

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]

Agreed

30 November 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 agreed by SEAC 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)

¹ Delete the unnecessary part(s)

and]³ 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.

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Brief description: Restriction of lead 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) and a 10-year derogation for PVC silica separators in lead acid batteries.

Lead compounds	<ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> (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: <ul style="list-style-type: none"> - 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. <p>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: <i>'Contains recycled PVC'</i> or with the following pictogram: (same as for entry 23...)</p> (b) PVC-silica separators in lead acid batteries for a period of 10 years from entry into force. (c) Articles that can be placed covered by paragraph 7 of Entry 63 of Annex XVII. (d) Articles covered under existing legislation: <ul style="list-style-type: none"> - 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.
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	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).
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THE OPINION OF RAC

See the opinion of RAC.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction proposed by the Dossier Submitter on lead stabilisers in PVC articles is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs, provided that the conditions are modified, as proposed by RAC and SEAC.

The conditions of the restriction proposed by RAC and SEAC are:

Substance Identity (or group identity)	Conditions of the restriction
<p>– Lead compounds</p>	<ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> (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: <ul style="list-style-type: none"> - profiles and sheets for exterior applications in buildings and non-buildings. (or example, gutters, fascias, shutters, blinds and wall cladding); - decks and terraces provided the 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 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, flanges for pipes, furniture, coachwork, etc). <p>All virgin PVC used in combination with recyclate in the above applications shall comply with paragraph 2.</p> <p>Suppliers shall ensure before the first placing on the market of mixtures and articles specified above and</p>

	<p>containing recycled PVC that these are visibly, legibly and indelibly marked as follows: '<i>Contains recycled PVC</i>'.</p> <p>(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:</p> <ul style="list-style-type: none"> - mats for stables and greenhouses; - multi-layer hoses; - noise insulation sheets; - the following applications provided the recycled PVC is entirely enclosed with a layer of virgin PVC: roofing and waterproofing, road furniture, traffic management systems and professional footwear. <p>All virgin PVC used in combination with recyclate in the above applications shall comply with paragraph 2.</p> <p>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: '<i>Contains recycled PVC</i>'.</p> <p>(c) PVC-silica separators in lead acid batteries for a period of 10 years from entry into force.</p> <p>(d) Articles covered by paragraph 7 of Entry 63 of Annex XVII.</p> <p>(e) Articles covered under existing legislation:</p> <ul style="list-style-type: none"> - 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. <p>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).</p> <p>6. By way of derogation, paragraphs 1 and 2 shall not apply to the use of the following pigments :</p> <ul style="list-style-type: none"> • Lead sulfochromate yellow
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	<ul style="list-style-type: none">• Lead chromate molybdate sulfate red
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RAC proposed various changes to the wording during the opinion making in co-operation with the Dossier Submitter and SEAC. These were mainly in relation to the proposed derogation for the use of recycled PVC in articles, as follows:

1. The list of articles was modified to explicitly separate rigid uses of recycled PVC from flexible uses. This was because the initial list was based on rigid PVC only.
2. The article types listed in the derogation were further refined to reflect the potential of different articles to result in human exposure during their subsequent service lives, both indirect (via the environment) and direct (through the potential to form dusts mediated through polymer degradation and abrasion). As such, article types used for the external parts of building and non-building structures were separated from article types used in the occupied parts of buildings. "Occupied" is interpreted to mean any part of a building that is intended to be occupied by humans, e.g. residential, commercial, industrial, etc. Non-building structures include bridges, dams, industrial, etc., that are not specifically designed for occupancy as such, but which could use PVC materials in their construction.
3. Use of mono-extruded recycled PVC articles (e.g. cable ducts) was derogated, but only within the concealed spaces (voids) of buildings as there is limited potential for dust formation or contact with sensitive populations (e.g. children). Examples include joist or truss spaces that are part of floor-ceiling assemblies; spaces above suspended ceilings; spaces inside stud walls; crawl spaces; vertical chases between floors for pipes, ducts and mechanical systems. Areas that are occupied or used for storage would not be considered to be concealed spaces.
4. Fittings for a number of specified applications were derogated as it was assumed that these have limited potential for human exposure during their service life as they are either not accessible to users under normal conditions of use (e.g. if they are present in internal parts of a more complex article) and/or these are small articles compared to the main article they are attached to (pipes, furniture, coachwork etc.), implying a limited potential for exposure. These article types are listed on EU databases².
5. The use of rigid PVC articles produced using recycled PVC were derogated for use in occupied buildings but only where these were produced using a co-extrusion process with all 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 windows and other PVC profiles is already widely practiced by industry.
6. Similarly, on the basis of comments submitted by industry during the public consultation, various uses of articles produced using recycled flexible PVC have been included in the proposed derogation. However, as these uses result in greater potential for leaching to the environment than rigid articles, RAC considers that some of the uses of flexible PVC recyclate should be in a co-extruded article, with virgin PVC encapsulating the recycled PVC to prevent leaching during article service life.

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

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

Information on hazard(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Information on emissions and exposures

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Characterisation of risk(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Uncertainties in the risk characterisation:

See the opinion of RAC.

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of RAC and SEAC

Summary of proposal:

This restriction proposal on lead stabilisers in PVC mainly targets articles used for building and construction applications such as window and door profiles; tubes, pipes and hoses; Floor coverings in rolls or tiles; shutters and blinds; fittings for furniture; cables and others. These types of articles, mainly made of rigid PVC, cover the large majority (more than 70%) of all PVC uses.

The proposal is aimed at reducing human exposure to lead from the use of lead-based stabilisers in PVC. Human exposure to lead from this use can occur through direct and particularly through indirect (exposure via the environment) routes of exposure. EFSA (2010) concluded that there is no scientific evidence for a threshold for developmental neurotoxic effects in children as well as for renal effects in adults.

The use of lead-based stabilisers in PVC has been phased out in the EU due to a voluntary industry agreement. However, an increasing trend in imports of PVC articles, which still may contain lead-based stabilisers, has been observed (see Table A1 in the Annex).

PVC articles containing lead-based stabilisers are placed on the market in all EU member states. EU-wide action ensures the protection of all EU citizens from lead exposure resulting from the use of lead-based stabilisers in PVC articles, while creating a level playing field for industry inside and outside the EU supplying the EU market.

RAC and SEAC 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 lead and its compounds in PVC should be implemented in all MS.

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

SEAC notes that the assessment of the Dossier Submitter indicates that lead-based stabilisers are mainly used in imported PVC articles, which are placed on the market in all EU Member States. Therefore, it can be expected that lead emissions from these articles contribute to human exposure across the EU. Hence, Union-wide risk management measures should be taken to ensure a level playing field for industry in all Member States.

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

Justification for the opinion of RAC and SEAC

In addition to the proposed restriction, the Dossier Submitter analysed the appropriateness of other risk management options to address the identified risk, including legislative and non-legislative measures. Specifically, authorisation under REACH, Art. 68(2) of REACH, other EU directives (product safety legislation, Waste Framework Directive, Water Framework Directive, CLP Regulation, Construction Products Regulation), taxation, labelling instruments, voluntary agreements or information campaigns to consumers were examined. The Dossier Submitter concluded that none of these options are appropriate to address exposure to lead from the use of lead-based stabilisers in PVC, either because they are not as effective (e.g. because not all relevant articles or life-cycle stages would be covered) or as practical (e.g. because of lack of enforceability in the case of voluntary instruments) as a restriction under REACH. SEAC agrees with the arguments given by the Dossier Submitter and considers that the options that have been assessed are likely to be less appropriate than a restriction under REACH.

Besides the proposed restriction (option 1), the Dossier Submitter has assessed two alternative restriction options: a restriction without any derogations (option 2) and a restriction with a higher concentration limit in the range between 0.1 to 0.5 % (w/w) and no derogation for recycled PVC (option 3). These options are discarded by the Dossier Submitter, because they were considered to be less proportionate than the proposed restriction due to negative impacts on industry and society at large mainly resulting from the constraints for PVC recycling (option 2 and 3). Moreover, a concentration limit up to 0.5% would be very close to the lead content that might result from the intentional use of lead-based stabilisers in PVC (e.g. 0.5 % can be used in pipes), which would complicate the enforceability of the restriction (option 3). Option 2 also could lead to difficulties for enforcement due to double-regulation, because other regulations on lead in PVC would not be exempted.

SEAC concurs with the conclusion of the Dossier Submitter that these two additional restriction options are less appropriate than the proposal. Based on the data provided by the Dossier Submitter and received in the Public Consultation, SEAC concludes that with no derogation for recycled PVC both options would result in greater costs to society without providing significantly greater risk reduction (see the assessment of the impacts on the recycling of PVC below). With regard to the concentration limit, SEAC notes that no information was provided in the Background Document or received in the Public Consultation indicating that a higher concentration limit than 0.1 % would be easier for industry to comply with. The consideration of other possible options, e.g. including a lower concentration limit as proposed in the Public Consultation (#1674), could have strengthened the RMO analysis.

However, the analysis conducted has provided sufficient justification for SEAC to agree that the proposed restriction is an appropriate EU-wide measure to address the risk from the use of lead-based stabilisers in PVC.

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Justification for the opinion of SEAC

Summary of proposal:

The Dossier Submitter proposed a restriction on lead and its compounds in all (except for the derogated) PVC articles with a concentration limit of 0.1% (w/w) for lead and a transitional period of 24 months. The restriction is expected to mainly affect imported PVC articles in building and construction applications, because lead-based stabilisers have been phased out in the EU due to a voluntary industry agreement. During the opinion making the Dossier Submitter clarified that the proposal refers to the use of lead-based stabilisers and not to other uses of lead in PVC. Derogations are proposed for:

- recycled PVC:
 - Specific PVC articles (in building and construction applications) containing rigid recycled PVC with a concentration limit of 2.0% for a period of 15 years
 - Specific PVC articles (mainly in building and construction applications) containing soft recycled PVC with a concentration limit of 1.0% for a period of 15 years
- PVC-silica separators in lead acid batteries for a period of 10 years
- Articles covered under existing EU legislation
- Second-hand articles
- Lead pigments in PVC (added to clarify that the Dossier Submitter's assessment was only intended to cover the use of lead and its compounds as stabilisers in PVC)

A **concentration limit** of 0.1 % (w/w) is expected to effectively prevent the intentional use of lead-based stabilisers in PVC, because a minimum concentration of 0.5 % of lead (w/w) is needed to achieve the required technical function (UV- and heat stability of the PVC material during production and service life).

A **transition period** of 24 months is considered to be sufficient to allow depleting existing stocks and to ensure that relevant information on the restriction can be efficiently communicated within the supply chains.

According to the Dossier Submitter, a restriction with a concentration limit of 0.1 % lead in PVC would significantly constrain the **recycling of post-consumer PVC waste** (i.e. the waste arising at the end of the service life of PVC articles). Currently, more than 500 000 tonnes of PVC waste are recycled, of which approximately 60 % (350 000 tonnes) concerns rigid PVC applications (e.g. window frames, fitting and pipes). It is expected that by 2020 (the likely year of entry into force of the proposed restriction) the volume of PVC waste to be recycled will rise to 800 000 tonnes. In order to comply with a concentration limit of 0.1% (w/w), recycling companies would only be able to use a small fraction of post-consumer PVC waste in the production of new PVC articles. This is because, post-consumer PVC waste typically contains lead at concentrations above 0.1 %. Usually the lead concentration ranges between 0 and 2 % depending on the PVC type (rigid or soft) and the use of lead in the original PVC material. The restriction without the derogation for recycling would limit the capacity to use post-consumer PVC waste, which in turn could render recycling not economically viable due to the extra costs of co-processing recycled and virgin PVC. At worst case, a limit of 0.1 % of lead could effectively end the recycling of post-consumer PVC waste in the EU (a detailed assessment of the impacts on PVC recycling is given by the Document Submitter in the Background). Accordingly, the Dossier Submitter expects the following socio-economic impacts, if the recycling of post-consumer PVC waste in rigid PVC applications would cease:

- releases of lead to the environment due to the disposal (incineration and landfilling) of PVC waste of about 23 t per year;
- additional disposal costs of about €60 million per year for the incineration and landfill of PVC waste that would not be recycled from 2020 onwards;
- increase in the price of PVC articles due to a higher price of virgin PVC (the Dossier Submitter used a PVC window as an exemplary item to illustrate the potential price increase compared to current prices).

According to the Dossier Submitter, it can be expected that the restriction would result in the closure of most of the PVC-recycling companies in the EU, entailing job losses and value added forgone in the PVC recycling and conversion sectors. These impacts have not been assessed quantitatively by the Dossier Submitter. Industry has confirmed in their comments in the Public Consultation that there would be a significant negative socio-economic impact from including recycling of PVC into the scope of the proposed restriction.

In order to avoid these negative impacts and to allow the recycling of post-consumer PVC waste to continue, the Dossier Submitter originally proposed a concentration limit of 1 % (w/w) for certain types of articles used in building and construction applications containing recycled PVC and proposed a labelling requirement for such articles in order to be identifiable. When defining the articles, for which a derogation was considered to be justified, it was the intention of the Dossier Submitter to allow for the recycling of post-consumer PVC waste while keeping human exposure to lead as low as possible. The initial list of articles proposed by the Dossier Submitter was mainly based on the existing restriction of cadmium stabilisers in PVC (entry 23, Annex XVII of the REACH regulation). During the Public Consultation several comments from industry were received indicating that this list did not include all eligible articles and requesting an extension of the derogation in the form of a non-exhaustive list of articles (#1521, #1550, #1633). According to industry a number of applications using soft PVC (traffic management, roofing, mats, 3-layer hoses, noise insulation sheets, footwear and boots for professionals) and one rigid application (monolayer pipes) should be added to the derogation as originally proposed by the Dossier Submitter. To underpin this request, industry provided information on the PVC article types concerned, related volumes and emissions as well as on the economic impact of their inclusion in the proposed restriction (#1633). They assumed that the total annual volume, which is currently recycled and used for the requested derogations (approximately 150 000 tonnes), will be replaced by virgin PVC and that the lead-containing PVC that industry would no longer be able to use would be incinerated or landfilled. Based on these estimated cost and estimates of releases per application the cost-effectiveness was assessed and compared with the cost-effectiveness estimates of the original proposal. Taking into account the information from industry, RAC and the Dossier Submitter have reassessed and changed the list of derogated articles (see further discussion below).

The concentration limit of 1 % (w/w) originally proposed by the Dossier Submitter was based on a projection of lead concentrations in the PVC waste stream and in different articles containing recycled PVC based on modelling the material flow (Tauw, 2013). During the Public Consultation, industry commented that a limit of 1 % would be too low to allow current recycling activities and that a limit of 2 % would be necessary to ensure the use of post-consumer PVC without any limitation imposed by the proposed restriction.

During the opinion development, the Dossier Submitter has confirmed that virgin PVC, which is used together with recyclate in the production of exempted PVC articles, shall comply with the limit of 0.1 %. This has been reflected in the revised proposal for the entry text.

In addition, The Dossier Submitter proposed that the derogation for recycled PVC shall be limited to a period of 15 years, based on an assessment of the projected concentration of lead in recycled PVC from 2020 to 2050 (also given by Tauw, 2013). Accordingly, the Dossier Submitter expects that after 2035 to 2040, the lead content of PVC waste would have decreased sufficiently to allow articles made with recycled PVC to comply with the proposed concentration limit for all PVC articles of 0.1 % (w/w) of lead. In order to account for the uncertainty in the available data on trends of the quantities of post-consumer PVC waste going to recycling and the lead content in post-consumer PVC waste, the Dossier Submitter recommends that the derogation is reviewed after 10 years from entry into force. The time limit of 15 years has also been challenged by industry in the Public Consultation as being too short. Industry indicated that lead is likely to be present in the material loop in concentrations above 0.1 % over a longer time period than expected by the Dossier Submitter considering the long service life of the relevant articles (e.g. 40 years for window profiles).

In addition, the Dossier Submitter proposed a derogation for **PVC-silica separators** used in lead-acid batteries. Information was submitted in ECHA's call for evidence by a European company claiming that the effect of a potential restriction on lead would impact the manufacture of microporous PVC separators in lead-acid based batteries due to a lack of technically feasible alternatives. This company (an SME) is the only European company that uses a lead stabiliser (tetralead trioxide sulphate) for producing these PVC-silica separators and indicated that it would need a period of approximately 10 years to replace the use of a lead-based stabiliser in the PVC used in the separators. The annual volume currently used has been communicated to ECHA, but was claimed as confidential. During the Public Consultation the company submitted further information on their R&D activities on different alternatives, the timeframe of the steps needed to substitute lead in the PVC separators as well as on the end of life of the PVC separators (#1610).

Furthermore, **articles already covered by other EU legislation** are proposed by the Dossier Submitter to be exempted from the restriction to avoid inconsistent and double regulation. These articles include food contact materials, electrical and electronic equipment, toys, packaging material and mouthable articles (covered by current restrictions under REACH).

Second-hand PVC articles containing lead-based stabilisers are also proposed by the Dossier Submitter to be excluded from the scope of the proposed restriction. This was justified by the Dossier Submitter on the basis that it would simplify the enforcement of the proposal, as inspection activities concerning the second-hand market are not easy to undertake by authorities. It was considered by the Dossier Submitter that the additional costs for carrying out inspections would not be proportionate to the risk reduction achieved.

During the opinion development, the Dossier Submitter specified that the restriction covers only lead substances used as stabilisers but not **lead compounds used as pigments**. To reflect this intention in the opinion text, the Dossier Submitter added a derogation for the use of lead sulfochromate yellow and lead chromate molybdate sulfate red in PVC.

SEAC conclusion(s):

SEAC concludes that the proposed scope is appropriate to achieve the aim of limiting the risks from lead used as lead-based stabilisers in PVC. In this respect, SEAC agrees that the derogations proposed by the Dossier Submitter improve the clarity and the proportionality of the restriction by keeping negative impacts on industry to a minimum, whilst still preventing the intentional use of lead-based stabilisers in PVC.

SEAC finds the derogation of recycled PVC to be appropriate taking into account that the recycling of PVC will postpone lead emissions, the articles to be derogated will have a very low potential to contribute to human exposure, and the available information on the socio-economic impact of limiting the recycling of PVC waste.

SEAC points out that the use of lead pigments in PVC also contributes to overall lead emissions, which may reduce the effectiveness of the proposed restriction in terms of reduction of total lead emissions from PVC. However, SEAC notes that the Dossier Submitter included this derogation to ensure that the wording of the proposal reflected the scope of its assessment (and the original request of the Commission to prepare the Annex XV dossier on the use of lead in PVC as stabilisers). Accordingly, the overall impact of the derogation is out of the scope of the restriction proposal evaluation, and thus not assessed by SEAC.

Key elements underpinning the SEAC conclusion(s):

The restriction proposal is targeted at reducing human exposure to lead compounds used as stabilisers in PVC articles. According to the Dossier Submitter, the restriction mainly (but not exclusively) addresses indirect exposure to humans via the environment. Overall, SEAC agrees that the proposed **scope** is appropriate to achieve the aim of limiting the risks from lead used as lead-based stabilisers in PVC. Specifically, as it:

- covers all articles made of PVC meaning that all emissions to the environment (except those that occur as a result of the proposed derogations) are addressed.
- sets a limit value of 0.1 % (w/w) of lead (as metal), which will effectively prevent the intentional use of lead-based stabilisers in PVC and will cover all possible lead compounds used as stabilisers.

In the following, the appropriateness of the derogations proposed by the Dossier Submitter are discussed.

Derogation for articles containing recycled PVC

SEAC agrees with the conclusion that a restriction without a derogation for articles containing recycled PVC would hamper the recycling of post-consumer PVC waste. The information presented by the Dossier Submitter and submitted in the Public Consultation shows that

- lead-based stabilisers have been widely used in PVC articles in concentrations between approximately 0.5 and 2.5 % (e.g. 2 % in window profiles)
- post-consumer PVC waste usually contains lead in concentrations above 0.1 % (up to about 2 %)

- new PVC articles can contain high amounts of recycled PVC (e.g. up to 70 % of recyclate in window profiles)
- even though recycling of post-consumer PVC waste is not a closed loop process, waste from a specific article is preferably used as recyclate in the production of the same article, at least in some cases (e.g. waste from window profiles is used in new window profiles)
- PVC articles containing lead often have a long service-life (e.g. typically 40 years for window profiles)

Based on this evidence, SEAC concludes that a concentration limit of 0.1 % would limit the use of post-consumer PVC waste in recycling. Taking into account the conditions of the recycling process and the investment needed to process two types of material (recycled and virgin PVC), SEAC considers it to be possible that the capacity to use PVC recycled from post-consumer waste would be limited to such an extent that it would no longer be profitable (compared to using virgin PVC). As a consequence, overall recycling rates would decline.

In the following, the key elements of the derogation including changes of its scope requested by industry in the Public Consultation are discussed in detail.

Impacts on human health and the environment

SEAC notes that a derogation will not decrease the effectiveness of the proposed restriction, because it will not lead to additional emissions of lead. On the contrary, the recycling of post-consumer PVC waste postpones lead emissions associated with disposal via municipal landfill and incineration, which is the main route of human exposure to lead from PVC articles covered by the restriction (as confirmed by RAC). In this respect, SEAC highlights that the revised wording of the derogation clarifies that for the virgin PVC material used in conjunction with recycled PVC the general concentration limit of 0.1 % applies.

In order to minimise the risks to human health through direct exposure from articles containing recycled PVC, the Dossier Submitter only has proposed articles to be derogated, if they have a low potential for direct exposure. Accordingly, the derogation is not expected to result in higher human exposure. RAC has agreed with this conclusion and considers the derogation to be appropriate in terms of its effect on risk reduction.

SEAC notes that the potential effect of the derogation on the exposure of workers has not been assessed in detail by the Dossier Submitter and RAC.

Furthermore, SEAC considers that PVC recycling is likely to result in less primary energy and raw material consumption as well as lower emissions of greenhouse gases and other air pollutants compared to the use of virgin PVC, although these impacts have not been quantified.

Economic impacts

SEAC considers that the information and the analysis presented by the Dossier Submitter represents an illustration of possible impacts of the proposed restriction on recycling. The assumption of an overall decrease in recycling (and associated impacts to the sector), in the absence of a derogation, is well substantiated. Although, SEAC has limited information to evaluate, if the extent of additional disposal of post-consumer PVC waste and corresponding replacement with virgin PVC is a realistic or rather a worst case scenario, it can be concluded that the impact assessment by the Dossier Submitter indicates the order of magnitude of economic impacts.

SEAC notes that further estimates on the cost of a restriction on PVC recycling related to certain articles, which were not included in the derogation originally proposed by the Dossier Submitter, was submitted by industry in the Public Consultation. SEAC notes that the estimates were partly based on a large number of assumptions and that the uncertainties linked to these assumptions were not transparently documented. For an in-depth evaluation, SEAC would require further justification on how the values were derived (and the inclusion of a sensitivity analysis for the most important parameters).

List of derogated articles

The Dossier Submitter has provided an exhaustive list of articles to be included in the derogation that excludes some types of articles, to which humans are more likely to come into direct contact with, such as flooring. For other types of articles, e.g. pipes, the derogation states that recycled material must be encapsulated within layers of virgin PVC material in order to prevent exposure. In general, SEAC considers that this approach is consistent with the objectives of the restriction proposal.

SEAC notes that some of the article types that were excluded from the derogation are unlikely to be affected by a concentration limit of 0.1 % (w/w), because of i) the lower content of recycled PVC typically used in these types of articles (e.g. 10 % of recycled PVC in flooring) and ii) product safety standards setting lower thresholds for lead that SEAC understands will be applied in the future (e.g. CE mark for flooring, which also imposes a limit of 0.1 % of lead).

SEAC notes that the revised list of derogated articles seems to be clearer and more consistent in terms of the inclusion criteria (high economic impact and low human exposure).

Comments received from industry in the Public Consultation indicated that the list of derogated article types does not cover all articles that are currently made with recycled PVC and which have low inherent potential to contribute to human exposure during their service-life (#1633). Taking into account the assessment by RAC, SEAC considers that the extension of the list of derogated articles will help to ensure that current recycling activities can be retained without major economic losses. According to industry, a non-exhaustive list of articles would be more appropriate to facilitate recycling. SEAC considers a non-exhaustive list as less suitable for the enforcement of the proposal (as confirmed by Forum). Moreover, the scope of the derogation is considered to be sufficiently broad to prevent major economic impacts to the recycling sector.

Concentration limit for articles containing recycled PVC

With regard to the limit value of 1 % (w/w) lead for derogated PVC articles, SEAC notes that the information available does not allow to draw a firm conclusion on the impact of this concentration limit on recycling. SEAC has examined the study by Tauw (2013) on the impact of lead restrictions on the recycling of PVC that the Dossier Submitter used to base their conclusions on. The data in the study indicates that there is a possibility that the lead content of articles containing recycled PVC could be greater than 1% (w/w), if the proportion of recycled PVC in the article is high (e.g. in window profiles) and/or the lead content in the recycled PVC used was high.

Moreover, the proportion of recycled PVC to virgin PVC used in the production of new articles varies depending on article category. From the list of article categories proposed to be derogated by the Dossier Submitter, it can be expected that profiles will have the greatest proportion of recycled PVC (up to 70 % according to information received from industry in the Public Consultation). Concerning the lead content in PVC waste, it is important to take into account that this can vary considerably depending on several factors, including:

- the source: whereas post-consumer waste may contain lead in different concentrations, post-industrial waste (e.g. cut-offs from the production of new PVC articles) is usually free of lead (as it is made of virgin PVC stabilised with alternatives to lead-based stabilisers)
- the article type: Lead stabilisers were used in variable amounts depending on the article type and related production process. Accordingly, profiles (e.g. window frames) may have relatively high lead contents (up to 2 % according to Tauw, 2013), whereas pipes on average contain lead in lower concentrations (< 1%)
- year of production of the specific article: The market share of lead-based stabilisers differed between years and article types. For example lead was mainly used in profiles from the mid1990s until recently, whereas for other article types lead was used much earlier

Taking into account these factors, Tauw (2013) modelled the lead content in new articles made with recycled PVC within the building and construction sector. The results show that lead concentrations in final articles can be expected to be far below 1 % lead, which has also been confirmed by measurement samples taken from window profiles.

However, during the public consultation several requests were received by industry indicating that a concentration limit of 1 % (w/w) would still adversely affect PVC recycling and that a limit of 2 % lead (w/w) is necessary to ensure that recycling continues at current volumes, and that recycling rates can increase in the future, as foreseen (#1633). SEAC has scrutinised the data received by industry, including measurement data of lead in post-consumer PVC waste and in recycled PVC material (consisting of a mixture of post-consumer and post-industrial waste) from the years 2012, 2015 and 2016. The data indicates that

- there is a considerable variability in concentration levels, which makes it difficult to draw a firm conclusion on the lead content in rigid and soft post-consumer PVC waste.
- taking into account this data variability, the measurement data indicate that rigid post-consumer PVC waste seems to contain lead in concentrations above 1 %, whereas soft post-consumer PVC waste contains lead in quantities far below 1 %.
- the lead content seems to be decreasing over time, but again it is difficult to draw a solid conclusion on the trend of lead in PVC waste given the variability of the data.

SEAC points out that the lead content in the recycled material is usually lower than in the post-consumer PVC waste (although only when mixed with post industrial waste, according to industry not all recyclers have access to post-industrial waste) and that this material will usually be mixed with virgin PVC in the production of articles. Therefore, SEAC considers that it is possible that the majority of articles containing recycled PVC contain lead in concentrations below 1 %. In this respect, SEAC points out that the request for a 2 % concentration limit by industry is based on worst case assumptions, i.e. high lead content in the post-consumer PVC waste, no addition of post-industrial waste and very high content of recycled PVC (e.g. 100%) in the final article.

SEAC notes that raising the limit value to 2 % could further complicate enforcement, because nearly the whole range of concentration levels covered by the intentional use of lead stabilisers would be allowed for articles containing recycled PVC. Hence, in particular for imported articles, enforcement authorities would have to mainly rely on the label marking the article as "containing recycled PVC" in order to distinguish between e.g. window profiles produced with lead in virgin PVC or with recycled PVC.

However, for articles made of rigid PVC, SEAC still considers a concentration limit of 2 % to be appropriate taking into account that

- no additional risk is to be expected from this limit (as confirmed by RAC) and
- a 'safety margin' in the concentration limit would facilitate the smooth operations of the processing of post-consumer PVC waste and decrease the efforts spent by recycling companies on the testing of lead content.

For articles made of soft PVC, SEAC concludes that the available evidence does not provide justification for a concentration limit of 2 % as it indicates that the lead content of soft PVC articles containing recycled PVC will be far below 1%.

Time limit of the derogation

With regard to the time limit of 15 years, SEAC considers that the projections of lead content in post-consumer PVC waste provided by the Dossier Submitter do not provide sufficient certainty to conclude that the targeted articles will comply with a lead concentration of 0.1 % (w/w) after 2035. The information provided by industry in the Public Consultation indicates a decreasing trend of the lead content in post-consumer PVC waste, however the variability of the data is too high to draw a solid conclusion on the future development. Hence, SEAC supports a review of the time limit of the derogation after 10 years from entry into force (as proposed by the Dossier Submitter).

With regard to **PVC-silica separators** in lead acid batteries, SEAC considers that the information submitted by the company concerned provides further explanation on the reasons why it is currently not feasible to replace lead-based stabilisers in this application (#xxxx). SEAC notes that this information was not challenged by potential competitors (e.g. importers of PVC-silica separators) in the Public Consultation.

SEAC concurs with the proposed derogations of **articles covered by current legislation** since they clarify the interface between the proposed restriction and other regulations and will avoid double-regulation.

SEAC agrees with the exclusion of **second-hand articles** from the scope, for ensuring the practicality and proportionality of the proposed restriction.

Concerning the addition of a derogation for the use of **lead pigments** in PVC, SEAC notes that according to information received in the Public Consultation lead pigments are used in PVC in concentrations above 0.1 % and would be affected by the proposed restriction. Furthermore, an estimate of the annual volume of lead pigments used in PVC manufacture inside the EU was provided by the authorisation holder (but was claimed as confidential). There is no information on the use of lead pigments in imported articles. Currently, the derogation covers only two compounds (lead sulfochromate yellow and lead chromate molybdate sulfate red), because these are the only pigments, for which there has been information on their use in PVC. SEAC points out that more compounds could be added to the derogation if evidence of the use of additional lead pigments in PVC is provided in the Public Consultation of the SEAC Draft Opinion.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of proposal:

The Dossier Submitter considers **substitution costs** to be the main economic impact of the proposed restriction, ranging between €0.9 and €3.3 million per year with a central estimate of €2.1 million (based on 2016 as a reference year). In addition, minor costs for enforcement are expected (around €60 000 per year).

The Dossier Submitter has estimated these economic impacts on the basis of a restriction scenario (compared to the baseline) expecting that industry will switch to calcium-based stabilisers as alternative to lead-based stabilisers. Cost estimates were derived based on various assumptions about the volume of lead-based stabilisers that will have to be replaced due to the proposed restriction. The costs of replacing lead-based stabilisers in PVC result from a difference in price to calcium-based stabilisers (see Table 1). For this difference in price the Dossier Submitter has not estimated any sensitivity values, but used an average of €0.7 per kg (provided by ESPA for 2015). These costs will mainly arise from the substitution of lead-based stabilisers in imported PVC articles, because most of EU industry has already switched to alternatives due to a voluntary agreement (Vinylplus). The Dossier Submitter conservatively assumed that switching costs would be passed down the supply chain onto EU consumers. It is also implied that the total amount of lead stabilisers produced in the EU will be replaced in response to the restriction, except from lead stabilisers produced for export.

Table 1. Substitution costs estimated for PVC articles expected to be placed on the EU 28 market in 2016 (assuming the targets of the voluntary phase out of ESPA members are met). The percentiles reflect the range of predictions derived by Monte Carlo simulation of the volumes of lead-based stabilisers relevant for the EU market.

	min	25 th	50th	75th	max
Pb stabilisers imported in articles (tonnes/year)	1 321	2 322	3 142	3 921	4 974
Pb stabilisers used in the EU28 (t/year)	0	72	165	295	354
Total amount of Pb stabilisers (t/year)	1 321	2 394	3 308	4 216	5 328
Dosage ratio Ca stabiliser/Pb stabiliser			0.88		
Equivalent amount of Ca stabilisers needed for substitution (t/year)	1 163	2 107	2 911	3 710	4 688
Price difference between Ca stabilisers and Pb stabilisers (€/kg)			0.7		
Substitution costs (€ million /year)	0.9	1.5	2.1	2.6	3.3

According to the Dossier Submitter, substitution will not entail significant **investment** (to EU industry) **or testing costs**. The Dossier Submitter stated that alternatives to lead stabilisers are widely used by European industry and on the basis of ESPA (2015) concluded that increased investment is not expected, because substitution has already been completed in the EU.

The **enforcement cost** estimated is based on average administrative costs of enforcing a new restriction. This value is estimated based on numbers of controls over the period 2010-2014 reported by EU Member States. The calculation is based on an average cost per control (inspection) and an average number of controls per restriction. As indicated by the

Dossier Submitter it should be seen as only illustrative in terms of the order of magnitude of the cost.

SEAC conclusion(s):

SEAC in general supports the cost assessment provided by the Dossier Submitter. It provides sufficient evidence to conclude that no major economic impact is to be expected from the proposed restriction.

However, SEAC considers there to be several uncertainties that could affect the magnitude of the total costs of the proposed restriction, i.e. concerning the volumes of lead stabilisers that will be still used in imported PVC articles (in the baseline scenario), the price difference between lead-based stabilisers and alternatives, the potential for additional investment costs to be incurred by industry, the probability that costs would be passed on to EU consumers and the potential benefits due to the enhanced technical performance of the alternatives. Based on available information, SEAC considers that, overall, these sources of uncertainty are more likely to point to lower total costs of the proposed restriction, at least for actors in the EU, than the estimates provided by the Dossier Submitter.

Key elements underpinning the SEAC conclusion(s):

SEAC emphasises that the total impact of the proposed restriction will be fundamentally driven by the extent to which lead-based stabilisers are still used in (mainly imported) PVC articles, which is uncertain. A more detailed discussion on the uncertainties of the projected amounts of lead-based stabilisers in PVC articles produced in and imported to the EU will be included below (in the section “uncertainties”).

SEAC notes that the total substitution costs, estimated by the Dossier Submitter, mainly result from the price increment (estimated at €0.7 more per kg of calcium-based stabiliser) and lower loading (ratio of 0.88 compared to lead-based stabilisers) of calcium-based stabilisers (as most likely alternative) compared to lead-based products. SEAC notes that the data used to estimate the price difference between lead-based and calcium-based stabilisers is limited, but was obtained from the relevant industry sector group (ESPA). Furthermore, the price difference is likely to decrease in the future (as recognised by the Dossier Submitter).

According to the Dossier Submitter, investment (one-off) costs to EU industry can be considered to be negligible because the voluntary industry agreement to phase out lead (VinylPlus) already covers more than 95% of the EU production of stabilisers. ECHA received information in the Public Consultation from two companies not participating in Vinylplus. One of the companies stopped producing lead-based stabiliser for the EU market in 2015, whereas the other provides a lead-based substance used in the manufacturing of lead-based stabilisers destined to export. Hence, there is no indication that there may be substantial investment costs as a result of the proposed restriction incurred by EU-based companies (and related supply chains) that have not voluntarily phased out lead-based stabilisers. However, it is possible that a part of the investment costs incurred by industry outside the EU will be passed on to EU consumers. In order to assess the potential significance of these costs SEAC would need at least qualitative information on how complex and costly the substitution of lead-based stabilisers to producers and PVC converters is (no relevant information on this was submitted in the Public Consultation).

SEAC notes that the improved technical performance of calcium-based stabilisers may have an effect on the total economic impact. As explained in the Background Document, calcium-based systems have certain improved technical characteristics compared to the lead-based systems that they replaced, such as more effective stabilisation (during production) and better colour stability (during the service life of the article, e.g. for window frames). However, the economic impacts of this improved technical performance were not quantified by the Dossier Submitter (and it is not clear if, and to what extent, the performance is reflected by the price difference of calcium- and lead-based stabilisers). In case the improved technical performance of calcium-based stabilisers are not or only partly reflected in the price increment, SEAC notes that these have to be considered as additional benefits of the proposed restriction, which would mean in turn that the costs of the restriction may be overestimated.

These uncertainties have to be taken into account in the evaluation of the cost estimates provided by the Dossier Submitter. However, overall SEAC agrees that the values provided by the Dossier Submitter are adequate to indicate the magnitude of recurrent substitution costs arising from the substitution of lead-based stabilisers in PVC articles.

Benefits

Summary of proposal:

The restriction proposal is expected to **reduce exposure of the general population** to lead and resulting adverse health effects, in particular by preventing lead emissions from the disposal of post-consumer PVC wastes containing lead (accounting for 90 % of lead emissions from PVC). However, there is evidence that articles falling under the restriction (e.g. mini-blinds) contribute to direct human exposure.

Total lead emissions from PVC articles placed on the EU market in 2016 were estimated to be between 4.3 and 10.3 tonnes with a central estimate of 6.8 tonnes. The Dossier Submitter has provided these **emission estimates as a proxy of the risk reduced** by the proposal and, has chosen to undertake a qualitative, rather than quantitative, health impact assessment accounting for the non-threshold effects of lead on the neurodevelopment in young children.

Lead is a **non-threshold toxic substance** of particular concern for the developing brains of children and unborn infants. According to EFSA (2013) the current human exposure (both from food and non-food sources) still exceeds tolerable exposure levels leading to adverse neurodevelopmental effects on children. Lead exposure, at levels commonly observed in the EU today, can impair the neurodevelopment and can affect cognition and behaviour. Early-life exposure to lead is related to neurologic deficits, leading to reduced cognitive ability. The latter may be measured with standardised IQ tests. Referring to findings in the public health literature, the Dossier Submitter considers that a small reduction in IQ can in turn have a significant population effect in terms of reduced lifetime earnings.

In addition to the reduced risk to human health, there may also be benefits of the proposed restriction to the environment, because lead can accumulate in the environment after it is released and cause damage to the ecosystems due to its adverse effects on aquatic and terrestrial species including invertebrates, birds and mammals. These **potential environmental benefits** have not been further assessed by the Dossier Submitter.

SEAC conclusion(s):

SEAC accepts the benefits assessment carried out by the Dossier Submitter using emissions as a proxy for the risk. SEAC considers this approach to be appropriate taking into account lead as a non-threshold toxic substance. Even though the impacts on human health of the proposed restriction are uncertain (e.g. in terms of IQ loss prevented), overall, SEAC considers it to be likely that the proposed restriction would result in benefits to society.

SEAC underlines that the restriction may also result in environmental benefits taking into account that the emissions reduced will not add to the stock of lead in the environment.

SEAC points out that the benefits of the proposed restriction also depend on the current use of lead-based stabilisers in imported PVC articles (discussed under uncertainties).

Key elements underpinning the SEAC conclusion(s):

The main benefits of the proposed restriction is expected to result from a reduction in human exposure to lead leading to non-threshold adverse neurodevelopmental effects in unborn and young children (as assessed by RAC). Taking into account the non-threshold nature of toxic effects of lead, as well as the difficulties in assessing exposure via the environment, these benefits have not been quantified directly. Instead, the Dossier Submitter estimated the emissions of lead that will be reduced by the proposed restriction as a proxy for the risk reduction. SEAC accepts this approach. As already stated in the section on costs, SEAC points out that the exposure reduction resulting from the proposed restriction depends on the current use of lead-based stabilisers in imported articles, which is uncertain (see 'uncertainties').

SEAC underlines that the neurodevelopmental effects of children exposed to lead can lead to IQ losses, which may have considerable socio-economic impacts, amongst others in terms of reduced life-time earnings or higher spending for education. However, based on the information at hand it is not possible to quantify the effect of the proposed restriction in preventing the socio-economic costs of lead exposure. In this respect, SEAC considers that the distribution of lead exposure in the general population may have an influence on the overall benefit of the proposed restriction. Evidence provided by the Dossier Submitter on the direct human exposure resulting from the use of lead stabilisers in PVC (e.g. from mini-blinds) further strengthens the conclusion that the restriction will potentially lead to human health benefits.

The information provided in the Background Document indicates that industry will mainly switch to Calcium-based stabilisers in response to the proposed restriction, which are not expected to cause any adverse human health or environmental effects.

Concerning the emission estimates provided by the Dossier Submitter, SEAC notes that the contribution of lead in PVC (6.8 tonnes emitted per year) to total lead emissions (476 tonnes per year in the EU from industrial point sources) may be small compared to other sources. However, taking into account the non-threshold effects of lead, SEAC considers that in principle any emission reduction can be considered as a potential benefit to society.

In addition, SEAC notes that lead is identified as a Priority Substance under the Water Framework Directive. SEAC agrees that although it is difficult to link lead release from PVC articles to environmental effects, reducing overall exposure of the environment to lead is likely to be beneficial for ecosystems (and contribute to the objectives of the Water Framework Directive). However, as environmental impacts have not been in the focus of the proposal, SEAC has not assessed them further.

Other impacts

Summary of proposal:

The Dossier Submitter assessed **social impacts** on relevant market actors that will be potentially affected by the proposed restriction, namely PVC converters, producers of stabilisers, importers of PVC articles, PVC exporters as well as on SMEs.

Accordingly, no major negative social impacts are expected from the proposal, because substitution of lead stabilisers will not result in significant costs to industry and associated consequences (e.g. job losses). This conclusion is underpinned by the fact that nearly all companies (producers of stabilisers and PVC converters) have already replaced lead-based stabilisers in their operations. Many of the companies within the affected supply chain are likely to be SMEs for which it may be more difficult to phase out lead-based stabilisers. However, the Dossier Submitter considers the impact of the restriction on SME to be small, because of the minor investment involved with the substitution of lead-based stabilisers.

Furthermore, the Dossier Submitter expects that it is unlikely that the minor cost increase resulting from the substitution of lead stabilisers in imported articles will be passed on to consumers in the EU.

No major **wider economic impacts** of the proposed restriction (e.g. on article price, international trade, competition or economic development) are expected by the Dossier Submitter.

Furthermore, the proposed restriction will not have significant **distributional impacts** according to the Dossier Submitter

SEAC conclusion(s):

SEAC supports the conclusion that no major social, distributional or wider economic impacts can be expected by the proposed restriction.

Key elements underpinning the SEAC conclusion(s):

SEAC considers it to be likely that the restriction will not have major social or wider economic impacts taking into account that alternatives are available and already used by EU supply chains.

Taking into account the overall size of the costs expected and the actors involved in the supply chain of PVC articles, SEAC considers it unlikely that the restriction will result in significant distributional impacts.

Overall proportionality

Summary of proposal:

The Dossier Submitter assessed the proportionality of the proposed restriction by means of two approaches, namely by analysing the cost-effectiveness of the proposal in terms of emission reduction and by conducting a break-even analysis.

In the **cost-effectiveness analysis**, the Dossier Submitter based the assessment on the cost estimates derived in the cost assessment for 2016 (including both substitution and enforcement costs) and the emission estimates obtained by modelling the releases of lead during the article service life and disposal stages. The central value of cost-effectiveness is 308 €/kg of lead emissions avoided, with a range of 99 to 2 484 €/kg; the corresponding interquartile range is 258 to 356 €/kg (see Table 3).

Table 3. Cost-effectiveness for articles placed on the market in 2016, including imported articles

	min	25th	50th	75th	max
Pb stabilisers (tonnes/year)	1 321	2 394	3 308	4 216	5 328
Pb emissions (tonnes/year)	0.35	4.3	6.8	10.3	33.8
Compliance costs* (€ million /year)	0.87	1.53	2.09	2.65	3.34
Cost effectiveness** (€/kg emission avoided)	2 484	356	308	258	99

* Compliance costs include substitution and enforcement costs

** Cost effectiveness = Compliance costs / Pb emissions

Figures might not agree due to rounding.

The Dossier Submitter compares these cost-effectiveness estimates with the cost-effectiveness of other measures taken under REACH, including restrictions on lead. This comparison indicates that the cost-effectiveness per kg emission of lead reduced is in the same order of magnitude, or lower, as the cost-effectiveness of other restrictions under REACH (Tables 4 and 5).

Table 4. Comparison of the cost-effectiveness of the proposed restriction and previous restrictions under REACH

Restrictions under REACH	Central value	Range
Proposed restriction (€/kg of emission avoided)	308	99 – 2 484
Mercury-in-measuring-devices (€/kg of Hg used)	4 100	0 – 19 200
Phenylmercury compounds (€/kg of emission avoided)	649	n/a
DecaBDE (€/kg of emission avoided)	464	30 – 756
PFOA(€/kg of emission avoided)	<1 649	0 – 6 551
PFOA-related substances (€/kg of emission avoided)	734	4 – 3 533
D4D5 (€/kg of emission avoided)	400 - 430	<0 – 1 200

Table 5. Comparison with the cost-effectiveness of previous restrictions on Pb

	Pb in articles for consumer use	Pb in PVC
Substitution costs (€/year)	11.8	2.1
Pb to be substituted (tonnes/year)	369	2 646*
Cost-effectiveness (€/kg of Pb substituted)	32	<1

* To derive the estimate, the tonnes of Pb stabiliser are multiplied with a factor of 0.8 to convert to tonnes of metallic Pb (3 308 tonnes of Pb stabiliser x 0.8 = 2 646 tonnes of metallic Pb).

During the public consultation, industry has provided additional figures of cost-effectiveness for the articles they proposed to include in the derogation for recycling. The Dossier Submitter has re-calculated the cost-effectiveness figures submitted by industry, including the releases over the whole service life of a given article (and not only the yearly release), see Table x in the Annex.

In addition to the cost-effectiveness analysis, the Dossier Submitter provided a **break-even analysis** based on the value of IQ loss due to lead exposure of young children. Accordingly, the benefits would outweigh the costs of the restriction, if at least 1.24 g of the lead currently emitted per year under the baseline scenario would accumulate in members of the EU population at risk (i.e. children aged 7 and younger). In addition of this analysis, the Dossier Submitter provided further evidence of direct human exposure resulting from PVC articles containing lead-based stabilisers (e.g. from mini-blinds in the USA, as reported in the BD).

RAC and SEAC conclusion(s):

Taking the properties of lead as a non-threshold toxic substance and the human health impact that may occur from these properties, the affordability of the costs of the proposed restriction, the cost-effectiveness of the measure to reduce lead emissions as well as the break-even analysis into account, SEAC concludes that the proposed restriction is likely to be proportionate.

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

SEAC notes that based on the information at hand, it is difficult to reliably quantify the expected impacts on human health and the environment of the proposed restriction. Lead is considered a non-threshold toxic substance and the main exposure route targeted by the proposal is humans exposed via the environment, which complicates the exposure assessment compared to direct exposure (which was the relevant exposure path for other restriction proposals on lead). SEAC accepts the approach taken by the Dossier Submitter to focus on the cost-effectiveness to assess the proportionality of the proposal.

SEAC has scrutinized the cost-effectiveness estimates provided by the Dossier Submitter

and concludes that they are adequate to indicate the possible range of cost-effectiveness that can be expected from the proposed restriction. In terms of assessing proportionality, SEAC underlines that cost-effectiveness per se does not provide information on the ratio of costs and benefits of the restriction. Furthermore, the comparability with the cost-effectiveness of previous restrictions, which mainly covered PBT(-like) substances is limited, because the risks and concerns differ between these substances and lead. In this respect, the comparison with the restriction on lead in consumer articles seems more appropriate, which supports the conclusion that the proposed restriction is a cost-effective measure to reduce lead emissions. However, exposure pathways and conditions are different, which also limits the comparability of the cost-effectiveness in terms of risk and impacts involved with these different cases.

SEAC has also scrutinised the cost-effectiveness estimates for the additional applications proposed to be included in the recycling derogation, as re-calculated by the Dossier Submitter. The cost-effectiveness is at least one order of magnitude lower (meaning higher costs per kg emission avoided) than the restriction of lead-based stabilisers in virgin PVC. SEAC considers this to be in support of extending the derogation to include these articles.

When assessing the proportionality of the proposal, SEAC considers the usefulness of the break-even analysis presented by the Dossier Submitter to be limited, in particular taking into account that the analysis makes no assumption about the distribution of lead exposure within the population at risk. Consequently, it is not possible for SEAC to evaluate how realistic the break-even point is and what human health impacts are to be expected from this exposure. With the additional evidence provided by the Dossier Submitter on the direct exposure to lead from PVC articles, SEAC has more confidence in the reliability of the break-even analysis. Overall, SEAC concludes from the break-even analysis that due to the small economic impact of the restriction only limited human health impacts in terms of IQ loss would be necessary for the restriction to break-even with the costs of the proposal. SEAC has not sufficient information to assess the probability of these human health impacts. SEAC points out that the affordability of the costs of the proposed restriction is also an aspect that has to be taken into account when assessing proportionality. The costs of the restriction are minor and not likely to lead to any significant price increase of PVC articles affected. Also, it is not expected that the total costs will be passed on to consumers.

SEAC considers it appropriate to base the conclusion on proportionality on all relevant available evidence: namely the properties of lead as a non-threshold toxic substance and the human health impact that may occur from these properties, the affordability of the costs of the proposed restriction, the cost-effectiveness of the measure to reduce lead emissions as well as the break-even analysis.

Uncertainties in the proportionality section

Table 6. Overview of sources of uncertainty and their effect on the proportionality of the proposed restriction of lead-based stabilisers. Effects in brackets are possible, but not well substantiated by available evidence.

Source	Description/explanation	Effect on proportionality
Costs		
Price difference of lead-based and calcium-based stabilisers	It is likely that the price of calcium-based stabilisers will decrease in the future due to economy of scales.	(↑)
Distribution of costs within the supply chain	It is likely that no or not all substitution costs of lead-based stabilisers in imported articles will be passed on to EU consumers.	↑
Improved technical performance of calcium-based stabilisers	Consumer surplus may be higher than indicated by the price of calcium-based stabilisers.	(↑)
Investment costs incurred by EU companies or passed on to EU consumers	Major costs to EU entities are unlikely. It is uncertain to what extent investment costs to non-EU companies (to switch to Pb-free stabilisers) would be passed on to EU consumers.	(↓)
Testing costs	Costs to industry to monitor and ensure compliance have not been estimated	↓
Enforcement cost	It is unlikely that the restriction will cause additional costs to the annual enforcement budgets of Member States	↑
Benefits		
Other human health impacts	The neurodevelopmental effects of lead do not only affect IQ, but may have other negative impacts (e.g. hyperactivity, impaired cognitive functions) Apart from neurodevelopmental effects, lead exposure can cause other human health effects, e.g. renal	↑

	effects, high blood pressure.	
Environmental benefits	Lead may cause adverse effects in aquatic ecosystems. Lead has been identified as a priority substance under the Water Framework Directive	↑

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

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

There are alternatives (mainly calcium-based systems) with lower risk available, which are technically and economically feasible (see section on costs). The widespread voluntary substitution of lead-based stabilisers in the EU demonstrates that the restriction is implementable and manageable for all affected actors. Furthermore, the Dossier Submitter expects that the proposed transition period gives sufficient time to the impacted supply chains to transition to alternatives, and no contradictory information has been received in the Public Consultation.

In general, the scope of the restriction covers lead-based stabilisers in all PVC articles above a concentration of 0.1 % and hence it is clear to identify articles falling under the restriction. Also, the Dossier Submitter considers that the derogations proposed have been sufficiently defined in order to identify relevant articles. In particular, the labelling requirement for articles containing recycled PVC is expected to ensure proper enforcement of the derogation without entailing a significant cost to industry actors to comply with the restriction.

Effective and cost-efficient analytical methods (e.g. XRF) are available to facilitate the enforcement of the restriction.

RAC and SEAC conclusion(s):

SEAC concludes that the proposed restriction is implementable and enforceable. The cost of enforcement is expected to be within the range of other restrictions under REACH.

For the effective enforcement of the derogation of articles containing recycled PVC labelling is essential as it is the only means to identify exempted articles. The exhaustive list of the articles exempted has been clarified, however it may still leave some room for interpretation by enforcement authorities.

Also the derogation of the use of lead pigments may cause difficulties to clearly identify relevant articles, hence practical guidance to enforcement authorities may be useful.

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

With regard to articles containing recycled PVC, the labelling requirement is crucial, because without a label it will be hardly possible for enforcement authorities to clearly identify relevant articles given the fact that a lead content of up to 2 % covers nearly all intentional uses of lead-based stabilisers in virgin PVC. SEAC notes that the labelling requirement will impose a cost on recyclers and PVC converters. These costs may increase if the label would have to contain further information, e.g. on the lead content, as suggested as a possibility by RAC.

The derogation of lead pigments may require additional supply chain communication and more advanced testing during enforcement. Forum indicated that enforcement authorities may have difficulties to identify the original use of lead in the PVC material. It was confirmed by industry that it was possible to recognise the use of lead pigments by the colouration of the PVC material as well as through analytical methods detecting chromium and/or molybdenum in a specific ratio to lead. Taking into account Forum's advice, SEAC notes that this could require additional effort from enforcement authorities to clearly identify the use of lead in the PVC material examined.

Furthermore, the applicability of XRF could be limited, e.g. for co-extruded articles, hence wet analytical testing may be needed, which would entail higher costs.

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.

According to the Dossier Submitter, no additional costs for monitoring are anticipated (apart from enforcement-related costs).

RAC and SEAC conclusion(s):

SEAC concludes that the costs of monitoring of the proposed restriction can be expected to be within the range of other restrictions under REACH.

The monitoring involved with the review of the derogation of articles containing recycled PVC is likely to cause additional efforts to authorities and industry, but SEAC cannot evaluate these costs.

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

SEAC considers that a solid data base on the trend of the lead content in post-consumer PVC waste (preferably from building applications) would facilitate the review of the derogation of articles containing recycled PVC.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

SEAC

Summary of proposal:

Uncertainties related to the proportionality of the proposed restriction have been summarized above.

The Dossier Submitter has used a large number of assumptions, which have been listed in the Background Document (Annex F), including on the volumes of lead-based stabilisers used in the EU and in imported articles, the releases from PVC during waste disposal and re-use as well as in the cost assessment.

SEAC conclusion(s):

SEAC concludes that the uncertainties have been adequately assessed and presented by the Dossier Submitter.

SEAC considers that major uncertainties are related to the volumes of lead-based stabilisers in imported articles, which are expected to be a main driver of the overall effect of the restriction.

Key elements underpinning the SEAC conclusion(s):

There is a lack of information on the use of lead-based stabilisers outside the EU and the corresponding volumes in imported articles. Also, there is no information to what extent imported PVC articles contain recycled PVC and thus would be exempted from the proposed restriction. The Dossier Submitter has addressed these uncertainties by applying a broad range of volumes (i.e. assuming that 20 to 60 % of imported PVC articles falling under the restriction currently contain lead-based stabilisers). SEAC notes that there is not sufficient information to evaluate if this range adequately reflects possible scenarios.

ANNEX

Table A1. EU imports (annual quantities in thousand tonnes) for main PVC (construction relevant) articles during 2006-2015 (Eurostat, 2016)

ARTICLE TYPE / YEAR	2006	2008	2010	2012	2013	2014	2015
1. Rigid tubes, pipes and hoses	7.9	9.7	7.7	11.7	11.3	13.3	15.5
2. Doors, Windows and their frames	22.5	30.8	31.5	37.4	41.9	67.8	67.3
3. Floor, wall and ceiling coverings (in rolls or tiles)	36.4	59.8	73.4	121.9	170.0	219.6	270.5
4. Fittings (joints, elbows, flanges, for tubes)	31.9	36.2	37.2	38.9	39.4	44.5	46.5
5. Shutters, blinds (incl. venetians and parts)	21.1	18.3	17.5	14.9	16.0	18.4	18.2
6. Fittings for furniture, coachwork etc.	12.9	18.9	15.7	15.8	18.9	24.3	25.0

Table A2. Cost-effectiveness values for PVC article categories based on VinylPlus release factors – re-calculated by the Dossier Submitter

Application		Traffic	Roofing	Mats	Other ^a	Pipes (rigid)
Tonnage of articles		88 651	12 528	7 761	34 315	5 687
Total lead (T)		443.3	62.6	38.8	171.6	159.2
Costs of foregone recycling (€)		89 639 701	9 379 412	5 810 439	25 689 839	1 916 370
Total release (recycling + service life)	kg	1 756.44	1 365.78	10.81	30.63	15.87
Cost-effectiveness^d	€/kg	51 035	6 867	537 506	838 715	120 754

Notes: a – includes 3-layer hoses, noise insulation sheets, footwear and boots for professionals.

Cost-effectiveness in this context was considered as the private costs (of article producers) to prevent the release of one kg of lead during the service life of a PVC article. Cost effectiveness values are based on the additional costs associated with using virgin PVC instead of recycled PVC to produce articles. Although the additional [social] costs of landfilling/incineration were included into the cost effectiveness calculations made by VinylPlus these cost elements were omitted in the calculations reported here (as recycling temporarily delays disposal rather than replacing it).