types of article made mainly from recycled PVC needs to be greater to facilitate the recycling of existing articles with long service lives, since they will contain concentrations of lead greater than 1 % w/w. RAC concludes that this is appropriate and necessary, since the alternative would be to divert such articles to landfill or incineration at the end of their service life rather than recycle them, which would increase emissions to the environment and not reduce risk. In addition, it will also incur additional environmental impacts such as increased raw material use and energy consumption in the production of new articles.

The 1 % limit proposed by the Dossier Submitter seems appropriate for derogated article types made from soft PVC recyclate, but a higher limit (e.g. 2 % w/w) may facilitate recycling of rigid PVC without changing the level of risk due to low expected emissions (particularly in articles where the recycled part is encapsulated, for example by virgin PVC, or otherwise prevented from coming into contact with people and/or water, etc.).

Following the public consultation, RAC agrees with the clarification of the derogated list of article types provided by the Dossier Submitter (including the addition of a small number of further article types to the list on the basis of limited risk).

RAC agrees that the derogation for PVC silica separators in batteries is appropriate in view of the low risk and lack of suitable alternatives.

The derogation of second-hand articles and articles subject to existing legislation is proportionate. Specifically, regarding the derogation related to RoHS, an exemption request was submitted by industry for electric windows and doors. When these article types contain recyclate stabilised with lead, they are produced by co-extrusion, whereby the recyclate is fully encapsulated by virgin PVC. In consequence, RAC agrees that direct releases from these applications are sufficiently controlled.

RAC does not see any need to adjust the derogation period, since it can be reviewed.

Key elements underpinning the RAC conclusion(s):

In general, inclusion in a polymer matrix appears to limit (though not entirely prevent) the release of lead during service life. Recycling therefore significantly delays releases of lead associated with the end-of-life stage, and spreads service life releases over a longer time frame. Whilst this means that an undesirable substance will continue to circulate in the technosphere for a long time, it is still an effective form of risk management as it contributes to the minimisation of releases.

Conflicting requests were made over the proposed concentration limit during public consultation, due to either concerns about limiting recycling potential (e.g. #1513, #1521, #1547, #1550, #1633) or undesirable 'contamination' of the recycling loop (e.g. #1609 and #1674). In particular, RAC notes that a limit of 0.01 % (w/w) for virgin PVC has been in place in Denmark since 2000 (and a concentration of 0.02 % has been recommended for mini-blinds in the USA), suggesting that a limit below 0.1 % is technically feasible. However, whilst a lower limit may reduce risks further, the actual additional amount of risk reduction has not been assessed and the Dossier Submitter has pointed out that it would not change the effectiveness of the restriction (in terms of preventing use of lead compounds for PVC article manufacture). There may also be enforcement issues (e.g. should more than one analytical technique be needed to reliably measure a lower concentration). RAC does not know if the potential for unintentional contamination is a relevant issue, since Industry has not commented on the feasibility of a lower concentration limit. RAC notes that this issue will be addressed with a specific question in the second SEAC public consultation.

Regarding derogated articles, Industry requested that the concentration limit was increased to 2 % w/w, to avoid placing constraints on the amount of recyclate that could be re-used and avoid additional analysis and mixing. The Dossier Submitter points out that from the data provided it seems that recyclate from flexible (soft) PVC typically has lead contents below 1 % w/w. Recyclate originating from rigid PVC generally has higher concentrations and in some cases may exceed 1 % w/w (up to 2 % w/w). Whilst it is important not to set a limit so high that it allows intentional use of lead stabilisers, Industry (comment #1633) highlighted that to be sure of compliance at all times with a 1 % w/w limit without having to measure lead content at an impractical frequency and allowing for a large inventory of high/low lead content PVC for subsequent mixing, converters/recyclers would need an appropriate margin to take account of the variability of lead concentrations in the input stream.

Since the average lead concentration in recyclate appears to be around 1 % w/w and the standard deviation is around 0.5 % w/w, a limit of 2 % w/w would allow practical compliance with a notional 1 % w/w limit 95 % of the time. RAC considers that the allowable concentration limit in derogated articles could be greater than the 1 %w/w limit initially proposed by the Dosser Submitter in rigid PVC without substantially affecting the risk reduction potential of the restriction, particularly in cases where there is little potential for

release (e.g. where recycled PVC is completely encapsulated or used in articles that do not come into contact with people, light or water).

Counter-intuitively, a lower concentration limit in recycled PVC articles is likely to increase overall releases of lead from PVC and therefore risk. This is because a lower limit is likely to result in a larger portion of the end-of-life PVC articles (waste arising) being directed to the end-of-life disposal route associated with the greatest release to the environment (i.e. incineration) rather than being recycled. Indeed, the Dossier Submitter estimated that for each tonne of material that is not recycled there would be an average increase in lead releases of around 40 g (provided the current mix of disposal routes is maintained). The concentration limit does not need to be relaxed for applications involving flexible (soft) PVC.

Overall, RAC considers that the Dossier Submitter's proposal for the concentration limit for rigid PVC (1 % w/w) should be modified (to 2 % w/w) to minimise the amount of lead-containing PVC that is diverted to waste disposal rather than being recycled. Whilst it is very difficult to reliably estimate the volume of PVC involved, a limit of 2 % w/w for rigid PVC will maximise the quantity of lead that can be retained within article types that have a low potential for release during service life.

Requests for additional derogations were submitted during public consultation based on release estimates prepared by industry (see exposure section). One comment (#1553) also suggested that specifying a 'positive' list of derogated articles will hinder the development of recycling markets, and therefore only a 'negative list' should be established to exclude applications where it is believed that the use of recycle is inappropriate. RAC suggests that a positive list would provide greater clarity for both industry and enforcement authorities.

Ideally, the derogation list would be based on the likelihood of low indirect and direct exposure. However, as noted in the risk characterisation section above, it is very difficult for RAC to specifically rank risks from different article types, and no explicit criteria have been proposed. The critical issue is to avoid the presence of lead in external layers of any article types to which children can reasonably be exposed (e.g. interior surfaces). In principle many types of article that could be produced from PVC recycle could be suitable for derogation if the recycled PVC is not used in the external layer (including articles made from soft PVC that are exposed to water and light). **Therefore RAC considers that most article types currently produced using recycle could be derogated with suitable caveats relating to encapsulation**. If industry believes that additional article types should be derogated in future, they should be able to submit evidence to the Commission to justify their case.

The original derogation proposal was based on an existing restriction entry for cadmium, on the assumption that Industry and enforcers have developed experience with its application. The Dossier Submitter subsequently suggested to amend the list of derogated articles to provide some further clarification for article types made with rigid PVC. In particular, to minimise risks arising from direct human exposure. Specifically, the original proposal to derogate interior shutters and blinds was deleted and the derogation for doors, windows and interior walls was caveated by specifying enclosure within a layer of virgin PVC (expanded to also include exterior decking or terrace). RAC agrees with this approach.

Derogation of monolayer pipes that are used below ground to connect water systems in buildings to public sewerage networks or in technical applications (e.g. ground stability) might pose a low risk too (since the potential for direct human exposure is low). However, since

contact with wet soil might potentially lead to diffuse release from the outside of the pipe, RAC suggests that further information should be provided about the technical (in)feasibility of co-extrusion for such applications (as can be done for other types of pipe) to justify a potential derogation.

Articles made from flexible (soft) PVC tend to have somewhat higher release factors than rigid PVC. The relevance of this to risk depends on the amounts of PVC involved as well as whether the release is based on worst- or best-case assumptions. In principle, RAC considers that outdoor articles made from soft PVC (e.g. for roofing/waterproofing, road furniture and traffic management articles, and professional footwear) may contribute disproportionately to service life emissions (overall service life releases from road furniture are likely to be of a similar order of magnitude to roof tiles, so in theory pose a similar level of risk). Derogation of flexible PVC articles used outdoors is therefore only acceptable if the lead-containing recyclate layer is encapsulated (assuming this is technically feasible).

If it is proven that for some applications encapsulation is not technically feasible, it also needs to be examined if the soft PVC material currently used in these applications could be diverted and used in soft PVC applications with less potential for service life releases instead. That way releases would be controlled without diversion of PVC material to end-of-life disposal.

Some other applications of soft PVC (e.g. mats for stable and greenhouse uses, multi-layer hoses, noise insulation sheets) do not appear to result in significant direct or indirect human exposure during their service life, so could be derogated without encapsulation. In principle, mats for both soil stabilisation and industrial settings could also be derogated. However, similar to the use of monolayer pipes for ground stabilisation, use of mats for soil stabilisation could in theory lead to diffuse releases from contact with wet soil, so the technical (in)feasibility of encapsulation should be explored before derogation is granted. In addition, neither use was included in the latest cost-effectiveness calculations from industry so it is unclear if they are still relevant.

In addition, there is no explicit proposal from the Dossier Submitter to derogate several other article types requested by industry (examples include "other" rigid PVC applications such as "wall and stable equipment", "honeycombed thermoformed films for cooling towers", "drainage elements", and brooms). In this respect, RAC can foresee ambiguity arising for Industry and enforcers without further guidance about whether these are included in the proposed derogations. Since the uses involve rigid PVC, RAC considers that they could be derogated in line with the considerations on encapsulation mentioned above.

Some comments received during public consultation requested longer (e.g. #1513) or shorter (e.g. #1662) time periods for derogated uses to continue. From a risk perspective, the length of the derogation period is not particularly important. It provides a target for phase out for industry and can be reviewed at any time to see if the assumptions remain valid. The Dossier Submitter has proposed 15 years as an appropriate length for the derogation, as the concentration of lead in articles containing recyclate is forecast to have reduced substantially over this period (estimated to be 40 % lower for window frames compared to current concentrations, as presented in the Background Document).

Any change in lead concentrations may not be detectable statistically within a shorter time period. Equally, a period longer than 15 years would also be inappropriate given the uncertainty in the release estimates. It is therefore advisable to re-assess the concentration of lead in PVC waste in the future in order to determine if the derogation is still needed or

whether it ought to be modified. A possible modification in the future could be to progressively reduce the concentration limit in the derogation in response to reductions in the lead concentration in PVC recyclate. RAC agrees with the Dossier Submitter that a 15 year derogation is a reasonable compromise between achieving a progressive reduction of lead concentrations in PVC recyclate and uncertainty.

Justification for the opinion of SEAC

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

By delaying the disposal of lead-containing PVC articles as waste – which is the life cycle stage at which the majority of the environmental emissions are expected to occur – the restriction will minimise the risks (since it is a form of containment).

The European industry has made significant progress to find suitable replacements for lead-based stabilisers in PVC. Calcium-based systems (generally fatty acid salts, sometimes also containing zinc and incorporating a range of co-formulants such as phenolic antioxidants) are the most common replacement in rigid PVC, and are used at concentrations of approximately 3.5 % (w/w). The Dossier Submitter's analysis focusses exclusively on these. Although other substances are mentioned (e.g. tin compounds and liquid mixed-metal systems based on barium, zinc, calcium, magnesium or potassium carboxylates), they are not considered to be relevant substitutes for lead in the PVC articles addressed by the restriction (e.g. liquid mixed metals are mainly used for semi-rigid and flexible applications; some dibutyl tin stabilisers are also subject to partial EU restriction already, although this does not preclude their use entirely).

The Dossier Submitter concludes that calcium-based stabilisers have a much lower hazard profile (non-classified) than the lead compounds used as PVC stabilisers, and consequently they present a much lower risk.

RAC conclusion(s):

RAC agrees that the proposal, with modifications, is the most effective way of reducing risks from lead in PVC articles.

RAC agrees that the most common substitutes (calcium-based systems) pose a much lower

level of hazard and risk than lead compounds. RAC notes that some of the co-formulants present in calcium-based systems (specifically phenolic anti-oxidants) might be subject to regulatory scrutiny, but this cannot be confirmed as information on substance identity is lacking. In addition, RAC cannot evaluate the relative risk that some other potential alternatives (containing other heavy metals) may present due to lack of information about their actual relevance.

Key elements underpinning the RAC conclusion(s):

As noted above, the risks to human health from lead contained in PVC are not negligible, but on the other hand are likely to be rather low in comparison with other sources. The restriction may create a perception that risks are being "prolonged" because a hazardous substance will be allowed to remain in circulation in some article types over a long time period. However, RAC agrees with the Dossier Submitter that containment of lead in articles that have a low potential for release during their service life is the best risk management option available.

Although there will be ongoing service-life emissions from many derogated articles that contain lead-containing recycled PVC, RAC agrees that the restriction is the most effective risk management measure. The restriction is about reducing risk – it is not explicitly linked to facilitating the circular economy. Given the generally low risk posed by PVC articles containing lead, the restriction should be designed so as not to prevent effective recycling.

RAC notes that calcium-based systems are the most likely replacement for lead compounds in rigid PVC applications. In principle, RAC agrees that since they are not classified as hazardous for human health or the environment, they are of much lower hazard than lead. As their concentration in PVC is similar to lead compounds, human health risks in particular will be lower. However, it is not clear whether different substances are actually used in other PVC applications subject to the restriction (particularly if manufactured outside the EU), especially as the Annex XV report says that calcium-based systems are "most commonly used" in rigid PVC (implying that other substances are in fact in use, both in rigid and flexible PVC). Some of the other substances contain heavy metals like tin, but RAC cannot assess the relative risk in the absence of relevant information in the Annex XV report.

In addition, the identity of the phenolic antioxidants that are co-formulants in calcium-based systems is not provided, but RAC notes that several phenolic substances are currently under assessment as potential endocrine disrupters or PBT substances.

Comment #1610 received during public consultation explains why substitution of lead compounds in separators for lead-acid batteries is difficult. The battery environment is aggressive, corrosive and oxidative so alternatives developed for other PVC articles are not appropriate. The use of lead introduces no new elements (especially metallic impurities) in the battery, which could otherwise affect the functioning of the battery in an unpredictable way.

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Benefits

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Other impacts

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Overall proportionality

Summary of proposal:

See the opinion of SEAC.

RAC and SEAC conclusion(s):

Although direct and indirect human health risks are relatively low compared to other sources of lead, the European industry has already stopped using lead stabilisers to make PVC articles. The restriction will prevent imports from adding further lead to the European environment, so is proportional provided that recycling is facilitated for existing articles containing lead.

Key elements underpinning the RAC and SEAC conclusion(s):

N/A

Uncertainties in the proportionality section

See the opinion of SEAC.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter concludes that the proposed restriction is practical because it is implementable, enforceable and manageable.

As demonstrated in Section E.2 of the Background Document, the replacement of lead-based systems in PVC applications with alternative lead-free stabilisers seems to be economically and technically feasible. Switching to lead-free stabilisers (e.g. calcium-based systems) does not require major changes in production techniques, machinery, or training of staff. Thus, the proposed restriction option is considered to be implementable and manageable for all parties affected.

To be enforceable, a restriction needs to have a clear scope so that it is obvious to enforcement authorities which products are within the scope of the restriction and which are not. Moreover, the restriction needs a concentration limit value that can be subject to compliance checking (either by enforcement authorities or internal company monitoring and audit trails). The scope of the proposed restriction is clear and unambiguous and covers all the uses (consumer and professional) of lead compounds as stabilisers in PVC (see E.7.2.1 of the dossier).

To be implementable within a reasonable time frame, the appropriate analytical methods should be available and is practical for enforcement authorities. The proposed restriction has been structured to meet all of the above requirements.

RAC and SEAC conclusion(s):

RAC concludes that the proposed restriction is practical and enforceable provided that labelling is done appropriately. If the scope is limited to the use of lead as a stabiliser (which was the original intention of the Dossier Submitter) then enforcement authorities must be confident about the function of any lead detected in an article. This may require some additional measures, such as provision of supply chain information on the function provided by the lead compounds present in the PVC. Otherwise this restriction could be difficult to enforce. It is therefore simpler not to specify the use, provided that existing authorised uses of lead compounds are derogated.

Key elements underpinning the RAC and SEAC conclusion(s):

As the restriction applies only to final articles placed on the market and the long-term goal is to allow the recycling of PVC, it is essential that both users and enforcers can clearly distinguish those PVC articles containing recyclate with lead from those that are effectively "lead-free". This will make recycling and enforcement easier. On the other hand, this is complicated by the fact that lead can be added to PVC for reasons other than as a stabiliser (e.g. in pigments). The burden of proof is on the actor who places the article on the market (especially if the use is authorised), but to aid the enforcement authorities, this information has to be readily available. In the case of lead pigments, the colour of the PVC should act as a guide (white PVC will not contain any pigment).

Enforcement may be more challenging for imported articles. Recycled PVC should be properly labelled for all the derogated article types (other types cannot be made with lead so do not need a label). Otherwise it will be difficult to determine if an article contains recycled PVC or not. The Dossier Submitter made their original proposal based on an existing restriction entry for cadmium, which also referred to a pictogram. However, the pictogram actually indicated "contains PVC", and so they are in favour of deleting this from the new restriction text. RAC has no objection to this. However, as more PVC made without lead enters the technosphere, an increasing amount of recyclate can be expected to have lead levels below the proposed limit for virgin PVC. A label that only states "contains recycled PVC" is therefore not sufficient by itself to differentiate between lead-free recyclate and recyclate containing lead.

The existence and promotion of a label that would explicitly specify the presence of lead in PVC may theoretically incite recyclers to create such a 'clean' recycling loop in the long-term (and was a suggestion made during public consultation (comment #1524)). The Forum for Enforcement was asked for a view on this matter. They suggested that a concentration value on the label could be useful for enforcement purposes, provided it also indicated whether recyclate was present (so for example "Containing Recycled PVC – less than X % lead"). The Forum suggested that mixtures made from recyclate (which are not subject to the restriction) could also be labelled to aid traceability. The Dossier Submitter has not assessed the practicality of including this extra component to the labelling.

The proposed concentration limit for lead in the derogation applies to the whole article (including any part that can be readily separated). The Forum commented that sample preparation could be complicated for composite (co-extruded) articles where the location of recycled PVC is not clear. In general, it is expected that co-extruded articles (e.g. pipes for non-drinking water) will have a lead-containing PVC layer entirely encapsulated within (and fused with) a layer of virgin PVC, so will not be separable in practice. In this situation, the limit applies to the whole article, so the recycled layer can have a lead content that exceeds the concentration limit provided that the final concentration in the whole article is below the limit.

The wording of the restriction should clearly indicate that any virgin PVC material in a composite article must comply with the lower concentration limit (0.1 % w/w). The Dossier Submitter has indicated that it was their intention that all types of derogated articles containing both recycled and virgin PVC should follow the same principle (to avoid a loophole whereby inclusion of a small amount of recyclate allows an article to comply with the higher limit), although this may limit the use of recyclate for some product types where the risk is low without encapsulation (e.g. fittings contained with the fabric of a building that are not

exposed to weathering, abrasion, etc.).

The Dossier Submitter suggests that producers of PVC articles should clearly indicate the percentage of recycled PVC in their products (as well as where in the article the recycled PVC is used, e.g. in case of multi-layered or co-extruded PVC articles), although this is not part of the restriction text itself. The Forum for Enforcement noted that there is no information to explain how the producer would do this, and that including such an obligation would be difficult to enforce. However, the Forum notes that it may be helpful to specify a limit on the amount of recycled PVC that can be used in articles. In addition, there may be a need for quality standards to provide assurance that encapsulation (where used) remains intact for the lifetime of the product.

Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter anticipated that monitoring of the proposed restriction will be done through enforcement. To follow up this restriction the Dossier Submitter suggests to monitor the evolution of the fraction of PVC articles with a lead content above the proposed limit, i.e. the percentage of non-compliant articles over time.

Monitoring of blood lead levels in children to see if the exposure decreases following the restriction is discussed. However, current blood lead levels are the result of many different routes of exposure, and it might be difficult to attribute changes in blood lead levels to this specific restriction in PVC articles.

RAC and SEAC conclusion(s):

RAC concludes that compliance with the restriction appears to be monitorable in general, although additional practical advice may need to be issued to enforcement authorities for composite articles. Its risk reduction effect is not monitorable directly by monitoring blood levels in the general population. The reason for this is that current blood lead levels are the result of many different routes of exposure, and that PVC is likely to be a relatively minor source of exposure to lead compared to other sources.

Key elements underpinning the RAC and SEAC conclusion(s):

The Forum for Enforcement has indicated that suitable standard analytical methods are available for the determination of lead (ICP, AAS, XRF). Handheld XRF is widely available for the specific purpose of non-destructive measurement of lead at the 0.1 % threshold for RoHS compliance (comment #1609). The Forum also notes that it may be necessary to confirm the presence of PVC (e.g. by XRF, for chlorine content).

Regarding the proposed addition of a derogation for authorised use of lead pigments, comments submitted by industry following closure of the public consultation process[6] indicate that PVC containing lead pigments will be coloured, in which case the best evaluation techniques are metal analysis using atomic absorption or inductively coupled plasma to assess the ratio of lead:chromium or lead:chromium:molybdenum. The practicalities of these

[6] Personal communication to ECHA.

techniques have not been described.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

The assessment is based on a large number of assumptions, including the non-threshold nature of the hazard, the quantities of lead in PVC articles currently on the market (especially from imports) and release factors for various stages of the life cycle (this has been accounted for using Monte Carlo analysis). In addition, environmental risks are not addressed.

RAC conclusion(s):

RAC considers that the uncertainties have been adequately assessed by the Dossier Submitter, and do not affect the justification for the restriction.

Key elements underpinning the RAC conclusion(s):

N/A

SEAC

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.