ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAMES: Lead compounds-PVC

IUPAC NAME(S): Not applicable

EC NUMBER(S): Not applicable

CAS NUMBER(S): Not applicable

CONTACT DETAILS OF THE DOSSIER SUBMITTER:

European Chemicals Agency

Annankatu 18, Helsinki, Finland

DATE: 16 December 2016

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Annex A: Manufacture and uses

A.1. Manufacture and uses of PVC

A.1.1. Manufacturing of PVC

Polyvinyl chloride (PVC) is a synthetic polymer material (or resin), which is built up by the repetitive additions of the monomer vinyl chloride (VCM) with the formula CH_2=CHCl. PVC is used extensively in a broad range of industrial, technical and everyday applications. PVC is recyclable and like all plastics, is a relatively lightweight material, with a density one-sixth that of steel and half that of aluminium (Vinyl Progress report, 2015[1]).

Pure PVC is a rigid material, which is mechanically tough, fairly weather resistant, water and chemicals resistant, electrically insulating, but relatively unstable to heat and light. Heat and ultraviolet light lead to a loss of chlorine in the form of hydrogen chloride (HCl). This can be avoided through the addition of stabilisers as will be discussed in detail under the section A.2. The main distinction between the numerous PVC applications is between *rigid* PVC (accounting for about two thirds of total use) and *flexible* PVC.

According to European Council of Vinyl Manufacturers (ECVM, 2013[2]) most PVC products are long-lasting – in some cases more than 70 years – providing a reliable service through their entire life-span and cutting down massively maintenance and repair needs. A large number of different methods are employed in the transformation of PVC, notably extrusion, calendaring, injection moulding, blow moulding, rotation moulding, thermoforming, and film blowing. During compounding and further transformation, emissions of a number of dangerous substances and therefore some exposure of workers may occur. This will be further elaborated under section B.9.1.

A.1.2. Main uses of PVC in articles at Union level

The demand for PVC is determined largely by construction activity (Kunststoffe, 2013). The main applications of PVC in Europe are in the building/construction sector, which accounts for 70% of all uses and where products also have the longest average lifetimes (see Table A1). Corrugated PVC sheeting is used extensively in both the domestic and industrial environments. Further to the construction products, packaging is the second most important application for PVC (e.g. for cosmetics, toiletries and blow-moulded bottles).

[1] Available under: http://www.vinylplus.eu/uploads/docs/VinylPlus_Progress_Report_2015_English.pdf

[2] "100 years of PVC-The European industry's journey from patent to sustainability", see: http://www.stabilisers.eu/wp-content/uploads/2015/06/100-years-of-PVC-2.pdf

Table A1. Main use categories of PVC in EU 28 for 2014 (ECVM 2015).

Use / application	**Percentage Average (%)**	**life-time (years)**
Building/Construction	70	10-50
Packaging	9	1
Electric/Electronic	3	21
Automotive	3	12
Furniture	1	17
Other miscellaneous	14	10

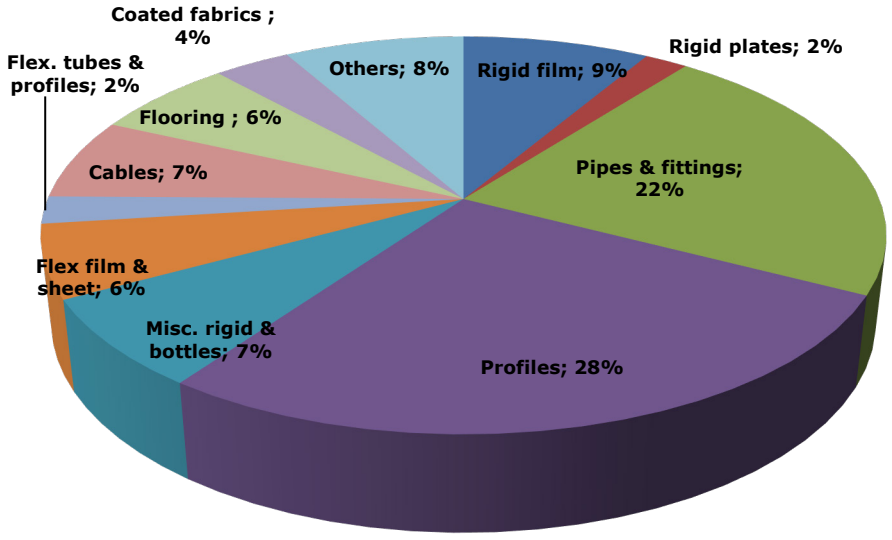


Figure A1. Distribution of main PVC uses in Europe for 2014 (ECVM 2015)

The PVC-products most often sold in the EU (as indicated in Figure A1) are: rigid profiles (28%), pipes and fitting (22%), flooring (6%), cables (6%), flexible tubes and profiles (2%), whereas others (8%) include: roofing and waterproofing membranes, coated fabrics for temporary structures.

Up to 20 000 plastic converter companies[3] are processing PVC and a fraction of them may use lead stabilisers to produce articles such as discharge water pipes and window profiles (CSRs for lead compounds 2015).

[3] Plastics converters manufacture semi-finished and finished plastic products for a wide range of industrial and consumer markets. They buy in raw material in granular or powder form, subject it to a process involving pressure, heat and/or chemistry to manufacture their products. They often undertake additional finishing operations such as printing and assembly work.

According to ECVM (2016)[4], PVC makes a major contribution to the quality, safety and cost-effectiveness of construction materials, as well as contributing to lower environmental impacts of completed projects. It is the most widely used polymer in building and construction applications and over 60 per cent of Western Europe's annual PVC production is used in this sector. PVC's resistance to chemicals and corrosion made it the best option for building applications such as window profiles, roofing membranes or wall coverings. Enhancing the material's resistance to extreme temperatures enabled PVC to be used in piping water to homes and industries ("100 years of PVC", ECVM report 2013).

A.1.3. PVC market and industry

In 2012, the worldwide production capacity for PVC was 54 million tonnes (source: Kunststoffe, 2013), an increase of 9 million tonnes since 2009. Most of this capacity increase again occurred in China, which now has about 44% of the world's capacity. Around 6 million tonnes of PVC/year is produced in Europe according to ECVM (2014). Demand in developed countries such as Japan has stabilised, however, the growing economies and populations of booming countries such as India and China will require increasing volumes of PVC in the near future. Latin America and the Middle East may also require increasing quantities.

The consumption of PVC resin (the raw material to manufacture PVC products) in the EU was 4.9 million tonnes in 2014 (RIVM, 2016). As highlighted by ECVM (2016), PVC contains significant amounts of additives, hence the total weight of PVC articles produced in Europe is higher than 4.9 million tonnes. At European level, 32% of PVC resin is used for flexible and 68% for rigid applications. On average, rigid products include 10% of filler and additives, and plasticised products include 50% of additives, plasticiser and filler. This means that 4.9 million tonnes of PVC resin will result in approximately 6 million tonnes of PVC articles.

According to Kunststoffe International (2013), a moderate PVC growth of between 3% and 4% per year is expected worldwide. In the emerging markets, e.g. China or the Indian subcontinent, growth is expected to be between 5% and 8% per year, while only slight growth is expected for Western Europe. For the USA and Eastern Europe, a relatively dynamic development with growth rates between 4% and 5% is projected. Overall, in the current economic climate, market growth forecasts for Europe seem to be constant.

The PVC industry can be roughly divided into four groups: PVC polymer producers, stabiliser producers, plasticiser producers, and PVC transformers. PVC polymer is produced by a relatively small number of companies, mostly located in Europe, the US, and Japan. Production capacity in developing countries is growing steadily as well.

Recent statistics produced by the PVC industry estimate that the total PVC producing and transforming industry in EU comprises more than 21 000 companies with more than 510 000 jobs, and a turnover of more than 72 billion (ECVM 2014). 95% of these companies are small or medium size enterprises (between 100 employees and 500 employees).

[4] Information available under: http://www.pvc.org/en/p/pvc-for-building--construction

A.1.4. ECHA Analysis of Eurostat data (May 2016) on PVC articles imported in the EU

ECHA has contacted Eurostat (May 2016) with a request for data on EU imports of the main PVC article categories of relevance for this restriction proposal following their selection through codes identification. Eurostat has provided data for the last decade (2006-2015) on the requested article categories that are presented in the Table A2.

Table A2. 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

Overall, the data concerns the total annual quantities (expressed in *thousand tonnes*) for imports to the EU of the main articles of concern in this assessment (pipes, tubes, frames, fittings etc.). There articles are mainly prepared by rigid PVC and be used for building/construction related applications. The section 0 describes the sensitivity analysis performed on these data which has been subsequently used in the exposure assessment (section B.9.3) to estimate lead emissions due to the imported articles based on PVC for the year 2015.

According to the data analysis for these specific article categories, during the last decade there is a clear and steady increase of the total annual quantities of imported PVC articles with a higher percentage growth reported after 2010. For example, considering the total annual values for all 6 categories of articles, the increase for the period 2010-2015 is approximately + 140%, much higher than for the period 2006-2010 (+ 37%).

The above discussed tendency is clearly represented in the following Figure A2 (data for higher PVC bound)**:**

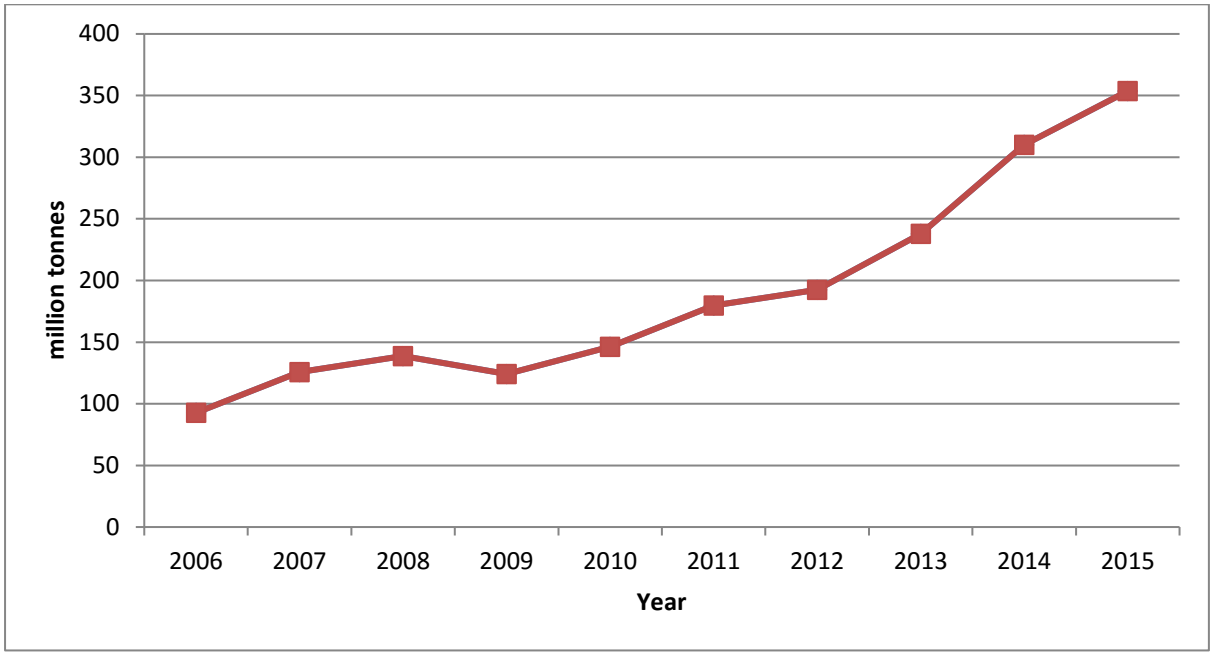


Figure A2. Change (%) of total annual quantities of the selected categories of PVC imported articles for the period 2006-2015 (Eurostat 2016)

This trend indicates that the PVC imports in the EU steadily increase in the last decade, a tendency that is likely to remain unchanged in the future due to likely price differences or other reasons.

A follow-up contact with Eurostat (June 2016), yielded information on the origin of the imports (per country) for the specified PVC based categories. A check of the 2015 data was done for the most relevant types based on rigid PVC frames (such as frames and shutters) and revealed that the vast majority (approximately 80%) of the imports come from Asia (China, Hong Kong, Korea, Taiwan), approximately 10-15% in total from other (non-EU) European countries (e.g. Turkey Switzerland, Serbia) and less than 5% from elsewhere (USA, Canada, Australia or Africa). Actually, in the frame of the TBT consultation for lead in PVC (December 2015-March 2016), responses were received from several Asian countries (Taiwan, Philippines, etc.) indicating exports of PVC articles to EU. This observation has been further considered in other parts of this report where these data have been used for the purpose of lead emission estimations.

Eurostat also provided data on the total value (million euros) of PVC important items per category per year (presented below in the

Table A3). Similarly to the previously discussed tendency for annual quantities, the total value for of the market these EU imported article categories is steadily increased during the last decade.

Table A3. Total annual value (million euros) 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	20.2	23.9	12.8	27.2	28.1	29.9	34.2
2. Doors, Windows and their frames	62.2	82.7	85.0	109.7	116.7	133.7	159.4
3. Floor coverings in rolls or tiles	58.3	89.9	113.9	180.2	250.2	308.3	418.3
4. Shutters, blinds (incl. venetians and parts thereof)	53.2	45.1	52.1	55.4	57.9	65.9	79.0
5. Fittings for furniture, coachwork and the like	88.5	127.6	124.5	152.9	166.6	197.6	253.2

The above presented data are further discussed and elaborated for the purpose of the exposure assessment where an estimation of lead emissions to the EU environment, released through the life cycle of these selected imported PVC articles, is provided.

A.1.5. PVC waste management

A.1.5.1. General information on PVC waste management and life cycle of PVC articles

The life cycle of PVC articles which starts in the conversion facility of the convertor (1) is pictured below in the Figure A3.

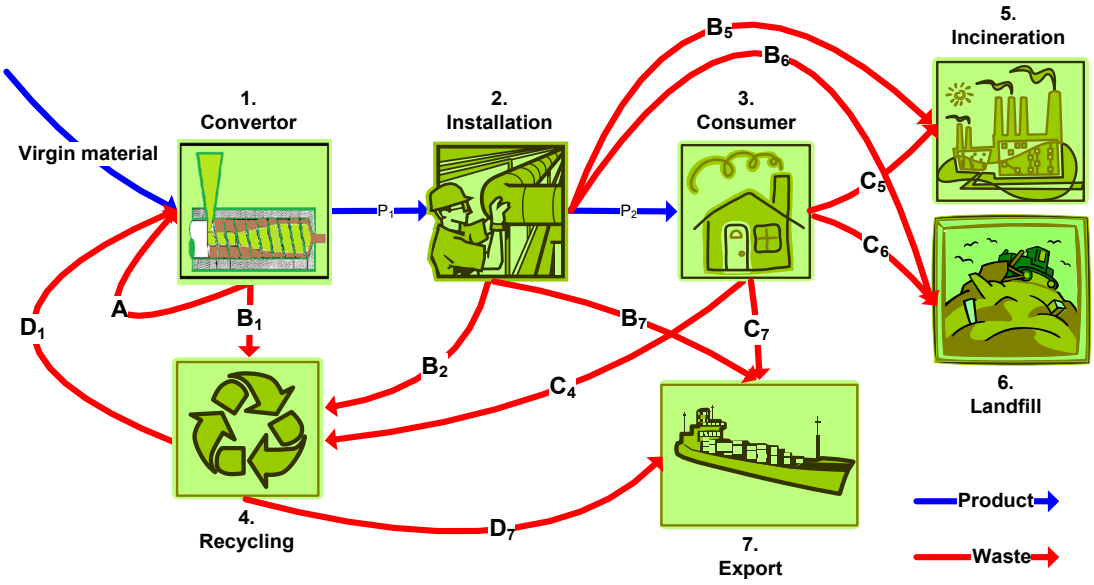


Figure A3. Schematic representation of PVC material streams in society (Source: Tauw IA, 2013)

During conversion, PVC articles, for example pipes, are made of virgin and recycled material. Often the articles are sold and installed by a professional, such as a plumber, during installation (2). Next the articles are being used by consumers (3). After a certain period the article is discarded, for example when the consumer wants a new bathroom. If the articles are not reused, for example as second hand articles, the product life of the pipe ends and the waste stage commences. PVC waste can be **recycled** (4), **incinerated** (5), **landfilled** (6) or **exported** (7).

After incineration or landfilling, PVC waste is removed from society. If the material is sent to a recycler, the PVC will start a new cycle. Another option to reuse the material is export out of Europe where the material is used again abroad. It has to be noted that waste is produced during all stages of the PVC article life. The first place where waste arises is during production. Waste might result of machinery failure, for instance because an extrusion nozzle is partially blocked (Tauw IA 2013[5]).

The total quantity of PVC waste is a function of PVC consumption. However, due to different lifespans, which can reach up to 50 years and more for some applications such as pipes and profiles, there is a "time-lag" between PVC consumption and PVC presence in the waste stream (Green paper, European Commission 2000[6]). According to RIVM (2016), the total annual amount of plastic waste in the EU is estimated at 25.9 million

[5] http://www.vinylplus.eu/uploads/Modules/Documents/2013_07_13-impact_lead-restrictions_pvc_recycling-tauw.pdf

[6] http://ec.europa.eu/environment/waste/pvc/pdf/en.pdf

tonnes, approximately 10.5% of which is PVC waste. This figure is in accordance with the German consultancy *Consultic*, indicating that the total amount of PVC waste generated in the EU for 2013 was approximately 2.45 million tonnes, out of which around 20% is recycled (Plastics Europe, 2016). It should be noted that Eurostat official waste statistics[7] have reported a total of 17.5 million tonnes of plastic waste for 2014. This value is approximately 30% lower than those provided from previous indicated sources).

A.1.5.2. Trends in PVC waste management

The trends in PVC waste management are governed by current development mainly at EU policy and legislation level.

Overall, recycling of PVC is expected to further increase in the EU as a result of Industry voluntary actions (VinylPlus) and furthermore encouraged by EU policies. In addition, the capacity of incineration in the EU will continue to grow as consequence of the EU policy to divert waste from landfills leading to Member States investments. Other aspects such as landfill taxes also influence the route which the waste will take. Furthermore, the demand for raw materials will increase in developing countries leading lead to an increase in export of PVC waste.

More background information on the trends is presented below:

(I) Recycling: The recycling of PVC has been boosted by both Industry initiatives and EU policies in the last few years. Around 250 000 tonnes of PVC waste were recycled in 2010 accounting for approximately 10% of post-consumer PVC waste arising in that year. This amount was almost doubled in less than 5 years, since in 2014 more than approximately 480 000 tonnes of PVC waste were recycled in the EU within the VinylPlus frameworks (VinylPlus progress report 2015). As indicated in this report, although nearly all European countries have improved their performance, the increase in volume was particularly linked to the consolidation of the PVC profile recycling schemes in France and Poland, as well as to significant growth in flooring recycling in France. VinylPlus has made a commitment to recycle 800 000 tonnes of PVC in 2020, out of which 500 000 tonnes are expected to be recycled from post-consumer waste (Tauw IA, 2013). European Industry has made an investment of over €5.6 million, from which €1.6 million was spent on R&D. Further elaboration of these figures and more discussion about PVC recycling is provided in the Impact Assessment Annex (section E.3.2) of this report. Overall, it should be noted that the recycling effort is undertaken for the sake of resource efficiency, in line with the Circular Economy package.

(II) Incineration: Pure PVC waste is not usually accepted at waste incinerators (usually a maximum concentration between 0.5 to 1.5% of PVC is accepted). Ecoprog (2015[8]) has recently made an inventory of the global capacity of waste incineration. In the period 2007-2012 the worldwide capacity increased by 12%, while by the end of 2016 capacity is expected to increase by a further 16%. This tendency can be explained by large investments in countries like the UK and China. A study (Pruvost, 2011) claimed that a significant increase of incinerated waste at approximately 55% will occur between 2006-2020 (from 65 million tonnes per year in 2006 to 125 million tonnes in 2020). The

[7] Eurostat relevant data are available under:

[8] http://www.ecoprog.com/fileadmin/user_upload/leseproben/ext_market_report_plastic_recycling_Europe_ecoprog.pdf

capacity increase in the EU will still grow after 2016 (and 2020). Under the conditions that Member States lagging behind will further invest, a steady increase of 20% even after 2020 could still be feasible.

(III) Landfilling: Landfilling is still the most used method of disposing of PVC wastes in Europe. Although it has environmental drawbacks, (surface withdrawal from usable land area; leaching of pollutants) it is still the most cost effective method of disposing of wastes in many EU countries. Since European legislation (Waste Framework Directive and the Directive on the Landfill of Waste 99/31/EC) aims at diverting waste from landfilling to other waste management material options, the major trend is a reduction. Between 1995 and 2007 landfilling of PVC waste[9] has decreased for the EU27 from 62% to just 42% [EEA Report, 2009][10] and this decreasing tendency continued unchanged in the last few years.

(IV) Export: There are two scenarios linked to the export of PVC waste outside the EU. According to the first scenario, PVC waste is exported separately from other wastes and will most likely be recycled. The second scenario foresees export of PVC waste is mixed with other wastes, where not easy to predict what will happen (and uncontrolled emission to environment cannot be excluded). The export of plastics out of the EU has increased by a factor of 5 to 6 since the turn of the century (Tauw IA, 2013). Though the largest amount of exported plastics is non-PVC material the amount of exported PVC has most likely increased considerably over time. Recycling companies in developing countries usually accept lower quality PVC waste than their European counterparts. This is due to acceptance of B-quality goods by consumers, but also due to lower labour costs which make sorting of low quality waste cost effective. At the same time the demand for raw materials has increased in developing countries as wealth is increasing in these countries. These two trends have stimulated export.

Distribution of PVC waste over the management options

As indicated by Tauw IA(2013), *EuPC* has developed a computer model which estimates the mass of post-consumer PVC waste that is arising for all the various applications in Europe. By using some of the above indicated values for each waste management option, the model produced a prognosis (for the period 2010-2050) for the ratios between the waste management options (as further discussed under the section E.3.2). The expected tendencies are summarised below:

- Recycling increases linearly from 250 000 tonnes (approximately 10%) in 2010 to 500 000 tonnes (approximately 20%) in 2020 (VinylPlus). After 2020 the increase in recycling is expected at approximately 1% per year.
- 1.5% point increase of incineration per year in the period 2010 – 2020 and 1% point increase of incineration per year in the period 2020 – 2030 and after 2030.
- Landfilling decreases by 3% point per year until landfilling reaches 0%.
- Export balances the total of the waste management options.

[9] It has to be noted that PVC waste is mostly not municipal waste, but mainly construction and demolition waste.

[10] Report available under: http://www.eea.europa.eu/publications/diverting-waste-from-landfill-effectiveness-of-waste-management-policies-in-the-european-union

A.2. Uses of lead compounds as PVC stabilisers

A.2.1. Introduction to PVC stabilisers

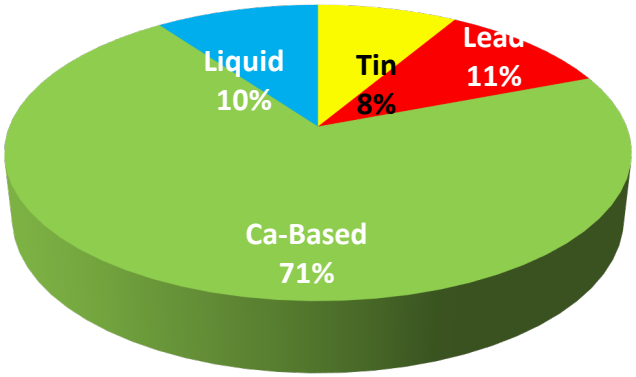
For PVC to be processed into various products, it is often heated to temperatures of around 200°C. This would normally cause the polymer to decompose and disintegrate, and thus, heat stabilisers are needed to prevent this. Thus, the term (stabilisation) implies a set of methods or techniques used to improve the resistance of the polymer or composite to various degradation-promoting factors during processing, storage, and service (Emanuel, 1977). The stabilisation of PVC-based polymer products is a more serious problem than the stabilisation of many other commercial polymers due to the complex nature of degradation of the former and the multitude of requirements for an effective stabiliser. Apart from protecting the polymer from as many degradation-promoting factors as possible, an effective stabiliser must:

- have a favourable effect on the processing properties of the polymer;
- have no adverse effect on the service characteristics of the material;
- meet the desired mixture of physical, chemical and other properties.

There are two principal ways in which polymers can be stabilised (Al Malack, 2001):

- by adding special stabilising agents;
- by chemical modification including conversion of functional groups by reaction of the polymer with low-molecular compounds.

A range of compounds have been historically used worldwide as PVC stabilisers including: lead compounds, cadmium compounds, calcium-based stabilisers (including Ca-Zn ones), liquid mixed metal stabiliser systems (based on Ba, Zn, Ca, Mg or K carboxylates), tin stabilisers (tin carboxylates, tin mercaptides). Figure A4 gives an overall picture of the consumption by PVC stabiliser category for 2014 in EU-28.



Type	kt/annum
Lead	14
Calcium based	92
Liquid MM	13
Tin	11
TOTAL*	**130**

Figure A4. European consumption by stabiliser category for 2014 ESPA[11] (2015)

This section focuses exclusively on the use and applications of lead stabilisers and more specific information on the other PVC stabilisers are presented elsewhere in the report (mainly in the section E.2, "Alternatives"). In addition, more updated market information and trends about the lead stabilisers are presented under the Section A.2.3.

A.2.2. PVC applications of lead stabilisers

Lead has the longest history as a stabiliser for PVC. Lead compounds are very cost-effective and their stabilising results are excellent, particularly for PVC products with long service life and required to endure longer fabrication (heating) time. A number of different lead compounds are used in PVC formulations, plus other additives, to provide the right performance in particular applications (PVC Europe 2012).

In the manufacturing of PVC articles, lead-stabilisers are added during the compounding phase to the PVC-matrix prior to the extrusion process to provide protection of the final PVC-product against the influence of temperature and light.

There are various types of lead stabilisers such as tetra-basic lead sulphate, tri-basic lead sulphate, di-basic lead phosphite, di-basic lead phthalate, dibasic lead stearate, neutral lead stearate. In recent years, lead compounds have been replaced by other stabilisers, most notably Ca/Zn stabilisers.

As indicated in the CSRs for lead compounds (2015), there are less than 10 sites manufacturing lead stabilisers in the EU, totalling probably between 100 and 500 employees directly involved with lead stabilisers.

The major properties of lead stabilised PVC (PVC Europe 2012) include:

- Heat and light stability;
- Good electrical properties;
- Good short and long-term mechanical properties;
- Low water absorption;

[11] ESPA stands for European Stabilisers Producers Associations: http://www.stabilisers.eu/

- Wide processing range;
- Good cost/performance.

Lead-containing PVC products have been primarily used in construction applications where long product life and durability are required. The assessment is restricted to the following PVC articles which are deemed to have the largest impact: profiles, pipes and fittings, flooring, roofing, cable jacketing and sheathing.

More details about lead stabilised PVC articles (e.g. concentrations, application) applications are given below (Tauw IA, 2013).

- **Profiles**: Profiles usually receive a high dosage of UV light. Therefore the amount of lead in profiles is relatively high compared to other products. The amount of lead in profiles (% w/w) is estimated according to different sources as follows: window profiles (1.9 - 2.0); profiles for cable ducts 1.6%; profiles for furniture 2.0%. However, in practice there is a difference in collection of post-consumer profile waste. Window profiles are collected to a higher percentage than other profiles because a collection scheme is in place for window profiles and roller shutters whereas there is no collection scheme for other profiles.

- **Pipes and fittings:** Pipes and fittings are usually buried in the ground or covered in buildings. They therefore have a low exposure to UV light. This would indicate a low lead concentration. However pipes and fittings generally have a very long life span therefore the amount of lead cannot be too low as this would result in product failure near the end of the lifespan of the product. Pipes (0.5 - 0.8% w/w) and fittings (2.0 - 2.5% w/w) have a relative broad range of lead concentrations as a result of the difference in production process. Piping is made by extrusion. Fittings are injection moulded. In the latter case the residence time is longer and therefore the PVC is at a higher temperature for a longer time and products need higher amounts of stabiliser Lead has always been the preferred stabiliser in piping. Around the turn of the century lead stabiliser started to be phased out in favour of calcium zinc stabilisers. According to the industry, the voluntary commitment of VinylPlus assure that no new lead will be used in these applications after 2015.

- **Flooring**: According to the industry (Tauw 2013), the phasing out of lead in flooring in the EU was finished already in 2000. As flooring trends changes quite fast the flooring products change quite fast too. Therefore it is difficult to currently estimate an average lead content in PVC flooring products, but before 2000 it has been used at 0.8% w/w for the flooring applications. Not all flooring products made of PVC have contained lead stabilisers. For instance, the market share of lead stabilisers in compact flooring was never very high as lead is known to cause staining. The best estimate assumes a steady decline starting in the mid ‘70s. The voluntary commitment of VinylPlus was bound that no new lead will be used after 2015.

- **Roofing:** Although Information on the lead content in roofing is very limited an average lead concentration of 1.2% w/w in the roofing material can be considered to be valid. Since 2010, European industry associated has no longer used in these applications, thereby compliance with the voluntary commitment of

VinylPlus is expected to phase out lead stabilisers before the end of 2015 also for roofing.

- **Cable jackets/sheaths:** Cables can have a PVC jacket or sheathing. PVC is chosen as it is relatively fire retardant. As there are many different cable types with different specifications, the concentration of lead (% w/w) varies across a wide range such as: domestic cable jacketing (0.7%), domestic cable insulation (1.0%) finished jacket (1.6%), car cables (2.1-4.2%), high temperature cables (3.5%).

The first four items in the above list are products that in general can contain recycled material originating from post-consumer PVC waste. As post-consumer waste can contain lead, these products will in practice also contain lead if they are made of recycled material. Cable jacketing/sheathing in general contains no recyclate from post-consumer waste as this might lead to shortcuts of electrical current. As waste PVC from cables has been stabilised with lead and is being used in other articles, it is an application of interest for this study.

It should be noted that the European Commission commissioned BiPRO (2015) to assess whether certain complex materials, in particular plastics, could be exempted from the application of the concentration limits for classification which are provided in annex III of the Waste Framework Directive (WFD). In some cases this is linked to mirror entries in the EU hazardous waste list[12]. A key element of this study was to prepare an overview of hazard and risk properties of different plastics, including to what extent various hazardous substances (such as lead) are liberated from that waste. More details about this study and the results are given in the Appendix to Annex A.

It should be noted that since the EU industry - through its voluntary schemes (VinylPlus)- has committed to phase out the use of lead in PVC by end of 2015 (as discussed in the next session), the above presented information of lead concentration in PVC articles could be considered rather historical concerning the EU produced PVC articles. However, the lead concentration ranges for the different applications could still be applicable for the PVC imported articles, since these are produced mainly in Asian countries where lead compounds are still widely used as PVC stabilisers.

According to KEMI 2012 lead based stabilisers are assumed to be the source of lead in plastic details in reflective bracelets, interior decoration but also in plastic prints on textiles and polymer materials in clothes and accessories. It might be a source of lead in PVC coated rainwear and other coated textiles, but this has not been confirmed. It must be noted that these consumer uses are already restricted by the new restriction provisions of Entry 63 (paragraphs 7-10) for lead and its compounds in consumer articles and be therefore out of the scope of this assessment.

[12] The EU Waste Framework Directive (WFD) (2008/98/EC)[12] stipulates a number of specific obligations for waste producers and waste holders in case waste is considered hazardous. Hazardous Waste" is defined by Article 3(2) WFD as "waste which displays one or more of the hazardous properties listed in Annex III", further specified by Commission Decision 2000/532/EC establishing a list of waste. Member States have to ensure that hazardous waste is subject to specific control (Article 17 of 2008/98/EC), including a tracking system. According to the Annex III of the Waste Framework Directive, the waste classification threshold for lead compounds is 0.3%.

A.2.3. Current trends in lead stabilisers (VinylPlus voluntary commitment)

After concerns have been expressed about possible adverse effects of lead on health and the environment, independent experts completed a full Risk Assessment on lead and the results have been passed on to the European Union authorities. In the VinylPlus Voluntary Commitment[13], ESPA (European Stabilisers Producers Association) and EuPC (European Plastics Converters) committed to completely replacing lead-based stabilisers (see list below) by the end of 2015 on the EU-15, with interim targets of a 15% reduction by 2005 and a 50% reduction by 2010. The commitment of 100% phase-out by the end of 2015 was extended to the EU-27 in 2007 (EU-28 in 2014).
In 2014, ESPA's and EuPC's commitment to replacing lead-based stabilisers by the end of 2015 across the EU-27 was extended to the EU-28. The outcome of an ESPA Survey (December 2015) indicated that at the end of 2014 ESPA members (all together supplying > 95% of lead stabilisers of the EU 28 market) were still selling globally about 14 000 tonnes per year in the EU.

According to the VinylPlus Progress report (2016), substitution of lead stabilisers progressed rapidly and further during 2015. As a result of this ESPA (April 2016) informed that the EU sales of formulated lead stabilisers in 2015 by ESPA members must be in a range between 8 000 and 12 000 tonnes, of which a significant amount (approximately 30%) has been used to stabilise PVC articles that are exported from the EU.

In addition, ESPA (September 2016) further updated that they have fully replaced lead stabilisers for PVC sold to their EU 28-based customers, as from 1st January 2016. This is also confirmed by Vinyl 2016 project report[14], claiming that products from virgin PVC resin by European converters will no longer contain lead as of 2016. The gradual phase out of lead stabilisers during the last decade is plotted in the Figure A5.

[13] Analytical info on the VinylPlus Voluntary Commitment on: http://www.vinylplus.eu/programme/about-vinyl-plus

[14] VinylPlus progress report of 2016 available under: http://www.vinylplus.eu/documents/42/59/New-Progress-Report-2016

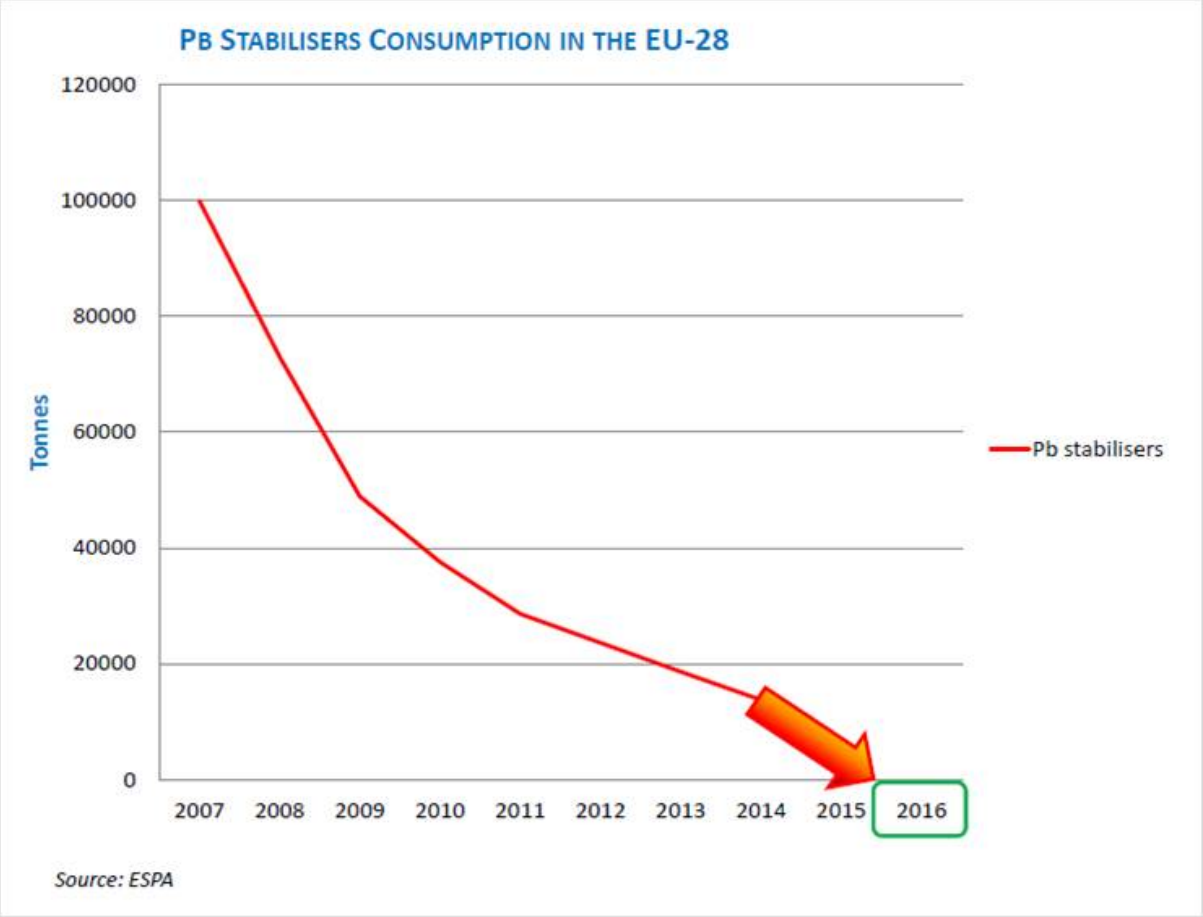


Figure A5. Use of lead stabilisers in the EU during the period 2007-2016 (VinylPlus 2016)

ESPA also informed that an external audit (agreed by ESPA companies) is ongoing to gather evidences about the effective replacement. The first report of this audit confirmed that zero tonnes of lead stabilisers were placed on the EU market in the 1st quarter of 2016. ESPA clarified that to their information only 2 SME European companies were still producing lead stabilisers in the EU 28, (one of which announced they recently stopped this production, the other one only exporting their lead stabilisers outside the EU).

For the purpose of this assessment (as also discussed under Annex F.1.), ECHA has made a forecast for 2016, through a sensitivity analysis foreseeing that tonnes of lead stabilisers to be sold in the EU during 2016 will be in the range between 0 and 600 tonnes considering that:

- **Zero tonnes (lower bound)** reflects a completion of lead phase out via the successful implementation of VinylPlus targets by ESPA members (if confirmed by final outcome results of the ongoing 2016 audit);
- **600 tonnes (upper bound)** accounts for 5% of the maximum estimates for tonnes of lead stabilisers sold in the EU market in 2015 (8000-12000 tonnes). This would account for the production of lead stabilisers from non-ESPA members, thereby non-participants of the VinylPlus initiative (if any).

As will be analytically discussed in other sections of this report, this indicative range of 0-600 tonnes of lead stabilisers sold in the EU market for 2016 will serve as basis for

subsequent estimations of lead emissions (Section B.9.3) and substitution costs (Section E.4.1) for PVC articles produced in the EU 28.

Having put in place commercially viable alternatives to cadmium and lead-based compounds, the European PVC industry has been taken as example by other associations in the world such as the Australian Vinyl Council and SAVA (the Southern African Vinyl's Association), that are addressing the issue of cadmium and lead-based stabilisers in their Product Stewardship Programs. In China, the Beijing-based China Plastics Piping Association (CPPA) recently announced the adoption of a policy to encourage companies to eliminate lead by 2015, mirroring the European PVC industry's Voluntary Commitment. However, ECHA's consultation with WTO (2016) revealed that in Thailand there is a steady and significant increase of use of (imported) lead oxide as PVC stabilisers in the last few years (from approximately 690 tonnes in 2011 to approximately 1900 tonnes in 2015). Since this compound is a main lead stabiliser the fact itself may provide an indication that lead is not to be phased out in the PVC applications in this country.

Overall, it must be noted that lead-based stabilisers have been widely used in PVC products over many years. Due to the long life time of most PVC products (e.g. typically 40 years for window profiles, more than 50 years for pipes), lead is expected to be present in PVC waste for many years to come (CSRs for lead compounds 2015).

A.3. Uses advised against by Registrants

As previously mentioned, the CSRs of the registration dossier have been screened and information on the specific uses of lead compounds in PVC compounding and articles have been extracted. As indicated in 2.3 section of the CSRs of all registered lead PVC stabilisers there are no *'Uses advised against by the registrants'.*

Appendix A

In 2014, the European Commission commissioned *BiPRO* (2015) to assess whether certain types of plastics and rubber, containing hazardous substances above the thresholds defined in Annex III of the Waste Framework Directive, could be exempted from being classified as hazardous waste[15].

A key element of this study was to prepare an overview of hazard and risk properties of different plastics, including to what extent various hazardous substances (such as lead) are present in different types of waste PVC. Table A4 below contains selected data on relevant PVC waste streams and average concentration of lead (BiPRO, 2015). These data indicate that lead is present in a variety of waste PVC articles at concentrations up to 2.5%.

Table A4. PVC waste streams and average concentration of lead (BiPRO, 2015)

Type of PVC	Type of waste	Waste amount (total)	Amount recycled input	Amount recycled output	Fate of recyclate	Average concentration of lead
Rigid	PVC window profiles and related building products (such as shutters, cladding, doors, panels, cable ducts)	245 kt/y	110kt	100kt	Profiles (36%) Sewer pipes (64%)	2.0%
	Pipes and fittings	100 kt/y	27.5kt	25kt	Sewer pipes (70%), other rigid (30%)	
Flexible	Cables	200 kt/y	99kt	90kt	Miscellaneous flexible applications (e.g. membranes, road management, mats).	0.6%
	Flooring	400 kt/y	4.4kt	4kt	Flooring (90%)	0.8% (max)
	Roofing and waterproofing	20 kt/y	4.4kt	4.2kt	Miscellaneous flexible applications	2.5% (max)

[15] The EU Waste Framework Directive (WFD) (2008/98/EC)[15] stipulates a number of specific obligations for waste producers and waste holders in case waste is considered hazardous. Hazardous Waste" is defined by Article 3(2) WFD as "waste which displays one or more of the hazardous properties listed in Annex III", further specified by Commission Decision 2000/532/EC establishing a list of waste. Member States have to ensure that hazardous waste is subject to specific control (Article 17 of 2008/98/EC), including a tracking system. According to the Annex III of the Waste Framework Directive, the waste classification threshold for lead compounds is 0.3%.

Annex B: Information on hazard, exposure/emissions and risk

B.1. Identity of the substance(s) and physical and chemical properties

This Annex XV report concerns lead compounds used as PVC stabilisers and addresses effects both to human health and the environment (during compounding of PVC and by use of PVC articles). These effects are induced not directly by elemental lead (not used as such in PVC) but by the lead ions which could be released during the stabilisation of PVC and the subsequent life cycle of PVC articles containing them as stabilisers. PVC is used in a variety of applications (such as window profiles, cable insulation, pipes and flooring) where lead compounds can be added as stabilisers to endure longer fabrication (heating) time. On average, a PVC article may contain 2-3% weight of lead stabilisers. It may be that these lead compounds are mixed as such to the PVC, but can be also present in articles produced by PVC recyclate containing "legacy lead".

The Table B2 is listing the registered lead compounds, which are commonly used as in PVC in Europe. However, this may still be considered as an indicative list since it is rather difficult to identify all those lead compounds with a potential use as PVC stabilisers (in articles that could be potentially imported in the EU in the future). Consequently, this restriction proposal targets all lead compounds, in a thinking analogous to what described in the Annex XV reports proposing the restriction provisions of entry 63 of Annex XVII for lead in jewellery and lead in consumer articles.

B.1.1. Name and other identifiers of the substances

Nine registration dossiers were submitted to ECHA under REACH Regulation for lead compounds with a registered use as PVC stabiliser. These dossiers have been screened to review and extract any relevant information (e.g. on substance composition / physicochemical properties). For the purpose of this analysis, it has been considered relevant to present indicative information concerning the lead stabilisers which are registered in higher quantities (tonnes per year) such as: trilead dioxide phosphonate (dibasic lead phosphite), tetralead trioxide sulphate (tribasic lead sulphate), and pentalead tetraoxide sulphate (tetrabasic lead sulphate). The following Table B1 reports the name and other identifiers of the indicative list of the selected lead based stabilisers. These are mainly mono constituent substances (origin: inorganic) having the following characteristics and physicochemical properties.

Table B1. Identification of certain lead stabilisers (registered in higher tonnages/year) (Source: REACH registration dossiers/ECHA's website)

EC number	235-252-2	235-380-9	235-067-7
EC name	Trilead dioxide phosphonate	Tetralead trioxide sulphate	Pentalead tetraoxide sulphate
CAS number	12141-20-7	12202-17-4	12065-90-6
Molecular formula	HO5PPb3	O7Pb4S	08Pb5S
Molecular weight range	733.5754	972.8564	1196.0547

B.1.2. Composition of the substances

The Chemical Safety Reports submitted to ECHA for the registered lead stabilisers were screened for the relevant information (CSR for lead compounds, 2015). The degree of purity (% w/w) was broadly found to be at > 95%. Most typical identified impurities were water (EC:213-791-2) in the range 0.5-2.5% and fatty acids C16-18 (EC:266-928-5) in the range 0.2-1.5%.

B.1.3. Physicochemical properties

The main physicochemical properties of the selected lead compounds used as PVC stabilisers are discussed under the section B.6 of this report, based on information extracted from the CSRs of the registration dossiers submitted to ECHA by associated industry.

B.1.4. Justification for grouping

This restriction proposal targets the human health and environmental effects that may result from an exposure to lead which can migrate from PVC materials during the compounding phase (PVC production) and/or its subsequent conversion to articles, where various lead compounds have been used as stabilisers. For that purpose, the proposal globally concerns all the lead compounds. This grouping is justified by the following facts:

- The toxic species which causes the harmful effects is the lead ion itself;
- Since it is not easy to identify all lead compounds which can be used as PVC stabilisers (in particular outside the EU), a restriction of individual lead compounds may lead to a non-efficient risk management;
- There are no methods available to analyse all the specific (organic/inorganic) lead compounds in the relevant articles but only for lead which poses the concern.

Table B2. List of registered (via REACH) lead compounds with a use as PVC stabiliser

Substance name*	**CAS No.**	**EC No.**	**Type of substance**	**Registration band (tonnes per year)**
Trilead bis(carbonate) dihydroxide (Basic lead carbonate)	1319-46-6	215-290-6	inorganic	10 – 100
Tetralead trioxide sulphate (Tribasic lead sulphate)	12202-17-4	235-380-9	inorganic	1 000 000 – 10 000 000
Pentalead tetraoxide sulphate (Tetrabasic lead sulphate)	12065-90-6	235-067-7	inorganic	10 000 – 100 000
[Phthalato(2-)] dioxotrilead (Dibasic lead phthalate)	69011-06-9	273-688-5	organic	100 – 1 000
Lead oxide sulfate (Basic lead sulphate)	12036-76-9	234-853-7	inorganic	0 – 10
Dioxobis(stearato)trilead	235-702-8	235-702-8	inorganic	10 000 – 100 000
Trilead dioxide phosphonate (Dibasic lead phosphite)	12141-20-7	235-252-2	inorganic	10 000 – 100 000
Sulfurous acid, lead salt, dibasic	62229-08-7	263-467-1	inorganic	100 -– 1 000
Fatty acids, C16-18, lead salts	91031-62-8	292-966-7	organic	10 000 – 100 000

B.2. Manufacture and uses (summary)

In the frame of this assessment, ECHA has performed extensive consultations and information exchanges with the various stakeholders and reviewed the most updated information from available EU reports and studies concerning "Manufacturing and Uses" of PVC articles and lead PVC stabilisers. Therefore, the following important sets of information and data are presented and discussed in the Annex A:

- An overview of the PVC manufacturing and applications in the EU, along with a broad picture of the PVC market and industry (mainly consultation with ECVM, EuPC etc.);
- Information on the -currently implemented in the EU-PVC waste management practices (landfill, incineration, recycling) along with a prognosis of their distribution over the next decades (mainly consultation DG-ENV; Plastics Europe etc.);
- Information on lead compounds used as PVC stabilisers in the EU, their main PVC applications and market trends (mainly consultation with ESPA, VinylPlus etc.).

It has to be noted that quite a few of the information and data presented in Annex A: offered the basis for further analysis and estimates in critical parts of the assessment presented in this report. An indicative list of the most important figures is given below:

- The figures provided by Industry and presented in section A.1.2 (e.g. share of construction relevant PVC uses; average service life of relevant PVC articles) have been used as inputs in the exposure estimates (as analytically discussed in the analysis of assumptions/uncertainties under section F.1.1);
- The data submitted by Eurostat on the PVC imports to the EU during the last decade have been further used in the exposure assessment (see sections 0 and B.9.3);
- The prognosis over the distribution of waste management practices in the EU served as basis for the estimation of lead emissions after the disposal of PVC articles (see sections B.9.1 and F.1.1);
- The figures provided by Industry and presented in Section A.2 for the sales of lead PVC stabilisers in the EU and their market trends offered the basis for cost and exposure estimations, which are discussed in sections E.4.1 and B.9.3.

Overall, the information concerning the manufacturing and uses of PVC articles stabilised by lead compounds were proven to be essential in the risk assessment (in particular the exposure estimations) as well as on the cost/benefit assessment of the proposed restriction.

B.3. Classification and labelling

B.3.1. Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

The classification of lead compounds depends of the intrinsic properties of the lead cation as well as the intrinsic properties of the anion of the compound.

There are several harmonised classifications for lead compounds according to Annex VI of the CLP Regulation[16], under the entry "lead compounds with the exception of those specified elsewhere in this Annex (Index No 082-001-00-6)". The classification is given in the Table B3 below:

Table B3. Harmonised classification for the lead compounds (Annex VI of CLP Regulation)

Index No	**International Chemical Identification**	**EC/ CAS No**	**Classification**		**Spec. Conc. Limits**	**M-factors**
			Hazard Class and Category Code(s)	**Hazard statement code(s)**		
082-001-00-6	lead compounds with the exception of those specified elsewhere in Annex VI	-	Repr. 1A Acute Tox. 4* Acute Tox. 4* STOT RE 2* Aquatic Acute 1 Aquatic Chronic 1	H360-Df H332 H302 H373** H400 H410	Repr.2; H361f: C C≥2.5% STOT RE 2; H373: C≥0.5%	Aquatic Acute 1: 10 Aquatic Chronic 1: 1

Therefore, the most critical harmonised classifications for lead compounds in general are:

- Repr. 1A, H360Df (May damage fertility or the unborn child);
- STOT RE 2*H373 (May cause damage to organs through prolonged or repeated exposure);
- Acute tox. 4* H302 (Harmful if shallowed);
- Acute tox. 4* H332 (Harmful if inhaled);
- Aquatic Acute 1, H400 (Very toxic to aquatic life);

[16] Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. OJ L 353, 31.12.2008, p.1.

- Aquatic Chronic 1, H410 (Very toxic to aquatic life with long lasting effects).

The Table B3 also makes reference to (i) the Specific Concentration Limits (SCL) (ii) M-Factors[17] assigned for both acute and chronic effects to the aquatic environment, which are common for all the lead compounds in question.

It has to be noted that a proposal for harmonised classification of metallic lead has been submitted to ECHA in 2012, on which the scientific opinion of ECHA's Risk Assessment Committee[18] concluded that that (i) all physical forms of metallic lead should be classified as Repr. 1A-H360DF (Repr. Cat 1; R60-61) (May damage fertility; May damage the unborn child) similar to the classification that apply for "lead and lead compounds"; (ii) According to the criteria in the CLP Guidance (3.7.2.5), the generic concentration limit would underestimate the hazard therefore the metallic lead should be assigned a specific concentration limit of 0.03% for developmental toxicity (H360D, C ≥ 0.03%).

With reference to the main CLP hazard statements of relevance, the following Table B4 is therefore listing the labelling elements to which the commercially available lead stabilisers have to comply in the EU market.

Table B4. CLP labelling requirements for the lead stabilisers

Hazard statements	Hazard pictograms
H410: Very toxic to aquatic life with long lasting effects. H400: Very toxic to aquatic life. H360Df: May damage the unborn child. Suspected of damaging fertility. H332: Harmful if inhaled. H302: Harmful if swallowed. H332: Harmful if inhaled. H373: May cause damage to central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion.	Signal word: Danger GHS07: exclamation mark  GHS08:health hazard  GHS09: environment 

[17] M-Factors[17] assigned for both acute and chronic effects to the aquatic environment are based upon results of T/dp testing and use of the Unit World Model to evaluate removal of the Pb ion from the water column

[18] Available under: http://echa.europa.eu/documents/10162/57ceb1ac-aafc-4852-9aa5-db81bcb04da3

B.3.2. Classification and labelling in classification and labelling inventory/Industry's self classification(s) and labelling

A search has been performed via the classification inventory at the ECHA web-site for the lead compounds with registered use as PVC stabiliser. This contains classification and labelling information on notified and registered substances received from manufacturers and importers. These are self-classifications which are used by the suppliers of the chemicals. There have been cases where the same compounds may be classified differently by different notifiers. This may be due to e.g. different data sources for the notifications or different interpretation of the data by the notifiers, or maybe errors.

The outcome of this searching is listed in the following Table B5 where the number of notifiers is recorded (including the joint notifications).

It has to be noted that for hazard classes not covered by Annex I (discussed under B.3.1), the manufacturer or importer is required to self-classify the substance in accordance with the criteria described in the guidance to the DSD.

Table B5. Outcome of CLP's inventory searching for lead compounds registered as PVC stabilisers (Source: CLP Inventory, 2016)

Substance name*	CAS No.	EC No.	Number of Notifiers
Trilead bis(carbonate) dihydroxide (Basic lead carbonate)	1319-46-6	215-290-6	10 (158)
Tetralead trioxide sulphate (Tribasic lead sulphate)	12202-17-4	235-380-9	7 (53)
Pentalead tetraoxide sulphate (Tetrabasic lead sulphate)	12065-90-6	235-067-7	2
[Phthalato(2-)] dioxotrilead (Dibasic lead phthalate)	69011-06-9	273-688-5	0
Lead oxide sulfate (Basic lead sulphate)	12036-76-9	234-853-7	0
Dioxobis(stearato)trilead	235-702-8	235-702-8	2
Trilead dioxide phosphonate (Dibasic lead phosphite)	12141-20-7	235-252-2	18 (37)
Sulfurous acid, lead salt, dibasic	62229-08-7	263-467-1	1
Fatty acids, C16-18, lead salts	91031-62-8	292-966-7	1

B.4. Environmental fate properties

The information presented in this section is a compilation of data primarily extracted from the voluntary Risk Assessment (VRAR) on lead and lead compounds (LDAI, 2008)[19], the 2014 EPA (Denmark) survey on lead and lead compounds[20] as well as the REACH registration dossiers for lead compounds and the available literature.

Lead is present in the environment due to natural processes (resulting in a natural background concentration of lead in all environmental compartments, including biota). Chemical processes affect the speciation of lead in the environment which, in turn, influences exposure and effects (LDAI, 2008).

Information on the environmental fate and behaviour of lead is based on either monitoring data for lead in water, soil, sediment, suspended matter and biota or the results of speciation studies with lead (di) nitrate and lead chloride. All reliable data are expressed as elemental lead concentrations and grouped together (for all lead compounds) in a read-across approach.

B.4.1. Degradation

The classic standard testing protocols on hydrolysis and photo-transformation are not applicable to lead and inorganic lead compounds. This was recognised in the Guidance to Regulation (EC) No 1272/2008 Classification, Labelling and Packaging[21], of substances and mixtures (metal annex):

"Environmental transformation of one species of a metal to another species of the same does not constitute degradation as applied to organic compounds and may increase or decrease the availability and bioavailability of the toxic species. However as a result of naturally occurring geochemical processes metal ions can partition from the water column. Data on water column residence time, the processes involved at the water – sediment interface (i.e. deposition and re-mobilisation) are fairly extensive, but have not been integrated into a meaningful database. Nevertheless, using the principles and assumptions discussed above in Section IV.1, it may be possible to incorporate this approach into classification."

As outlined in the CLP Guidance, the understanding of the transformation of lead into more or less bioavailable species is relevant to environmental hazard assessment and is described below.

B.4.1.1. Abiotic degradation

In general, (abiotic) degradation is an irrelevant process for inorganic substances that are assessed on an elemental basis. As the chemical safety assessment is based on elemental lead concentration physicochemical processes like photo-transformation and hydrolysis are not relevant. Formation of different lead hydroxides may occur, but the chemical assessment will not make any differentiation among the different lead species

[19] Voluntary Risk Assessment on lead metal, lead oxide, lead tetroxide and lead stabilisers. (2008) Lead development Association International

[20] Survey of lead and lead compounds (2014). Danish Ministry of the Environment, Environmental Protection Agency: http://www2.mst.dk/Udgiv/publications/2014/01/978-87-93026-93-3.pdf

[21] Available under: https://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf

(pooling of different speciation forms). This elemental-based assessment (pooling all speciation forms together) can be considered as a worst-case assumption.

B.4.1.2. Biodegradation

Biotic processes may alter the speciation of lead in organic, but will not eliminate it from the environment by degradation or transformation. An elemental-based assessment (pooling all speciation forms together), such as that undertaken in this restriction report, can be considered as a worst-case assumption.

According to Annex VII of REACH and Chapter R.7B of the ECHA REACH Guidance (2008)[22], the requirements for "ready biodegradability" can be waived if the substance is inorganic.

B.4.2. Environmental distribution

B.4.2.1. Lead speciation

Lead in its metallic form (Pb°) needs to be transformed to its ionic forms to become available for uptake by biota. Therefore, the rate and extent of the transformation/dissolution of lead in its powder forms have been assessed from transformation/dissolution tests (in accordance to the OECD guidance, Annex 10 of the GHS). The initial data demonstrated that the release of soluble lead - ions from Pb° is greater at lower pH. The results of the transformation/dissolution tests are summarised as follows:

For massive lead materials, transformation/dissolution tests were carried out at pH 6, in accordance to the OECD protocol on transformation/dissolution[23]. The results were used to derive the release of lead- ions from 1 mm particles at loadings of 1, 10 and 100 mg/L.

7-day transformation/dissolution testing of a massive particle of 1 mm diameter at pH 6, and a loading of 100 mg/L results in a total release of 428.9 µg Pb/L.

The results from 28 day transformation/dissolution test of a massive particle of 1 mm diameter at pH 6, and a loading of 1 mg/L, corresponds to 14.2 µg Pb/L. These results are relevant for hazard classification.

For lead powders, transformation/dissolution tests were carried out on fine lead powders (<75µm,) in accordance to OECD protocol at pH 6, 7 and 8.

The release of lead to aqueous medium at 24h for the 100 mg/L loading at pH 6 was 3211.2 µg/L. For the 100 mg/L loading at pH 7 and 8, the average concentrations of lead released at 24h was 607 and 187.5 µg/ respectively.

Lead ions have more than one oxidation state in the environment. The principal ionic form is Pb(II) (Pb^{2+}), which is more stable than Pb(IV) (Pb^{4+}). In all environmental compartments (water, sediment, soil), the binding affinities of Pb(II) with inorganic and

[22] Available under: https://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf

[23]Available under: http://www.ime.fraunhofer.de/content/dam/ime/de/documents/AE/OECD_ENV_JM_MONO_2001_9.pdf

organic matter are dependent on pH, the oxidation-reduction potential in the local environment, and the presence of competing metal ions and inorganic anions.

B.4.2.2. Aquatic compartment

Lead enters the aquatic environment via municipal and industrial wastewater, runoff and leaching from natural and anthropogenically burdened soils, atmospheric deposition and corrosion and abrasion of lead containing materials (EPA-Denmark, 2014).

Freshwater environment

The amount of lead that is dissolved in surface waters depends on the pH of the water and the properties of specific lead salts. For example, solid lead is virtually insoluble (dissolving relatively slowly), whereas the solubility of lead oxide is 107 mg/L at 25°C. At pH values at or below 6.5 most of the dissolved lead is in the form of the free Pb^{2+} ion. In waters containing natural organic matter (NOM), organically bound lead also influences speciation and bioavailability, with increasing amounts of NOM generally reducing the concentration of the free Pb^{2+} ion. Sulphate ions limit the dissolved lead concentration through the formation of poorly soluble lead sulphate. At higher pH levels lead carbonates ($PbCO_3$ and $Pb_2(OH)_2CO_{3)}$, determine the amount of lead in solution. The carbonate concentration is in turn dependent upon the partial pressure of carbon dioxide, pH, and temperature.

In most surface waters and ground waters, the concentration of dissolved lead is low because the lead will form complexes with anions in the water such as hydroxides, carbonates, sulphates, and phosphates that have low water solubility and these complexes will precipitate out of the water column. A significant fraction of lead carried by river water is expected to be in an undissolved form, which can consist of colloidal particles or larger undissolved particles of lead carbonate, lead oxide, lead hydroxide, or other lead compounds incorporated in other components of surface particulate matters from runoff. Lead may occur either as absorbed ions or surface coatings on sediment mineral particles, or it may be carried as a part of suspended organic matter in water. The ratio of lead in suspended solids to lead in dissolved form has been found to vary from 4:1 in rural streams to 27:1 in urban streams (LDAI, 2008).

An overview of the partitioning coefficients (Log K_D (L/kg)) for lead between freshwater and suspended particulate matter (SPM) (LDAI, 2008) is provided in Table B6.

Table B6. Reported log KD, SPM values for lead in freshwaters in Europe (LDAI, 2008)[24]

Location	Log K_D (L/kg)	Remarks	Reference
Four Dutch Lakes	6.0	average	Koelmans and Radovanovic, 1998
Calder River, UK Nidd River, UK Swale River, UK Trent River, UK All rivers All rivers	4.45 - 5.98 4.69 - 6.25 4.58 - 6.20 4.61 - 6.06 5.41 5.71	min-max range min-max range min-max range min-max range observed mean predicted mean	Lofts and Tipping, 2000
Scheldt, Belgium	5.3	salinity of 1.5 ppm	Nolting et al., 1999
Po River, Italy	5.5	median value	Pettine et al., 1994
Dutch freshwater	5.81	mean	Stortelder et al., 1989; in Crommentuyn et al., 1997
Upland-influenced river water, UK Low-salinity water, UK	4.6 5.5	modelled value modelled value	Tipping et al., 1998
7 freshwater locations in The Netherlands	5.93		Venema, 1994; in Crommentuyn et al., 1997
54 Czech rivers / 119 locations	5.44 5.18	median K_D median K_A(1)	Veselý et al., 2001
RANGE	4.45 – 6.25		

Marine environment

A median $K_{D,SPM}$ for Pb was calculated for suspended particulate matter in the marine environment as shown below in Table B7. Four reported marine log $K_{D, SPM}$ values were below 5.0 and were representative for the Atlantic Ocean, the Adriatic Sea, the Greek coast near Lesbos and the Scheldt estuary (4.7, 4.8, 4.1 and 4.9, respectively). Log $K_{D, SPM}$ values for the North Sea are between 5.0 and 7.25. The maximum value was found for the Adriatic Sea (log $K_{D, SPM}$ of 7.8). All reported log $K_{D, SPM}$ for other marine water bodies were reported to be between 5.0 and 7.8.

[24] (1)K_A: based on the acid soluble concentration for the calculation of local and regional exposure concentrations the median log $K_{D, SPM}$ value of 5.47 is selected. This value corresponds with a $K_{D, SPM}$ of 295,121 l/kg. For freshwater sediments, the selected K_D value was 153 848 L/kg (Log K_D: 5.19).

Table B7. Reported log KD, SPM values for Pb in marine surface water (LDAI, 2008)

Location	Log K_D (L/kg)	Remarks	Reference
Belgian coastal waters	5.30-5.60	Min-max range	Baeyens et al, 1987
North Sea coastal waters	5.0-7.0	Min-max range	Balls, 1989
Scottish Sea Loch	6.47	Average value of 3 sampling stations	Hall et al, 1996
Southern North Sea	5.9-7.1[2]	Min-max range, NSP-data	McManus and Prandle, 1996
Dover strait	5.71[2]	Summer/winter value	
Northern North Sea	6.68[2]	Late summer	
Humber/Wash, UK	6.53[2]	Winter/spring	
Humber/Wash, UK	7.24[2]	Summer	
Scheldt, Belgium	4.9	Salinity of 30 ppm	Nolting et al, 1999
Baltic Sea	5.78[2]	10th percentile	Pohl and Hennings, 1999
	6.49[2]	50th percentile	
	7.10[2]	90th percentile	
North Sea	5.51[2]	10th percentile	Tappin et al, 1995
	6.30[2]	50th percentile	
	7.25[2]	90th percentile	
Seawater, UK	6.2	Modelled value	Tipping et al, 1998
Oceans	6.3-6.5	Min-max range	Valenta et al, 1986
Mytilene, Greek coast	4.1	Calculated value	Angelidis et al, 2003
Adriatic Sea	4.8-7.8	Min-max range	Tankéré et al, 2001
Black Sea	5.9-6.6	Min-max range	Tankéré et al, 2001
Atlantic Ocean	4.7-6.4	Min-max range	Helmers, 1996
RANGE	4.1-7.8		

[2]Values and/or percentiles were calculated based on reported dissolved and particulate Pb-concentrations

Waste water treatment plants

Removal of lead in waste water treatment plants may take place by adsorption to particles (EPA Survey, 2014). The proportion of lead that either remains in the solution (and thus is released in the effluent) or becomes associated with suspended solids (and removed with sludge) is in part dependent on the chemical form and speciation of the metal in the incoming sewage. Table B8 reports input and output data for lead in sewage

treatment plants in the Netherlands and Belgium and the corresponding removal. The Voluntary European Risk Assessment report for lead reports a typical removal efficiency for Pb in waste water treatment plants in EU of 84% (LDAI, 2008).

Table B8. Lead input, output data (tonnes Pb/year) and removal data (%) for sewage treatment plants in the Netherlands and Belgium (LDAI, 2008)

Sewage Treatment Plant, year	**Total input (T Pb/year)**	**Total output from STP (T Pb/year)**	**Removal**
The Netherlands			
1993	81.7	12.7	84.4%
2000	59.4	8.6	85.6%
2001	66.3	10.2	84.5%
2002	55.2	8.1	85.4%
2003	50.7	8.5	83.3%
2004	49.3	6.6	86.7%
Belgium			
Flanders, 2000	3603.3	648.6	82%
Flanders, 2001	2323.3	418.2	82%
Flanders, 2002	960	172.8	82%

According to information on the lead concentration measured in the influent and effluent of Danish sewage treatment plants (13 µg/L and 1.8 µg/L, respectively - based on data from 1998-2009), a removal of approximately 86% is achieved during wastewater treatment (Danish Nature Agency, 2011).

From the literature overview (data source: REACH Registration dossiers for lead compounds) specific partitioning coefficients have been derived for lead. These are listed in the following Table B9.

Table B9. Partition coefficients for lead (Registration dossiers for lead compounds, 2015)

Partition coefficient (Compartment)	**Value (L/kg)**
Aquatic environment	
Freshwater suspended matter	Kpsed = 153 848
Estuarine suspended matter	Kpsusp= 667 954
Marine suspended matter	Ksusp= 1 518 099
Marine sediment	Kpsed = 457 088
Soil compartment Kd value soil: 6 400	

According to the available literature, volatilisation is not an applicable endpoint for the various lead compounds used as lead stabilisers.

B.4.2.3. Air lead emissions

This section gives an overview of the most relevant information presented in the Voluntary Risk Assessment for Lead (LDAI, 2008). The most important anthropogenic sources of lead entering the atmosphere are combustion of fossil fuels and releases during production processes (smelters and chemical production, Ecolas 2003). The transport and distribution of lead from major emission sources is mainly atmospheric. Most of the lead discharged to the atmosphere is deposited near the source, approximately 20% is widely dispersed. The extent of long-range transport is dependent on the particle size. Small particles can travel 10-30 days before settling. Lead can be removed from the atmosphere by wet and dry deposition, wet deposition being the more important (IPCS, 1995).

In the atmosphere, non-organic compounds of lead exist primarily in the particulate form. Upon release to the atmosphere, lead particles are dispersed and ultimately removed from the atmosphere by wet or dry deposition. Approximately 40–70% of the deposition of lead is by wet fallout; historically, 20–60% of particulate lead emitted from automobiles when leaded petrol was used was deposited near the source. An important factor in determining the atmospheric transport of lead is particle size distribution. Large particles, particularly those with aerodynamic diameters of >2 μm, settle out of the atmosphere fairly rapidly and are deposited relatively close to emission sources (e.g., 25 m from the roadway for those size particles emitted in motor vehicle exhaust in the past); smaller particles may be transported thousands of kilometres. The dry deposition velocity for lead particles with aerodynamic diameters of 0.06–2.0 μm was estimated to range between 0.2 and 0.5 cm/second in a coniferous forest in Sweden, with an overall particle-size weighted dry deposition velocity of 0.41 cm/second (Lannefors et al. 1983).

The amount of lead scavenged from the atmosphere by wet deposition varies widely; wet deposition can account for 40–70% of lead deposition depending on such factors as geographic location and amount of emissions in the area (Nielsen 1984). An annual scavenging ratio (concentration in precipitation, mg/L, to concentration in air, μg/m³) of 0.18×10^{-6} has been calculated for lead, making it the lowest value among seven trace metals studied (iron, aluminium, manganese, copper, zinc, cadmium and lead); this indicates that lead (which initially exists as fine particles in the atmosphere) is removed from the atmosphere by wet deposition relatively inefficiently. Wet deposition is however more important than dry deposition for removing lead from the atmosphere; the ratio of wet to dry deposition was calculated to be 1.63, 1.99, and 2.50 for sites in southern, central, and northern Ontario, Canada, respectively (Chan et al. 1986). Lead particles from automobile emissions are quite small (<0.1 μm in diameter) but can grow in size by coagulation (Chamberlain et al. 1979).

It must be stressed that most of the above discussion relates to the period in time where leaded petrol was the main source of emissions. However emissions to air from leaded petrol use are now negligible in the EU. Ambient and natural background lead concentrations in air for different EU countries are summarised in Table B10.

The World Health Organisation set an air quality guideline for lead of between 0.5 and 1.0 μg/m³ as an annual average (WHO, 1997), although a WHO working group recently recommended revising the guideline to 0.5 μg/m³. The EU lead in air standard is currently 0.5 μg/m³.

LDAI (2008) provided the following Table B10 with available typical ambient and background Pb concentrations in air for different EU countries extracted predominantly from the airbase database.

Table B10. Typical ambient and background Pb concentrations (µg/m³) in air for different EU countries (LDAI, 2008)

EU country	**Background rural**	**Traffic urban/suburban**	**Industrial urban/suburban**
United Kingdom (2000)	0.019	0.023	0.117
Belgium (1999-2000)	0.032	0.0618	0.2926
Denmark (1999-2000)	0.005	0.0105	-
Finland (2000)	0.005	0.01	-
Germany (2001)	-	0.02	0.05
Ireland (1999-2000)	-	0.050	0.64
Spain (1999)	-	0.0856	0.1275
The Netherlands (2001)	0.0113	0.0127	-
France (2000-2002)	-	0.0165	0.166

Furthermore, ECHA has recently (April 2016) contacted the European Environmental Agency (EEA) that provided some EU monitoring data concluding that:[25]

- Across the EEA-33 countries, emissions of lead decreased by 92% between 1990 and 2013 (while emissions of mercury fell by 73% and cadmium by 75% over the same period).
- Lead emissions from the road transport sector decreased by 98% between 1990 and 2013 – a particular success story. Nevertheless, this sector still remains an important source of lead, contributing around 15% of the remaining lead emissions in the EEA-33 region. Since 2004, little progress has been made in reducing emissions further; 99% of the total reduction from 1990 levels of lead emissions was achieved by 2004.

B.4.3. Bioaccumulation

B.4.3.1. Aquatic bioaccumulation

Bioconcentration (BCFs) and bioaccumulation factors (BAFs) for lead from water to aquatic invertebrates and fish are summarised in the voluntary risk assessment of lead (LDAI, 2008; REACH registration dossier for lead compounds 2015). A key consideration in terms of data reliability were whether steady-state tissue concentrations were achieved in the test and whether metal concentrations were measured over the duration

[25] More information and data available under: http://www.eea.europa.eu/data-and-maps/indicators/eea32-heavy-metal-hm-emissions-1/assessment-5

of the exposure period. In that context, the lead concentration from biota sampled from natural environments are assumed to be at equilibrium. In addition, BCF data based on exposure concentrations that resulted in significant effects on the exposed organisms were not included.

An overview of the reliable whole-body BCF/BAF values obtained for freshwater organisms is summarised, listed in Table B30 and Table B31 of the Appendix B1.

With regard to the choice of using BCF values or BAF values the use of BAF values is preferred since the latter include all possible exposure routes (i.e. next to the uptake via water also exposure via food or soil/sediment) and are therefore considered to be ecologically more relevant than BCF values.

Within typical environmental concentration range (i.e. between 0.18 µg/L[26] (background concentration) and 15 µg/L (based on the 95th percentile of the PEC_{local} values), the gathered BAFs for fish ranged between 11 and 143 L/kg_{ww} (10 – 90th%) with a median value of 23 L/kg_{ww} while the BAFs for molluscs ranged between 18 and 3 850 L/kg_{ww} (median value of 675 L/kg_{ww}), for insects between 968 and 4 740 L/kg_{ww} (median value of 1 830 L/kg_{ww}) and for crustaceans between 1 583 and 11 260 L/kg_{ww} (median value of 3 440 L/kg_{ww}) (Table B10). The results are summarised in the following overview Table B11.

Table B11. The range of bioaccumulation factor (BAF in L/kgww) of lead in freshwater organisms (LDAI, 2008)

Diet	**Variable**	**10th percentile**	**50th percentile**	**90th percentile**	**n**
Crustaceans	All exposures	1 187	3 159	10 570	8
	0.18-15 µg/L	1 583	3 440	11 260	7
Molluscs	All exposures	11	473	3 535	14
	0.18-15 µg/L	18	675	3 850	11
Annelids	All exposures	1 620	1 620	1 620	1
	0.18-15 µg/L	1 620	1 620	1 620	1
Acarides	All exposures	1 730	1 730	1 730	1
	0.18-15 µg/L	1 730	1 730	1 730	1
Insects	All exposures	968	1 830	4 740	7
	0.18-15 µg/L	968	1 830	4 740	7
Fish	All exposures	11	24	245	16
	0.18-15 µg/L	11	23	143	16

According to the TGD (2003) it is assumed that the diet consists entirely of one realistic food type, i.e. fish. It is recognized that ideally, for a more realistic assessment, data on

[26] The measured aquatic Pb concentrations below detection limit of 0.2 µg/L were considered as falling within the typical environmental concentration range.

food consumption of birds and mammals should be considered. Thus, a realistic mixed diet BAF value can be calculated using the following formula:

$$\mathrm{BAF}_{\mathrm{mixed\,diet}} = \sum_{\mathrm{i}=1}^{\mathrm{n}} f_i \times BAF_{\mathrm{i}}$$

with BAF_i the representative bioaccumulation factor (10^{th}, 50^{th} or 90^{th} percentile) for an individual prey species i (L/kg); n: the number of prey species considered in the mixed diet of the predator; f_i: the proportion of the different food types in the mixed diet (value between 0 and 1). To reflect such mixed diet scenario it is assumed (as no data are available on food type consumption and proportion of the different food types in the mixed diet) that birds/mammals consume equal proportion of the different food types as reported in Table B11 i.e. crustacean, mollusc, annelid, acaride, insect and fish. Based on significant high bioaccumulation for many metals in molluscs, secondary poisoning was also considered for a "mollusc food chain". The range of bioaccumulation factors (BAFs in L/kg_{ww}) of lead in the mixed and mollusc food diet is presented in Table B12 shows that the 50^{th}% of the mixed diet BAF for aquatic organisms is 1 553 L/kg (90^{th}%: 3 890 L/kg) and that the mixed diet scenario is driven by the BAF values retrieved from the invertebrates.

Table B12. The range of bioaccumulation factor (BAF in L/kg ww) of lead in the mixed diet (LDAI, 2008)

Diet	**Variable**	**10^{th} percentile**	**50^{th} percentile**	**90^{th} percentile**	**n**
Mixed food diet	All exposures	921	1 472	3 740	49
	0.18-15 µg/L	988	1 553	3 890	44
Mollusc food diet	All exposures	11	473	3 535	14
	0.18-15 µg/L	18	675	3 850	11

The 50^{th}% BAF of the mollusc food diet is somewhat lower, i.e. 675 L/kg (90^{th}%: 3 850 L/kg). The mollusc food chain results in lower overall BAF values for lead than the mixed diet food-chain. Therefore, the mixed diet median BAF value of 1 553 L/kg is further used for the assessment of the secondary poisoning in the aquatic environment.

B.4.3.2. Terrestrial bioaccumulation

A wealth of data is available on bio concentration factors or bioaccumulation factors. Only a selection of BAF data is given here, merely as an illustration rather than to serve as a complete survey. Data were considered reliable:

- if the data came from field studies or laboratory studies using soil and biota collected at the same field site. This is to ensure that biota lead burdens are in equilibrium with soil lead concentrations. Data from laboratory studies where lead was added to the soil as a lead salt are excluded;
- if lead concentrations were measured in soil and biota. The lead concentration in soil has to be expressed as "total" soil lead (e.g. lead measured after *aqua regia* destruction), extractable lead fractions (e.g. water-extractable lead) are not considered reliable;

- if guts from the biota were voided prior to analysis;
- if it was indicated how BAF values were expressed, i.e. on a dry or wet weight basis.

According to the REACH Guidance Document (Chapter R16)[27], the food-chain soil, earthworms and earthworm eating predators is considered for risk characterisation purposes. Bioaccumulation factors (BAFs) for lead from to soil to earthworms are summarised in the voluntary risk assessment of lead, VRAL (LDAI, 2008). Results of lead bioaccumulation studies in soil are presented in Table B31 and Table B32 of Appendix B1.

A median BAF for earthworms on a dry weight basis is 0.39 kg_{dw}/kg_{ww} (median of 101 values) and 10-90th percentiles are 0.13-1.17. On a fresh tissue weight basis, BAF values are 0.10 kg_{dw}/kg_{ww} (median) and 0.03-0.27 (10-90th percentiles). The influence of soil properties on the BAF of earthworms (*A. calluginosa*) was studied in different soils and the equation describing the BAF as a function of pH reads, with BAF on a wet weight basis (kg_{dw}/kg_{ww}).

BAF=13.9*exp(-0.76*pH) (Ma, 1982). This equation predicts that the median BAF of the 101 data points above (BAF= 0.10 kg_{dw}/kg_{ww}) is found at pH=6.5. At pH 4.5, this BAF is 4-fold larger. There is no significant effect of total soil lead on the BAFs (LDAI, 2008).

A few literature data are available for bioaccumulation of lead in isopods from soil or litter, 14 BAFs were collected and listed in

[27] Available under: https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

Table B33. Values range from 0.001-0.65 kg_{dw}/kg_{dw}. A median BAF for isopods on a dry weight basis is 0.04 (median of 14 values).

From the literature overview, the following bioaccumulation/bioconcentration factors have been derived for lead:

- Aquatic compartment: Bioaccumulation/bioconcentration factors in freshwater: 1 553 L/kg (wet weight)
- Soil compartment: Bioaccumulation/bioconcentration factors in soil: 0.39 kg/kg (dry weight)

B.4.4. Secondary poisoning

Based on the available information on the bioaccumulation potential of lead, secondary poisoning is considered relevant and will be further assessed.
The VRAR (LDAI, 2008) has considered that the use of the traditional lower-tier methodology for assessing the secondary poisoning risk of lead is unsuitable and therefore recommended an alternative approach. Basically, the dose/response assessment is based on internal dose, using lead concentrations in blood for expressing the internal dose, and the SSD concept is applied to limited toxicity data sets for mammals and birds (Buekers et al 2008).
Several mammalian and avian toxicity data from laboratory feeding studies are applied by the VRAR in deriving the $PNEC_{oral}$. According to the TGD methodology the $PNEC_{oral}$ should be calculated from the lowest $NOEC_{oral}$ using an assessment factor. The lowest NOEC's are 150 mg kg^{-1} for mammals and 100 mg kg^{-1} for birds.

B.5. Human health hazard assessment

The information in this section is mainly drawn from the following reports submitted to ECHA:

a. Sweden/KEMI: Annex XV report for restriction of lead in consumer articles (2012)[28];

b. Sweden/KEMI: CLH Proposal for Harmonised Classification and Labelling of Lead (2012)[29];

c. CSR of the REACH registration dossiers on lead compounds used as PVC stabilisers (2015);

d. Voluntary Risk Assessment Report on lead RAR (LDAI, 2008).

ECHA's Risk Assessment Committee (RAC, 2014) has previously assessed the health hazards of lead and its compounds for several previous opinions and this has been taken into account in the brief overview given of the relevant hazards.

[28] Available under ECHA's website: http://echa.europa.eu/documents/10162/ab0baa9c-29f8-41e2-bcd9-42af796088d2

[29] Available under ECHA's website: http://echa.europa.eu/documents/10162/13626/lead_clh_proposal_en.pdf

B.5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

B.5.1.1. Absorption

The oral and the inhalation routes are the most significant routes of exposure to lead, whereas dermal absorption is considered as minimal (LDAI 2008). However, even though absorption directly through the skin is considered negligible, the lead can become systemically available through hand-to-mouth behaviour. This route of exposure is possible for both children and adults that come in contact with lead containing articles, both at home and occupationally (Klein and Weilandics 1996).

The efficiency of oral uptake of lead can vary depending on e.g. particle size and shape (surface area), amount of time spent in the GI tract, concurrent food intake and the iron- and calcium status of the individual. A number of case reports prove that even one larger piece of lead ingested orally can create sufficient systemic exposure to produce clinical lead intoxication or even death. As a worst-case assumption, one can assume that the bioavailability of metallic lead is equivalent to that of soluble lead compounds such as e.g. lead acetate (LDAI 2008).

Representative uptake rates for lead in adults and children via different exposure routes are presented in the following Table B13. These representative uptake rates can be applied to calculate the uptake of lead oxide from individual exposure sources, but are put forward with the caveat that the kinetics of lead uptake can be curvilinear in nature and subject to modification by a number of variables. The uptake estimates given are thus representative values that are only applicable to relatively low exposure levels yielding blood lead levels <10 – 15 µg/dL.

Table B13. Representative lead uptake rates (CSRs for lead compounds, 2015)[30]

Intake route	Adults	Children
Oral (food)	10%	50%
Oral (soil)	6%	30%
Dermal	<0.01%	<0.01%
Air (deep lung deposition)	100%	100%
Air (upper airway deposition)*	Variable	NA

B.5.1.2. Metabolism

The lead ion is not metabolised or bio-transformed in the body, though it does form complexes with a variety of proteins and non-protein ligands. It is primarily absorbed, distributed and then the non-accumulated lead is excreted (WHO 2003).

[30] Upper airway deposition is expected for many occupational aerosols and uptake will thus vary as a function of pulmonary deposition patterns and the extent of translocation to the gastrointestinal tract where GI uptake kinetics will predominate. Non-linearity as a function of exposure level imparts additional variability into upper airway uptake estimates. Given that upper airway deposition is expected primarily in the occupational setting, upper airway deposition is Not Applicable (NA) to children.

B.5.1.3. Distribution

Once it is absorbed, inorganic lead appears to be distributed to both soft tissues (blood, liver, kidney, etc.) and mineralising systems (bones, teeth) in a similar manner regardless of the route of absorption.

The distribution of lead seems to be similar in children and adults, but in adults a larger fraction of lead is stored in skeletal tissue. More than 90% of the total amount of accumulated lead ends up in bone and tooth in adults, while in children, 75% is accumulated in bones.

The distribution of lead in the body is initially dependent on the rate of delivery by the bloodstream to the various organs and tissues. A subsequent redistribution may then occur, based on the relative affinity of particular tissues for the element and its toxicodynamics there (ATSDR 2007).

Lead concentration is also related to calcium status; stored lead can therefore be released from bone tissue into the blood stream in situations where a person suffers from calcium deficiency or osteoporosis (LDAI 2008).

It should be noted that lead is easily transferred to the foetus via the placenta during pregnancy. The foetal/maternal blood lead concentration ratio is approximately 0.9 (Carbone et al. 1998). As explained by Bradbury and Deane, (1993) the blood-cerebral barrier is permeable to lead ions and the most sensitive end-point is connected to neurotoxicity and developmental effects.

B.5.1.4. Elimination

Lead has a different half-life in different tissue pools. Blood lead and lead in soft tissue is considered the most labile with a half-life of approximately 40 days, while bone lead is very stable with a half-life of several decades (ATSDR 2007). In lead exposed infants and children, lead is progressively accumulated in the body and is mainly stored in skeletal tissue. As mentioned previously, lead is eliminated from bone very slowly; the half-life can be 10 to 20 years or more. In this way, lead can lead to an internal exposure long after the external exposure has ended, by redistribution between different tissue pools (LDAI 2008). Elimination takes place mostly via urine (>75%), and 15–20% is excreted via bile and faeces (TNO 2005).

B.5.1.5. Summary and discussion on toxicokinetics

Lead is most easily taken up into the body through inhalation or ingestion, dermal uptake makes a negligible contribution to systemic lead levels. Once taken up into the body, lead is not metabolised. However, it will distribute to various tissue compartments such as blood, soft tissue and bone. The half-life of lead in the body varies depending on body compartment; lead is retained far longer in bones, up to several decades.

B.5.2. Acute toxicity

Very limited data are available describing lead acute toxicity. According to KEMI (2012), human data for acute toxicity actually describe effects after exposure to lead over a period of weeks or years (sub-acute or chronic duration). The US National Institute of

Occupational Safety and Health (NIOSH) estimated the acute lethal dose for an adult to be approximately 21 grams (equivalent to 450 mg/kg bw) by the oral route, and 21 000 mg/m3 for 30 minutes via inhalation (LDAI 2008).

Acute lead intoxication in children has been reported following the ingestion of lead paint chips containing 1% or higher of lead (Lin-Fu 1992). Acute lead intoxication is serious and can be fatal, especially in children. In 2006, a four year old boy in the USA died after swallowing a bracelet charm containing 99% lead. The boy's blood lead level was 180 µg/dL at the time of death (CDC 2006). It should be noted that during acute lead poisoning (e.g. after oral ingestion of an object composed of lead), the lead blood level reaches a peak, but it does not reflect the total amount present in the body.

Symptoms of acute lead poisoning include but are not limited to: dullness, restlessness, irritation, poor concentration, muscle "vibration" and weakness, headaches, abdominal discomfort and cramping, diarrhoea, memory loss and an altered mental state including hallucinations. These effects can occur at Pb blood levels of 800–1000 µg/L in children (TNO 2005). Furthermore, the US EPA has identified a LOAEL value of 600–1000 µg/L related to colic in children as a result of lead poisoning. Then a LOAEL of 800 µg/L (ATSDR 2007) and a NOAEL of 400 µg/L (TNO 2005) could be identified for acute effects in children. Due to the long elimination half-life of lead in the body, chronic toxicity should generally be considered a greater risk than acute toxicity.

According to information submitted (CSR for lead compounds, 2015), acute toxicity from lead is not observed in animals after oral, inhalation or dermal exposures up to the limit value of acute toxicity testing. Similarly, toxicity in humans after true acute exposures is limited and, when documented, is generally under conditions that yield sub-chronic or chronic exposures.

B.5.3. Irritation

Not relevant for this report

B.5.4. Corrosivity

Not relevant for this report

B.5.5. Sensitisation

Not relevant for this report

B.5.6. Repeated dosed toxicity[1]

According to the group entry in Annex IV of CLP, all lead compounds are classified as STOT RE 1 or 2/H373 (causes or may cause damage to organs through prolonged or repeated exposure). EFSA (2013) concluded based on available human data that the most critical effects in relation to small increases in blood lead (PbB) levels were developmental neurotoxicity; effects on blood pressure, and chronic kidney disease. The lead level in blood is often the best reflection of the lead exposure status of the individual (EPA-Denmark, 2014). Signs of chronic lead poisoning include among others: sleepiness, irritation, headache, pains and others (LDAI, 2008).

B.5.6.1. Haematological effects

Effects of lead on blood can be detected at low levels of exposure but are not considered to be adverse (KEMI, 2012). As exposure rises, greater impact on haematological parameters can be expected. At blood lead levels <100 µg/L an inhibition of enzymes such as ALAD is observed, ALAD is an enzyme involved in the synthesis of haeme (LDAI, 2008). These enzymatic effects are not considered adverse but are sometimes used as biomarkers of lead exposure. At higher levels of lead exposure, the cumulative impacts of lead upon multiple enzymes in the haeme biosynthetic pathway begin to impact the rate of haeme and haemoglobin production (EFSA 2013). Decreased haemoglobin production can be observed at blood lead levels above 400 µg/L in children. Impacts on haemoglobin production sufficient to cause anaemia are associated with blood lead levels of 700 µg/L or more.

B.5.6.2. Effect on blood pressure and cardiovascular effects

Exposure to lead has been associated with a variety of adverse effects on the cardiovascular system in animals and humans. The most studied dose-response relationship is on the effect of lead exposure on blood pressure; more frequently reported for systolic than for diastolic blood pressure (Victery, 1988).

Based on detailed analyses of five human studies, EFSA (2013) concluded a blood lead level of 36 µg Pb/L was associated to a 1% increase in systolic blood pressure. This blood lead level was then based on modelling converted to a daily lead exposure of 1.50 µg Pb/kg bw per day. According to data submitted by Industry (CSRs 2015), reviews and meta-analyses of the current literature on the blood lead/blood pressure relationship indicate that there is at best a weak positive association between blood lead and blood pressure in general population and occupational studies with average blood lead levels below 45 µg/dL. However, it can be hypothesised that a modest increase in blood pressure would increase the overall incidence of cardiovascular disease in a large population of individuals. This consideration of "societal risk" as opposed to "individual risk" thus merits careful examination. As indicated in the CSRs, given the findings of the more recent studies that there is a lack of an impact of environmental exposures upon blood pressure, dose response functions cannot be derived that would serve as the basis for any health based limits linked to blood pressure. The lack of dose dependent impacts indicates that lead impacts upon blood pressure are not a health endpoint that should be applied in quantitative risk assessment.

B.5.6.3. Kidney effects

Exposure to lead has been associated with functional renal deficits e.g., changes in proteinuria, glomerular filtration rates or creatinine levels and clearance. From the most recent human data EFSA (2013) concluded a blood lead level of 15 µg Pb/L to be associated with a 10% increase of chronic kidney disease in the population. This blood lead level was then, based on modelling, converted to a daily lead exposure of 0.63 63 µg Pb/kg bw / d. Furthermore, EFSA's CONTAM Panel concluded that there is no evidence for a threshold for a number of critical endpoints including developmental neurotoxicity and renal effects in adults.

The CSRs on the lead compounds (2015) have reviewed relevant studies (e.g. Roels et al. 1994; Weaver et al. 2003) and concluded that of blood lead levels at or below

60 µg/dL appears to guard against the onset of lead nephropathy. A NOAEL of 60 60 µg/dL, combined with five years or more of lead exposure, is thus adopted for renal effects and provides the basis for the DNEL to be carried forward to risk characterisation.

B.5.6.4. Neurotoxicity and developmental effects

According to CLH (2012) report submitted by KEMI, the nervous system is the main target organ for lead toxicity. The developing foetus and young children are most vulnerable to lead induced neurotoxicity, their nervous system is still under development and therefore more vulnerable to toxic insults. The immaturity of the blood-brain barrier may contribute to the vulnerability, as well as the lack of high-affinity lead binding proteins in the brain that trap lead ions in adults (Lindahl et al. 1999). Young children often exhibit hand-to-mouth behaviour and also absorb a larger percentage of orally ingested lead than adults, thus leading to a greater systemic exposure (EFSA 2013). Several epidemiological studies have been conducted examining the impacts of pre-natal lead exposure upon birth outcome and neurobehavioral development in children. Negative effects of perinatal lead exposure upon neurobehavioral performance have been demonstrated both in experimental animals as well as in human prospective studies. The nervous system is the main target organ for lead toxicity and the developing foetus and young children seem to be the most vulnerable to lead induced neurotoxicity.

JECFA (2010)[31] and Lanphear et al. (2005) concluded that *regarding lead exposure, negative impact on IQ is the most sensitive end-point and no safe blood lead level has yet been established.* This study has particularly examined data collected from 1 333 children who participated in seven international population-based longitudinal cohort studies. This meta-study is a highly valued key study and was put forward by EFSA (2013) as being of great importance when investigating lead's toxicity on the developing nervous system.

A broad picture of the relationship between blood lead levels in children and IQ deficits as established by this study is presented below in Figure B1 (KEMI 2012). The larger sample size of the pooled analysis permitted the authors to show that the lead-associated intellectual decrement was significantly greater for children with a maximal blood lead of < 7.5 µg/dL than for those who had a maximal blood lead of ≥7.5 µg/dL. The authors conclude *there is no evidence of a threshold for negative effects caused by lead exposure, thus no level of lead exposure can be considered as safe*.

[31] JECFA, FAO/WHO Expert Committee on Food Additives, 2010. Summary report of the seventy-third meeting of JECFA.

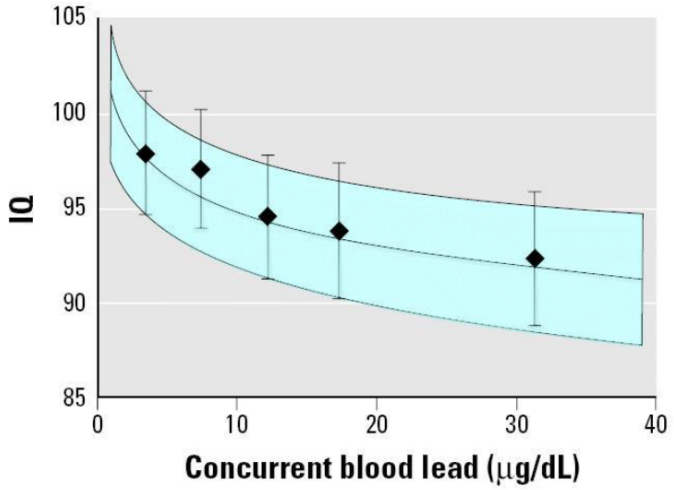


Figure from Lanphear et al. 2005; *Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environmental Health Perspectives, 113, 894-899.*

Log-linear model (95% CIs shaded) for concurrent blood lead concentration, adjusted for HOME score, maternal education, maternal IQ, and birth weight. The mean IQ (95% CI) for the intervals < 5 µg/dL, 5–10 µg/dL, 10–15 µg/dL, 15–20 µg/dL, and > 20 µg/dL are shown.

Figure B1. Relationship between blood lead levels in children and IQ deficits as established by this Lanphear et al. (KEMI, 2012)

Therefore, lead should be regarded as a non-threshold toxic substance. The central nervous system is still under development well over a decade after birth and lead-induced IQ deficits in children should be considered developmental in nature.

ECHA's Risk Assessment Committee, following the assessment of KEMI's proposed restriction, has stated with its scientific opinion (RAC 2014)[32] their agreement with the conclusions that *neurotoxicity, specifically neurobehavioral and neurodevelopmental effects from repeated lead exposure, are the key effects that this restriction is aimed at protecting against*. Small children will be particularly sensitive to this hazard, given that their central nervous system is still under development. In children, an elevated blood lead level is inversely associated with a reduced Intelligence Quotient (IQ) score and reduced cognitive functions up to at least seven years of age. There is some evidence that this subsequently leads to a reduced adult grey matter volume, especially of the prefrontal cortex (EFSA 2013). In line with EFSA, RAC has previously (RAC 2011)[33] established a maximum exposure value for children of 0.05 µg/kg bw per day for exposure to lead. This exposure potentially increases the blood lead level by 1.2 µg/L and is equivalent to an IQ reduction of 0.1 point.

An update to the registrants CSRs) has further commented on EFSA's (2010/13) analysis based on a study by Budtz-Jorgenson et al. (2010), see the discussion in Appendix B2. The following Table B12 from that analysis provides the benchmark dose (BMD) and the lower 90th percentile (BMDL) of the BMD estimate for various methodologies to calculate the BMD and the blood lead levels in children.

[32] RAC/SEAC compiled opinion on the Annex XV report proposing a restriction of lead its compounds in consumer articles: http://echa.europa.eu/documents/10162/f5a59251-8ef0-4f44-bfd4-95bffca7f807

[33] RAC scientific opinion on the Annex XV report proposing a restriction of lead its compounds in jewellery: http://echa.europa.eu/documents/10162/13641/lead_rac_restriction_opinion_20110310_en.pdf

Table B14. Benchmark Dose Calculations for the Blood Lead Level in µg/dL Associated with a 1-IQ Point Loss Using Different Model Assumptions and Blood Lead Metrics (EFSA, 2013)

Blood Lead Metric	**Nonlinear (logarithmic)**		**Linear**		**Piecewise linear**	
	BMD	**BMDL**	**BMD**	**BMDL**	**BMD**	**BMDL**
Concurrent	0.354	0.260	5.58	4.05	1.80	1.20
Peak	0.393	0.273	9.67	6.57	1.03	0.70
Lifetime Average	0.355	0.250	6.45	4.50	1.48	0.97
Early Childhood	0.558	0.343	8.06	5.24	3.80	1.61

The REACH registrants calculate, using the dose response functions adopted by EFSA (2010) for the impacts of concurrent blood lead levels in a piece-wise linear model, that a population-wide 4.28 IQ point decrement would be associated with a concurrent blood lead level of 7.7 µg/dL. If early childhood blood lead levels were of primary concern, this populations wide IQ decrement would require blood lead levels in excess of 16 µg/dL. The registrants conclude that current EU blood levels are significantly lower than those associated with population-wide IQ point decrements used in the Benchmark Dose derivations for other environmental neurotoxins.

Despite some concerns with these calculations and the assumptions chosen, the overall conclusion that lead is non threshold and that current allowable blood lead levels need to be lowered is not disputed. In addition, Budtz-Jorgenson et al. (2013) still conclude that further prevention efforts are needed to protect children from lead toxicity.

A number of studies have been included in the CRSs that were not considered by RAC and the previous Annex XV restriction report from Sweden (Kemi 2012). These studies are listed in the Table B15).

Hyperactivity or attention deficit disorder

In addition to the IQ effects previously described are suggestions that lead exposure may redispose to hyperactivity or attention deficit disorder (Braun, 2008, Ha et al., 2006 and Li et al (2009); Wang et al., 2008). Such a link of lead exposure to these specific health effects continue to be suggested by Nigg et al., (2008), Nie et al., (2011); Nicolescu et al., et al., (2010); Kim et al., (2012); and Liu et al. (2011).

At times the association appears to express in association with exposure to other environmental toxins such as PCB's (Eubig et al, 2010) or environmental tobacco smoke (Cho et al., 2010, Apostolou et al., 2012). Interpretation of many of these studies is difficult since most fail to account for family history of the disorder and a strong genetic component is known to exist. As best articulated by Brondum (2009), the strength of the genetic association is such that failing to account for family history is such studies would be similar to not including smoking history in a study of lung cancer causes. Criminality and anti-social behaviour has also been associated with lead exposure by a number of

authors (Fergusson et al., 2008; Mielke and Zahran, 2012; Naiker et al., 2012; Marcus et al., 2010; Olympio et al., 2009; Plusquelles et al., 2010; Szkup-Jablonska et al., 2012).

Less intensively investigated have been impacts upon academic performance, with some recent studies suggesting associations (Amato et al., 2012; Zhang et al., 2013 while others do not (Chandramouli et al., 2009). Linkages to autism have been suggested by some studies (El-Ansary et al., 2011; Tian et al., 2008; but not others (Albizzati et al., 2012). Mental retardation (Liu et al., 2010; Nevin, 2009) and other neurological disorders Mahmoudian et al., 2009) are occasionally associated with lead exposure. Altered auditory evoked brainstem responses are also suggested by some studies (Counter et al., 2007, 2012).

Although perhaps indicative of an effect, the current evidence is not strong enough at present to use further in the risk assessment.

Neurological Effects of Post-natal Exposure in Children

The primary target organ for lead toxicity in young children is the brain. High levels of lead exposure can have serious effects on the intellectual and behavioural development of individual young children. Blood lead levels of 80 µg/dL or greater can result in clinical encephalopathy characterised by ataxia (inability to coordinate movements), coma and convulsions and can be fatal. In the absence of encephalopathy, children with symptomatic lead poisoning may show more subtle neurological and behavioural impairments.

Lower levels of lead exposure will affect the nervous system of the child, but the impacts to be expected are qualitatively and quantitatively different from impacts upon the nervous system of the adult. Although the mechanism(s) of neurotoxicity in children have yet to be elucidated, studies of experimental animals suggest that lead can alter developmental and maturation processes that are important to cognitive function. Thus, the dose effect relationships and cognitive impacts observed in adults are not representative of the most sensitive cognitive alterations that have been observed in children.

Overall, the available evidence indicates that e*xposure to lead causes IQ deficits in children at very low blood lead levels and since no safe blood lead level has been established, lead should be regarded as a non-threshold toxic compound.*

Table B15. Description of additional studies in CSRs

Reference	Exposure setting	Main characteristics of the population		Exposure assessment, duration and intensity	Observations	Confounders, examined	Study quality score and comments
Huang et al', 2012	Prospective study of infants in Taiwan	Infant=105 Age 2-3 = 119 Age 5-6 = 76 Age 8-9 = 66	2-3 yr 5-6 yr 8-9 yr	Mean PbB Cord: 1.30 µg/dL Age 2-3: 2.48 µg/dL Age 5-6: 2.49 Age 8 – 9 1.97	Bayley Scales WPPSI-R WISC III	Lagged effect observed between blood lead at age 2-3 and IQ at age 8 – 9. No correlation with material or cord blood lead	2 (reliable with restrictions) Maternal IQ not measured. Significant cohort attrition which introduces potential participation bias. Number of children studied small and power of study to observe the effects reported is low.
Claus-Henn et al., 2012	Young children in Mexico	Infant = 455 12 mo = 275 18 mo = 271 24 mo = 273 30 mo = 260 36 mo = 250	12 – 36 mo	PbB 12 mo 5.1 +/- 2.6 µg/dL PbB at 24 mo 5.0 +/-2.9 µg/dL	Balley Scales MDI and PDI	Inverse relationship between PbB and MDI/PDI at blood lead levels less than 10 µg/dL. Co-exposure to manganese seems to increase this effect. Confounder correction for maternal IQ but not SES or Home scores. No later measures of developmental or cognitive outcome.	2 (reliable with restrictions) Mirrors the results of the prospective studies in finding impacts upon MDI and PDI but follow-up inadequate to determine later impact upon more stable measures of cognitive function. Interaction with Mn of interest but long term significance not known. Bayley Scales not normalized for Mexico

Reference	Exposure setting	Main characteristics of the population		Exposure assessment, duration and intensity	Observations	Confounders, examined	Study quality score and comments
							and average values abnormally low.
Al-Saleh et al., 2009	Infants and young children in Saudi Arabia	Infants = 653 6 mo = 107 12 mo = 107 18 mo = 77 24 mo = 43	6 mo interval from birth	Mean blood lead of 2.73 µg/dL at birth increasing to 4.45 +/- 2.31 µg/dL at 24 mo.	Bayley MDI and PDI	Blood lead levels at birth inversely associated with Mental Development Index (MDI) and Psychomotor Development Index (PDI) scores at 24 mo suggesting affects under 10 µg/dL. Confounders restricted to demographic and socioeconomic factors; maternal IQ not included.	2 (reliable with restrictions) Generally mirrors the results of the prospective studies in finding a correlation between PbB at birth and 24 mo MDI and PDI. Cohort attrition was unusually rapid and precludes definitive conclusions since number of children in different exposure ranges is small (e.g. 2 children in low exposure group at 24 mo.). Not able to evaluate significance for IQ or performance at later developmental stages
Lucchini et al., 2012	Italian adolescents aged 11 – 14 years	299	11 - 14	Mean blood lead of 1.17 µg/dL (range 0.44 – 10.2)	WISC III Connor-Wells Adolescent Self-Report test	Small decrements in IQ were associated with blood lead levels less than 5 µg/dL Very limited data on confounders such as alcohol	2 (reliable with restrictions) Unclear whether concurrent blood lead actually associated with psychometric test

Reference	Exposure setting	Main characteristics of the population		Exposure assessment, duration and intensity	Observations	Confounders, examined	Study quality score and comments
						intake, maternal IQ or Home score	performance. Very poor confounder control makes meaningful interpretation difficult.
Pilsner et al., 2010	Mother-child pairs in Mexico	255	2 yr	Cord blood lead: 6.7 =/- 3.6 µg/dL. Maternal patella lead 14.7 +/- 13.7 ppm.	Bayley Scales of Infant Development	MTHFR genotype associated with decrements in MDI at age 2. Lead also affected MDI but no interaction with lead exposure seen. Folate metabolism noted to be an independent predictor of development,	2 (reliable with restrictions) Results mirror findings of prospective studies finding impacts of blood lead upon MDI and PDI but not indication of whether impacts translate into subsequent IQ impacts or other developmental deficits.
Yorifuji et al., 2011	Children in the Faroe Islands	896 age 7 808 age 14	7 and 14	Cord lead 1.57 µg/dL	WISC-R	Study evaluated impacts of mercury and lead exposure. No consistent impact of lead upon overall test performance and no interactions with mercury observed. PCB co-exposure however noted to be of potential concern. Authors report adverse impacts of	2 (reliable with restrictions) Confounder correction limited and post-natal lead exposure not determined. No consistent impact of lead is actually present in the analysis.

Reference	Exposure setting	Main characteristics of the population		Exposure assessment, duration and intensity	Observations	Confounders, examined	Study quality score and comments
						lead exposure but both positive and negative impacts upon performance were in fact noted.	

B.5.7. Mutagenicity

Not relevant for this report.

B.5.8. Carcinogenicity

Not relevant for this report.

B.5.9. Toxicity for reproduction

As discussed in section B.1.3 the lead compounds (and thereby the ones used as PVC stabilisers) are classified under CLP in category 1A (H360: DF) for reproductive toxicity. Furthermore, the KEMI CLH report on lead (2012) highlights that strong evidence by studies in both humans and experimental animals have demonstrated the lead negative impacts upon male fertility (e.g. semen quality). The report concluded that lead clearly fulfils these criteria for reproductive toxicity and should therefore be classified as reprotoxicant category 1A under CLP. The ECHA's Risk Assessment Committee following the assessment of the KEMI CLH report has adopted a scientific opinion (RAC 2014) 34 concluding that all physical forms of metallic lead should be classified as Repr. 1A-H360DF (Repr. Cat 1) (May damage fertility; May damage the unborn child) similar to the classification that apply for "lead and lead compounds").

In addition, the KEMI (2012) Annex XV report proposing a restriction of the lead and its compounds in consumer articles, has provided a good review of both animal and human studies on lead toxicity for reproduction. An overview of the studies is given below:

Male fertility

The available data show that moderate to high lead exposure can have a marked adverse impact upon semen quality. Aberrant sperm morphology, decreased sperm count and decreased sperm density have all been demonstrated in exposed individuals. Bonde et al. (2002) conducted a cross sectional study of 503 men employed by 10 different companies in the UK, Italy and Belgium. Among other things, semen volume and sperm concentration were measured. The study group was of sufficient size to model dose-effect relationships and indicated a threshold for an effect upon semen quality at 45 µg/dL of concurrent PbB. As blood lead levels increase above 50 µg/dL, progressively greater impact on fertility can be expected. According to KEMI, a few studies that did not find an adverse effect of lead upon male fertility have been conducted using very small study populations and confounders have not always been taken into account which can further compromise the study results.

Female fertility

Effects of lead on female reproduction have been observed in numerous animal species. These effects include alterations in sexual maturation, hormone levels, reproductive cycles, impaired development of the fertilised egg as well as decreases in fertility (LDAI 2008). Effects on female reproduction in animal studies are usually not apparent at the blood lead levels that impair male fertility; higher blood lead levels are generally needed to see an adverse effect on

[34] Available under: http://echa.europa.eu/documents/10162/57ceb1ac-aafc-4852-9aa5-db81bcb04da3

the fertility of females. In addition, human data are inconsistent and cannot be estimated with precision.

The reprotoxic effects of lead compounds are also confirmed in the CSRs for lead compounds (2015). The literature review analysed by Industry has concluded that:

(i) an effect upon semen quality at moderate to high levels of lead exposure is likely to manifest itself in a subtle and progressive fashion as evidenced by the relevant human studies;

(ii) the animal data, and "anecdotal" historical human data, indicate fertility effects in females are probable as well. (Impacts upon female fertility likely occur at blood lead levels in excess of 50 µg/dL as probable side effects of more generalized systemic toxicity).

B.5.10. Derivation of DNEL(s)/DMEL(s)

B.5.10.1. Tolerable Daily Intake (TDI)

In 1995, a TDI value of 3.6µg/kg bw/day was established for both children and adults by the WHO. This value was established based on the assumption that an intake of 3–4µg Pb/kg bw/day does not affect the Pb levels in blood (PbB) in children or increase the body burden of lead. In 2003, the WHO (World Health Organization) reported a possible correlation between PbB levels below 100 µg/L and a reduction in IQ.

EFSA (2010) concluded that no TDI value could be placed upon lead exposure for children due to the fact that no known threshold for the decrease in IQ scores in relation to lead exposure has been found. Furthermore, EFSA reported (i) for children aged one to three years of age, an average lead dietary estimates range from 1.10 to 3.10 µg/kg bw/day. These dietary estimate values were based on lower and upper bound assumptions; (ii) for high consumers an estimated lead exposure range, 1.71 to 5.51 µg/kg bw/day. Dietary exposure is the main source of lead exposure for adults as well as children, although high soil intake can be a factor for children especially in contaminated areas.

B.5.10.2. Chronic DMEL (DMELc)

As already discussed under the section B.5.6, "No exposure threshold has been determined for chronic exposure to lead in regards to neurotoxic effects in children".

EFSA (2013) proposed a BMDL (benchmark dose level) based on the smallest measurable variation of the PbB level expressed as daily intake. EFSA reported that "for changes in full scale IQ score a BMDL value of 12 µg/L was derived from the PbB levels in 6 year old children". This value corresponds to an exposure of 0.50 µg/kg bw/day. These conclusions has been also supported by RAC in their 2011and 2014 scientific opinions as previously mentioned. Budtz-Jorgenson et al., 2013 reported BMDLs of 0.1 – 1.0 µg/dL as the dose leading to the loss of one IQ point.

In the CSR for lead compounds (2015), for adults in the general population (Long-term - systemic effects/Neurological function), a DNEL of 20 µg lead per dL blood is put forward (based upon a NOAEL of 40 µg lead per dL blood) and an Assessment Factor of 2. A broad

picture from the CSR data for DNELs for the general population is presented in Table B16. below.

Table B16. DNELs for the general population (CSR for lead compounds, 2015)[35]

Exposure pattern	**Route**	**Descriptors**	**DNEL/DMEL (appropriate unit)**	**Most sensitive endpoint**
Acute - systemic effects	Dermal (mg/kg bw /day)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA
	Oral (mg/kg bw /day)	NA	NA	NA
Acute - local effects	Dermal (mg/cm^2)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA
Long-term - systemic effects Neurological function	Systemic (µg lead /dL blood)	NOAEL = 40 µg/dL NOAEL = 10 µg/dL NOAEL = 5 µg/dL NOAEL = 2 µg/dL	20 µg/dL 5 µg/dL 5 µg/dL 2 µg/dL	Adult neurological function Foetal development for a pregnant woman IQ development in individual child IQ development large population of children
Long-term – local effects	Dermal (mg/cm^2)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA

These calculated DNELs will not be used in the risk assessment as only a qualitative assessment will be made due to the non-threshold nature of the key effects.

[35] General population includes consumers and humans via the environment. In rare cases it may also be relevant to derive a DNEL for specific subpopulations, such as children. In this case the table need to be repeated. In addition as the respiration rate is taken into account for the derivation of the DNEL, this table need to be repeated in case different exposure scenarios lead to different respiration rate.

B.6. Human health hazard assessment of physicochemical properties

The following Table B17 reports the main physicochemical properties of the selected lead compounds used as PVC stabilisers as extracted from the CSRs of the registration dossiers submitted to ECHA by associated industry. No physicochemical property is critical in defining the specific risks for human health or the environments due to the use of lead compounds as PVC stabilisers.

Table B17. Overview of the physicochemical properties of certain lead stabilisers (Source: CSRs for lead compounds, 2015)

Property/ Compound	Trilead dioxide phosphonate	Tetralead trioxide sulphate	Pentalead tetraoxide sulphate
Physical state at 20°C and 1013 hPa	Solid, powder, white, inorganic (common for all 3)		
Melting / freezing /boiling point	No melting/boiling point at atmospheric pressure/ decomposition at approximately 230 °C	No melting/boiling up to 500°C/Onset of solid-solid transformation at approximately 211°C	No melting/boiling up to 600°C
Relative density (D4R) compared to water at 4°C	6.74	6.84	7.15
Water solubility (mg/L at 20°C)	12.2	102	32.7
Flammability	*Highly flammable*. The burning rate was between 2.4 and 3 mm/s (ADR test)	Non flammable	Non flammable
Explosive properties	Non explosive	Non explosive	Non explosive
Self-ignition temperature	The relative self-ignition temperature is 261 °C (study result, EU A.16 method).	n.a	n.a
Oxidising properties	No oxidizing	No oxidizing	No oxidizing
Granulometry Mean particles size/D50 (laser diffraction method Mass median aerodynamic/MMAD diameter of airborne fraction (rotating drum method)	 D50 = 1.20 µm. MMAD = 54.0 µm.	 D50 = 1.84 µm. MMAD = 12.9 µm.	 D50 = 2.43 µm. MMAD = 10.0 µm.

B.7. Environmental hazard assessment

The principal health risk addressed in this restriction dossier is that of neurodevelopment effects in humans which was already assessed in previous Annex XV dossier. As such, the analysis has focussed on estimating emissions of lead to the environment (as a proxy to risks) during the service and waste life-cycle stages of lead-stabilised PVC articles with a view to preventing additional exposure of humans via the environment.

Due to the environmental hazard properties of lead compounds used as PVC stabilisers (classified as toxic to aquatic species, as discussed under the section B.3), their release into water may also result in risks for aquatic organisms. However, this is not the focus of the current report and therefore an environmental risk assessment (for potential environmental risks associated to lead PVC stabilisers) has not been carried out in details under this report.

In the frame of this assessment, however, ECHA has reviewed a few relevant reports including: (i) the Voluntary Risk Assessment Report RAR (LDAI, 2008), along with the assessment carried out by the Scientific Committee on Health and Environmental Risks (SCHER) on its environmental part the VRAR report (LAID, 2008) as reflected in their scientific opinion adopted on 13 January 2009[36]. (i) The EPA-Denmark Survey on lead and lead compounds (2014) and the CSRs of the main (i.e. registered under REACH) lead PVC stabilisers (2015).

For the purpose of this section, Table B18 provides an overview of the calculated predicted no effect concentrations (PNEC) for various environmental compartments. Both the data from the VRAR report (LDAI, 2008) and from CSR for lead compounds (2015) were checked. Where different values exist, these are indicated in the separate columns of the table. It has to be noted that the PNEC data are provided for general information since have not been further used on the exposure and risk characterization sections of this report.

Table B18. Overview of predicted -no effect-concentrations (PNEC values) for the European environmental compartments (Data compilation from by LDAI, 2008; CSRs 2015)

	LDAI (2008)	**CSRs (2015)**
$PNEC_{freshwater}$	**PNEC: 4.0** (µg Pb dissolved/L) Species mean HC_5* (log normal distribution, $EC_{16}/2$ value of 13.5 µg/l for *Daphnia magna* included in the dataset) = 8.0 µg/L; AF**= 2	**PNEC: 3.1** (µg Pb dissolved/L) Based on the use of the species sensitivity distribution approach. A reasonable worst case for freshwater PNEC derived from the HC5-50 value of 6.2 µg dissolved Pb/L and AF=2.
$PNEC_{marine}$	**No PNEC value is provided** At TCNES II 07 it was agreed that due to the limited availability of marine toxicity data, further work was required before a robust PNEC could be set.	**PNEC: 3.5** (µg Pb dissolved/L) A reasonable worst case for freshwater PNEC derived from the HC5-50 value of 7 µg dissolved Pb/L and AF=2.
$PNEC_{sediment}$	**PNEC: 174** (mg Pb/kg dry wt) Species mean HC_5* (log normal distribution)= 522 mg/kg dw; AF**= 3	

$PNEC_{sediment\ bioavailable}$	**PNEC: 81.0** (mg Pb/kg dry wt) In the VRAL of lead (2008) the statistical distribution method has been used to derive a PNEC bioavailable of 81 mg/kg dry wt. (Species mean HC_5* (log normal distribution) of toxicity data expressed as bioavailable Pb = 244 mg/kg dw; AF**= 3)	**PNEC: 41** (mg Pb/kg dry wt) SCHER (2009) recommended the use of the classical AF factor approach applying a factor of 10 to the lowest unbounded bioavailable NOEC. In this case the lowest NOEC was 2.0 µmol excess Pb/g dry wt, resulting in a bioavailable PNEC of 0.2 µmol excess Pb/g dry wt or 41 mg Pb/kg dry wt.
$PNEC_{sewage\ treatment\ plant}$	PNEC: 100 (mg/L) According to the assessment performed in the VRAL (LDAI, 2008) an assessment factor of 10 was used for the derivation of PNEC for sewage treatment plant resulting in a PNEC of 0.1 mg/L. This value also recorded in the CSRs	
$PNEC_{micro-organisms}$	**PNEC: 100** (µg Pb dissolved/L) dissolved fraction only; AF**= 10	
$PNEC_{soil}$	**PNEC: 166** (mg Pb/kg dry wt). Species mean HC_5* (log normal distribution) = 333 mg/kg dw; AF**= 2	**PNEC: 212** (mg Pb/kg dry wt) The generic aged PNEC is 212 mg Pb/kg dry soil (statistical extrapolation method with the log-normal distribution). Taking into account bioavailability of Pb in soil results in PNEC values between 170 and 440 mg Pb/kg soil for the 10^{th} and 90^{th} percentile of the eCEC in European arable soils
$PNEC_{oral}$ (secondary poisoning)	**$PNEC_{oral}$ = 10.9** mg/kg food (**mammals**) **$PNEC_{oral}$ = 16.9** mg/kg food (birds) With standard soil-worm bioaccumulation factor 0.1, this translates to a critical soil Pb limit for mammals of 10.9/0.1=109 mg Pb/kg_{soil} and for birds of 16.9/0.1=169 mg Pb/kg_{soil} above which secondary poisoning is to be expected.	

*HC_5: Hazardous Concentration 5% (Concentration of a compound that is hazardous to 5% of the organisms/population tested) **Assessment Factor (AF) (LDAI, 2008).

B.8. PBT and vPvB assessment

Not relevant for inorganic substances (with the exception of organo-metals). Therefore this section has not been elaborated for this assessment.

[36]SCHER opinion available under: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_114.pdf

B.9. Exposure assessment

B.9.1. General discussion on releases and exposure

B.9.1.1. Introduction

Lead and lead compounds can have an adverse effect on human health and the environment (RAC opinion for lead in jewellery 2011, lead in consumer articles 2014). Lead is considered a non-threshold neurotoxic substance. Dietary exposure is the major source of human exposure to lead while house dust and soil are also known to significantly contribute to lead exposure (EFSA, 2010). Even at low doses, lead remains a concern for the developing brains of young and unborn children through pregnant women (WHO, 2009). Lead compounds are classified under CLP for their human reprotoxic and aquatic toxic effects as discussed in Section B.3.

Lead can accumulate in the environment leading to accumulation in food (EFSA, 2010) and impacts on wildlife. Although the use of lead and lead compounds have been restricted at Union level by various legislative measures, the use of certain lead compounds is still permitted in the EU for certain applications, including as a stabiliser in PVC articles (KEMI 2012). Figure B2 outlines the main life-cycle steps of lased-based PVC stabilisers and lead containing PVC articles.

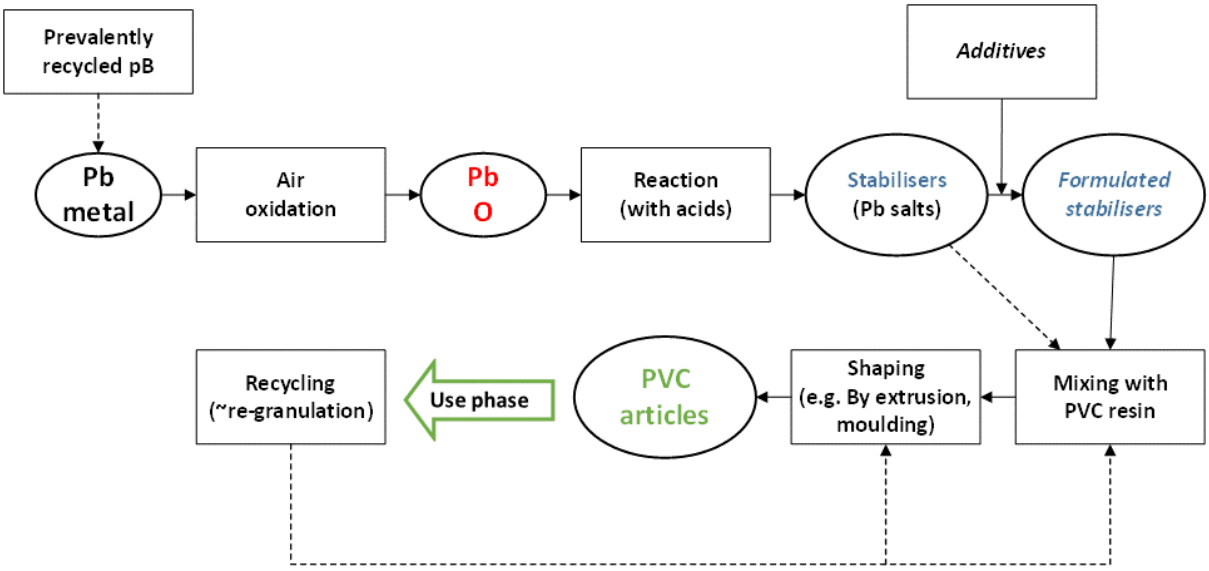


Figure B2. Manufacture, use and recycling of lead-based stabilisers in PVC articles (reproduced from CSRs for lead compounds, 2015).

Section B.9.1 of the Annex XV report will initially present:

i. an overview of the existing legal requirements at Union level concerning lead and its compounds;
ii. a summary on relevant international agreements; and
iii. a summary of the existing risk reduction measures to limit occupational and environmental exposure to lead during the manufacturing of lead-based PVC stabilisers and PVC articles.

Section B.9.2, provides information (including from REACH registration dossiers) on potential consumer exposure to lead during the service life of PVC articles. The findings of recent European studies on the release of lead to water from PVC articles containing lead are also briefly discussed.

Section B.9.3 presents an estimate of the total releases of lead to the environment resulting from its use in PVC articles. Releases are associated with both the service life of articles and releases as a consequence of waste management decisions at the end of article service life. The pathways via which humans are indirectly exposed to lead and its compounds, with a focus on sources relevant to lead release from PVC articles, are described and discussed.

A comprehensive exposure assessment for lead compounds used as PVC stabilisers has not been undertaken for this report. Lead and its compounds, in terms of its neurodevelopmental effects in children (and kidney effects in adults), are non-threshold substances (see Appendix B2) and as such Annex I of REACH only requires a qualitative assessment to be carried out (Annex I para 6.5). Therefore, similar to the approach adopted in previous REACH restrictions for other substances where it is not possible to derive a threshold[37], releases will be used as proxy for risk.

B.9.1.2. Summary of the existing legal requirements (and international agreements)

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, separating general legislative frameworks, human health legislation and environmental legislation. Some of the most relevant legislation is also outlined below.

Occupational health legislation

There is a binding occupational exposure limit (OEL) value of 0.15 mg/m³ for lead and inorganic lead compounds in the Chemical Agents Directive (98/24/EC). In addition, biological limit values (70µg/dl for men and 40µg/dl for women) and health surveillance measures (e.g. biomonitoring) have been established for lead and its compounds. Specific measures under current EU legislation are also in place to protect young workers and pregnant women.

Classification and labelling

There are several harmonised classifications for lead compounds in Annex VI of CLP (see Section B3). Lead metal has also been classified for reprotoxic properties (Cat IA). The 9thATP to CLP introduces two harmonised classification and labelling (CLH) entries for lead metal

[37] e.g. Annex XV restriction proposals for mercury, phenyl mercury, decaBDE, PFOA (and related substances) and D4/D5 (Available under ECHA's website: https://echa.europa.eu/restrictions-under-consideration

which are added to Table 3.1 of Part 3 of Annex VI. One entry applies to lead metal in powder form (particle diameter <1mm) and one to lead metal massive (particle diameter ≥1mm)[38].

REACH Regulation

Registration: A total of 65 lead compounds have been registered under REACH (of which 30 are intermediates) and currently cover substances manufactured or imported in volumes exceeding 100 tonnes per year. The registered lead compounds used as PVC stabilisers are listed in Table B2 of section B.1.

Restriction: Annex XVII of the REACH regulation contains several restrictions for lead or its compounds:

- Entry 16 and entry 17: Lead carbonates and lead sulphates, as substances or in mixtures for their use in paints.
- Entry 30: Substances classified as CMR may not be sold to the public (lead compounds are Toxic to Reproduction Category 1A and lead hydrogen arsenate is also a Carcinogen Category 1A[39]).
- Entry 63: Lead and lead compounds shall not be placed on the market or used in concentration of more than 0.05% by weight:
    - in jewellery articles (paragraphs 1-6), and
    - in articles supplied to the general public (or accessible parts thereof) that children can place in their mouth during normal or reasonably foreseeable conditions of use (paragraphs 7-10).

It should be noted that some PVC articles - if mouthable by small children (e.g. for articles such as garden hoses, or interior decorative items made by PVC) - lead and its compounds are already restricted according to the paragraphs 6-10 of entry 63 of Annex XVII to REACH. However, the current proposal targets PVC articles used in construction and building applications (e.g. pipes, flooring, frames, roofing), which are not in the scope of entry 63 of REACH.

Authorisation: There are currently 31 lead compounds defined as Substances of Very High Concern (SVHC) and included on the candidate list (of which nine are potential lead stabilisers). Among the substances proposed in ECHA's 7th recommendation[40] for potential inclusion in Annex XIV (widely known as the REACH Authorisation list) are four of the lead compounds on the candidate list:

[38] The 9th ATP to CLP was published in the OJ EU in July 2016. (OJ L 195, 20.7.2016, p. 11–25). In addition, the relevant RAC opinion is available under: https://echa.europa.eu/documents/10162/57ceb1ac-aafc-4852-9aa5-db81bcb04da3

[39] Classification as carcinogenic is based on the presence of AS rather than of Pb.

[40] Info available under: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list (The public consultation on ECHA's 7th draft recommendation ended on 18 February 2016). The Background documents for each lead compound indicate the registered uses (among which PVC is mentioned for some of them).

- pentalead tetraoxide sulphate and tetralead trioxide sulphate (both have been used as a PVC stabiliser, as described in the Background Documents for the prioritisation),
- lead monoxide (lead oxide), used as intermediate in the manufacture of PVC stabilisers, and
- lead tetroxide, which is not used in PVC applications.

In addition, the Water Framework Directive (2000/60/EC) and Waste Framework Directive (2008/98/EC) are relevant to lead environmental emissions (as indicated in Table B37). Both pieces of legislation are discussed in further detail in section B.9.2.

B.9.1.3. Summary of the effectiveness of the implemented operational conditions and risk management measures

B.9.1.3.1. EU Voluntary agreement

As already discussed in Annex A, the European voluntary commitment (VinylPlus) has been signed and implemented during the last two decades by the main key players of the European industry in plastics/stabilisers (EVMA, EuPC, ESPA). The voluntary agreements aims, amongst other elements:

(i) to increase PVC recycling levels;

(ii) to ensure the use of additives on the basis of accepted sustainability criteria.

The European stabilisers association has further committed to completely phase out the use of lead compounds as PVC stabilisers by end of 2015. More relevant information about this voluntary agreement is presented in Annex D: (Baseline). However, this voluntary action is acknowledged not to be completely effective as a few - mainly SME - companies may not currently participate to the scheme and imported articles are not covered.

B.9.1.3.2 Summary of the existing risk reduction measures

In order to limit occupational and environmental exposure to lead during the manufacturing of lead-based PVC stabilisers and PVC articles, several measures have already been taken.

<u>Occupational exposure</u>

The current EU maximum exposure concentration of lead compounds in air is 0.15 mg/m^3 (Chemical Agents Directive, 98/24/EC). In addition, health surveillance is required when occupational exposure to lead is foreseen. The maximum level of lead allowed by the EU in blood is 70 µg/dl for men and 40 µg/dl for women. Some countries have lower limits, e.g. Germany permit only up to 40 µg/dl for men and 20 µg/dl for women.

In the industry voluntary risk assessment report (VRAR), occupational exposure to lead during PVC-production is specifically addressed using data from seven companies using lead stabilisers obtained between 1998 to 2006 (LDAI, 2008). These data, (presented in Table B19. for the 90th percentile), indicated that no exceedance of blood lead-concentration occurred during production of PVC articles.

Table B19. Blood lead concentration in different workplace categories (LDAI 2008)

Workplace category	Max blood lead [µg/dl]	90th percentile [µg/dl]	Median [µg/dl]	No. of data
Lead stabiliser production*	71	55	35	144
Raw material handling**	55	39	25	90
Mixing operations**	48	32	19	217
Forming**	46	25	15	27
Others (cleaning, quality control)**	32	19	12	35

* data collected from 1998-2001, ** data collected from 1998-2006, German biological limit value (TRGS 903): 40µg/dl

Occupational exposure data for workers using lead-stabilisers in PVC-production was reported in Germany for the period (2000-2011) and is presented in Table B20.

Table B20. Air lead concentration (data collected from 2000 to 2011, IFA, 2011)

Work area group	No.	95th percentile [µg/m³]	90th percentile [µg/m³]	75th percentile [µg/m³]
Mixing of lead-containing compounds	41	73.8	61.9	33
Extruder, processing of moulded parts	31	50	30.1*	9.8*
Storage, mill, weighing, laboratory	15	320	171	28.3

* Distribution value is below the largest limit of quantification (LOQ) of the data collective.

The International Lead Association (ILA) has conducted a survey (2009-2012) aiming to update the existing blood lead database. Analytical data are presented in the CSRs of the lead compounds registered under REACH as PVC stabilisers. According to the results, *occupational exposures in manufacturing and use of lead compounds 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 and even stricter limits set by the different member states.*

Input received from an industry association (ECHA's Call for evidence, 2016) claims that: *in general, employees working in lead compounding operations use the appropriate personal protective equipment. When required, also periodic medical checks including blood tests may be performed by the companies. Records of the blood tests must be kept for some decades depending on national legislation.*

Some further input was submitted by EuPC (December 2016) and included a recent study prepared by CATS Consultants (Fruijtier-Polloth, 2016) concerning the health risk of occupational lead exposure in conventional PVC recycling and converting operations. In this study Pb-B levels were obtained from 127 workers employed in PVC recycling and converting industries. The median Pb-B level of workers in PVC compounding sites was 3.9 µg Pb/dL. The greatest Pb-B levels were found in workers employed in shredding and micronisation operations (median: 5.9 µg/dL), where operations are usually carried out under open conditions and often without respiratory protection equipment. The study concluded that:

- Average (mean and geometric mean) lead levels in blood were generally within the range of background values reported in literature for the general population, thereby no significant health risks were expected.
- However, a few (5%) occupationally exposed individuals had values exceeding 10 µg/dL, a level where subclinical neurotoxicity may occur, although it was not possible to make a direct link between current occupational exposure and these blood lead levels.
- It is important to keep current occupational lead exposure under control and the importance of wearing personal protection equipment should clearly be communicated in the workforce.

Industry also noted the conclusions reported by other occupational studies.

Sleeuwenhoek and Tongeren (2016) consider that significant exposure of workers to lead *via* the dermal route was unlikely, given the prescribed use of gloves and results of a study showing that levels of lead removed from lead stabilised PVC were relatively low (Sleeuwenhoek and Tongeren, 2016).

Similarly, no indication of health risks for workers in PVC compounding and converting sites (dermal exposure to lead) was reported by Vangeluwe et al. (2016) through migration skin absorption studies. As also indicated by Fruijtier-Polloth (2016), in more recent years, the use of encapsulated stabiliser formulations and closed systems has reduced occupational lead exposure at PVC industrial sites.

Overall, during the manufacturing of lead compounds and production of PVC articles, the health risk associated with lead exposure appears to be properly controlled by the specific requirements of the relevant Occupational Health and Safety acts (indicated in the Table B36 of the Appendix B3): Council Directive 98/24/EC; Council Directive 92/85/EEC; and Council Directive 94/33/EC.

Environmental exposure

Lead and its compounds are also covered by various EU environmental legislation (listed in Table B37, of the Appendix B3) and the Industrial Emissions Directive (IED - 2010/75/EC), which is a recast of previous directives concerning Integrated Pollution Prevention and Control (IPPC - 2008/1/EC12), waste incineration (2000/76/EC), solvent emissions (1999/13/EC) etc. As from January 2016, IED has replaced Directive 2001/80/EC on the limitation of emissions of certain pollutants from large combustion plants.

Overall, there has been a significant reduction in releases of lead from industry, which is consistent across 26 Member States of the EU, with 22 reporting reductions of greater than 85% since 1990 (CSRs for lead compounds, 2015).

In addition, according to a recent survey of the European Environmental Agency (EEA) on heavy metal emissions[41] across the EEA-33 countries, industrial emissions of lead decreased by approximately 92% between 1990 and 2013 (emissions of mercury fell by 73% and

[41] Available under: http://www.eea.europa.eu/data-and-maps/indicators/eea32-heavy-metal-hm-emissions-1/assessment-5

cadmium by 75% over the same period). The most significant legislation to influence lead emissions in the EU was undoubtedly the requirement to reduce the lead-content of petrol under Council Directives 85/210/EEC, 98/70/EC and 2003/17/EC. Nonetheless, the EEA survey clearly demonstrates that many sectors have successfully reduced lead emission levels over the previous 25 years.

B.9.2. Review of information on lead exposure from PVC articles during their service life and disposal

This section presents an overview of relevant information from various European sources investigating release of lead from PVC articles:

(i) during service life (consumer exposure);

(ii) during end-of-life as PVC waste (lead emissions during recycling/landfill/incineration).

Subsequently section B.9.3 presents an assessment of potential releases of lead to the environment from its use as a stabiliser in PVC and subsequent potential for indirect exposure to humans via the environment. Consumer exposure from PVC articles containing lead stabilisers

The main downstream uses of lead stabilised PVC are:

1. **Lead-stabilised PVC used as internal structural components of buildings:** Lead-stabilised PVC is used in construction for applications requiring electrical, thermal or moisture-proof insulation. Lead-stabilised plastics are used within walls, doors, floors and the foundations of buildings. Recovery of PVC for recycling would be expected during building remodelling or demolition.

2. **Lead-stabilised PVC in external construction.** Lead-stabilised plastics, generally rigid PVC, are used for architectural purposes such as window profiles, pipes, building siding material and window mini-blinds. Lead stabilisers increase the resistance of PVC to degradation in response to heat and sunlight, increasing product longevity, colour stability and service life.

As discussed in the section A.2.2, lead content varies across the different applications (pipes 0.75%; wires and cables 1.6%; window profiles 2% etc.).

According to ESPA (June 2016) the last remaining rigid PVC applications in the EU contain lead concentration between 1.5 to 2%. The use of lead stabilisers is expected to be has been phased out by end of 2015 in all new PVC articles made from virgin PVC (via VinylPlus voluntary schemes). However, it cannot be excluded that articles containing lead stabilisers may be newly placed on the market (e.g. imported articles) as discussed under sections A.1.4 and B.9.3.

The CSRs (2015) included in REACH Registration dossiers for the lead compounds principally used as PVC stabilisers (e.g. trilead dioxide phosphonate; tetralead trioxide sulphate) include a limited number of consumer service life exposure scenarios (Table B21).

Table B21. Exposure scenarios addressing the service life from the main downstream uses (CSRs for lead compounds, 2015)

Category of article service life /main uses	*Short assessment of lead exposure from these applications*
Lead-stabilised PVC used as an internal structural component of buildings. Use of lead-stabilised PVC for functions such as: - electrical wire sheathing - electrical conduits - potable water pipes - sewer pipes - fittings - cable ducts - internal construction (e.g. fasteners, wall anchors, vapour barriers)	As an internal structural component of walls, floors, doors etc., physical barriers preclude a significant consumer contact with the plastic articles used in these applications. This prevents exposure mediated through dermal contact or oral exposure. The vapour pressure of lead compounds at room temperature is negligible and negates opportunities for inhalation exposure.
Lead-stabilised PVC in external construction. Use of lead-stabilised PVC for extruded articles, such as: - window profiles - window mini-blinds, injection moulded articles (typically fittings for gas and water pipes and similar) - misc. architectural functions (e.g. siding)	Lead-stabilised PVC used for potable water systems could potentially expose consumers to lead through drinking water. Assessments for this product-specific exposure scenario are made based upon data from standardised leach tests and observational field data. Although physical barriers may prevent routine consumer contact with PVC materials in water or gas pipes and wire/cable sheathing, *occasional contact with these items may occur during routine maintenance activity that some consumers may undertake* (more info is provided in the assessment below)

Plastic water pipes used in potable water systems represent a special case since the potential for exposure through drinking water must be assessed. PVC water pipes may utilise lead stabilisers, but the use of such products is generally permitted only after appropriate compliance testing to ensure that unacceptable leaching of lead into potable water supplies does not occur. The use of lead stabilisers has been widely approved in Europe for many years and they are on the German, Italian and Dutch public positive lists (EPA 2014). Such pipes are subject to appropriate testing under different regulatory regimes in a number of Member States. France has, however, never approved lead stabilisers because their pipes are regulated by their law on food-contact plastics. More recently, the UK has ceased to allow the use of lead stabilisers in drinking water pipes, as also has Denmark.

General conclusion on consumer exposure

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. A report prepared by the European Commission (2004) on the Life Cycle Assessment of PVC and of principal competing materials, concluded that the *risk of diffused losses to the environment, or of consumer exposure, is minimised by the PVC encapsulation effect that immobilises the lead stabiliser and prevents it from harming people or the environment.*

An overview of the main findings of various sources (IQM[42], 2005; Kiwa, 1998[43]; LDAI, 2008; REACH Registration CSRs, 2015) is given below:

(i) Degradation of exterior PVC surfaces is not expected to yield significant exposure to lead due to slow release rates, removal of released lead due to weathering and low frequency of contact with exterior surfaces *(VRAR, 2008).*

(ii) Interior PVC surfaces will similarly be expected to have an initial lead residue that might yield exposures upon initial contact but exposure would be self-limiting as this residue is removed *(CSR for lead compounds, 2015).*

(iii) Levels of lead removed from lead stabilised PVC are low and dermal exposure of consumers is likely to be minimal *(IOM, 2006).*

(iv) Pipes that have been in service for approximately 10 years show very low lead levels in the inner surface layer, indicating that no further leaching of lead seems to occur from within the wall of the pipe to the surface *(KIWA, 1998).*

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 neurotoxic substance, a restriction on lead stabilisers in PVC

[42] The IOM (2006) study was designed to provide information about the potential for dermal lead exposures caused by direct skin contact with lead sheet material, and lead surface levels of polyvinyl chloride (PVC) profiles, as might occur in a consumer or residential environment. Twenty dermal samples were collected from the surface of PVC profiles either using wiping or microvacuuming techniques. Low levels of lead were removed by wiping from both old and new PVC and exposures ranged from 0.14 to 0.45 µg/cm2.

[43] Kiwa (1998) has been performed by on the long term leaching of lead from rigid PVC pipes. This investigation had been ordered by the Netherland's manufacturers of PVC pipes to examine whether the quality of drinking water transported in PVC pipes, stabilised with lead-based substances, was in line with the national regulatory limits. The study examined whether the impact of various parameters (e.g. pH, rinsing with acids) may influence the leaching behaviour of lead.

would reduce additional exposure for consumers, including small children and pregnant women.

B.9.2.1. Environmental emissions of lead (during service life of PVC articles)

B.9.2.1.1. Water Framework Directive

The key objective of the WFD is to achieve good status for all water bodies by 2015. This comprises the objectives of good ecological and chemical status for surface waters and good quantitative and chemical status for groundwater. As indicated in Table B37 (Appendix B3), lead is identified as a Priority Substance (PS) under the Water Framework Directive (WFD - 2000/60/EC)[44], as well as Directive 2008/105/EC on environmental quality standards (EQS[45]), and Directive 2006/118/EC on the protection of groundwater against pollution and deterioration[46]. The annual average environmental quality standard (EQS) for lead in freshwaters is currently 7.2 µg/L. A revised limit of 1.2 µg/L bioavailable lead in freshwaters was proposed in January 2012 as part of a wider package of revisions to WFD EQS.

As part of the implementation of the Water Framework Directive, the European Commission (DG ENV) developed "source screening sheets[47]" for priority substances (PS) and priority hazardous substances (PHS), including lead. These sheets were developed to identify relevant sources of PS or PHS to the water environment, particularly highlighting those that could contribute to potential failure of WFD objectives (e.g. EQS threshold values). Sources were classified into one of three categories:

Category-1: The source/pathway may result/contribute to potential failure of WFD objectives.

Category-2: Not enough quantitative information available to allow classification /pathway will be reviewed as more date become available.

Category-3: No potential release from source/pathway, no contribution to potential failure of WFD objectives.

Use of lead compounds as PVC stabilisers was identified in this analysis (European Commission 2004). Various sources of lead that could be associated with uses as a PVC stabiliser were considered as Category 1 sources i.e. to result or contribute to the failure of WFD objectives (Table B22). For example, "discharges in sewage effluents or storm water as a result of run-off from buildings and constructions in paved urban areas". This could include losses of lead (via degradation / weathering) from the external parts of buildings where ridged PVC materials are often used (e.g. in roofing, guttering and rain water downpipes). Similarly, emissions from

[44] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy [OJ L327 of 22.12.2000].

[45] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards-EQS in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council. [OJ L348 of 24.12.2008]. An EQS is defined as the concentration of a particular pollutant or group of pollutants in water, sediment or biota which should not be exceeded in order to protect human health and the environment' (WFD Article 2.35).

[46] Directive 2006/118/EC European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration, [OJ L372 of 12.12.2006].

[47]Available under: https://circabc.europa.eu/d/a/workspace/SpacesStore/1d915775-ff68-4134-9e1c-e8782d323622/20-Lead%20SS%20sheet%202010%20v2.1.pdf

"waste disposal and treatment areas" are also identified as potentially affecting WFD objectives.

This analysis does not explicitly identify PVC applications as a significant contribution to overall lead releases to the aquatic environment (for example, other sources such as metallic lead roofing material are also likely to contribute significantly). However, such an analysis, provides a useful conceptual link between uses of lead in PVC and pathways to the environment i.e. urban run-off. Further, it provides an indication that future reductions in lead emissions from these applications could further reduce potential risks for the environment or humans exposed via the environment.

Table B22. Table of sources of lead (aquatic and atmospheric emissions) most relevant to PVC applications of this assessment (Source: analysis of European Commission/DG ENV, 2004)

Source category (area/code)	*Classification*
Discharges to surface waters by point sources	
- (S7) Discharges in sewage effluents or storm water as a result of run off from buildings and constructions in paved urban areas (roofs, paints)	Category 1
- (S8) Discharges in sewage effluents or storm water as a result of households, consumer use (water pipes; fittings).	Category 1
Emissions to atmosphere	
- (A3) From buildings	Category 3
- (A5) From industry IPPC categories (lead)	
o Primary and secondary metal production	Category 1
o Production of plastics	Category 3
- (A7) From waste disposal/treatment areas (landfill and others)	Category 1

B.9.2.1.2. Migration of lead from PVC

FABES Forschungs–GmbH was commissioned by VinylPlus in 2014 to investigate the migration of some heavy metals and plasticisers, including lead from PVC (1st FABES study).

The study investigated migration (diffusion and partition coefficients) from samples of both rigid and flexible PVC granules containing 1.5% w/w elemental lead (surface area of one m^2) Migration was determined in contact with distilled water (30°C) flowing at a rate of 20 L/minute for up to 70 days. This scenario was based on of the practice of washing waste granules after shredding.

The results of this investigation for lead are shown in Table B23. It can be concluded from these data that lead migrates to water from both rigid and flexible PVC granules under the conditions

of the study and that diffusion would appear to be appreciably greater from flexible PVC than from rigid PVC.

A supplementary study (2nd FABES study) was conducted in September 2015 to further investigate diffusion rates of lead in rigid and flexible PVC. Summary details of this study, including results, were made available to ECHA by VinylPlus during the development of this Annex XV report (seeTable B24). The results and conclusions of this investigations have also been reported by Mercea et al. (2016). In this study four samples of rigid PVC and four samples of flexible PVC were maintained in distilled water in glass vials at 30 and 70°C, respectively, and the lead concentration in solution measured after 28, 42, 56 and 70 days.

As observed in the first study, diffusion coefficients were greater for flexible PVC than for rigid PVC. Equally, greater diffusion was observed at 70°C than at 30°C. Diffusion coefficients for lead in rigid PVC samples were confirmed to be in the range of 10^{-17} cm^2/s that was observed in the first FABES study. This was considered by the authors to be comparable to the diffusion coefficients for organic compounds with similar molecular mass in stiff polymers such as polyethylene terephthalate (PET), polycarbonate or poly(methyl methacrylate (PMMA).The diffusion rates observed in flexible PVC were considered to be comparable to those for other substances in other soft plastics.

Table B23. Migration of lead from rigid and flexible PVC granules (1st FABES study, 2015)

Parameter	Rigid PVC	Flexible PVC
Diffusion coefficients derived from measurements (cm^2/s)	$1.1\text{-}2*10^{-17}$	$0.6\text{-}5.8*10^{-14}$
Partition coefficients derived from measurements	7 500 – 9 500	1 700 – 7 000
Diffusion coefficients used for modelling (cm^2/s)	10^{-16}	$5*10^{-14}$
Partition coefficients used for modelling	1 000	50 000
Concentration in water (µg/L)	0.003	0.42

Table B24. Migration of lead from rigid and flexible PVC (2nd FABES study, 2016)

Sample		Diffusion coefficients (cm^2/s) x 10^{-17}	
		30°C	70°C
Rigid	1	0.6	2.0
	2	1.5	3.0
	3	0.04	0.7
	4	0.2	1.5
Flexible [a]	5	60.0	85.0
	6	4.0	12.5
	7	5.7	350.0

Notes: [a] only results from three samples of flexible PVC were available.

B.9.3. Exposure scenario

B.9.3.1. Indirect exposure of humans via the environment

The principal risk addressed in this restriction report is that of non-threshold neurodevelopment effects in humans (particularly young and unborn children) associated with lead exposure, which were 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, KEMI 2012). 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).

Lead and its compounds, in terms of its neurodevelopmental effects in children, are considered as non-threshold substances (see section B.5). As such Annex I of REACH only requires a qualitative assessment of risks (Annex I para 6.5). Therefore, a comprehensive exposure and risk assessment for lead compounds used as PVC stabilisers has not been undertaken for this report. In analogy to the approach used in previous REACH restrictions for lead and lead compounds (lead in consumer articles, KEMI 2012) and other substances where it is not

possible to derive a threshold[48], releases of lead from PVC articles will be used as proxy for risk.

In general, there is not considered to be a "direct" exposure pathway from the use of lead in PVC to humans i.e. exposure of the general population through mouthing or via direct and prolonged contact with skin. However, certain uses and specific populations may have greater potential for direct exposure e.g. children and infants could be considered to have greater potential for direct and prolonged contact with PVC flooring (hand to mouth exposure) than other populations.

As such, human exposure is considered to occur predominantly via the environment (including indoor environment) and diet (food and drinking water). Therefore, relevant conceptual pathways for human exposure to lead associated with uses in PVC are outlined below. Each of these pathways may be predominantly associated with either the service life or waste life-cycle stages of PVC articles.

B.9.3.1.1. Sources of lead to the environment

Releases of lead occur directly and indirectly to the atmosphere and water from numerous diverse sources, including:

- metal production and processing (steel, iron and lead);
- manufacturing industries;
- electricity / heat production;
- old (legacy) lead-based paint systems;
- use of lead ammunition;
- automotive applications (lead-acid batteries), including during recycling;
- Lead-water distribution systems (and fittings); and
- PVC articles (including water distribution systems).

Lead accumulates in soils through atmospheric deposition of particulates from anthropogenic sources but also directly through the disposal of sewage sludge. Lead is not considered to be particularly mobile in soils and leaching from soil to groundwater is slow under most environmental conditions (ATSDR, 2007). Although lead may be present in soils, the lead content of plants is reported to be largely the result of atmospheric deposition as uptake via roots is reported to be limited, but there are notable exceptions to this observation such as the tobacco plant, which can concentrate lead from soil in the harvestable parts of plants (Rodriguez-Ortiz et al, 2006). Levels of lead in leaves often correlate with atmospheric concentrations (Kabata-Pendias and Mukherjee, 2007; reported in EFSA, 2010).

Urban runoff and atmospheric deposition (via releases to air) are considered to be significant indirect sources of lead found in the aquatic environment (EFSA, 2010). However, direct releases to aquatic environments are considered to be relatively small compared to the releases to the atmosphere or to sewage sludge (EFSA, 2010).

[48] E.g. Annex XV restriction proposals for mercury, phenyl mercury, decaBDE, PFOA (and related substances) and D4/D5.

B.9.3.1.2. Releases of lead to the environment from PVC articles

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.

Although 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) there is extensive data indicating that long-term leaching does occur (Brink and van der Jagt, 1998; Hameter and Hanause, 1995; Al-Malack, 2001; Wong et al, 1998; Zhang and Lin, 2015), which will contribute to overall release of lead to the environment (and directly to humans via drinking water[49]).

An assessment of the quantities of lead that diffuse from PVC articles produced using recycled PVC, such as water pipes and fittings, window frames, window roller shutters, roof tiles and road furniture was reported by Arche (2016). The study utilised the release rates calculated from the recent FABES study (see section B.9.2.1.2) and combined these with an estimate of the surface area of PVC articles that could come into contact with water in a typical 'standard' town in the EEA of 10,000 people.

A summary of the results are provided in Table B25. The total quantity of lead leached per year into wastewater from these articles in a standard town of 10,000 people was estimated to be 276 g/year. This was predominantly from PVC roofing materials.

As the study only considered releases from recycled PVC articles there were no releases from either pipes and fittings or window frames as these are produced using a co-extrusion process where the recycled PVC material that contains residual lead stabiliser is either encapsulated within layers of virgin PVC material, or is only used in internal parts of the construction (see section E.3.2.1). As such, the authors considered that no migration of lead would occur over the service life of the articles. However, in practice, legacy PVC pipes and fittings and window frames produced from virgin PVC intentionally stabilised with lead-based stabiliser in the portions of articles in contact with water are still 'in service' in buildings, and thus the estimates of annual release from this study should be considered to potentially underestimate the release of lead from PVC articles. Equally, whilst the release per year is relatively small, total release of lead over the entire service life of articles (50+ years), whilst also considering the whole of the EU building stock, could potentially be significantly greater. Based on the estimates of annual release and service life reported in the Arche (2016) study and an EU population of 500 million people (rather than 10,000), total release of lead from PVC articles during their whole service-life could readily exceed a total of 50 tonnes.

[49] EFSA (2010) concluded that approximately 4% of lead exposure in typical adults is via drinking water, but did not apportion the relative important of different sources to this value.

Table B25 Annual release of lead from recycled PVC articles in a standard town of 10,000 people.

Use	Total surface exposed to water in a standard town (m^2)	Leaching rate (mg lead/m^2/year)	Lead leached
Pipes and fittings	9 500	0	0
Window frames	12 195	0	0
Roller shutters	14 400	1.812	26.09
Roof tiles	4 000	55	220
Road furniture	550	55	30.27
Total			**276.36**

The treatment of PVC waste will lead to release of lead to the environment (ARCHE, 2013; TNO, 2001). PVC articles disposed in landfill are considered to be relatively stable with limited potential for release from the PVC matrix, although some release is expected over time.

PVC articles that are incinerated at the end of their service life will contribute to the releases of lead to air (and water[50]) from municipal waste incinerators. Incinerator fly-ash (or air pollution control residue) is acknowledged to be heavily contaminated with unstable (potentially mobile) lead, which can be readily released from the fly-ash matrix through leaching. Thus, fly-ash is a long-term reservoir of lead that could be released to the environment.

Stabilisation of fly-ash (e.g. with cement) prior to disposal in a hazardous waste landfill can be successfully reduce the leaching potential of lead (and other heavy metals) from fly-ash, but cannot completely prevent it. Whilst hazardous waste landfills are subject to strict regulation, even limited potential for leaching from fly-ash suggests that lead cannot be considered to be completely contained within a hazardous waste landfill as losses, albeit relatively small, could still occur to the environment after the treatment of leachate (as treatment cannot be considered to be 100% effective in removing lead from treated leachate prior to release to the environment) or, potentially over longer time horizons, via leaching through the underlying geological substrate.

These sources, amongst others (such as recycling of PVC articles and the re-use of incinerator bottom ash), are described quantitatively in section B.9.3.2[51]).

B.9.3.1.3. Pathways of human exposure to lead via the environment

Relevant pathways for human exposure include drinking water and food, indoor / outdoor air (including swallowing household dust or dirt containing lead) and soil. For the general population, which is not occupationally exposed, food and water are considered to be the most important sources of exposure to lead (EFSA, 2010). However, ingestion of contaminated soil, dust and old lead-based paint as a result of hand-to-mouth activities are an important source of lead intake in infants and young children (EFSA, 2010).

[50] Where scrubbing water is treated in a wastewater treatment facility before release to the aquatic environment.

[51] From this analysis it is clear that most of the release of lead from PVC articles is associated with their disposal at the end of their service life.

The mail conceptual pathways for indirect exposure of humans to lead from PVC sources are summarised in Figure B3, Figure B4 and Figure B5. These conceptual pathways outline plausible routes of potential exposure of humans based on known sources and reasonable environmental pathways. However, the relative importance of each of these pathways for lead from PVC, is not considered at this stage. Quantitative estimates of release of lead from PVC to the environment are outlined in section B.9.3.2

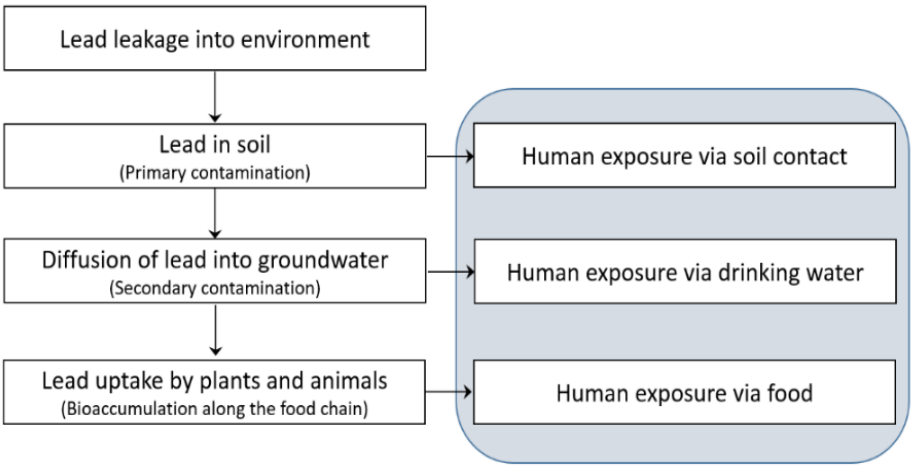


Figure B3. Environmental fate of lead released into the environment in link to the subsequent human exposure

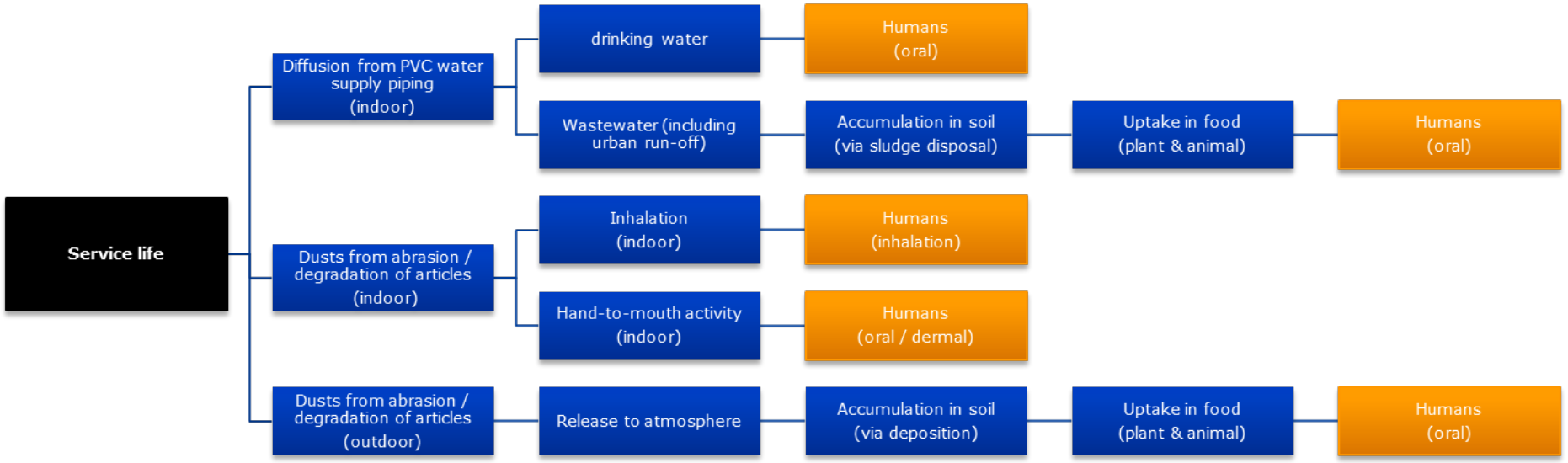


Figure B4. Conceptual exposure pathways for humans relevant to the service life of PVC articles

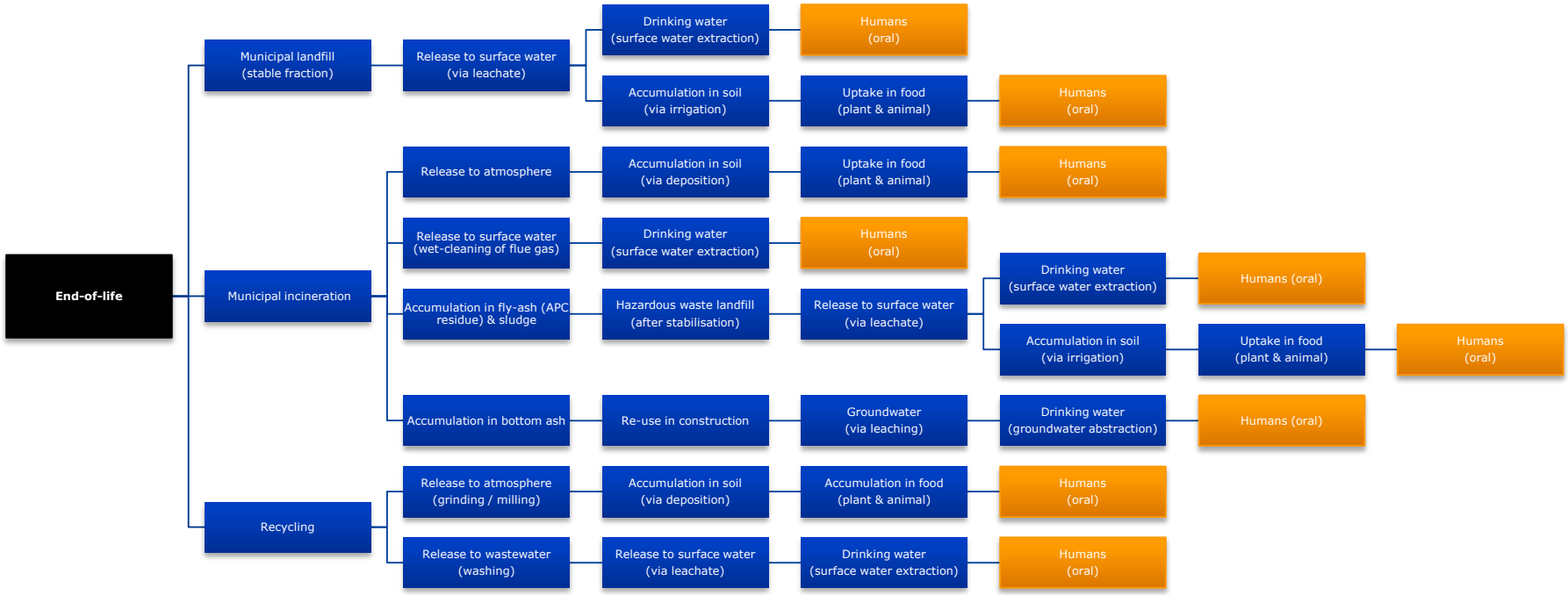


Figure B5. Conceptual exposure pathways for humans relevant to the end of life of PVC articles

B.9.3.1.4. Lead in soil

Lead in soils continues to be an important source of lead exposure to humans via the EU environment. Sources include particulates from industrial sources, flaking, chipping or weathering of lead-containing paints and improper disposal of waste lead-based paints removed during building renovation and maintenance.

The concentration of lead in the top layer of soils varies considerably because of the deposition and accumulation of atmospheric particulates from anthropogenic sources (ATSDR, 2007). In Europe, lead concentrations in top soils are geographically heterogeneous (EFSA, 2010) and vary from below 10 mg/kg up to >70 mg/kg. The median value was estimated by WHO (2007) to be 23 mg/kg.

A well-documented correlation exists between lead level in soil and blood lead level in children. Mielke et al. (2007) found a strong curvilinear correlation between blood lead levels of more the 55.000 children coupled with soil measurements (more than 5400 samples). Thus based on this correlation an increase in lead level in soil from 40 mg Pb/kg to 400 mg/kg would result in an increase in the blood lead level of approx. 23 µg Pb/L.

B.9.3.1.5. Lead in food and drinking water

Plants and animals may bioconcentrate lead, but lead is not considered to biomagnify in the aquatic or terrestrial food chain (ATSDR 2007). This is partly explained by the fact that in vertebrates, lead is stored mainly in bone, which reduces the risk of lead transmission to other organisms in the food chain (EFSA, 2010).

In contaminated areas, high concentrations of lead were observed in roots of vegetables (up to 10.7 mg/kg dry mass), while the lead concentrations in soil were in the range of 129 to 1 996 mg/kg dry mass (Gzyl, 1995).Lead is commonly present in food and is regulated as a contaminant (EFSA, 2010). EFSA (2010) assessed dietary lead exposure in the European population across the aggregated food categories specified in the EFSA concise European Food Consumption database.

According to the EFSA study, the largest contributor to overall exposure were vegetables, nuts and pulses (14 to 19% lower and upper bound estimates) and cereal products (13 to 14% lower and upper bound estimates). Other food groups that were considered to contribute significantly to overall exposure to lead were starchy roots and potatoes (8%), meat and meat products, including offal (8%), alcoholic beverages (7%), and milk and dairy products (6%). Drinking water was considered to account for 4% of overall exposure. Average consumption of lead for adults was estimated to be 0.36 – 1.24 µg/kg bw per day. Consumer groups with higher lead exposures included those with diets that included game meat (1.98 to 2.44 µg/kg b.w. per day) and game offal (0.81 to 1.27 µg/kg bw per day).

In addition, exposure to lead from drinking water may contribute significantly to lead exposure, especially where release of lead from taps, PVC pipes and fitting occurs (EPA, 2014). Drinking water in houses containing lead pipes may contain elevated levels of lead, especially if the water is acidic or soft (ATSDR, 2007). Overall, dietary exposure was concluded by EFSA to be the major source of exposure to lead in all age groups, although for children ingestion of soil and dust was also an important contributor.

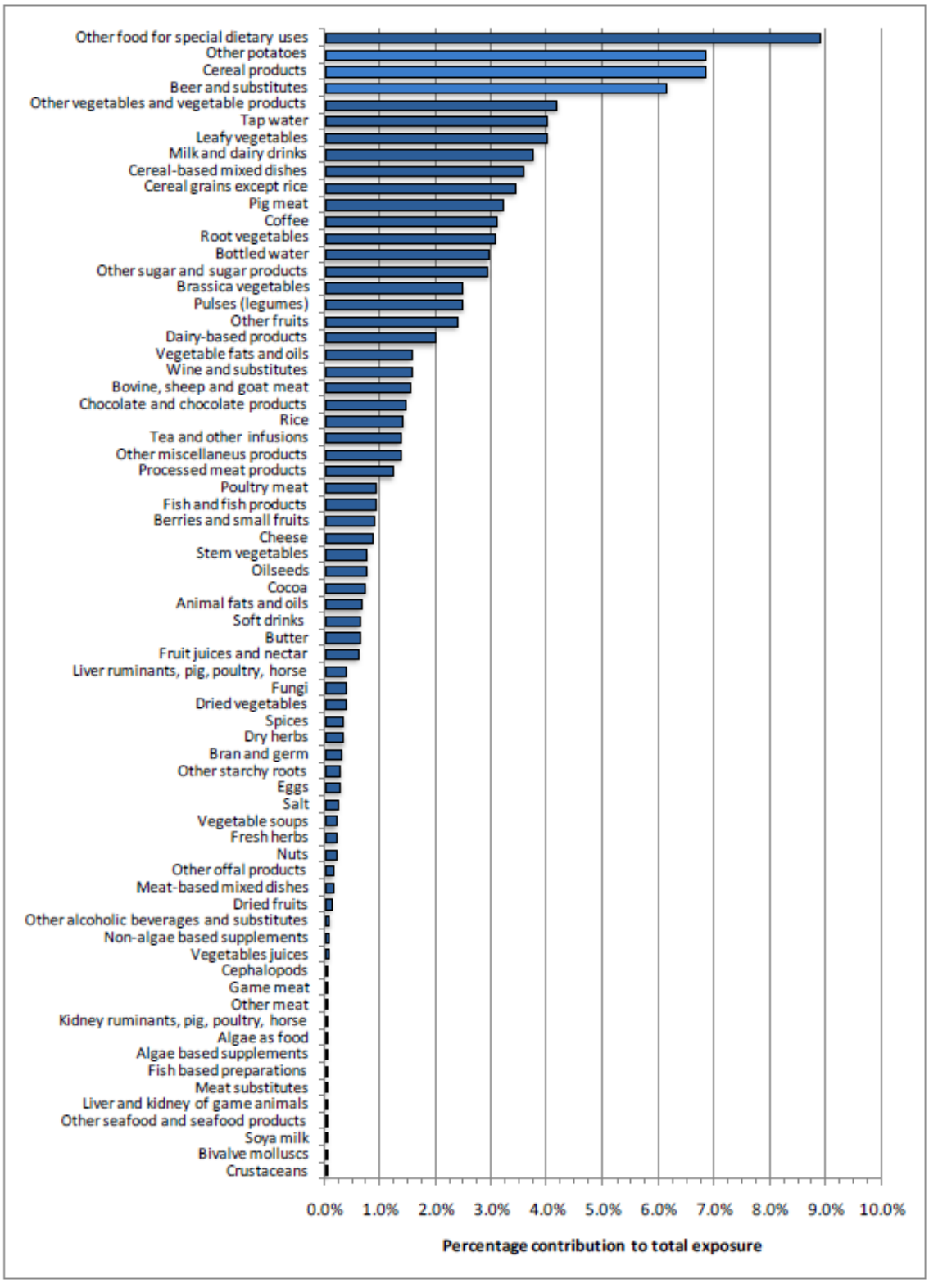


Figure B6. Lower bound estimated consumer exposure to lead from different food sub-categories and sub-classes (Reproduced from EFSA, 2010).

B.9.3.1.6. Indoor environment

Dust in homes can contain lead releases from surfaces painted using lead-based paints that rub against each other or degrade over time. Windows and doors painted with lead-based paints are considered to be a large source of this type of lead dust.

The use of lead stabilised PVC in mini blinds (venetian blinds) in the US was also found to result in the formation of lead containing dusts and exposure to humans via the indoor environment (Normal et al, 1997)[52]. In addition, Sleeuwenhoek and van Tongeren (2006) reported that lead can be removed from the surface of both old (manufactured in 1990) and new (manufactured in 2006) PVC profiles using a standardised wiping method intended to replicate the dermal exposure that could occur in a consumer or residential environment. Concentrations of lead on the surface of 20 PVC samples were reported to range from 0.14 to 0.45 µg/cm^2. Sleeuwenhoak and van Tongeren (2006) further stress that whilst dermal adsorption of lead is thought to be minimal, dermal exposure may be important as it can contribute to the ingestion of lead due to the transfer from the skin to the mouth via the fingers (so called ' hand to mouth' behaviour).

Therefore, further to paints some exposure to humans from the degradation and abrasion of PVC articles used in the indoor environment can also be reasonably foreseen. Routes of exposure could be via the inhalation of dust, or via hand to mouth behaviour.

Using an ingestion rate of house dust of 60 mg/day for 1-6 year-old children (US-EPA exposure handbook 2009) with a content of 135 mg Pb/kg in the dust would result in a lead exposure of 0.6 µg Pb/kg bw/d for a child weighing 13 kg (EPA-Denmark, 2014). This exposure is 12 times above the DMEL value of 0.05 µg/kg bw/d as indicated by the opinion of ECHA's Risk Assessment Committee opinion (2014) during the assessment of the lead in consumer articles dossier. However, it is not possible to determine what proportion of lead exposure can be associated with lead from PVC sources (i.e. degradation and abrasion of PVC flooring or profiles).

B.9.3.1.7. Relative contributions of different sources

Evaluation of the relative contributions of different sources is therefore complex and likely to differ between areas and population groups (von Schirnding YE, 1999).

The relative importance of different lead sources varies as a function of age. For adults, lead in food and beverages is generally the primary source of lead exposure. For children, as a result of play habits, a more significant exposure contribution is expected from soil and dust (CSR for lead compounds, 2015). Table B26 presents typical lead exposures for a 1-2 year old child (wt. 10.9 kg), a 5-6 year old child (19 kg) and an adult female (35 years of age) in the general population from all of the exposure sources (LDAI, 2008).

Although it is not possible to apportion the source of lead that lead to the indirect exposure, it is reasonable to assume that lead from PVC stabilisers will contribute to this exposure either from contamination of food, water or dust.

[52] Further information available under: https://www.cpsc.gov/content/cpsc-finds-lead-poisoning-hazard-for-young-children-in-imported-vinyl-miniblinds

The most significant release of lead to the environment from PVC articles containing lead stabilisers is likely to take place during their eventual disposal at the end of their service life. Under section B.2 of this report the current and future trends in PVC waste management have been discussed, which are governed by EU legislative developments and industrial policies. Therefore, PVC waste recycling which is generally recognised as the most sustainable and resources efficient waste management option) on a steady increase in the last decade, with an objective of 800 000 tonnes by 2020 (RIVM, 2016). However, as there is always some loss of material during the recycling operations, part of the lead contained in PVC will be removed from stock and will be disposed of, either in an incineration facility or in landfills (Tauw IA, 2013).

In addition, it is well known, that if PVC is incinerated it will lead to air emissions whereas releases of lead from landfill (via leachate) are also expected (TNO, 2001; Arche, 2013). This is further elaborated in the section B.9.3.2 where estimates of lead release associated with the service-life and disposal of PVC articles containing lead-based stabiliser are presented.

Table B26. Estimated Typical Daily Environmental Lead Exposures and Resulting Incremental Blood Lead Increases From Indirect Exposure via the Environment (LDAI, 2008).

Population	Air	Soil/Dust	Water	Food	Total Blood Pb
Adult Urban	0.05 µg/m3 0.15 µg/dL	250 mg Pb/kg 0.092 µg/dL	2 µg/d 0.18 µg/dL	25 µg/d 2.3 µg/dL	2.76 µg/dL
Adult Rural	0.01 µg/m³ (0.032 µg/dL)	40 mg Pb/kg 0.002 µg/dL	2 µg/d 0.2 µg/dL	25 µg/d 2.50 µg/dL	2.73 µg/dL
Child 5-6 yr Urban	0.05 µg/m³ 0.01 µg/dL	250 mg Pb/kg 0.71 µg/dL	0.8 µg/d 0.08 µg/dL	11.4 µg/d 1.59 µg/dL	2.44 µg/dL
Child 5-6 yr Rural	0.01 µg/m³ 0.003µg/L	40 mg Pb/kg 0.12 µg/dL	1 µg/L 0.08 µg/dL	11.4 µg/d 1.59 µg/dL	1.84 µg/dL
Child 1-2 yr Urban	0.05 µg/m³ 0.01 µg/dL	250 mg Pb/kg 1.0 µg/dL	1.0 µg/L 0.03µg/dL	6.5 µg/d 1.28 µg/dL	2.37 µg/dL
Child 1 -2 yr Rural	0.01 µg/m³ 0.001 µg/dL	40 mg Pb/kg 0.17 µg/dL	1.0 µg/L 0.03 µg/dL	6.5 µg/d 1.18 µg/dL	1.38 µg/dL

B.9.3.2. Estimated releases of lead from PVC articles (manufactured and imported)

B.9.3.2.1. Development of probabilistic release model

As discussed in section B.9.3.1, this restriction proposal is based on releases of lead to the environment during the service and waste life-cycle stages of PVC articles produced with lead-based stabilisers. A key consideration in the exposure assessment, because of the extended service life of the PVC articles within the scope of this restriction (50+ years), is that releases of lead will occur at an unspecified time in the future, potentially more than 50 years after

entering service. Thus, use of lead within a particular year will not lead to immediate releases, but can be associated with the potential for releases in the future dependent on how articles are disposed (and waste products re-used). This concept was also central to the exposure assessment of the flame retardant decaBDE, a PBT substance, where releases were distributed across both the service life and waste disposal life cycle stages.

The aim of the analysis is to estimate the magnitude of (total) likely releases of lead from PVC articles during their service life and following their disposal / recycling at the end of their service life. As discussed in earlier due to the non-threshold nature of lead releases are proposed to be used as a proxy for risk to humans exposed via the environment.

As there is appreciable uncertainty in the input data for the model (e.g. release factors to environment compartments, tonnage of lead stabiliser used, proportion of waste disposed via different routes in the future), a probabilistic modelling approach (using Monte Carlo) simulation was adopted. Probabilistic approaches incorporate the potential variability of input parameters and derive "most likely" median release estimates (and interquartile ranges) from within the theoretical minimum and maximum extremes of a model. A similar approach was used recently in the Background Document for the REACH restriction on decaBDE in a "reality check" of the estimated releases compared to the available environmental monitoring data.

Estimation of lead releases is based on the assumption that all the lead used in PVC applications eventually ends up in the waste following the disposal of the lead containing PVC articles at the end of their service life. The behaviour of lead during waste treatment is briefly discussed in section

The model used to estimate releases is based on a series of lower and upper bound estimates of lead-stabiliser tonnage used (or imported into the EU) and upper and lower bound environmental release factors for service life and various relevant waste treatment options (at end of life), including municipal landfill, municipal incineration and recycling. For the proportion of PVC waste associated with disposal via municipal landfill additional release are associated with the subsequent disposal of fly-ash or air pollution control residue (after stabilisation in hazardous waste landfill) and with the re-use of incinerator bottom-ash in construction projects (e.g. road construction).

The lower and upper bound release factors for the exposure estimates were selected from ECHA R.18 guidance, technical reports (TNO 2001) and REACH registration dossiers (Arche, 2013). Upper and lower bound release factors are elaborated in section F. The Monte Carlo simulation run multiple "versions" of the model (100 000 in this case) selecting a different value for the input parameters on each occasion. Input values are selected for each parameter from within the lower and upper bound ranges. A single release factor of 0.01% for all types of PVC articles was selected from the OECD Emission Scenario Document for heat stabilisers in plastics additives (OECD, 2009).

The assessment also considers that the proportion of PVC waste disposed via different routes will vary in the future. On each model run a "year of disposal" is selected from between 2025 to 2065, which corresponds to a proportion of PVC waste disposed by landfill, incineration and recycling. The model is weighted so that the year of disposal is 10 times more likely to be selected from the later part of the range than from the earlier part. This recognises that PVC

articles have relatively long service lives and are more likely to be disposed of in 50 years, rather than in 10 (See Annex F.1.3).

B.9.3.2.2. Input parameters

The tonnage of EU lead stabiliser in 2016 was estimated to range between 0 tonnes (lower bound) and 632 tonnes (upper bound). The lower bound is based on an industry audit by ESPA. The upper bound is derived from 5% of the 2015 stabiliser tonnage in the EU, which is consistent with EU manufacturers that are not members of ESPA and is recognised to be a worst-case estimate. The tonnage of lead in imported articles was estimated in 2016 to range between 1 057 and 3 980 tonnes.

Further discussion on the assumptions and sensitivity analysis for the model is given in the section F.1.

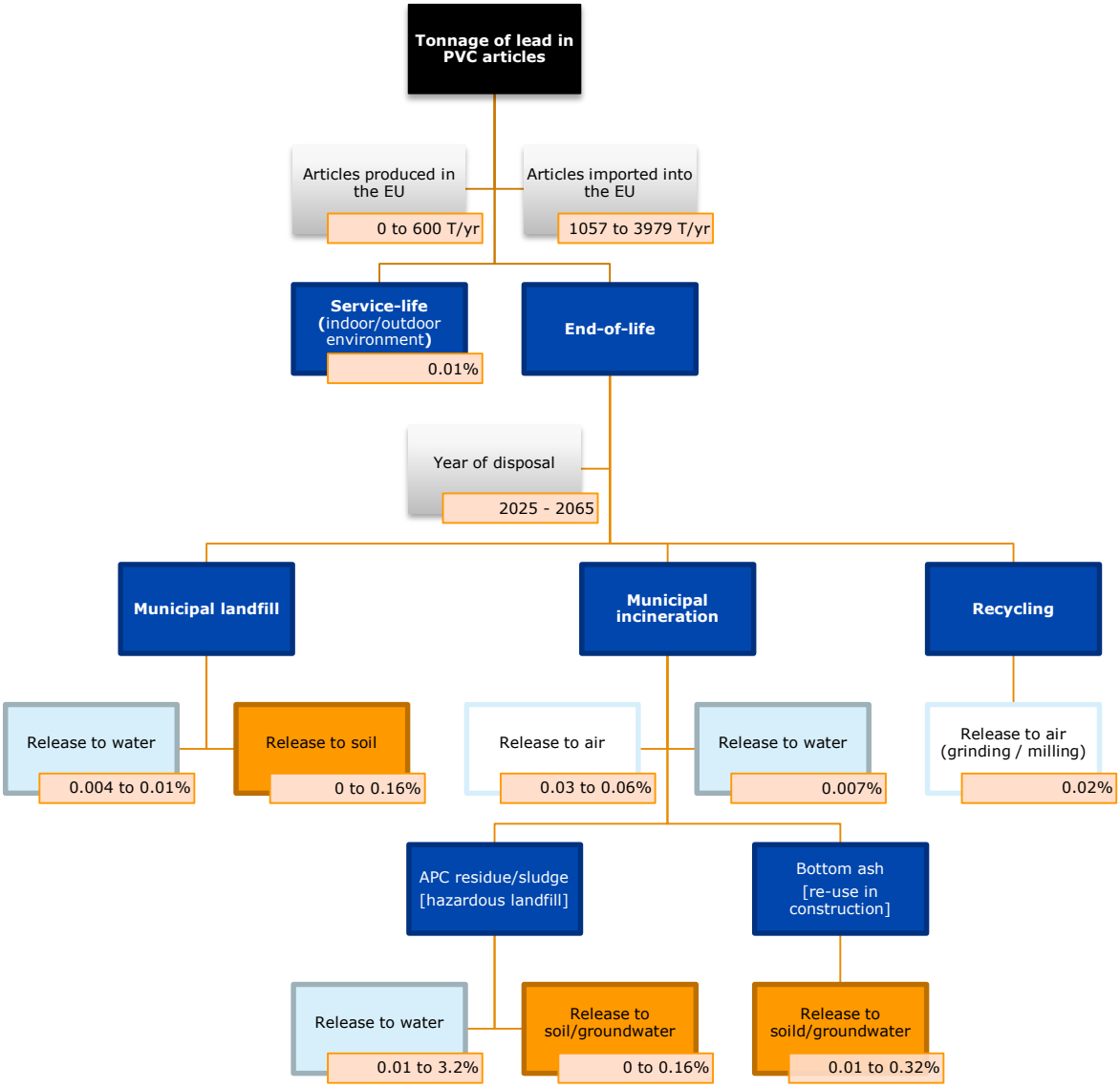


Figure B7. Overview of probabilistic model used to estimate release of lead to the environment

B.9.3.2.3. Summary of releases

Total lead releases from uses of lead stabiliser in PVC articles in 2016 are summarised in (Table B27). The minimum and maximum releases were estimated to range from 0.35 to 33.8 tonnes, respectively. The range of most likely releases, as denoted by the interquartile range of Monte Carlo simulations (25th to 75th percentile) range from 4.3 to 10.3 tonnes, respectively. The median release was 6.8 tonnes.

Table B27. Total lead released from PVC articles produced in 2016 (EU produced and imported articles), includes service life and end of life releases.

Total tonnes Pb released				
Min	25th percentile	Median	75th percentile	Max
0.35	**4.3**	**6.8**	**10.3**	33.8

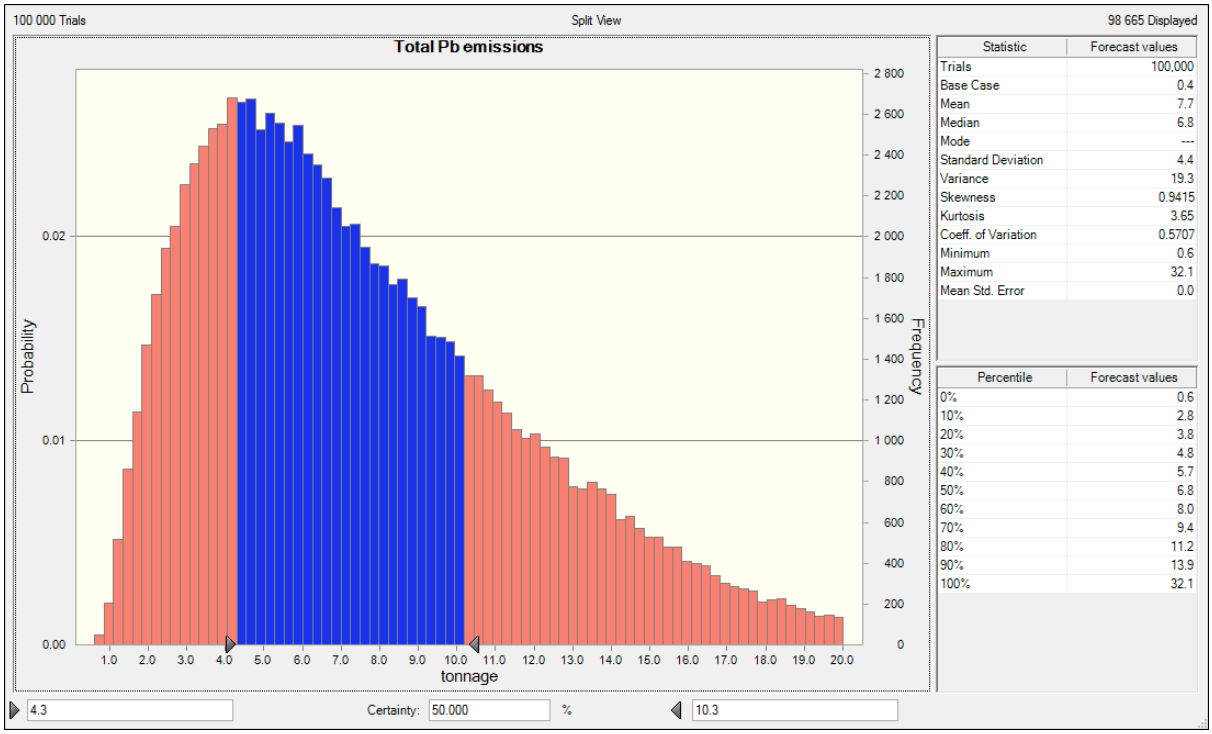


Figure B8. Probabilistic estimates of total lead release from PVC articles during service life and waste life-cycle stages.

The emission factors used for this exposure analysis are presented in detail in section F.1. Service life emissions (through gradual deterioration of articles via processes such as weathering and abrasion) were estimated using a default factor of 0.01% taken from the OECD emission scenario document for plastic additives and contribute between 3 to 5 of releases (based on the interquartile range of Monte Carlo simulations).

End of life releases (incorporating emissions from disposal, recycling and material "re-use") are more significant, contributing between 95 and 98 percent of overall release to the environment.

Table B28. Releases from article service life – absolute release and proportion of overall releases.

Releases from PVC article service life					
Unit	Min	25th percentile	Median	75th percentile	Max
percent	1.3	**2.6**	**3.5**	**5.4**	30.4
tonnes	0.11	**0.19**	**0.26**	**0.34**	0.43

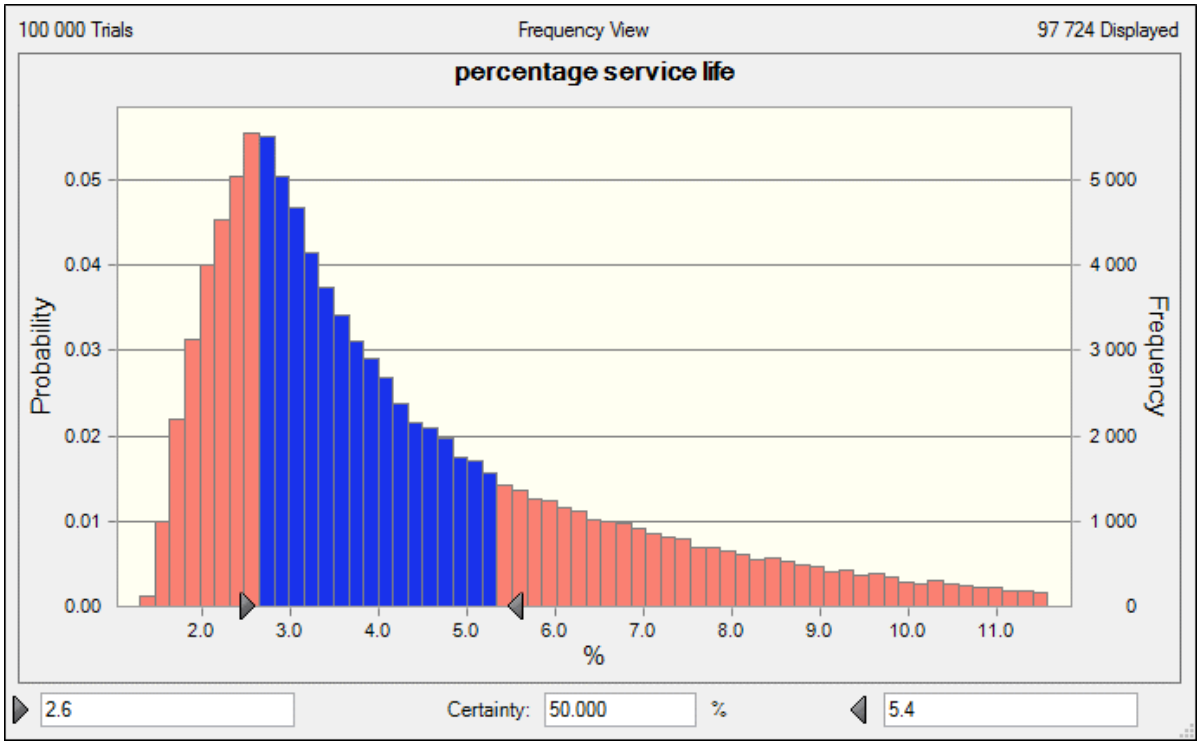


Figure B9. Probabilistic estimates of the percentage of total lead release from PVC article service life.

Emissions from recycling occur because of dusts generated during the mechanical shredding or milling of materials and potentially during the washing of materials. These were estimated to contribute (most likely interquartile range of Monte Carlo simulations) between 3 and 5 percent of total lead emissions.

Table B29. Releases from recycling – absolute release and proportion of overall releases.

Release from PVC article recycling					
Unit	Min	25th percentile	Median	75th percentile	Max
percent	0.6	**2.2**	**3.2**	**4.9**	33.4
tonnes	0.05	**0.16**	**0.23**	**0.30**	0.47

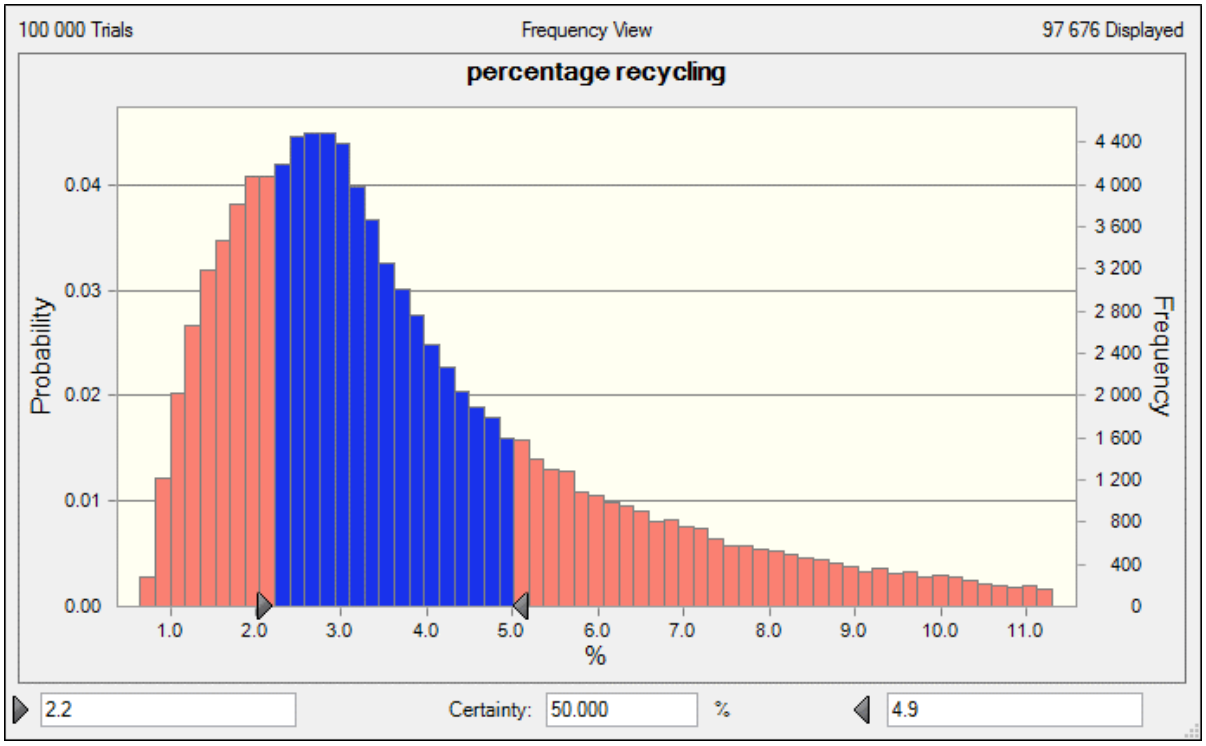


Figure B10. Probabilistic estimates of the percentage of total lead release from PVC article during recycling.

B.10. Risk characterisation

B.10.1. Approach in the current assessment

In general, due to the high uncertainties regarding long term exposure and effects, the risks caused by PVC applications of lead compounds of to the environment or to humans via the environment cannot be adequately addressed in a quantitative way, e.g. by derivation of DNELs or PNECs. A qualitative risk assessment has been carried out in this report, following thereby the same approach that has been used in previous reports for other very hazardous substances (e.g. PBT/vPvB substances, such as decaBDE, or the neurotoxic mercury compounds).

Therefore, exposure/emissions are used as a proxy for risk when considering the cost-effectiveness and proportionality to the risk of the proposed restriction as discussed in Annex E.

B.10.2. Human health

As concluded by the hazard assessment (Section B.5), the various recent risk assessments undertaken agree that exposure to lead results in IQ deficits in children at very low blood lead levels and since no safe blood lead level has been established, lead should be regarded as a non-threshold toxic compound.

The main risk addressed in this restriction dossier is the risk for humans exposed to lead via the environment due to the use of lead compounds as PVC stabilisers. This concern is well grounded:

- due to lead releases during the service life of PVC articles (as they gradually deteriorate), and
- the lead released during the disposal phase of the PVC based articles (PVC waste).

The main routes of human exposure to lead via PVC articles include indirect exposure via the environment are the following:

- PVC articles -> service life -> aquatic compartment -> general population (food/drink/soil);
- PVC articles -> waste disposal -> aquatic compartment/atmospheric deposition – general population (food/drink/soil).

The relative importance of different environmental lead sources varies as a function of age. For adults, lead in food and beverages is generally the primary source of lead exposure. For children, as a result of play habits, a more significant exposure contribution is expected from soil and dust (CSR for lead compounds, 2015).

In the PVC applications in scope of the restriction, lead is mainly emitted from the waste stage (recycling, landfilling and incineration) while some emissions are also expected during the service life of PVC articles). The total releases in the EU from lead containing PVC articles (placed on the EU market in 2016) are estimated in the range 4 and 10 tonnes, with a median of 7 tonnes. In addition, a release of 0.2 to 0.3 tonnes from article service life was estimated.

Some lead release from the formulation and processing stage ("production") of lead compounds is also expected as discussed under Annex B.9.1, but has not been further quantified since any releases are expected to be sufficiently controlled by the risk management measures implemented in industrial installations.

According to the analysis presented in section B.9, greater than 95% of the total lead releases from PVC articles can be associated with end-of-life activities (after their disposal). Currently the majority (approximately 70%) of PVC articles are either incinerated or landfilled at the end of their service life, followed by smaller amounts that are recycled or exported outside the EU (approximately 30%).

Lead released to the environment from PVC articles will contribute to overall human exposure to lead though various pathways. The most significant source of lead exposure in humans is considered to be dietary uptake, through drinking water and food. Although the quantities of lead that are likely to be released to the environment from its use in PVC articles are modest i.e. 4 to 10 tonnes (0.2 – 0.3 tonnes during service life as previously discussed) the potential routes of exposure are clear, even if it is not possible to apportion precisely the exposure of humans from uses in PVC that could be attributed to PVC articles.

Although the blood lead level of children in Western Europe has decreased to a level of 1.5-2 µg PB/dL blood this concentration is still considered to be associated with adverse effects on neurodevelopment and thus, any incremental reduction in lead exposure will contribute further to reducing adverse effects. Thus, further reduction of lead releases from PVC articles is likely to have beneficial effects on human health, particularly in specific target populations.

Based on the analysis presented in Section E.8.2, only 1.24 g of lead per year would need to accumulated within a European target population of children aged 6 years or younger (impacts on IQ) for the restriction to "break even".

Given the long service life of the PVC articles targeted by this restriction (10-50 years), the assessment considered the changes in prevailing waste management practice that are forecast to occur in the future i.e. a significant increase of recycling as the preferred waste management option associated along with a steady decline in landfill.

The releases of lead from PVC articles will occur gradually, in some cases, up 50+ years in the future. Data analysis (Eurostat 2016) shows that imports of relevant PVC articles contribute significantly to the lead emissions. During the next years, given the expected phase out of lead stabilisers in the Union (via the VinylPlus scheme), the contribution of lead containing PVC imports (to the total lead emissions) is significant.

This fact further substantiates the risk reduction (in terms of lowered lead emissions) targeted by this proposal and highlights the need for a Union wide action. It has to be noted as well that the voluntary agreement does not cover all EU suppliers of lead stabilisers and approximately 30% of EU produced lead stabilisers exported outside the EU).

Overall, it is concluded that the identified risk to humans due to the use of lead compounds in PVC articles (manufactured and imported) in the EU is not adequately controlled and needs to be addressed.

B.10.3. Environment

Due to the well-established environmental hazardous properties of the specific lead compounds used as PVC stabilisers their release into water compartments is also expected to cause risk for aquatic organisms. As discussed under section B.3, most lead compounds, including those used as PVC stabilisers (as discussed under Annex B.3) are classified by CLP Regulations for acute and chronic hazards to the aquatic environment: Aquatic acute 1, H400 (Very toxic to aquatic life (short term E(L)C50 ≤ 1 mg/L)) and Aquatic chronic 1, H410 (Very toxic to aquatic life with long lasting effects (short term E(L)C50 ≤ 1 mg/L and the substance is not ready biodegradable).

In the LDAI (2008) risk assessment report, Predicted No Effect Concentrations (PNECs) have been derived for the environmental compartments: water, sediment, soil as well as for sewage treatment plants. However, its subsequent evaluation by SCHER (2009) highlighted many uncertainties associated with both exposure and effects for all compartments at all levels so that further work should be undertaken to develop better understanding of lead bioavailability for all compartments (and any effect on RCR values). Existing evidence on the environmental fate along with the hazard and exposure aspects for PVC lead stabilisers have been discussed in the sections B.4 and B.7.

No further environmental assessment has been undertaken, though, in the frame of this report since the analysis does not focus on the environmental risks of lead but mainly to the risks for human exposed via the environment.

B.11. Summary of hazard and risk

As discussed under Section B.3, the most critical harmonised classifications for lead compounds, used as PVC stabilisers are: (i) for human health: Repr. 1A, H360Df (May damage fertility or the unborn child); and H373 (May cause damage to organs through prolonged or repeated exposure) (ii) for the aquatic Acute 1, H400 (Very toxic to aquatic life) and aquatic Chronic 1, H410 (Very toxic to aquatic life with long lasting effects).

As concluded under the analysis of Section B.5, the available evidence indicates that exposure to lead causes IQ deficits in children at very low blood lead concentrations and since no safe blood lead level has been established, lead should be regarded as a non-threshold toxic compound.

As elaborated in Section B.9, the general population is primarily exposed to lead through diet (food and beverage consumption, including drinking water) although non-food sources (dust, soil etc.) also contribute to overall exposure. Lead that enters into the human body either by oral, dermal or inhalational exposure progressively accumulates in body tissues. Although the blood lead level of children in Western Europe has decreased to a level of 1.5-2 µg PB/dL blood this concentration is still considered to be associated with adverse effects on neurodevelopment and thus, any incremental reduction in lead exposure will contribute further to reducing adverse effects. Thus, further reduction of lead releases from PVC articles is likely to have beneficial effects on human health, particularly in specific target populations.

Appendix B1: Tables on bioconcentration / bioaccumulation factors of lead in freshwater organisms and soil

Table B30. The whole-body bioconcentration factor (BCF in L/kg) of lead in freshwater organisms (LDAI, 2008)[53]

Species	Organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water (µg/L)	BCF (L/kg dw)	BCF (L/kg ww)	Reference
Crustaceans							
Asellus meridianus	isopod	20 000	4 000	500	40 000	8 000	Brown, 1977
Hyalella azteca	amphipod	1.3	0.26	0.4	3 250	650	Borgmann et al., 1993
Hyalella azteca	amphipod	5.8	1.16	3.3	1 758	352	Borgmann et al., 1993
Hyalella azteca	amphipod	7.1	1.42	2.6	2 731	546	Borgmann et al., 1993
Hyalella azteca	amphipod	15.8	3.16	11.6	1 362	272	Borgmann et al., 1993
Hyalella azteca	amphipod	1.1	0.21	0.2	5 000	1 000	Maclean et al., 1996
Hyalella azteca	amphipod	6.8	1.35	2.1	3 250	650	Maclean et al., 1996
Hyalella azteca	amphipod	25.9	5.18	20.7	1 250	250	Maclean et al., 1996
Hyalella azteca	amphipod	113.9	22.77	207.0	550	110	Maclean et al., 1996
Daphnia magna	cladoceran	4.9	0.98	0.9	5 765	1 153	Cowgill, 1976
Daphnia pulex	cladoceran	3.6	0.72	0.9	4 235	847	Cowgill, 1976
Molluscs							
Dreissenia polymorpha	mussel	0.9	0.09	0.5	1 800	180	Kraak et al., 1994
Dreissenia polymorpha	mussel	10	1	4	2 500	250	Kraak et al., 1994

[53] Following the assessment on the reliability of the data, all BCF/BAF values in both tables received a Klimish score of ≥2.

Species	Organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water (µg/L)	BCF (L/kg dw)	BCF (L/kg ww)	Reference
Dreissenia polymorpha	mussel	11	1.1	10	1 100	110	Kraak et al., 1994
Dreissenia polymorpha	mussel	40	4	36	1 111	111	Kraak et al., 1994
Dreissenia polymorpha	mussel	130	13	85	1 529	153	Kraak et al., 1994
Lymnaea palustris	snail	8.5	2.5	1	8 500	2 500	Borgmann et al., 1978
Physa integer	snail	100	20	32	3 125	625	Spehar et al., 1978
Physa integer	snail	400	80	67	5 970	1 194	Spehar et al., 1978
Physa integer	snail	500	100	136	3 676	735	Spehar et al., 1978
Physa integer	snail	500	100	277	1 805	361	Spehar et al., 1978
Physa integer	snail	1 000	200	565	1 770	354	Spehar et al., 1978
Insects							
Brachycentrus sp.	caddisfly	300	60	32	9 375	1 875	Spehar et al., 1978
Brachycentrus sp.	caddisfly	300	60	67	4 478	896	Spehar et al., 1978
Brachycentrus sp.	caddisfly	300	60	136	2 206	441	Spehar et al., 1978
Brachycentrus sp.	caddisfly	600	120	277	2 166	433	Spehar et al., 1978
Brachycentrus sp.	caddisfly	1 000	200	565	1 770	354	Spehar et al., 1978
Pteronarcys dorsata	stonefly	300	60	32	9 375	1 875	Spehar et al., 1978
Pteronarcys dorsata	stonefly	500	100	67	7 463	1 493	Spehar et al., 1978

Species	Organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water (µg/L)	BCF (L/kg dw)	BCF (L/kg ww)	Reference
Pteronarcys dorsata	stonefly	500	100	136	3 676	735	Spehar et al., 1978
Pteronarcys dorsata	stonefly	1 000	200	277	3 610	722	Spehar et al., 1978
Pteronarcys dorsata	stonefly	2 000	400	565	3 540	708	Spehar et al., 1978
Fish							
Poecilia reticulata	fish	4.1	0.82	3.1	265	1 322	Vighi, 1981
Poecilia reticulata	fish	12	2.4	27.5	87	436	Vighi, 1981
Salvelinus fontanilis	brook trout	8	1.6	34	235	47	Holcombe et al., 1976
Salvelinus fontanilis	brook trout	12.7	2.54	58	219	44	Holcombe et al., 1976
Salvelinus fontanilis	brook trout	0.36	0.072	0.9	400	80	Holcombe et al., 1976
Lepomis macrochirus	Blue gill sunfish	1.4	0.28	14.1	100	20	Wiener and Giesy, 1979
Lepomis macrochirus	Blue gill sunfish	1.0	0.20	14.1	70	14	Wiener and Giesy, 1979
Micropterus salmoides	Black bass	0.65	0.13	14.1	45	9	Wiener and Giesy, 1979
Esox niger	Chain Pickerel	1.25	0.08	14.1	25	5	Wiener and Giesy, 1979
Anguilla rostrata	American eel	0.5	0.10	14.1	35	7	Wiener and Giesy, 1979
Erimyzon sucetta	lake chubsuckers	0.5	0.10	14.1	35	7	Wiener and Giesy, 1979
Perca flavescens	Yellow perch	1.1	0.22	0.5	2 025	405	Draves and Fox, 1998
Perca flavescens	Yellow perch	0.5	0.10	0.2	2 120	424	Draves and Fox, 1998

Table B31. The whole-body bioaccumulation factor (BAF in L/kg) of lead in freshwater organisms (LDAI, 2008)

Species	**organism**	**Tissue (mg/kg dw)**	**Tissue (mg/kg ww)**	**Water (µg/L)**	**BCF (L/kg dw)**	**BCF (L/kg ww)**	**Analysis of Pb in aqueous media**	**Reference**
Crustaceans								
Asellus	isopod	3.44	0.688	<0.2	>17 200	>3 440	Filtered (0.45 µm)	Timmermans et al., 1989
Gammarus	amphipod	1.65	0.33	<0.2	>8 250	>1 650	Filtered (0.45 µm)	Timmermans et al., 1989
Cyclops		3.78	0.756	<0.2	>18 900	>3 780	Filtered (0.45 µm)	Timmermans et al., 1989
Daphnia magna	cladoceran	23	4.6	3.1	7 400	1 500	Filtered (0.45 µm)	Vighi, 1981
Daphnia magna	cladoceran	68	13.6	27.5	2 500	495	Filtered (0.45 µm)	Vighi, 1981
Daphnia magna	cladoceran	187	37.4	13	14 380	2 877	Filtered (0.45 µm)	Lu et al., 1975
Daphnia magna	cladoceran	154	30.8	2	77 000	15 400	Filtered (0.45 µm)	Lu et al., 1975
Daphnia magna	cladoceran	85	17	2	42 500	8 500	Filtered (0.45 µm)	Lu et al., 1975
Molluscs								
Amblema plicata	clam	13.5	1.35	2	6 750	675	Filtered (filter size not reported)	Mathis and Cummings, 1973
Dreissena	mussel	0.12	0.024	<0.2	>600	>120		Timmermans et al., 1989
Dreissena polymorpha	mussel	5.1	0.51	35	146	15	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	3.7	0.37	54	69	7	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	3.2	0.32	37	86	9	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	1.9	0.19	12	158	16	Unfiltered	Chevreuil et al., 1996

Species	**organism**	**Tissue (mg/kg dw)**	**Tissue (mg/kg ww)**	**Water (µg/L)**	**BCF (L/kg dw)**	**BCF (L/kg ww)**	**Analysis of Pb in aqueous media**	**Reference**
Dreissena polymorpha	mussel	1.4	0.14	8	175	18	Unfiltered	Chevreuil et al., 1996
Fusconaia flava	clam	18.5	1.85	2	9 250	925	Filtered (filter size not reported)	Mathis and Cummings, 1973
Lymnaea	snail	0.79	0.079	<0.2	>3 950	>395	Filtered (0.45 µm)	Timmermans et al., 1989
Potamopyrgus	snail	7.7	0.77	<0.2	>38 500	>3 850	Filtered (0.45 µm)	Timmermans et al., 1989
Quadrula	clam	11	1.1	2	5 500	550	Filtered (filter size not reported)	Mathis and Cummings, 1973
Physa	snail	334	33.4	13	25 692	2 570	Filtered (0.45 µm)	Lu et al., 1975
Physa	snail	88	8.8	2	44 000	4 400	Filtered (0.45 µm)	Lu et al., 1975
Physa	snail	56	5.6	2	28 000	2 800	Filtered (0.45 µm)	Lu et al., 1975
Insects								
Chironomus	midge	1.83	0.366	<0.2	>9 150	>1 830	Filtered (0.45 µm)	Timmermans et al., 1989
Glyptotendipes	midge	0.44	0.088	<0.2	>2 200	>440	Filtered (0.45 µm)	Timmermans et al., 1989
Holocentropus	caddisfly	1.32	0.264	<0.2	>6 600	>1 320	Filtered (0.45 µm)	Timmermans et al., 1989
Ischnura	damselfly	1.75	0.35	<0.2	>8 750	>1 750	Filtered (0.45 µm)	Timmermans et al., 1989
Limnephilus	caddisfly	4.36	0.872	<0.2	>21800	>4 360	Filtered (0.45 µm)	Timmermans et al., 1989
Stictochironomus	chironomid	5.31	1.062	<0.2	>26 550	>5 310	Filtered (0.45 µm)	Timmermans et al., 1989
Micronecta	corixid	1.87	0.374	<0.2	>9 350	>1 870	Filtered (0.45 µm)	Timmermans et al., 1989
Annelids								

Species	organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water (µg/L)	BCF (L/kg dw)	BCF (L/kg ww)	Analysis of Pb in aqueous media	Reference
Erpobdella	leech	1.62	0.324	<0.2	>8 100	>1 620	Filtered (0.45 µm)	Timmermans et al., 1989
Acarides								
Hygrobates	mite	1.73	0.346	<0.2	>8 650	>1 730	Filtered (0.45 µm)	Timmermans et al., 1989
Fish								
Astyanax mexicanus	fish	1	0.2	14	71	14	Unfiltered	Villarreal-Trevino et al., 1986
Astyanax mexicanus	fish	0.9	0.18	12	75	15	Unfiltered	Villarreal-Trevino et al., 1986
Astyanax mexicanus	fish	0.86	0.172	10	86	17	Unfiltered	Villarreal-Trevino et al., 1986
Astyanax mexicanus	fish	0.8	0.16	7	114	23	Unfiltered	Villarreal-Trevino et al., 1986
Astyanax mexicanus	fish	4.74	0.948	4	1 185	237	Unfiltered	Villarreal-Trevino et al., 1986
Cichlasoma cyanoguttatum	fish	0.5	0.1	9	56	11	Unfiltered	Villarreal-Trevino et al., 1986
Cichlasoma cyanoguttatum	fish	1.36	0.272	14	97	19	Unfiltered	Villarreal-Trevino et al., 1986
Cichlasoma cyanoguttatum	fish	1.3	0.26	10	130	26	Unfiltered	Villarreal-Trevino et al., 1986
Micropterus salmoides	fish	0.46	0.092	9	51	10	Unfiltered	Villarreal-Trevino et al., 1986
Notropos lutrensis	fish	0.8	0.16	14	57	11	Unfiltered	Villarreal-Trevino et al., 1986

Species	**organism**	**Tissue (mg/kg dw)**	**Tissue (mg/kg ww)**	**Water (µg/L)**	**BCF (L/kg dw)**	**BCF (L/kg ww)**	**Analysis of Pb in aqueous media**	**Reference**
Poecilia reticulata	Fish	16	3.2	3.1	5 160	1 032	Filtered (0.45 µm)	Vighi, 1981
Poecilia reticulata	fish	36	7.2	27.5	1 300	260	Filtered (0.45 µm)	Vighi, 1981
Poecilia formosa	fish	0.9	0.18	14	64	13	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia formosa	fish	1.3	0.26	9	144	29	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia formosa	Fish	2.26	0.452	12	188	38	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia formosa	Fish	2.16	0.432	10	216	43	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia formosa	Fish	1.3	0.26	4	325	65	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia formosa	Fish	2.8	0.56	7	400	80	Unfiltered	Villarreal-Trevino et al., 1986

Table B32. Bioaccumulation factors in soil. Lead concentrations in the biota are the product of BAF and soil Pb concentration (LDAI, 2008).

Test substance	**Organism**	**Medium**	**Test conditions**	**Duration (d)**	**Soil (mg/kg_{dw})**	**BAF (kg_{dw}/kg_{ww} or kg_{dw}/kg_{dw}[a])**	**References**
Pb-soil	*Lumbricus terrestris* *Allolobophora caliginosa* *Allolobophora tuberculata* *Allolobophora chlorotica* *Allolobophora longa* *Allolobophora rosea*	-control soil of orchard (Long Ashton); pH 6.5; average biomass 113.7 g/m^2; Cd 1 $\mu g/g_{dw}$; Pb 92 $\mu g/g_{dw}$; Zn 89 $\mu g/g_{dw}$ -polluted soil of pasture (Severnside); pH 6.8; average biomass 85.8 g/m^2; Cd 10 $\mu g/g_{dw}$; Pb 147 $\mu g/g_{dw}$; Zn 617 $\mu g/g_{dw}$	control soil polluted soil control soil polluted soil control soil polluted soil control soil polluted soil control soil polluted soil control soil polluted soil	whole life	92 147 92 147 92 147 92 147 92 147 92 147	0.32[a] 0.30[a] 0.48[a] 0.43[a] 0.22[a] / 0.23[a] 0.57[a] 0.26[a] 0.51[a] 0.27[a] 0.52[a]	Wright and Stringer, 1980
Pb-soil	*Allalobophera* sp.	Top 10 cm of 6 soil series	Bodine soil Captina soil	whole life	26 15	0.18[a] 0.30[a]	Van Hook, 1974

	Lumbricus sp. *Octolasium* sp.	from east Tennessee	Claiborne soil Emory soil Linside soil Tarklin soil		24 50 18 27	0.23[(a)] 0.11[(a)] 0.22[(a)] 0.15[(a)]	
Pb-soil	*Lumbricus terrestris* *Lumbricus rubellus* *Lumbricus castaneus* *Allolobophora caliginosa* *Allolobophora chlorotica* *Allolobophora rosea*	polluted soil around a primary smelting place; pH 5.56-7.32; OM 15-29.9%		whole life	/	0.26[(a)] 0.26[(a)] 0.08[(a)] 0.15[(a)] 0.16[(a)] 0.08[(a)] 0.06[(a)] 0.24[(a)] 0.24[(a)] 1.25[(a)] 0.19[(a)] 0.18[(a)] 0.22[(a)] 0.12[(a)] 0.25[(a)] 0.45[(a)]	Spurgeon and Hopkin, 1996
Pb-soil	*Lumbricadea* sp.	Landsdale 1 loam Hagerstown silt loam	control; pH 5.9-6.3 sludge; pH 5.5-6.2 control; pH 5.4-6.4; CEC 9 meq/100g; OM 3%	whole life	16 16 41 41 34 34 43	0.85[(a)] 0.2 0.42[(a)] 0.1 0.69[(a)] 0.16 0.65[(a)]	Beyer et al., 1982

		Landsdale 2 loam Readingston silt loam	sludge; pH 4.9-6; CEC 13 meq/100g; OM 4.9% control; pH 4.9-6.4; CEC 8 meq/100g; OM 2.5% sludge; pH 4.6-6.3; CEC 8 meq/100g; OM 2.8% control; pH 5.3-6.1; CEC 10 meq/100g; OM 2.6% sludge; pH 5.5-6.1; CEC 11 meq/100g; OM 3.8%		43 22 22 23 23 23 23 22 22	0.15 0.74[a] 0.17 0.71[a] 0.16 0.96[a] 0.16 0.75[a] 0.23	
Pb-soil	*Lumbricus rubellus* *Dendrodrilus rubidus*	topsoil of control soil and 12 heavily contaminated soils of non-ferrous metalliferous mines; pH 4.3-7.8; OC 1-27%; CEC 8-77 meq/100g	control soil polluted soil control soil polluted soil	whole life	170-24600 170-24600	0.1-0.13[a] 0.5-0.44[a]	Morgan and Morgan, 1988
Pb-soil	*Lumbricus terrestris*	topsoil along two highways	B-W parkway 3 m	whole life	700	0.47[a]	Gish and Christe

	Allolobophora chlorotica *Allolobophora trapezoides* *Allolobophora turgida*	(Maryland): B-W parkway; silt-clay; pH 6.97; OM 4.96-7.3 US-Highway1; pH 6.88-6.96; OM 4.8-6.36	6.1 m 12.2 m 24.4 m 48 8 m US-Highway1 3 m 6.1 m 12.2 m 24.4 m 48 8 m		204.3 94.2 60.1 81.6 313.3 90.3 54.1 38.6 34.9	0.82[(a)] 1.08[(a)] 0.82[(a)] 0.83[(a)] 0.70[(a)] 0.84[(a)] 1.18[(a)] 1.10[(a)] 1.18[(a)]	nsen, 1973
Pb-soil	*Allolobophora longa* *Allolobophora caliginosa* *Allolobophora rosea* *Allolobophora chlorotica* *Lumbricus terrestris*	experimental plots: soil 1: K-fertilised; pH 5.9 soil 2: NPK-fertilised (300 kg N/ha); pH 5.7 soil 3 Vejen sewage sludge (30 T/ha containing 396 mg Pb/kg_{dw}); pH 5.8)	soil 1 soil 2 soil 3 soil 4 soil 3 soil 4 soil 1 soil 2 soil 3 soil 4 soil 3 soil 4 soil 1 soil 3 soil 4	whole life	15.3 16.2 28.2 38.9 28.2 38.9 15.3 16.2 28.2 38.9 28.2 38.9 15.3 28.2 38.9	0.25[(a)] 0.35[(a)] 0.16[(a)] 0.15[(a)] 0.23[(a)] 0.24[(a)] 0.21[(a)] 0.20[(a)] 0.17[(a)] 0.14[(a)] 0.16[(a)] 0.15[(a)] 0.75[(a)] 0.39[(a)] 0.13[(a)]	Andersen, 1979

		soil 4: Lundtofte sewage sludge (30 T/ha containing 1850 mg Pb/kg_{dw}); pH 6					
Pb-soil	*Allolobophora caliginosa* (adults)		30% clay; CEC 26.3 meq/100g; OM 5.8%; pH 7.1; 0 T compost/ha	whole life	53	0.00[(a)]	Ma, 1982
					100	0.16[(a)]	
			30% clay; CEC 24.5 meq/100g; OM 6.7%; pH 7; 20 T compost/ha		163	0.30[(a)]	
					37	0.73[(a)]	
			30% clay; CEC 25.1 meq/100g; 8.4%; pH 6.9; 40 T compost/ha		87	1.20[(a)]	
					127	0.60[(a)]	
			10% clay; CEC 9.4 meq/100g; OM 2.8%; pH 6.6; 0 T compost/ha		90	0.21[(a)]	
					220	0.34[(a)]	
			10% clay; CEC 10.5 meq/100g; OM 4%; pH 7; 20 T compost/ha		257	0.51[(a)]	
					40	2.16[(a)]	
			10% clay; CEC 12.3 meq/100g; OM 4.9%;		166	0.77[(a)]	

			pH 7; 40 T compost/ha		227	0.67[(a)]	
			40% clay; CEC 26.4 meq/100g; OM 6.9%; pH 5.3; 0 T compost/ha		23	2.62[(a)]	
			40% clay; CEC 28.7 meq/100g; OM 9.2%; pH 5.8; 20 T compost/ha		80	0.93[(a)]	
			40% clay; CEC 28.7 meq/100g; OM 9.7%; pH 5.9; 40 T compost/ha		127	0.83[(a)]	
			10% humus CEC 20.5 meq/100g; OM 12.4%; pH 4.7; 0 T compost/ha		20	2.63[(a)]	
			10% humus CEC 19.2 meq/100g; OM 11.2%; pH 5.2; 20 T compost/ha		53	1.24[(a)]	
			10% humus CEC 18.3 meq/100g; OM 13.6%; pH 5.8; 40 T compost/ha		83	0.88[(a)]	
			7% humus CEC 13.5 meq/100g; OM 6.4%;				

			pH 5.4; 0 T compost/ha 7% humus CEC 12.7 meq/100g; OM 7.4%; pH 5.4; 20 T compost/ha 7% humus CEC 23.2 meq/100g; OM 8.1%; pH 5.7; 40 T compost/ha 3% humus CEC 5.3 meq/100g; OM 2.8%; pH 4.8; 0 T compost/ha 3% humus CEC 6.1 meq/100g; OM 3.7%; pH 5.5; 20 T compost/ha 3% humus CEC 7.1 meq/100g; OM 4.3%; pH 6; 40 T compost/ha				
Pb-soil	*Lumbricus rubellus*	top soil in region around zinc smelting works in Dutch Kempen region	grassland or heatherland on sandy podzolic soil: pH 3.5-6.1,% OM 2.2-8.6	whole life	14-430	1.68-1.69[(a)]	Ma et al., 1983

Pb-soil	*Lumbricus rubellus*	contaminated site in mid-Wales, Cwmystwyth	Pb 1594-8688 µg/g d.w., pH 5.9-6.3% OM 31.85-51.19	whole life	1594-8688	0.73-3.98[(a)]	Mariño and Morgan, 1999
Pb-soil	*Dendrobaena rubida*	soil from a mine spoil at Cwmystwyth, mid-Wales	P H 3.6-4.0,% OM 13.5-18.5	whole life	1810	6.86[(a)]	Ireland, 1975

Table B33. Bioaccumulation factors between soil or decomposed leaf litter and isopods. Lead concentrations in the biota are the product of BAF and soil Pb concentration (LDAI, 2008)

Test substance	**Organism**	**Test conditions**	**Medium**	**Duration**	**Soil/litter (mg Pb/kg_{dw})**	**BAF (kg_{dw}/kg_{dw})**	**Reference**
Pb-soil	Porcellio scaber	15 adult specimen were exposed for 14 days to approximately 600 mL of air-dried experimental soil (polluted and remediated with 2.5, 10, 40 and 4 x 40 EDTA, respectively) in plastic vessels with plastic covers.	polluted soil	14 days	4 603	0.04	Udovic et al. 2009
			polluted soil leached with 2.5 mmol kg^{-1} EDTA		4 323	0.04	
			polluted soil leached with 10 mmol kg^{-1} EDTA		2 712	0.035	
			polluted soil leached with 40 mmol kg^{-1} EDTA		2 112	0.035	
			polluted soil leached with 4 x 40 mmol kg^{-1} EDTA		1 239	0.025	
$PbCl_2$	Porcellio scaber	Isopods were kept in plastic boxes on a moist gypsum base	Control	21 days	7.1	0.41	Gräff et al. 1997
			100 mg Pb/L		517	0.14	
			500 mg Pb/L		2 777	0.08	

Test substance	Organism	Test conditions	Medium	Duration	Soil/litter (mg Pb/kg_{dw})	BAF (kg_{dw}/kg_{dw})	Reference
		covered by decomposed leaf litter material, i.e. partly decomposed leaf litter material soaked in an aqueous solution of 100, 500 or 1000 mg l^{-1} Pb^{2+} (as $PbCl_2$).	1 000 mg Pb/L		7 676	0.03	
Pb-soil	Trachelipus rathkei	Near a smelting complex a transect of 5 soil sampling sites was taken	0.3 km from the smelting complex	whole life	61 946	0.006	Rabitsch 1995
	Porcellio scaber		0.3 km from the smelting complex		61 946	0.002	
	Trachelipus ratzeburgi		0.5 km from the smelting complex on the other side of the low hill		1 190	0.649	
			1 km from the smeltin		4 618	0.248	

Test substance	**Organism**	**Test conditions**	**Medium**	**Duration**	**Soil/litter (mg Pb/kg_{dw})**	**BAF (kg_{dw}/kg_{dw})**	**Reference**
			g complex				
			2.5 km from the smelting complex		516	0.322	

Appendix B2: Benchmark dose estimated and IQ impacts of lead

EFSA (2010) proposed that blood lead limits protective of IQ should be indexed to benchmark dose calculations for the impacts of lead upon IQ. The benchmark dose estimates used by EFSA have since been updated (Budtz-Jorgenson et al., 2013). Several types of dose response models were used for benchmark dose calculations. Since there are multiple ways of modelling the dose response for lead, a benchmark dose could be calculated to estimate the blood lead level required to induce one IQ point change assuming a linear dose response, a non-linear dose response or a piece-wise linear dose response that assumes linearity from a blood lead level from 0 to 10 and non-linearity above that point. Since the relationship of blood lead to IQ can use a variety of blood lead metrics (e.g. concurrent blood lead at age 6, early childhood blood lead etc.,) an assortment of benchmark dose estimates can be made. The following Table B34 summarizes the different benchmark doses associated with different blood lead levels and modelling assumptions. Included in the following Table B34. are the benchmark dose (BMD) and the lower one-sided 95th percentile (BMDL) of the BMD estimate.

Table B34. Benchmark Dose Calculations for the Blood Lead Level in µg/dL associated with a 1-IQ Point Loss Using Different Model Assumptions and Blood Lead Metrics.

Blood Lead Metric	**Nonlinear (logarithmic)**		**Linear**		**Piecewise linear**	
	BMD	**BMDL**	**BMD**	**BMDL**	**BMD**	**BMDL**
Concurrent	0.354	0.260	5.58	4.05	1.80	1.20
Peak	0.393	0.273	9.67	6.57	1.03	0.70
Lifetime Average	0.355	0.250	6.45	4.50	1.48	0.97
Early Childhood	0.558	0.343	8.06	5.24	3.80	1.61

The wide range of BMD estimates above demonstrates the significant impact of modelling assumptions upon BMD calculations. BMD and BMDL estimates made assuming a nonlinear model are well below current EU blood lead levels measured in children, but linear models generally yield BMD's and BMDL's in excess of the 5 µg/dL NOAEL identified here for protection of the individual. Piecewise linear estimates are close to the geometric mean blood lead level of 2 µg/dL suggested here as required to minimize the number of individuals with a blood lead level of 5 µg/dL or greater.

It should further be noted that EFSA (2010) judged the piece-wise linear BMD estimates to be most relevant. These estimates were, however, made based upon Lanphear et al pooled analysis data now know to contain errors and some alteration of the BMD estimates might occur upon correction of data base errors. Moreover, the BMD estimates for piecewise linear modelling are predicting impacts at low blood lead levels where statistically significant

associations no longer exist between blood lead and IQ. Still, given these caveats, it is interesting to note that the BMD and BMDL estimates are similar to the population geometric mean blood lead levels proposed in this CSR that would be required to maintain the blood lead levels of most children below 5 µg/dL.

It is important to recognise that all of the preceding calculations are estimates of the lead exposure level that would be required to yield a reduction of IQ by one point. In and of itself, one IQ point loss is likely to have no significance for the individual but is hypothesized to have significance if this IQ decrement were to occur population-wide and thereby increase the proportion of individuals in a society judged to have impaired mental capacity. This would be more representative of the health endpoints for which BMD estimates could be made and has been the preferred manner in which to develop BMD's for other neurotoxins such as methylmercury (NAS, 2000).

For example, by definition 5% of individuals in the general population have an IQ of 70 or lower. BMD estimates can be made of the lead exposure level that would be required to increase this prevalence to 10%. This would entail a population wide decrement of 4.28 IQ points (Budtz-Jorgenson et al., 2013). Using the dose response functions adopted by EFSA (2010) for the impacts of concurrent blood lead levels in a piece-wise linear model, a population-wide 4.28 IQ point decrement would be associated with a concurrent blood lead level of 7.7 µg/dL**.** If early childhood blood lead levels were of primary concern, this populations wide IQ decrement would require blood lead levels in excess of 16 µg/dL.

Current EU blood levels are significantly lower than those associated with population-wide IQ point decrements used in the Benchmark Dose derivations for other environmental neurotoxins.

Appendix B3: Summary of the existing legal requirements (and international agreements)

Lead has been a substance of concern for many years. Due to the well-documented adverse effects of the metallic lead and lead compounds, these have been extensively regulated at national, Union and global level. This is reflected in the large number of sector specific Union legislative acts which restrict the use of lead and or its compounds in mixtures, articles and consumer products with regard to their risks to human health (incl. occupational) and the environment.

A comprehensive (but non-exhaustive) inventory of existing Union legal requirements related to lead, is listed in the following tables:

Table B35. EU General Legislation controlling lead and its compounds (non-exhaustive list)

EU Legislation	Legal requirements
Regulation (EC) 1123/2009 on cosmetics products	• List of substances that cosmetic products must not contain (including lead and its compounds)
Directive 98/70/EC on petrol	• Prohibition of leaded gasoline (except aircraft) • Lead content restricted to 0.005 g/l
Directive 1999/45/EC relating to the classification, labelling and packaging of dangerous preparations	• The label on the packaging of paints and varnishes containing lead in quantities exceeding 0.15% (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars: o 'Contains lead. Should not be used on surfaces liable to be chewed or sucked by children'. • In the case of packages the contents of which are less than 125 ml, the particulars may be as follows: o 'Warning! Contains lead'.
Council Regulation (EEC) 304/2003 on the export and import of dangerous chemicals (Rotterdam Convention)	Sets out the requirements for classification, packaging and labelling of dangerous substances and preparations, including lead compounds, when put on the market in non-EU countries or imported from non-EU countries.
Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators	• No prohibition on lead in batteries (though prohibitions in place for mercury and cadmium) • Sets out measures relating to the collection, treatment, recycling and disposal of waste batteries and accumulators containing lead, with specific recycling efficiency targets for lead-acid batteries

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) (to be replaced on 3 Jan 2013 by Directive). Directive 2012/19/EC on waste electrical and electronic equipment (WEEE)	• Substances (including lead) restricted in a waste management perspective • Maximum concentration of up to 0.1% by weight in homogeneous material tolerated • Articles concerned: electrical and electronic equipment including IT and telecommunications equipment, household appliances and consumer equipment, lighting equipment, electrical and electronic tools, toys, leisure and sports equipment, medical devices, monitoring and control instruments, and automatic dispensers • Exemptions include lead in cathode ray tubes; certain electrical and electronic components which contain lead in a glass or ceramic; lead in white glasses for optical applications; in certain printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses; bound in crystal glass; • Lead oxide is specifically exempted for certain applications including in surface conduction electron emitter displays (SED) used in structural elements, notably in the seal frit and frit ring; in seal frit used for making window assemblies for Argon and Krypton laser tubes etc. • Lead is exempted from certain medical devices and monitoring and control instruments • Sets criteria for the collection, recycling and recovery of such equipment and selective treatment of certain materials and components
Directive 2000/53/EC on end-of-life Vehicles	• MS shall ensure that materials and components of vehicles put on the market do not contain lead (certain exemptions apply) • products concerned: passenger vehicles comprising no more than eight seats in addition to the driver's seat, and goods transport vehicles not exceeding 3.5 tons • Maximum concentration of up to 0.1% by weight in homogeneous material tolerated • Exemptions include lead in alloys and in components such as batteries (to be reviewed in 2015), vulcanising agents and stabilisers, certain electrical and electronic components which contain lead in a glass or ceramic matrix (compound), pyrotechnic initiators etc.
Directive 2009/48/EC on the safety of toys	• Total prohibition of certain substances or preparations in toys except those which are essential to their functioning. In this case, they

	are submitted to a maximum concentration defined for each substance individually • Bioavailability resulting from the use of toys < 0.7µg/day (EN 71-3) • Lead migration limit from toys = 90 mg/kg (EN 71-3) • Lead migration limit = 13.5 mg/kg dry, brittle, powder-like or pliable toy material • Lead migration limit = 3.4mg/kg liquid or sticky toy material • Lead migration limit = 160mg/kg scraped-off toy material
Directive 2001/95/EC on General Product Safety	• Only safe products for consumers are placed on the market (conception and/or information) • Information system (RAPEX)
Directive 94/62/EC on packaging and packaging waste as amended by Directive 2004/12/EC	• Requirements on management of packaging and packaging waste effectively eliminated this application of lead by reducing the sum of the amount of lead, cadmium, mercury and hexavalent chromium present in packaging and packaging components to 100 ppm (mg/kg) • Exemption for packaging made of lead crystal glass • Derogation from heavy metal limit for glass packaging and for plastic crates and pallets
Directive 69/493/EEC on crystal glass	• Prescription of the use of lead in crystal glass • >30% of content of lead in "full crystal glass" cat. 1 • [24%, 30%] of content of lead in "full crystal glass" cat. 2
Food related EU legislation	
Directive 84/500/EEC on ceramic articles intended to come into contact with foodstuffs as amended by Directive 2005/31/EC Framework Regulation EC No. 1935/2004 on materials and articles intended to come into contact with food	• Lays down maximum limits for lead transferred by ceramic objects to the foodstuffs with which they enter into contact • Maximum permitted quantity of lead is 0.8mg/dm² for articles which cannot be filled or which can be filled but not deep (25mm), 1.5mg/l for cooking ware and storage vessels which have a capacity of more than 3 litres and 4.0 mg/l for other articles (+50% of these thresholds tolerated)
Commission Regulation 466/2001 on contaminants in foodstuffs	• Lead level in milk, meat, fish, shellfish, cereals, vegetables, fruits, berries, oils, fats, fruit juice and wine must be between 0.02mg/kg by wet

Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs	weight (cow's milk) and 1.5mg/kg w.w. (mussels) • Sets maximum levels for lead in a number of different foodstuffs. In various food items the maximum level are between 0.02 and 1.5 mg/kg
Directive 98/83/EC on quality of water intended for human consumption	• Lead content in water for human consumption must be <25µg/l (until 2014) and <10µg/l thereafter
Directive 88/344/EEC on extraction solvents in foodstuffs	• Residues of solvents used in food industry • Lead content in extraction solvents < 1 mg/kg
Directive 88/388/EEC on flavourings for use in foodstuffs and to source materials for their production	• Lead content in flavourings < 10 mg/kg
Directive 2002/32/EC on undesirable substances in animal feed as regards lead, fluorine and cadmium	• Sets maximum content of lead in different types of feed materials, between 5 and 40 mg Pb/kg.

Table B36. List of EU legislation related to lead and its compounds associated with human health protection (non-exhaustive list)

EU Legislation	Legal requirements
Annex XVII of REACH: restriction of the use of certain hazardous substances (entries 16, 17, 28, 30, 63)	• Direct restriction of lead carbonates and lead sulphates in mixtures intended to be used as paints • Restriction of lead and its compounds in jewellery and consumer articles that can be placed in the mouth by children • Substances classified as CMR may not be sold to the public (lead compounds are Toxic to Reproduction Category 1A and lead hydrogen arsenate is also a Carcinogen Category 1A)
Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work	• The principal objective is to prevent (personal) exposure to hazardous substances. Where this is not possible, the Directive requires adequate control through engineering and individual protective measures, and in the case of inorganic lead and its compounds, a binding occupational exposure limit value (BOELV) of 0.15 mg/m³ at European level has been set. • The binding biological limit value is 70 µg Pb/dl blood. The Directive requires medical surveillance to be carried out if: o exposure to a concentration of lead in air is greater than 0.075 mg/m^3, calculated as a time-weighted average over 40 hours per week, or

	○ a blood-lead level greater than 40 µg Pb/dl blood is measured in individual workers.
Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health of pregnant workers and workers who have recently given birth or are breast-feeding	• Sets out measures to protect pregnant workers and workers who have recently given birth or are breast-feeding, including the requirement to assess exposure to health risks including lead compounds due to their reprotoxic effects.
Directive 94/33/EC on the protection of young people at work	• Prohibits the use of certain chemical agents, including lead compounds as a reprotoxic agent, by young workers.

Table B37. List of EU environmental legislation related to lead and its compounds (non-exhaustive list)

EU Legislation	Legal requirements
Directive 2008/1/EC on integrated pollution prevention and control (IPPC) (to be replaced on 7 Jan 2014 by Directive 2010/75/EU on industrial emissions)	• Categories of activities subject to IPPC permitting are listed in Annex I of the Directive • Relevant activities controlled include processing of non-ferrous metals; manufacture of glass and ceramic products; chemical installations for the production of organic (e.g. synthetic rubbers, dyes and pigments) and inorganic (e.g. metal oxides) chemicals, and for the production of explosives • Where relevant, emission limit values along with other conditions have to be set in individual plant permits to control the emissions and other impacts to the environment • Best Available Technique Reference (BREF) documents and their BAT conclusions adopted by the Commission provide the reference concerning techniques to control/reduce emissions. Relevant BREFS include those on large volume inorganic chemicals, the ceramic manufacturing industry and the glass manufacturing industry
Regulation No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register (EPRTR)	• Member States have to report on the emissions of industrial facilities regulated (scope is similar to the IPPC Directive). Reporting covers a wide range of pollutants including lead and its compounds.
Directive 2008/50/EC on ambient air quality and cleaner air for Europe	• A limit value of the lead concentration in ambient air is established for the protection of human health (expressed as an average over a calendar year) of 0.5 μg/m^3. Member States shall ensure that, throughout their zones and agglomerations, levels of lead in ambient air do not exceed this limit value.

Waste and water EU legislation	
Directive 2000/76/EC on the incineration of waste (to be replaced on 7 Jan 2014 by Directive 2010/75/EU on industrial emissions)	• Total air emission limit values for certain metals and metal compounds (including lead) of 0.5 mg/Nm^3 • Emission limit value for lead and its compounds in discharges of waste water from the cleaning of waste gases of 0.2 mg/l (expressed as lead)
Directive 2008/98/EC on waste Decision 2000/532/EC establishing a list of wastes	• Sets out the requirements for the management of hazardous wastes such as wastes containing lead compounds above a certain threshold.
Directive 2000/60/EC establishing a framework for Community action in the field of water policy (Water Framework Directive - WFD) Directive 2008/105/EC on environmental quality standards in the field of water policy Directive 2006/118/EC on the protection of groundwater against pollution and deterioration Directive 2006/11/EC Dangerous Substances Directive (to be integrated into WFD by 2013)	• In relation to surface water, lead and its compounds are listed as priority substances in Annex X of the WFD and an annual average environmental quality standard of 7.2µg/l has been set. • In relation to groundwater, lead is listed in the minimum list of pollutants and their indicators for which Member States have to consider establishing threshold values.
Directive 86/278/EC on Sewage sludge in agriculture	• Prohibits sludge from sewage treatment plants being used in agriculture unless specified requirements are fulfilled, including the testing of the sludge and the soil • Limit value for lead concentrations in sludge for use in agriculture is 750-1200 mg/kg dry matter

Table B38. List of International agreements related to lead and its compounds (non-exhaustive list) (EPA, 2014)

Agreement *(entry into force)*	**Main provisions on lead**
The Convention for the Protection of the Marine Environment of the North-East Atlantic/**OSPAR Convention** (1992)	Lead in the form of tetraethyl and tetramethyl lead is on the OSPAR list of substances of possible concern, aiming to reduce discharges in order to reach near-background concentrations in the North-East Atlantic. Lead and 8 organic lead compounds are on the Priority action list of OSPAR.
Helsinki Commission /HELCOM (2000)	The Helsinki Commission has issued a range of recommendations regarding lead. This includes the reduction

	of emissions of lead from leaded fuel, restriction of discharge and emission of lead from treated metal surfaces, proper handling of waste and reduction of discharge from urban areas by the treatment of storm water.
Barcelona convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (1995)	Lead is listed in Annex II of the, the Annex regards Harmful or Noxious Substances and Materials for which the disposal in the Protocol Area is subject to a special permit.
Bucharest convention on the Protection of the Black Sea Against Pollution (1994)	The Bucharest convention on the protection of the Black Sea, lists heavy metals and its compounds, herein lead and its compounds, with the aim of reducing, controlling, and eliminating use and release of harmful substances in order to prevent the environment of the Black Sea.
Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989)	The Basel convention set out control measures of the movements of hazardous waste incl. waste containing lead between nations, and restricts the transfer of hazardous waste from developed to less developed countries (non-adopted). The convention also intends to minimize the amount and toxicity of wastes generated, to ensure their environmentally sound management as closely as possible to the source of generation, and to assist least developed countries (LDCs) in environmentally sound management of the hazardous and other wastes they generate.
Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (rev 2013)	Lead is not directly covered by the on prior informed consent (the PIC-procedure), but tetraethyl lead and tetramethyl lead are, however, covered by Regulation (EC) No 689/2008 implementing the Convention in the EU.

Annex C: Justification for action on a Union-wide basis

C.1. Considerations related to human health and environmental risks

As already discussed under section B.3, the lead compounds used as PVC stabilisers (the intrinsic properties of which are defined by the lead cation) have a harmonised CLP classification:

(i) for human health as 1.A reprotoxic compounds (1.A May damage fertility or the unborn child) as well as STOT RE 2*H373 (may cause damage to organs through prolonged or repeated exposure)

(ii) for the environment as very toxic for the aquatic life (H 400 Acute 1; H410 Aquatic Chronic). Furthermore, as noted in section B.9.1 since 2012 all the lead stabilisers were identified as SVHC substances and included in the REACH Candidate List (CL).

Therefore, the lead compounds used PVC stabilisers have a well-established hazardous profile for both human health and the environment.

In the section B.5, it has been also stressed that repeated exposure to lead can result in severe and irreversible neurobehavioral and neurodevelopmental effects, even at a low exposure. Actually, lead is considered a non-threshold neurotoxic substance with adverse impacts on the development of children's central nervous systems (such as IQ loss). In addition, EFSA (2013) has stated with their scientific opinion that currently, the background exposure to lead from food and non-food sources exceeds the highest tolerable exposure.

From the information presented in this report, it is clear that the use of lead stabilisers in PVC in the EU has been steadily and significantly decreased during the last decade. The European Stabilisers Producers Association (ESPA) informed that their Members have completed the phase out by of lead stabilisers by end of 2015 via the voluntary agreements (VinylPlus).

It cannot be excluded, however, that rigid PVC based articles stabilised by lead compounds can be still found on the EU market being manufactured and placed on the market by actors that do not participate in Vinyl agreement (in particular SMEs) or being imported from outside EU (in particular from Asian countries where lead is not restricted in rigid PVC applications (as explained in Annex A, Eurostat data confirmed a steady increase of imports of rigid-PVC based articles to the EU during the last decade).

The existing legal requirements, as described in the section B.9.1, are mainly sector specific and only target some article categories (e.g. for packaging, electric and electronic equipment). Furthermore, it has to be noted that the current EU restriction of lead and its compounds in consumer articles (Entry 63 of Annex XVII to REACH) may only partly address the concern for PVC based articles by covering those that can be mouthed by children (e.g. plastic decorative items, garden hoses).

Overall, the placing on the market of PVC based articles stabilised by lead compounds is a global issue which cannot be isolated to any specific EU country. Consequently, there is a remaining risk for the environment and humans exposed to lead via the environment resulting from placing on the EU market and use of PVC articles not in scope of the existing legal measures. As this concern is not limited geographically or nationally (but should be similar in

all Member States) regulating the risk at Union level is likely to offer the strongest protection all over the EU, and thereby *a Union wide action is justified*. It has to be noted that even if the risks could be managed on a national level, leaving regulatory action to national legislation is likely to create a plethora of incoherent, heterogeneous regulations which are less coercive and more difficult to manage.

C.2. Considerations related to the internal market

In spite of the successful implementation of the industrial voluntary agreements (Vinyl 2010/currently Vinyl Plus) which cover the large majority of the market there may still be a few companies, in particular SMEs, that do not participate at the commitments to phase out lead compounds in PVC by end of 2015. In addition, a certain percentage of lead containing PVC articles (even if low according to the industry) in the EU may still be imported from third countries, notably from Asia, by a diversity of actors. Therefore such lead containing PVC material and articles will in certain cases be available on the EU market.

In addition, regulating lead in PVC articles on a national level will likely cause internal market distortions. For instance, industry actors in one Member State will need to conform to strong requirements imposed by that government, whereas their competitors in neighbouring countries will face less strict national regulations or no regulations at all. Meanwhile, foreign EU competitors would be advantaged by the capture of a new demand (switch of the demand from the regulated – more costly – countries to the less regulated countries). The EC competition law states that flows of working people, goods, services and capital shall be free in a borderless Europe and that firms shall be equally treated on the common market. Isolated and non-harmonised national measures of lead restrictions in PVC articles, would likely constitute barriers to trade and be incompatible with the spirit of that law and single market principle.

A Union wide restriction of lead compounds in PVC based articles (manufactured or imported in the Union) will create a level play field for trade and will prevent the market distortions resulted from national regulations. It will not discriminate between PVC articles produced in the EU and articles imported from third countries, and it will not hinder commercial relations on the internal market. It will create a harmonised, manageable regulatory situation which can further reduce the administrative burden and the costs of compliance.

C.3. Conclusion

The primary reason to act on an EU-wide basis is to effectively reduce the human health and environmental risks caused by the use of lead compounds in PVC articles placed on the EU market. Lead is considered a non-threshold neurotoxic substance and lead compounds classified for their reprotoxic and aquatic toxic effects. Therefore, action on a Union-wide basis would further reduce additional exposure (environmental exposure and human exposure via the environment) to hazardous lead in the EU. In addition, the fact that goods need to circulate freely within the EU stresses the importance of Union-wide action rather than action by individual Member States (which could prevent the free flow of PVC based articles within the internal market).

Annex D: Baseline

D.1. Problem definition - Risk to be addressed

It is well known that lead and its compounds can have detrimental effects on both human health and the environment. According to ECHA's previous opinions (RAC/SEAC opinion on lead in consumer articles, 2014) and EFSA's assessment (EFSA 2013), lead is a non-threshold neurotoxic substance which at high levels in the human body can damage various organs. Lead can also accumulate in the environment and cause damage to the ecosystem. The general public is exposed to low doses of lead from many different sources of which dietary intake is a major source of exposure. Even at low doses, though, lead remains of concern for the developing brains of young children as well as to unborn children through their mothers' exposure (VRAR 2008).

As the presence of lead in articles and consumer goods can potentially increase the lead burden in the human population and the environment, several proposals have been made during the last years suggesting that the EU should impose regulations to limit the use of lead in articles. (KEMI 2012). In response, restrictions on the uses of lead and its compounds in jewellery and consumer articles that can be mouthed by small children have been recently imposed via the REACH Regulation (Entry 63 of Annex XVII). In addition, over the last two decades, a number of lead restricting legislative actions have been implemented, starting with the lead emission sources that had the highest impact on health. For instance, the use of leaded gasoline for cars, the major contributor to high blood lead in the population, as well the use of lead in car components, ended in Europe in the early 2000s.The use of lead in electric and electronic devices, in toys, in packaging and food contact materials has also been restricted at Union level via the specific EU legislative Frameworks for these product categories.

In spite of the above mentioned risk reduction measures, EFSA (2013) has concluded that given the detrimental neurodevelopmental effects of lead the current human exposure (both from food and non-food sources) still exceeds tolerable exposure levels. Thus, *any additional lead exposure should be avoided*. One feasible way of achieving further exposure reduction would be the introduction of new restrictions of lead. Indeed, *lead and its compounds are still used in various applications, among others as stabilisers in PVC articles.* This has been acknowledged by EU industry in the form of a voluntary agreement to replace the lead stabilisers by calcium based stabilisers. However, not all uses of lead stabilisers are subject to this agreement.

The main risk addressed in this restriction dossier is the risk for humans exposed to lead via the environment due to the use of lead compounds as PVC stabilisers. This concern is well-grounded as discussed in section B.10:

(i) Primarily via the released lead emissions during the disposal phase of the PVC based articles (PVC waste); and

(ii) to a lesser extend due to lead leakage during service life of PVC articles (as they gradually deteriorate).

Due to the environmental hazardous properties of the specific lead compounds used as PVC stabilisers (classified by CLP Regulations as Aquatic Acute 1 and Aquatic Chronic 1, *see section B.3*) their release into water compartments is also expected to cause risk for aquatic organisms. However, this is not the focus of the current assessment. The hazard and exposure aspects as well as the risk to humans due to the use of lead compounds as PVC stabilisers have been discussed in the relevant Sections of Annex B.

D.2. How the situation would evolve without any regulatory measures

To estimate how the current situation would evolve in the future, in the absence of further legislative measures on the use of lead compounds in PVC, we first establish the various activities that have been undertaken at Union level and continue to be in force.

Section B.9.1 of this report has listed the various legislative frameworks and International Agreements that aim at further reducing lead exposure to human health and the environment. The most relevant legislation related to this proposal is the recent REACH restriction of lead and its compounds in mouthable consumer articles (Entry 63 of Annex XVII that came to entry into force June 2016). This restriction covers some articles or individual parts of articles produced by lead stabilised PVC. Examples include PVC prints in clothes, PVC based decorative items, garden hoses etc. However, the proposal for lead used as stabilisers in PVC mainly targets articles used for building and construction application that cover the large majority (>70%) of lead-containing PVC articles (based mainly on rigid PVC) not yet regulated. Therefore, in the absence of further restriction measures, the current lead exposure from PVC applications would – in theory – remain present at Union level.

For the purpose of this assessment, the baseline analysis distinguishes between PVC articles manufactured in the EU and those imported to the internal market from non-EU countries.

D.2.1. PVC articles manufactured in the EU

Further to the existing REACH and other EU legislative actions on lead, the previously mentioned Voluntary Commitment to sustainable development by the European PVC industry, known as VinylPlus scheme[54], is relevant. In relation to the sustainable use of additives, VinylPlus was agreed upon to replace lead-based stabilisers across the EU-27 by the end of 2015. The substitution of lead-based stabilisers in Europe started under the previous voluntary programme, Vinyl 2010, which reduced the use of lead-based stabilisers in the EU-15 by 50% two years ahead of the 2010 target.

In section E.3.2, the Union-wide substitution of lead-based stabilisers by existing alternatives (mainly Ca-based systems) over the period 2007-2016 is depicted. It can be broadly claimed that, if VinylPlus is successfully implemented, lead and its compounds will be gradually

[54] VinylPlus is the legal entity set up to provide the organisational and financial infrastructure needed to manage and monitor the progress towards the goal set in the Voluntary Commitment of the European PVC industry. It groups European vinyl resin manufacturers and plastic converters, as well as producers of stabilisers and plasticisers. The four founding members are: the European Council of Vinyl Manufacturers (ECVM), the European Plastics Converters (EuPC), the European Stabiliser Producers Association (ESPA), and the European Council for Plasticisers and Intermediates (ECPI). VinylPlus closely involves external stakeholders and policy-makers through an independent Monitoring Committee, which supervises the implementation of the Voluntary Commitment, ensuring guidance, transparency and accountability. The VinylPlus programme was developed through open dialogue with stakeholders, including industry, NGOs, regulators, civil society representatives and PVC users. The regional scope of the programme is the EU-27 plus Norway and Switzerland.

removed from EU manufactured PVC applications. Therefore, their contribution to overall lead exposure for humans and the environment will fade out with time (following the gradual replacement of the recently placed on the market of lead-based PVC articles).

It has to be noted, though, that most (>90%) but not all EU companies in the stabilisers sector are members of the Vinyl Schemes. ECHA's Call for comments revealed that in a few EU countries there are SMEs that still use lead stabilisers in specific products (e.g. in vitro diagnostic medical equipment or in PVC silica separators in batteries) or more general applications (e.g. cables). Furthermore, in the absence of an EU legislative restriction of lead-based stabilisers in PVC, some users of lead-containing PVC who have switched to an alternative stabiliser (or who are currently considering a switch to an alternative) might consider switching back to lead compounds. Such a decision (in particular of smaller companies) could also depend on the cost of lead-based stabilisers relative to the cost of alternatives, specifications of upstream actors, and on any related investment cost (e.g. infrastructure needed for switching between different PVC stabilisers).

Therefore, in the absence, of any further restriction measure, a complete phase out of lead emitted to the environment from articles manufactured and subsequently placed on the EU internal market is unlikely to be achieved in real terms.

D.2.2. PVC articles imported to the EU

Concerning quantities of PVC articles imported to the EU and aimed at building or construction applications, the initial input from industry and related reports (ECHA's Call for comments 2016, Tauw IA 2013) indicated that this market is insignificant (compared to the total amount of PVC products made in Europe) and the situation will remain unchanged in the near future. However, a recent consultation of ECHA with Eurostat (May 2016) demonstrated that for the main categories of articles covered the proposed restriction (e.g. window frames, tubes, pipes, shutters, fittings etc.), there is a steady increase of imported quantities from non-EU countries during the last decade. More detailed information and figures are provided in section A.1.4, wherein it is noted that total annual imports of the main categories of articles based on rigid PVC have almost doubled over the period 2010-2015. Since the majority of the imports originate from Asia, where lead in PVC articles is not regulated, one may assume that a large part of imported PVC articles use lead-based stabilisers. Further to the analysis of Eurostat data, information received during consultation with WTO countries in early 2016 suggests that manufacturing of PVC stabilised by lead will continue in particular in Asia (e.g. Thailand, Philippines) and some imports of PVC articles stabilised by lead compounds from those markets to the EU are expected to continue.

Considering the business-as-usual scenario, one has to assume that lead will continuously be emitted to the EU environment through the steadily increased imports of the main covered PVC articles. That would further increase the lead environmental load, causing health risks to humans exposed via the environmental pathways.

D.3. Conclusion

Given the above considerations, there is no compelling justification to assume that a complete phase out of lead emitted from PVC applications would be achieved despite the downward trend of lead in the EU and the voluntary agreement. In the absence of a Union-wide

restriction of lead in PVC and as long as lead containing PVC material and articles would still be available in the world market, imports of relevant PVC articles to the EU will possibly remain unchanged or even further increase in the future. Overall, a restriction of the uses of lead-based stabilisers in PVC articles will be a proportionate measure to reduce a fraction of the current exposure of the European people to lead. This is likely to result in a lower blood lead level in humans, contributing to an improvement of the general health of the European people.

Annex E: Impact Assessment

E.1. Risk Management Options

E.1.1. Proposed option(s) for restriction

The preparation of this restriction dossier on lead and its compounds used as stabilisers in PVC was initiated on the basis of a request by the Commission. ECHA was requested to assess: 1) the risk to human health and the environment of lead released from articles produced from recycled or new PVC materials containing lead compounds as stabilisers, and 2) the need for European Union-wide action beyond any measures already in place. In response to this request, an analysis of possible risk management options (RMOs) was conducted to identify the most appropriate action to address the risks and to define any potential restriction's scope and conditions.

In a first step, existing EU legislation and other possible Union-wide RMOs were examined with regard to their effectiveness to address the risks to human health and the environment from lead and its compounds used as stabilisers in PVC (see Annex B:). However, these were deemed inappropriate to address all the article categories contributing to risk as described in section E.1.3.

Therefore, the possibility to impose a restriction under REACH was investigated further and the following three restriction options were considered:

Restriction option 1: A Restriction on lead and its compounds in all PVC articles with a concentration limit of 0.1%, by weight of the PVC material of the article with derogations for:

- Specific PVC articles (building and construction applications) containing recycled PVC with a concentration 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, and
- Second-hand articles.

The reasoning behind the granting of these exemptions (along with information on technical and socioeconomic aspects) is elaborated in details in section E.3.2).

Restriction option 2: A restriction on lead and its compounds in all PVC articles with a concentration limit of 0.1%, by weight of the PVC material for all articles. This option will not provide any specific derogations from the proposed restriction.

Restriction option-3: A restriction on lead and its compounds in all PVC articles with a concentration limit of in the range between 0.1 and 0.5% which will apply for all PVC articles (based on both virgin and PVC material) with the following derogations:

- PVC-silica separators in lead acid batteries for a period of 10 years,
- Articles covered under existing EU legislation, and

- Second-hand articles.

ECHA's assessment concluded that **restriction option-1** should be proposed since it was found to overall better meet the main criteria for restriction (effectiveness, practicality), with less uncertainties, in comparison to the other evaluated options (more details are given in the next sections of Annex E). The various aspects of the proposed restriction including human health and environmental impacts, risk reduction capacity, practicality-monitorability, socioeconomic impacts and benefit-cost comparison, are further discussed in this Annex.

E.1.1.1. Proposed restriction

Brief title: Restriction of lead compounds in PVC articles in concentrations equal to or greater than 0.1% (w/w) with a 15-year derogation for certain building materials produced from recycled PVC (with a higher restriction limit, 1% w/w) and a 10-year derogation for PVC silica separators in lead acid batteries.

Proposed restriction wording:

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 <u>following article types containing recycled PVC</u> 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 above. Suppliers shall ensure, before the placing in the market of mixtures and articles containing recovered PVC for the first time 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 toy. 4. By way of derogation, paragraph 1 shall not apply to articles placed on the market for the first time before xxxxx (based on the transition period of 24 months).

The wording of the proposed restriction was prepared on the basis of brief consultation with enforcement authorities (see Annex G: Stakeholder consultation).

E.1.1.2. Justification for the selected scope of the proposed restriction option

The proposed restriction option prohibits the placing on the market when the content of lead in the homogenous articles or in individual plastic parts is greater or equal to 0.1% by weight.

Lead compounds cannot stabilise PVC in a satisfactory way at concentrations below approximately 0.5% (Tauw IA, 2013). Therefore, a restriction with the proposed threshold concentration of 0.1% would result in ending the intentional addition of lead-based stabilisers, thereby gradually eliminating the presence of lead in PVC articles manufactured in or imported into the EU. Although the implementation of the ongoing voluntary abatement scheme of the associated EU industry (VinylPlus) has already led to a major reduction in the use of lead-based stabilisers in the EU, the proposed EU restriction is expected to:

(a) further strengthen the effectiveness of the voluntary abatement scheme, since a number of European actors—mainly SMEs—are not part of this agreement; and

(b) reduce the risk to humans exposed to lead emissions associated with lead-containing PVC articles that are imported into the EU (importers of these articles are not subject to the VinylPlus voluntary agreement).

The scope and conditions (restriction limit/transition period) of the proposed restriction are further discussed in the section E.7.2.

During the development of the proposed restriction option, and following the outcome of the ECHA's Call for comments and information exchange with the stakeholders, it was assessed that derogations from the proposed restriction option was justified for:

(i) Building and construction products manufactured by use of recycled PVC, maintaining recycling a viable waste management practice following the disposal of PVC articles; and

(ii) PVC-silica separators in lead-acid batteries due to the lack of existing alternatives for this industrial application.

These derogations are further analysed and justified in the Section E.3.2.

In addition to the above derogations, and for consistency with the existing restrictions of lead and lead compounds in jewellery and consumer articles (Entry 63 of Annex XVII to REACH), derogations were provided for:

(a) PVC articles already covered by specific Union legislation, regulating lead content or migration (in contact with food; toys; electrical and electronic devices; packaging materials);

(b) PVC articles covered by the paragraph 7 of Entry 63 of Annex XVII to REACH, thereby consumer articles that can be mouthed by small children (e.g. plastic decorative items, certain types of garden hoses) which are therefore excluded from the scope of this restriction proposal;

(c) Second hand articles.

Due to the diverse list of articles in scope it is unavoidable that the use of some of these articles is already governed by other European legislation, given the long-standing investigation of the risks associated with lead and its compounds. The derogations are included as it is recognised that sector-specific legislation, e.g. for medical devices, food contact materials, etc., have effective measures (or effective risk management systems) in place to assess and prevent risk to human health and the environment from these articles. The derogations are also included to further clarify to stakeholders which legislation governs the use of these articles.

The proposed restriction also introduces a derogation on articles placed on the EU market for the first time *prior* to the entry into force of the proposed restriction. This is deemed necessary due to:

- The existing stock of diverse PVC articles containing lead-based stabilisers. Some of the articles have long operating lives and are upgraded only every 10-15 years. Introducing the restriction retrospectively would mean this stock would have to be disposed of causing costs for example to retailers;
- Enforceability issues, since additional inspection activities concerning the second-hand market would not be easily implementable and would bring additional costs for competent authorities.

The proposed restriction is based on the assumption that the market will be able to comply with the restriction within 24 months of its entry into force. For the purpose of analysis, it is assumed that this would take place around the year 2020. This should give sufficient time for

producers to adapt as substantial substitution of the lead compounds has already occurred due to VinylPlus. The proposed transitional period will specifically allow:

- Remaining EU articles manufacturers to transition to alternatives;
- EU importers to communicate to their international suppliers the requirements for lead content. Although, the supply chains of many of the articles in scope could be complex, it is anticipated that one year would be sufficient time as industry already has experience with moving to the alternative;
- Non-EU manufacturers to transition to alternatives for the purpose of manufacturing of articles intended for placement on the EU market. Given the availability of a similarly priced alternative, one year is considered sufficient time for non-EU entities to comply with the proposed restriction;
- All actors to deplete existing supplies of articles produced under current EU regulatory requirements.

The reasoning behind the granting of these exemptions (along with information on technical and socioeconomic aspects) is elaborated in details in section E.3.2. The various aspects of the proposed restriction including human health and environmental impacts, risk reduction capacity, practicality-monitorability, socioeconomic impacts and benefit-cost comparison, are further discussed in this Annex.

E.1.2. Other evaluated restriction options

This section summarises the reasons for discarding some other restriction options which were considered during the drafting of the proposed restriction. Each of these options was assessed against the main criteria for proposing a restriction.

Alternative restriction option-2*: Restriction on lead and its compounds in all PVC articles. No specific derogations given from the proposed restriction.*

This option is similar to the proposed restriction option but does not foresee exemptions for recycled PVC or for separators in batteries.

The main rationale for restricting the placing on the market of all PVC articles containing lead and its compounds is that alternatives exist and that such a restriction would have a clear scope for compliance purposes. Furthermore, it could be argued that all articles would cause releases of lead in the environment during their service life and disposal and would, therefore, be a source of exposure to the environmental compartments or humans through the environment, as shown in Annex B:.

However, industry has claimed that the potential restriction would severely constrain the recycling of PVC because the average content of articles based on recycled PVC generally exceeds the 0.1% threshold. In addition, the producers of batteries have argued that there is currently no alternative to lead stabilisers in PVC-silica separators used in lead acid batteries. More information on the derogations and the justification based on technical and socioeconomic aspects is provided in section E.3.2.

Overall, it can be considered as the option presenting the higher risk reduction capacity (in terms of reducing lead emissions and thereby risks for humans). On the other side, if no derogations would be granted from the proposed restriction there would be adverse effects for various actors, such as:

- Recyclers, since no PVC recycling would be possible as detailed under the Section E.3.2.1);
- for industry producing lead stabilised silica separators in lead acid batteries (as discussed under Section E.3.2.2);
- for PVC converters, if second hand items would not be exempted (see Section E.3.2.3)

In additional enforceability issues for the Competent Authorities would be caused by not providing any derogation for other EU specific legislation regulating lead (as occurred with the other provisions of entry 63 for lead in jewellery and consumer articles)

Therefore, this option was discarded as, net of its cost, it would be less beneficial to society than the proposed restriction.

Alternative restriction option-3: A restriction on lead and its compounds in all PVC articles with a concentration limit of in the range between 0.1 and 0.5% which will apply for all PVC articles. Derogations for PVC silica separators and second market/other EU legislations will be provided (but maybe not for PVC recycling).

This option sets a higher limit than the option 1 (0.1%) but it is still lower than the minimum lead concentration required to achieve PVC stabilisation (this is assumed to be approximately 0.5%-at least for some uses e.g. pipes as indicated in section A.2.1 of Annex A).

We therefore assume that with this option the risk reduction capacity of the proposed restriction is not significantly compromised compared to other two options, in particular if the restriction limit would be toward the lower end (close to 0.1%). On the other side, selecting a restriction limit towards the upper end (0.5%) could potentially negate the need to derogate PVC recycling. This may not be simple according to Tauw analysis (see for instance figure E.4 for window frames), in particular for articles produced from greater than 40% recyclate. In addition, a restriction limit towards the higher end (close to 0.5% end some may trigger issues of enforceability since for a few "borderline" types of PVC articles it may not be that straightforward to exclude an intentional use of lead in PVC).

For the above indicated reasons, this option was discarded as a less appropriate option than the proposed restriction. If positive feedback from stakeholders on this restriction option is received in the Public Consultation Process, a re-assessment could be made during the opinion making process. We would suggest a specific question on this issue is asked in the Public Consultation.

E.1.3. Other Union-wide risk management options than restriction

The assessment of risk management options at Union level other than a REACH restriction is presented in the following Table E1.

Table E1. Possible other Union-wide options discarded at this stage

Option	Reasons for discarding this option
(I) Non-legislative measures	
Voluntary industry agreement to restrict the use of the lead compounds in PVC articles.	Annex A (Manufacture and Uses) and Annex D (Baseline) of this report provide detailed information of the voluntary abatement agreements of the EU industry, aiming at the phase out of lead-based stabilisers in PVC applications (VinylPlus). Their implementation by key industry players (e.g. producers of PVC stabilisers, PVC converters etc.) has resulted over the last few years in the replacement of large volumes of lead-based stabilisers with less hazardous alternative systems in the EU (e.g. ~81.4% reduction of the sales of lead-based stabilisers in the EU-27 has been reported for the period 2007-2014). As discussed under Section A.2.3, ESPA (2016) has confirmed that their Members have completed the phase-out of lead stabilisers by end of 2015. Although the VinylPlus agreement covers the large majority of the market there may still be a number of companies that do not adhere to the commitment of phasing out lead compounds in PVC by the end of 2015. Two of these companies were identified by ECHA through their responses at ECHA's Call for comments that suggest the continuous use of lead in specific PVC applications. In addition, importers of PVC articles from third countries (notably from Asia, as the outcome of ECHA's 2015 consultation with WTO countries revealed) are not bound by any European voluntary schemes. Therefore, in spite of the broad success of the industrial voluntary agreements, small amounts of lead-containing PVC material would still be placed on the EU market. In general, monitoring of a voluntary agreement is not straight forward as it requires sampling and chemical analysis done by competent authorities, accreditation bodies, or other third parties. With no regulatory basis to do so, such monitoring may not take place, leaving self-declarations of manufacturers and users as the only *de facto* "monitoring". For the above indicated reasons, voluntary agreements cannot be considered as the most appropriate risk management option when compared to a REACH restriction.
Voluntary agreement for industry to label articles.	Under the current assessment, which mainly concerns articles used in building/construction, it is considered that even if these articles are properly labelled (e.g. PVC window frames/PVC flooring), a problem is associated with their long service life (approximately 20-50 years). A house might change owners/tenants within the lifespan of the PVC window frames. Therefore, the person that is exposed might be different than the one who initially bought the frames. Hence, this measure implemented alone seems insufficient to effectively address the risk, and has therefore not been considered further. It also has to be noted that the

	implementation of labelling obligations for articles would imply additional costs for the industry for changing the labels on the packaging. In conclusion, the RMO option of providing information to consumers and retailers through labelling does not seem to be sufficiently effective to avoid health risks related to lead emissions from PVC applications. This RMO will also share many of the disadvantages of the voluntary agreement to restrict substances such as enforcement and coverage (as above).
Information campaign to consumers to avoid buying the articles in question.	Information to consumers, through targeted campaigns, has in some cases proved efficient in raising consumer awareness and thus in reducing risk. However, in this case the targeted campaigns would not enable consumers to identify precisely which PVC articles contain lead, for reasons relevant to long service life of the articles and the nature of these applications. In addition, an information campaign would be difficult to monitor and follow up. Hence this measure implemented alone is not sufficient to address the risk, and has therefore not been considered further. This option can, however, be effective in combination with another risk management option such as a restriction.
Economic policy instrument (taxation)	A risk management option could be the introduction of a fee (one-time tax) to reduce the use of lead compounds in PVC articles with the purpose to stimulate the use of alternative materials. This could be a possible option since there is a market for alternatives. However, economic policy instruments would more likely be implemented at Member State level rather than at Union level (e.g. since 2000 Denmark has imposed a tax on phthalates in PVC articles placed on the Danish market). Taxation in general is not a harmonised measure across the EU. Therefore, whilst it might be effective in encouraging substitution, it is not likely that all Member States would introduce relevant taxes and, therefore, not all EU citizens will be protected. This is likely to lead to a non-harmonised situation whereby different Member States apply different tax rates. For the scope of this dossier, such measures show little or no potential and will therefore not be further assessed.

(II) Legislation other than REACH	
Amendments to the General Product Safety Directive	The General Product Safety Directive (GPSD) (2001/95/EC) provides an opportunity to implement union-wide restrictions of products that pose a risk to consumer health and safety. This includes content of hazardous substances, the second most common type of risk (~20%) of the dangerous products notified to the RAPEX alert system. Consumer products that contain lead have also been the subject of attention previously in the RAPEX system *(voluntary recall applying of lead containing jewellery notification number 0191/06).* The GPSD has been in force for a number of years and is considered to work well according the reported experiences of enforcement Competent authorities. However, the duration of a restriction under the GPSD is limited to one year, although it may be extended year after year. Conceptually, restrictions under the GPSD are temporary interim solutions and aim to restrict unsafe products until a corresponding restriction has been implemented in another, sector specific regulation. In addition, it should be noted that the proposed restriction of lead compounds in PVC articles does not only cover consumer uses but also industrial/professional applications. Overall, the GPSD cannot offer an efficient risk management option as alternative to REACH restriction.
EU Environmental legislation addressing lead emissions	EU Waste (2008/98/EC) and Water (2000/60/EU) Framework Directives are broadly relevant legislative frameworks for this assessment since they target lead environmental emissions (along with the Industrial emission directive as discussed in Section B.9.1). Both legislative frameworks have identified lead as a hazardous substance and have set specific environmental thresholds. However, these specific environmental legislations do not distinguish between lead emissions from specific product categories and can therefore not impose restrictions on the use of lead-based stabilisers in PVC articles. When compared to a REACH restriction, these legislations cannot not offer appropriate risk management measures to tackle lead emissions from PVC applications.
Harmonised classification under CLP	There are several harmonised classifications for lead compounds in Annex VI of CLP. Most relevant for this assessment are Reprotoxic 1A, and Aquatic Acute/Chronic 1 classifications. Following entries 28-30 in Annex XVII to the REACH regulation, compounds classified as toxic to reproduction in category 1 or 2 are restricted in mixtures for consumer use. These include lead compounds, which are classified as toxic to reproduction in category 1A. Products that can be regarded as mixtures are subject to restriction. It has to be noted, though, that the PVC articles covered by this restriction do not belong in nature to the category of mixtures. Overall, classification will in itself not decrease the exposure to lead resulting from the use of lead compounds as PVC stabilisers. Following this reasoning, CPL provisions will not sufficiently address the risks identified in this dossier and therefore this risk management option measure has not been further assessed.

Construction Products Regulation (CPR)	Since the most common uses of lead-based PVC stabilisers concern articles for building and construction applications, CPR may be considered as a relevant Legislative Framework. However, CPR contains only generic provisions on the protection of workers and the general public from chemical exposure and risk. Under CPR, the information on the content of hazardous substances in the construction products should be included in the declaration of performance to reach all potential users. However, CPR concerns products and not chemicals used as additives. Art 56.1 and Art. 58 of CPR, which present a procedure to deal at national level with risky construction products, do not provide sufficient grounds for obliging the various actors to produce PVC products without lead-based stabilisers. Therefore, CPR is not considered an efficient risk reduction option compared to REACH Restriction.
(III) Other REACH processes	
REACH Authorisation process	Lead and its compounds meet the criteria laid down in Article 57 of REACH and could therefore be included in Annex XIV, meaning that they would be subject to an authorisation requirement under REACH. As already discussed in Section B.9.1, ECHA's 7th recommendation[55] for potential inclusion in the Annex XIV (widely known as "Authorisation list" of REACH) contains four lead compounds, out of which two have been used as PVC stabilisers (pentalead tetraoxide sulphate and tetralead trioxide sulphate). The authorisation option has, in general, the advantage that it can easily be monitored and enforced, as there are already established systems in place for monitoring and enforcing substances and uses subject to authorisation. However, the major disadvantage with the authorisation option is that it can only be applied for articles produced within the EU. Imported PVC-based articles containing lead would not be affected by authorisation requirements and continue to be placed on the Union market. Therefore, authorisation would not address the identified risk to the same extent as a restriction would. Adding the time perspective – the authorisation procedure is generally slower than the restriction procedure with regard to the implementation. For these reasons, the restriction option seems more favourable.
REACH Art. 68.2	REACH Article 68(2) stipulates that substances that are CMR categories 1a or 1b can be subject to a proposal from the Commission to inclusion in Annex XVII for consumer uses without using the procedures in article 69-73 in the REACH Regulation. Although lead compounds are classified with Repro 1A, the uses under consideration are not exclusively for consumer use but also concern professional or industrial applications.

[55]Information available under: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list (The public consultation on ECHA's 7th draft recommendation ended on 18 February 2016). The Background documents for each lead compound indicate the registered uses, among which PVC is mentioned for some of them.

	The procedures in articles 69-73 give an opportunity to investigate the human health and socio-economic implications of the combined exposure to consumers from various groups of articles containing lead compounds used as PVC applications. It is argued that, the investigations under Art. 68(2) may require an equal degree of scrutiny by article group and, thus, there may not be gains in terms of efficiency if this alternative regulatory route is explored.

E.2. Alternatives

E.2.1. Identification of potential alternatives/ techniques (overview of existing alternatives)

There are a number of stabilisers for PVC that have been traditionally used in the EU and worldwide in the various PVC applications (see www.stabilisers.eu). A summary of potential alternatives to lead stabilisers is presented in this section.

E.2.1.1. Cadmium-based systems

Cadmium-based systems were used in the past (before 2000) in form of a stearate or laurate for stabilising PVC in combination with barium ester (or even lead stabiliser). Cadmium stabilisers imparted excellent heat stability and resistance to weathering to PVC. They were mainly used in semi-rigid and flexible foil for products such as roofing membranes and in rigid applications for outdoor use such as window profiles.

However, Council Directive 91/338/EEC (now entry 23 of Annex XVII to REACH) has limited the use of cadmium compounds in various applications due to their high-risk profile. With the exception of very few derogated applications, placing on the market articles manufactured from plastic material coloured or stabilised with cadmium is prohibited if the content exceeds 0.01% (w/w) of the plastic material. With the implementation of the PVC industry's Voluntary Commitment in 2000, the use of cadmium in all stabiliser systems placed on the European market has been phased out voluntarily by all ESPA members: the use of cadmium was voluntary stopped in EU-15 in 2001. The commitment was extended to the new EU countries in 2007 (EU-27).

For the above-mentioned reasons, cadmium-based stabilisers are not considered in the further assessment.

E.2.1.2. Tin stabilisers

Tin stabilisers can be divided into two main groups (i) stabilisers with tin-oxygen bonds (*tin carboxylates*) and (ii) stabilisers with tin-sulphur bonds (*tin mercaptides*). By far the largest use for tin compounds is still the stabilisation of PVC, even if they are restricted in the EU, particular in Northern America. Examples of applications where tin stabilisers are widely used are: calendared films for pharmaceutical or food packaging, foils such as credit cards, sheets and sidings, extruded pipes and profiles, extruded blown films, injection moulding fittings and other technical articles.

In the past, tin stabilisers have been mainly used in Europe is for rigid, transparent PVC applications (including food contact/rigid medical applications, potable water applications etc.) (RPA, 2007). In addition to maintaining high transparency, tin stabilisers provide very good early colour (no yellowing) and colour retention (delay of yellowing).

According to ESPA (2016), since tin stabilisers are incompatible with lead (it forms a dark grey colour), EU converters have not favoured tin-based systems during the transition period of lead substitution. In addition, the sales statistics collected on behalf of ESPA do not indicate any growth of tin stabiliser volumes that could be attributed to lead-replacement.

It should be also noted that since early 2000s health and environmental concerns over certain organotins (especially for having endocrine disruptors properties) led to further investigations (Risk and Impact Assessments). The evaluation of these assessments (SCHER 2006) resulted into new EU restrictions (RPA, 2006) that concern uses of certain organotins in consumer articles (including PCV based articles), which were imposed via the Commission Decision 2009/425/EC[56] and transposed into REACH Regulation (Entry 20 of Annex XVII). Most relevant to this assessment and the covered items of the proposed restriction, is the following information extracted from the REACH restriction provisions:

- Dibutyltin (DBT) compounds, since 1 June 2012, are not used to articles for supply to the general public (in concentration greater than the equivalent of 0.1% by weight of tin). Since 1st June of 2015, the restriction was extended to a few article types that had been initially derogated such as those where DBT compounds were used as PVC stabilisers mainly for outdoor application *(fabrics coated with PVC containing DBT for outdoor applications, outdoor rainwater pipes, gutters and fittings, as well as covering material for roofing and façades).*

- Dioctyltin (DOT) compounds, since 1 June 2012, are not used to articles for supply to the general public (in concentration greater than the equivalent of 0.1% by weight of tin). Similarly to what discussed earlier for DBT, since 1st June of 2015, *the restriction was extended to a few article types that had been initially derogated, a few of which are often PVC containing articles, such as: gloves textile; wall and floor coverings, textile articles intended to come into contact with the skin).*

Therefore, for the above-mentioned reasons *tin compounds cannot be considered as appropriate alternatives to lead stabilisers in the Union market and are not further examined in this report.*

E.2.1.3. Liquid mixed metal stabilisers (LMMs)

Liquid mixed metal stabiliser systems are based on Ba, Zn, Ca, Mg or K carboxylates. They are mainly used in several PVC flexible applications like: calendared films; extruded profiles; injection moulded, soles, footwear; extruded hoses and plastisols (flooring, wall covering, artificial leather, coated fabrics, toys). (ESPA, 2016). In general, liquid mixed metals like Ba-Zn, Ca-Zn and Mg-Zn require the addition of co-stabilisers, antioxidants and organophosphates

[56] 2009/425/EC: Commission Decision of 28 May 2009 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of organostanic compounds for the purpose of adapting its Annex I to technical progress (notified under document number C(2009) 4084) OJ L 138, 4.6.2009, p. 11–13.

to provide optimum performance. The co-stabilisers are usually included in to the liquid mixed metal stabiliser system. To adjust the viscosity different solvents are used including hydrocarbon solvents and plasticisers. The LMMs stabilisers have successfully replaced cadmium-based stabilisers mainly in PVC semi-rigid and flexible applications.

By considering the information received from stakeholders, and since the proposed restriction mainly targets rigid PVC uses (for building/construction relevant applications), LMMs are not considered as the systems of choice for the substitution of lead stabilisers in the EU and are not further assessed in this report.

E.2.1.4. Calcium-based systems

According to EU industry associations (ESPA, ECVM), alternatives using calcium-based systems (in particular the calcium-zinc systems) are the logical replacement for the lead stabilisers. These alternatives were used for the implementation of the VinylPlus agreement and have been further developed to match the required performance in the applications still relying on lead, allowing to complete the reformulation from lead stabilisers by the end of 2015 in the EU-28.

E.2.1.5. Alternative techniques

No alternative technologies have been reported to ECHA as appropriate for lead substitution. By considering the information on the various alternative systems (as summarised above), ECHA has decided to focus its further assessment for potential alternative to lead stabilisers exclusively on the calcium based-systems.

E.2.2. Identification of the most likely alternative system to lead PVC stabilisers (calcium-based stabilisers)

E.2.2.1. Types/formulation of calcium-based stabilisers

Calcium-based stabilisers belong to the wider family of mixed metal stabilisers, which traditionally tended to be complex mixtures of metal soaps with a variety of non-metallic co-stabilisers and antioxidants (ECVM, 2016). These stabilisers are available in liquid or solid forms, with variation in composition resulting in some differences in performance and other important characteristics. This versatility is, however, one of the primary reasons that these calcium-based stabilisers are nowadays extensively used in the processing of PVC (Baerlocher, 2016)[57].

Actually, calcium-based stabilisers were originally known as calcium/zinc systems. As indicated by RPA (2007), the newer stabilisers sometimes required less or no zinc component, and hence the new name that replaced the word 'zinc' with 'organic'.

For the purposes of this report, we shall consider that calcium-based stabilisers include both:

(i) Calcium-zinc stabilisers; and

[57] Information available under the website of the company: http://www.baerlocher.com/products/metal-soaps/

(ii) So called calcium organic based stabilisers (OBS) which can be zinc-free.

In general, the Calcium-based stabilisers are based on (or used in the form of) metal carboxylates and will sometimes incorporate other elements to boost performance such as aluminium or magnesium.

Solid calcium based systems are usually based on stearic and lauric acids whereas the liquid mixed metal stabiliser systems are based on shorter chain fatty acids and organic co-stabilisers (such as polyols, epoxidised soya bean oil, and organic phosphates). In addition, phenolic antioxidants may be added to enhance the heat stability in some applications and provide a more balanced stabiliser system with the stabilisers frequently provided as pastes (RPA 2007).

It should be noted that calcium-based stabilisers that are used in PVC processing are supplied as "one-pack" including not only stabilisers but also other additives such as lubricants and co-stabilisers (ESPA, 2016). This is an important aspect of the assessment that will be further elaborated when discussing technical/economic feasibility under section E.2.3.

The

Table E2. contains typical compositions of (i) a calcium-based stabiliser without zinc, and (ii) a calcium/zinc-based stabiliser.

The main components typically present in calcium-based systems are:

(i) Metal soaps: such as calcium stearate (Fatty acids, C16-C18, calcium salts; EINECS: 286-484-6CAS: 85251-71-4) with (or without) zinc stearate (2Fatty acids, C16-C18, zinc salts; CAS: 91051-01-3, EINECS: 293-049-4). Other commercially available metal soaps are based on magnesium (magnesium stearate (CAS 91031-63-9)) and aluminium.

(ii) Inorganic co-stabilisers: mainly zeolites (not classified; food contact approved, widely used in washing powders);

(iii) Organic (co) stabilisers: mainly polyols;

(iv) Antioxidants: mainly phenolic antioxidant mixtures;

(v) Lubricants: mainly paraffin (hydrocarbon waxes) (not classified; food contact approvals), or even fatty acid derivatives and polyethylene waxes.

ESPA (2016) stated that for the most common rigid PVC applications (e.g. window frames), a typical composition contain mainly calcium/zinc stabiliser systems at a concentration of approximately 3.5% (w/w). In addition, ECVM (2016)[58] noted that the use of calcium/zinc stabiliser systems has been the most common in the rigid PVC applications for the last years in the EU.

Overall, the input from the stakeholders in ECHA's consultations indicated that more specifically the calcium-based stabilisers offer for the EU industry the stabilisers systems of

[58] More info available under: http://www.pvc.org/en/p/calcium-zinc-stabilisers

choice for lead substitution in rigid PVC applications (which are mainly targeted by the proposed restriction).

Table E2. Typical composition of calcium-based systems used in the EU as PVC stabilisers (ESPA, 2015)

Component	**Specific name**	**Calcium-based, zinc-free stabiliser**	**Calcium/zinc-based stabiliser**
Stabiliser	Calcium stearate	40.7%	23.7%
	Zinc stearate	0.0%	17.0%
	Zeolite co-stabiliser	23.7%	23.7%
	Phenolic antioxidant	1.7%	1.7%
	Polyol	6.8%	6.8%
Lubricant	Paraffin waxes	20.3%	20.3%
	Fatty acid esters	6.8%	6.8%
Total mix		*100.0%*	*100.0%*

E.2.2.2. Main PVC applications of calcium-based systems

As reported by ECVM (2016), the calcium-based stabilisers are widely used in many flexible and rigid PVC applications. Industry claims that this type of stabilisers can give products, which have a high degree of clarity, good mechanical and electrical properties, excellent organoleptic properties and good resistance to weathering. Therefore, calcium-based stabilisers have been incorporated and established in a wide range of applications (toys, healthcare products, semi-rigid and flexible foil for food packaging, bottles for potable water etc.).

In the frame of the Vinyl Schemes (European PVC industry's commitment to progressively phase out lead–based PVC stabilisers), considerable development work has been carried out on new, improved systems for building/construction relevant PVC applications including cable covering, pipe and window profiles, etc. (ECVM, 2016). These newer forms of calcium-based stabilisers are in general more complex than the traditional systems mainly because of the specialised co-stabilisers required to meet the specific requirements of these applications. As indicated in the 2015 progress report of VinylPlus, during the period 2007-2014, the use of lead stabilisers decreased by approximately 86 200 tonnes (a decrease of 86%) in the EU-28. In the same period, the use of calcium-based stabilisers, increased by approximately 29 500 tonnes. As discussed under the section A.2.3, ESPA (2016) informed that their Members have completely phased out the use of lead stabilisers by the end of 2015. A picture of the gradual substitution of the lead stabilisers by the Calcium-based systems in the EU for the period 2007-2015 is given in the Figure E1.

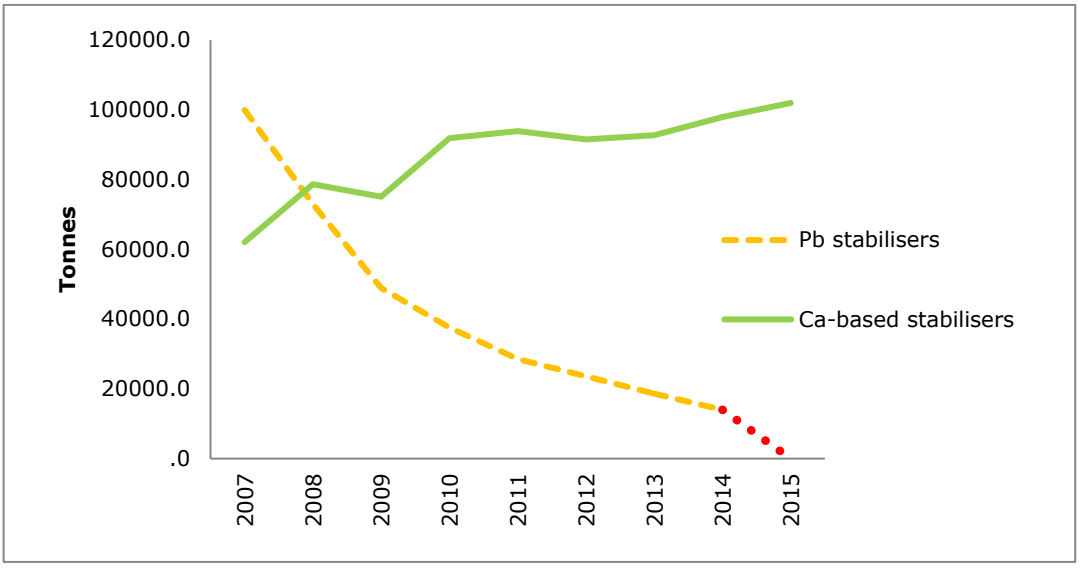


Figure E1. A broad picture of substitution of lead stabilisers (Pb-stabilisers) by Calcium-based systems (Ca-stabilisers) in the EU during the last decade (2015 VinylPlus progress report).[59]

E.2.3. Health and environmental risks related to calcium-based systems

E.2.3.1. Human health risks related to calcium-based systems

ECHA has reviewed the various assessments available (e.g. REACH Registration dossiers, Eurotox 2007) that provide information on health hazards and risks of calcium-based systems. Eurotox (2007) has undertaken an evaluation of the toxicity of calcium/zinc stabilisers in PVC rigid films by conducting a literature searching for the various components of the system. The study concluded that:

- No specific hazards to general human health due to systemic toxicity of the ingredients of calcium/zinc stabilisers were identified;
- For workers, however, inhalation of the insoluble compounds contained in the Calcium-zinc stabilisers is expected to pose a potential risk e.g. when formulating the stabiliser mixture or adding the stabiliser to PVC due to local effects of insoluble compounds in the lung. ECHA has reviewed the most updated data on occupational exposure, presented in the CSR for zinc stearates.[60]

[59] Red dots indicate the transition to the phase out of Pb stabilisers by end of 2015.

[60] The CSR for zinc stearates provide an overview of existing OELs for soluble zinc compounds represented by zinc chloride as well as slightly soluble/insoluble zinc compounds represented by zinc oxide. As stated there, "while a detailed scientific justification for the OELs is not available, these values have ensured workers safety for decades which correlates with the DNELs derived from the human volunteer studies".

In addition, as indicated by ECVM (2016):

- Calcium/zinc salts of any of the acids (stearate, palmitic etc.) have been evaluated and approved by the EU Regulation (EC) No 1333/2008[61] on additives approved for food contact use (although specific approval would depend on the co-stabiliser e.g. zeolites incorporated into the stabilising system);
- Solid calcium/zinc stabilisers have to meet the general requirements for dust emissions in the workplace although dust-free forms are readily available;
- Zinc is an essential element to human activity and health and has been the subject of various risk assessments.

ECHA has further reviewed the CSRs of the REACH registered main components in the Calcium-Zinc stabilisers[62], which as indicated in Table E2 are the metal soaps calcium stearate (Fatty acids, C16-C18, calcium salts; CAS: 85251-71-4), zinc stearate (Fatty acids, C16-C18, zinc salts; CAS: 91051-01-3). The relevant findings of the EU Risk Assessment on zinc metals (2010)[63], which also covers the zinc stearates, have been further considered.

In summary, the following should be noted:

(1) The fatty acid moiety is not considered to be hazardous to human health. Fatty acids (stearic, palmitic) are natural constituents of the human body and essential components of a balanced human nutrition. Fatty acids are generally judged as not representing a risk to human health which is reflected in their exclusion from REACH registration requirements by their inclusion in REACH Annex IV. Variability in the fatty acid moiety is not expected to have a relevant influence on the physiological activity of fatty acid zinc or calcium salts and thus systemic intrinsic activity is considered to be identical.

(2) Zinc and calcium are well-known essential nutrients effectively processed and regulated in the human body by natural physiological mechanism. Recent scientific opinions of EFSA have evaluated latest nutrition/dietary relevant evidence of both metals. In a nutshell:

- Calcium is an integral component of the skeleton; approximately 99% of total body calcium is found in bones and teeth as calcium hydroxyapatite, where it has a structural role. If the dietary supply of calcium is insufficient to meet physiological requirements, calcium is resorbed from the skeleton to maintain blood concentrations within the range required for normal cellular and tissue functions. This causes a reduction in bone mass, which leads to osteopenia and osteoporosis, and an associated increased risk of fracture. EFSA (2015)[64] published a Scientific Opinion assessing the evidence from human studies on the relationship between calcium intake and various health outcomes;
- Zinc is essential for growth and development, neurological function, wound healing

[61] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

[62] ECHA notes only zinc stearate has been registered. Communication with industry revealed that calcium stearate, for example, was not registered as it was considered to be exempt under Annex V point 7.

[63] The Risk Assessment was carried out (by JRC in collaboration with Netherlands) in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of "existing" substances. Available under: http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/15064/1/lbna24587enn.pdf

[64] EFSA's 2015 Scientific Opinion on dietary references values for calcium: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4101/pdf

and immunocompetence. (EFSA, 2014)[65]. The main clinical manifestations of zinc deficiency are growth retardation, delay in sexual maturation or increased susceptibility to infections. Zinc, however, may have an impact to human health only at very high doses (Berg, 1990). There is at this stage no evidence that zinc has any neurotoxicological or immunotoxicological effects under normal zinc exposure conditions and at recommended zinc intake levels. Zinc deficiency, however, adversely affects neurological function and immune competence.

ECHA has also briefly assessed the substances expected to be present in calcium-based systems as co-stabilisers. For the most frequently present substances, the following conclusions can be drawn:

- **Zeolites:** Since they have a wide range of uses, zeolites have been assessed under other legislative frameworks. The use of zeolites as builders in various detergent products have been investigated by in the past by industry (HERA, 2004[66]) and assessed by SCHER (2006)[67], concluding that it does not cause health risks. It has to be noted as well that natural Zeolite (Clinoptilolite) is an EU authorised feed additive. (EGTOP, 2011);[68]
- **Phenolic antioxidants:** Many of the substances of this group are of natural origin and be commercially available for use as EU approved food additives. EFSA has produced scientific opinions on various phenolic compounds as well for phenol[69] as food ingredients examining their chemical safety and potential hazards for human health**.** Overall, their use as co-stabiliser in calcium-based systems is not expected to pose any significant risks for human health;
- **Polyols:** Polyols are carbohydrates used and approved in the European Union as food additives with a long history of use all over the world for more than 30 years. They are chemically considered as polyhydric alcohols and are derived from carbohydrates, mainly from corn, wheat and sugar beet. (NCBI, 2016).[70] The most commonly used polyols are sorbitol (E 420), mannitol (E 421), isomalt (E 953), maltitol (E 965), lactitol (E 966), xylitol (E 967) and erythritol (E 968) have been chemically assessed by the European Commission and were found to be acceptable for use as food additives (SCF, 2003)[71]. Therefore, their use in calcium-based systems for PVC application can be generally considered as safe for Human Health.

[65] EFSA's 2014 Scientific Opinion on dietary references values for zinc is available under: https://www.efsa.europa.eu/en/efsajournal/pub/3844)

[66] HERA-Human & Environmental Risk Assessment on ingredients of European household cleaning products (2004), http://www.heraproject.com/files/8-f-be8d7cff-a805-0020-23f16e4b786891e8.pdf

[67] Scientific Committee on Health and Environmental Risks (SCHER, 2014). Non surfactant Organic Ingredients and Zeolite-based Detergents (http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_057.pdf)

[68] Expert Group for Technical Advice on Organic Production EGTOP (2011). Final report on Feed, http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports/final_report_egtop_on_feed_en.pdf

[69] Scientific Opinion on the toxicological evaluation of phenol (2013) EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3189/pdf)

[70] More information is available under http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4017274/

[71] The opinion of the Scientific Committee on Food on Erythritol, available under: http://ec.europa.eu/food/fs/sc/scf/out175_en.pdf

Overall, from the available studies and literature it can be generally concluded that calcium-based stabilisers (incorporating the proven range of co-stabilisers) have low toxicity.

E.2.3.2. Environmental risks related to calcium-based systems

The CSRs of the main ingredients of the Calcium- based systems were screened for any critical information. In addition, the previously mentioned EU Environmental Risk Assessment report on zinc stearate was reviewed. The following elements of the environmental hazard assessment have been considered:

- Fatty acids, C16-18, zinc salts consists of fatty acid anions and zinc cations. Fatty acids are generally not considered to represent a risk to the environment, which is reflected in their exclusion from REACH registration requirements (c.f. REACH Annex V (Regulation (EC) No 987/2008)).
- Zinc compounds, however, may have an impact to the environment. Information on fish toxicity is available from a study performed according to EU Method C.1 (Acute Toxicity for Fish) (Henkel KGaA, 1995). The acute toxicity of Fatty acids, C16-18 zinc salts to Daphnia magna was determined according to OECD 202 in M7 medium at pH 6 and 8 (Bouwman et al., 2003). These daphnia and fish toxicity data have already been assessed within the EU risk assessment on zinc stearate.

Overall, it is concluded that zinc stearates *do not require classification according to Directive 67/548/EEC and to Regulation (EC) No 1272/2008* (CSRs for zinc stearate). This conclusion is consistent with the conclusions from the EU risk assessment highlighting that zinc distearate is not classified for the environment." RPA (2007) highlighted that Calcium-based stabiliser systems "*represent state-of-the art*" for rigid PVC applications, as they are more environmentally friendly alternative compared to organotins or lead stabilisers. According to industrial sources (Baerlocher, 2016), the product development for Ca-based systems involves the choice of sustainable raw material sources and the compliance of all raw materials with current and future chemical legislations. In addition, it must be also noted that for the other co-stabilisers also commonly present in calcium-based systems (e.g. zeolites, polyols etc., which were briefly assessed above for their potential health risks) there is no evidence to support that their use in PVC stabiliser systems will result into environmental risks.

E.2.3.3. General Conclusion (for both HH-ENV assessment)

Overall, it is assessed that currently there are no risks to human health or the environment from the use of calcium-based systems as PVC stabilisers. The calcium-based systems have a much lower hazard profile (non- classified) than the lead compounds used as PVC stabilisers, which as discussed in Annex B: have *non-threshold neurotoxic/neurodevelopmental hazards for human health and are toxic for aquatic organisms.*

Therefore, the calcium-based systems can serve as significantly safer alternatives to lead PVC stabilisers.

E.2.4. Technical and economic feasibility of calcium- based systems

E.2.4.1. Technical feasibility of calcium-based stabilisers

ESPA (2016) submitted updated information concerning both the technical and economic feasibility of substituting lead-based stabilisers by calcium-based stabilisers. Industry highlights that stabiliser systems are generally supplied as a "one-pack", including not only the main alternative substance (i.e. the stabiliser) but also other additives such as lubricants and co-stabilisers (see section E.2.2). Therefore, in assessing total "cost/performance", a calcium-based system is to be compared versus a lead-based system by using this one-pack approach.

ESPA also notes that for evaluating the performance of the stabiliser systems, the following aspects are of most importance:

- Speed of processing;
- Colour retention;
- Mechanical properties;
- Long term resistance to weathering;
- Possibility for the article to be easily recycled at the end of its life;
- Electrical properties (for cables);
- Percentage of material that fails quality control (scraps and of out of specs); and
- Use of hazardous mixtures (triggering both air and worker's blood controls)

Regarding their technical characteristics, calcium-based systems are reported to give products which have a high degree of clarity, good mechanical and electrical properties, excellent organoleptic properties and good resistance to weathering capable of covering the whole area of PVC applications (RPA, 2007). In some applications, such as window frames, excellent colour stability weathering results have been obtained both in long-term testing and from practical experience" (KemI, 2007).

In addition, Sherman (2005) indicates that the calcium-based systems are priced competitively and provide some improved technical performance compared to other stabilisers. Their superior performance relates to low migration, low odour, low VOC emissions, good initial colour and excellent transparency, especially in plasticised PVC. The same source notes that calcium-based systems are also reportedly suitable for PVC recycling; there are no interactions (such as cross-staining) with other stabilisers and only a minor decrease in thermal stability after reprocessing five times.

The presence of metal salts (e.g. calcium, zinc, magnesium) in these lead-free stabiliser systems accounts for their improved technical characteristics compared to lead-based stabilisers (Baerlocher, 2016). These include among others: wide applicability for a wider range of PVC applications; better stabilisation effect; and better colour stability than the lead based systems both in artificial and natural weathering.

Conclusion: *Overall, calcium-based stabilisers offer a better technical performance than lead stabilisers in the various PVC applications*

E.2.4.2. Economic feasibility of calcium-zinc stabilisers

ESPA (2016) highlighted that within the cost comparison of calcium-based (Ca-based) versus lead stabilisers (Pb-based), the concept of one-pack, stabiliser systems should be considered in the assessment of economic feasibility of the calcium-based systems. Therefore, *the dosage and density of the stabiliser* must be taken into account as different amounts (weights) of stabilisers are needed to achieve an equivalent stabilisation. Industry also noted that dosage differences among a Pb-based one-pack and a Ca-based one, may depend on the application. For instance, in several cases, switching from Pb-based to Ca-based stabiliser, the percentage dosage of the stabiliser is decreased, not increased (see below Table E3). This has been achieved by enhancing the performance substantially by intensive R&D in the last 5-10 years. The Figure E1 of the section E.2.2.2 picturing the evolution of the volumes of lead stabilisers over the years (VinylPlus progress report, 2015) makes this visible: the sum of the lead and of the calcium-based stabilisers decrease with the progress of the substitution (even when correcting for the contextual decrease of the PVC consumption in EU-28).

Practical example of lead substitution by calcium-based stabilisers

A concrete example of lead substitution in window profiles (perhaps the most common rigid PVC application) has been elaborated in this report to assess the economic feasibility of calcium-based systems. Indicative figures on the substitution from a lead stabiliser to a calcium-based system for PVC window profiles is given in the Table E3.

According to ESPA (2015), a standard PVC window unit (1.23 x 1.48 m) incorporates approximately 15 kg of PVC compound in the profiles constituting its frame. Such a window, in which the PVC profiles will represent not more than 10% of the weight/mass, costs approximately 400 EUR on the average.

If we consider two similar window frames, one made of lead stabiliser (*Pb-based*) and the other one based on alternative calcium system (*Ca-based*), ESPA informed that:

- The Ca-based system is slightly more expensive than an average Pb-based system (approximately and additional 0.7 €/kg). However, the cost contribution of the PVC stabilisers in a window is very low, typically tens of Euro cents (source of data: http://eppa-profiles.eu/activities/sustainable-development);
- The cost/performance of a Ca-Based one-pack is at least equivalent to a Pb-based one (as the dosage is similar in both cases), therefore there is no significant impact on the price of a window frame.

Table E3. Information on the substitution from a Pb-based system to a Ca-based system in the production of window profiles (ECHA/ESPA 2015 communication)

(1) Typical dosage of Ca-based one pack for window profiles (% weight)	3.5%
(2) Typical dosage of Pb-based one-packs for window profiles (% weight)	4%
(3) Dosage ratio Ca-systems/Pb-systems	(1)/(2) = 0.88
(4) Indicative price differential between Ca & Pb systems (€/kg stabiliser)	0.7

The information presented in Table E3 will be further used in section E.4.1 to estimate the substitution costs of the proposed restriction.

According to ESPA (2016), *the overall cost/performance difference between a Pb-based formulation and a Ca-based one is negligible*. Industry highlights that evidence for this statement is provided by the massive substitution of Pb-based stabilisers by Ca-based stabilisers, which occurred over the last decade in the European PVC market. Notably, this switching resulted from a voluntary commitment (Vinyl Schemes) and was not forced by any legislation, indicating that production costs cannot be significantly affected by the use of the calcium-based stabilisers.

E.2.4.3. General conclusion

From the above analysis (and available information/studies) and considering the current industrial trends and practices, it can be broadly concluded that: *the Calcium-based systems in the various PVC applications (and in particular in the rigid PVC ones) offer a better technical performance than the lead stabilisers at comparable costs.*

E.3. Restriction scenario(s)

E.3.1. Proposed restriction

The following Sections support the justification of the restriction scenario including consideration on the behavioural response(s) of the affected stakeholders.

Proposed restriction

Brief title: Restriction of lead compounds in PVC articles in concentrations equal to or greater than 0.1% (w/w) with a 15-year derogation for certain PVC building materials produced from recycled PVC (higher restriction limit, 1% w/w) and (ii) 10 years derogation for PVC silica separators in lead acid batteries.

The full definition of the proposed restriction is presented in section E.1.1.

Once the restriction enters into force, it is expected that all EU actors and non-EU manufacturers will have completed their transition to the alternative described in section E.2. The primary alternative (calcium-based systems) has been shown to be technically and economically feasible as it can directly replace lead-based stabilisers at a comparable cost.

However, a number of specific applications were identified during ECHA's call for comments for which the transition to alternatives is not straightforward and a derogation is required; these applications are further detailed in section E.3.2.

E.3.2. Proposed derogations from the restriction.

During ECHA's Call for comments information on some uses of lead stabilisers that would be adversely affected by the proposed restriction (or longer transition periods) were submitted by industry. ECHA's assessment of this information is presented below.

E.3.2.1. Assessment of the impact of a restriction on lead in PVC for recycled PVC

E.3.2.1.1. Introduction

In the course of ECHA's Call for comments (2016), European Stabilisers Producers Association (ESPA) submitted a comment raising concerns about a potential restriction of lead in PVC articles, requesting that '*articles made from recycled PVC shall be out of scope of a restriction…'* ESPA highlighted that: *'a phrasing based only on the lead content – or not explicitly excluding articles made from recycled PVC – would kill this growing contribution to the circular economy and have a negative impact on the whole PVC supply chain…'*

ECHA has reviewed the available information submitted by the stakeholders (see Annex G:) and various reports on PVC recycling. Particular focus was given to Tauw IA (2013) that investigated the impacts of potential EU lead restrictions on PVC recycling. In addition, ECHA has made an assessment of various aspects (conditions/costs and environmental releases) of a potential derogation for lead in PVC recycling.

Therefore, considering the potential impact on the recycling of PVC of introducing a 0.1% concentration limit for lead stabilisers in PVC, ECHA is proposing to introduce a concentration limit of 1% for certain types of PVC articles prepared by recycled PVC for a period of 15 years. This derogation from the 0.1% limit would allow recycling of PVC to continue, as this is an effective way of preventing additional lead emissions to the environment, whilst recognising that regulatory pressure will help to reduce the concentration of lead in recycled PVC over time. The 15 year period has been chosen following an assessment of the projected concentration of lead in recycled PVC from 2020, the likely year of entry into force of the restriction) to 2050, (see Figure E4) and the costs of disposing of recycled PVC that couldn't be used if a 0.1% concentration limit was introduced in 2020 (see analysis in the Section E.3.2.1.2) The time period of 15 years would also allow a re-evaluation (if so desired) of the situation in the future to check if the projected lead concentrations are being met and to make any necessary changes to the restriction.

E.3.2.1.2. Analysis of the derogation (restriction limit and time frame)

Baseline

Recycled PVC is currently used to produce mainly articles used primarily in the construction sector. Recycled unplasticized (rigid) PVC and plasticized (flexible) PVC have several widespread applications, such as pipes and fittings, window frames, roller shutters, road furniture, roofing tiles, garden hoses, etc. (Vangeluwe et al., 2016).
Recycled PVC is not used at a concentration of 100% in manufacturing of PVC articles but in a concentration of between 40-70% with the remainder virgin PVC (for window frames). The

recycled PVC is often co-extruded with virgin PVC to provide an inside core of recycled PVC as it is often not a suitable quality and to reduce any potential emissions/exposure (see

Figure E3). Industry (ECVM, 2016) has provided the following diagram (see Figure E2) illustrating the PVC co-extrusion[72].

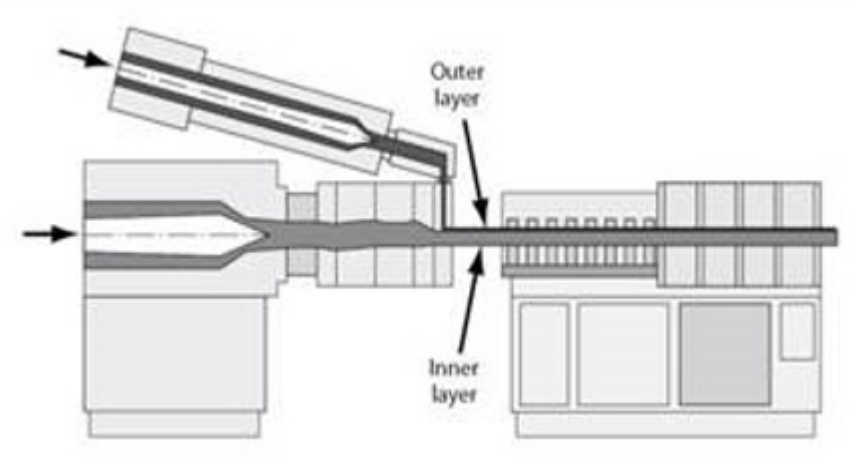


Figure E2. Illustration of the PVC co-extrusion process (ECVM, 2016)

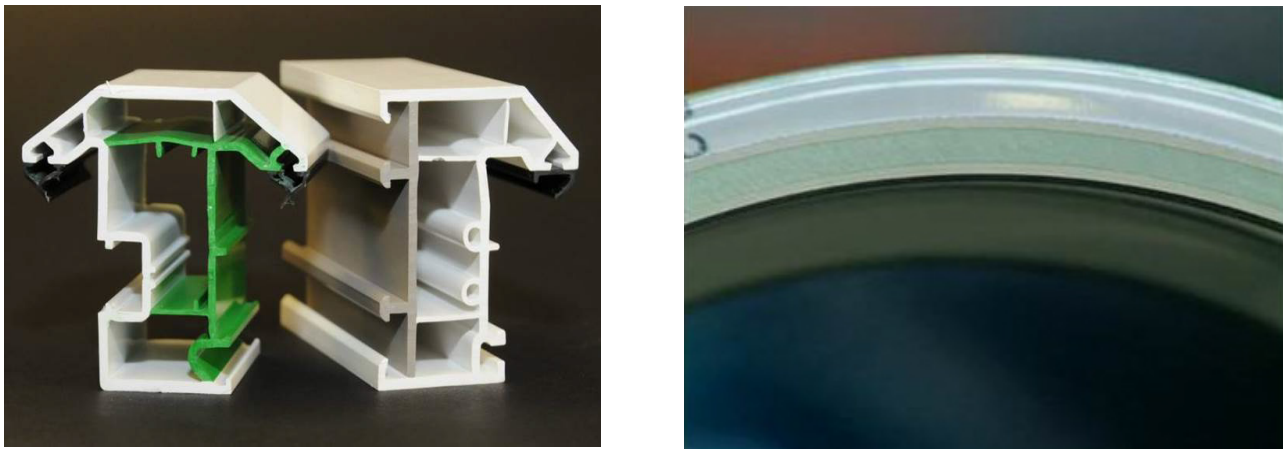


Figure E3. Picture co-extruded multilayer PVC articles (EPPA Profiles, 2016)

Tauw IA (2013) have estimated that over a period from 2010 to 2050 the projected concentration of lead stabilisers in PVC articles would reduce over time with some variation depending on the concentration of recycled PVC used in new articles produced. Figure E4

[72] According to ESPA (2016), as shown in Figure E2, two extruders (expensive pieces of equipment) are needed to convey the same total amount of material, one for the layer(s) of virgin resin and an additional one for the layer of recyclate; both flows of materials converge in a so-called "die" which is much more complex than in the case of monolayer extrusion (in particular when sandwiching a layer of recyclate between 2 layers of virgin). IND highlighted that at lower levels of incorporation of recycled PVC the cost saving on the material is offset by the higher processing costs and related complications.

shows the evolution of lead-content in PVC windows profile waste over time[73]. It provides with a projection of what would happen in the baseline scenario with the voluntary action in place (at the absence of any new restriction)[74].

Figure E4 illustrates that in either scenario presented (70% recycled material or 40% recycled material), the PVC articles produced can meet a limit of 1% by 2020 (projected entry into force date of any restriction). The projection also shows that by 2035, the concentration of lead in PC will have significantly reduced to 0.25% (40% recyclate) or 0.45% (70% recyclate). This reduction is of course subject to some uncertainty, for example demand for PVC articles. For some articles, the average share of recycled PVC is currently higher (e.g. in piping 65-100%).

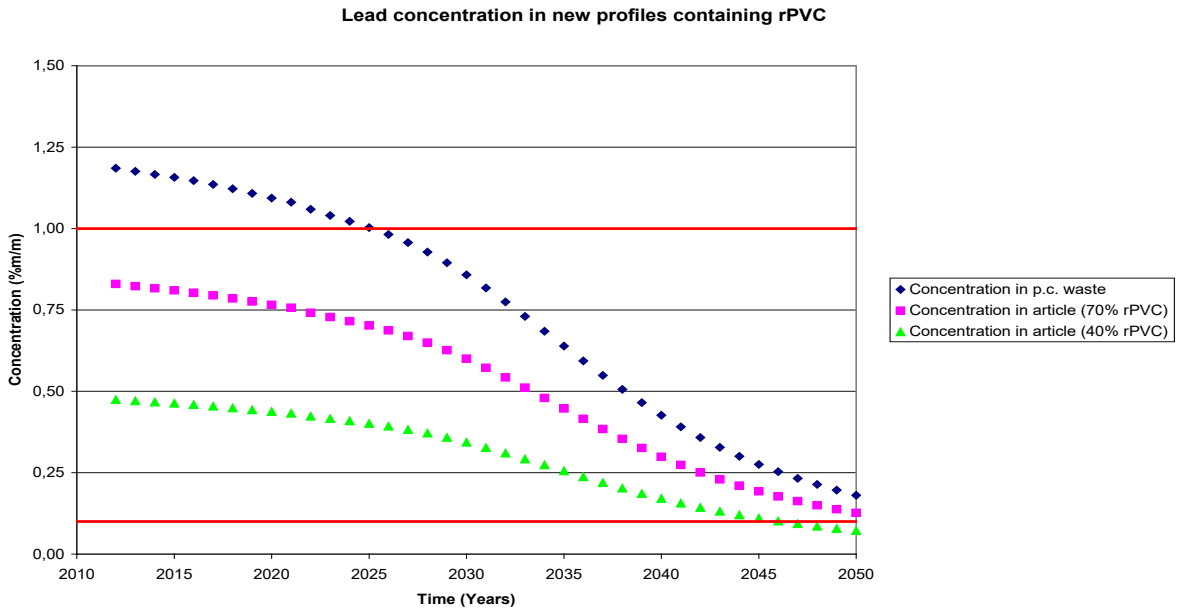


Figure E4. Pb concentration in new window frames containing recycled PVC in waste (Source: Tauw IA, 2013)

For the following calculations, it will be assumed that 40% recycled material will be used but the assumption of 70% recycled material used will be presented as a sensitivity analysis.

Effect of the proposed restriction on the baseline

Information submitted via Stakeholders Consultations: According to Tauw IA (2013, an EU restriction of lead in PVC at a concentration greater than 0.1% w/w, would significantly

[73] The Dynamic Waste Analysis tool of EuPC (European Plastics Converters) was adapted to model the average lead concentration calculated for the total waste from each of the main application selected for this assessment (window frames, pipes and fittings, flooring, roofing and cables). In this assessment, the window profile was selected as one of the most common PVC application of lead stabilisers relevant for the proposed restriction (on the x-axis:% m/m equal to% w/w).

[74] The expected lead concentrations for each scenario (Red: 70% recycled PVC; green: 40% recycled PVC; Blue: post consumption waste) are estimated via projection of lines representing 1% (baseline average lead concentration) and 0.1% (targeted lead concentration due to imposed restriction threshold).

restrain the recycling of PVC in the EU. This is because it would only be possible to incorporate a very limited amount of recycled PVC to virgin PVC resin during the production of articles to ensure that PVC articles have a lead content well below the 0.1% restriction threshold.

ECVM (2016) further clarified that with a limit at 0.1% the converters would only be able to mix about 10% of recyclate, which does not compensate for the extra cost of handling two sorts of materials and even less in the case of co-extrusion which requires to use more expensive extruders. In addition, at 10% mixing rate only a tenth of the available recyclate could find an outlet because the amount of articles produced is determined by market demand. Hence the recyclers would also see their business reduced 10 times, as there would be no outlet for incorporating the remaining 90%.

Overall, IND highlighted if only 10% of an article could be made from (the cheaper) recycled PVC, recycling would no longer be economically viable because of the fixed and variable costs needed to co-process the recycled PVC. As a result convertors would stop recycling PVC.

The assessment of Tauw IA (2013) concluded that: *a derogation should be granted for articles intended for building and construction applications (defined by the Construction Products Regulation-CPR, No (EU) No 305/2011) containing up to 1% of lead (w/w).*

It should be noted, however that:

- The associated industry (EuPC, 2016) claimed that all PVC articles should be covered by a derogation for PVC recycling. Industry provided the following Figure E5 indicating the main types of articles produced by recycled PVC and claiming that other than CPR products are also included. As shown there, the most common applications for PVC recycled material (but not all) concern articles for building and construction applications;
- A consulted enforcement authority (Tukes-Finland, 2016) mentioned that enforceability of the derogation would be manageable only if it could cover specific types of PVC articles. Such an approach had been followed in the past during the preparation of Entry 23 of Annex XVII to REACH (imposing restriction of cadmium and its compounds in plastics and other applications) where *a derogation for certain types of PVC articles was provided from the general restriction*.

Overall, for reasons related to:

- Health concerns related certain types of PVC articles (see Section E.3.2.1.4);
- Enabling the enforceability of the proposed derogation (see Section E.3.2.1.4); and
- Alignment with the existing relevant provisions of Annex XVII (see Entry 23).

ECHA is of the opinion that a potential derogation with a higher lead limit should be granted for certain types of PVC articles, which also account for the most common application based on rigid recycled PVC material such as: (a) profiles and rigid sheets for building applications; (b) doors, windows, shutters, walls, blinds, fences, and roof gutters; (c) decks and terraces; (d) cable ducts; (e) pipes for non-drinking water.

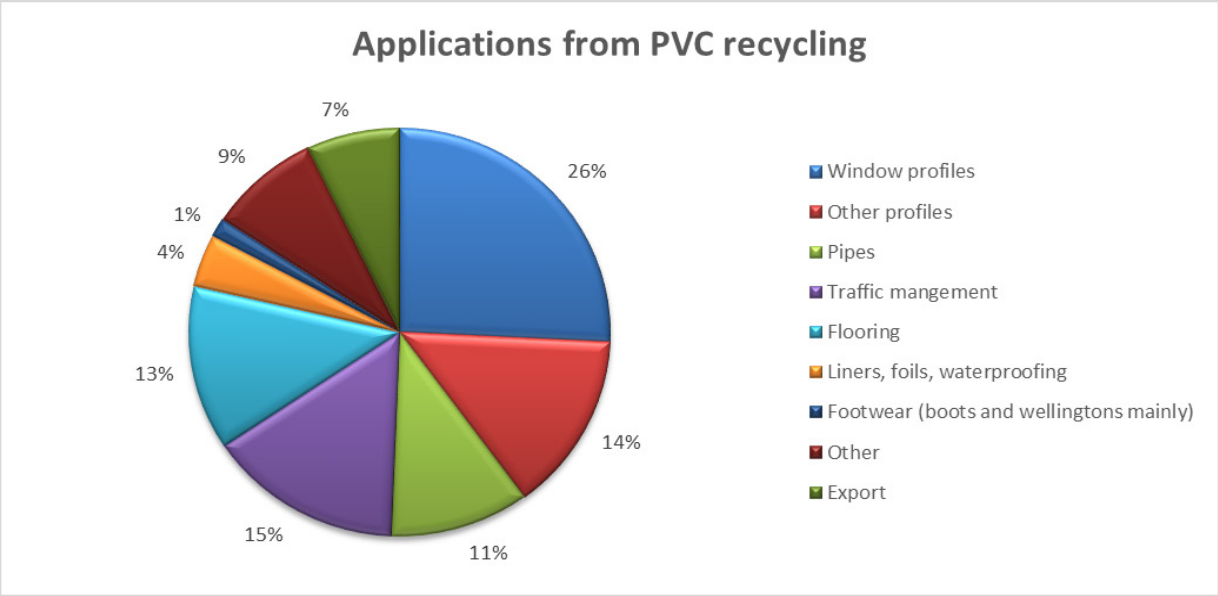


Figure E5. Types of PVC articles based on PVC recyclate (Source: VinylPlus 2016)

ECHA assessment/further analysis

Justification for the proposed lead restriction limit in recycled PVC

Through recent (2016) dialogue with Industry (see Annex G:), ECHA was informed that:

(i) Lead has been used at approximately 1.5 - 2% (w/w) levels in the last remaining rigid PVC uses before the expected phase-out of lead PVC stabilisers (2016 onwards);

(ii) In rigid PVC applications, the share of recycled PVC (in mixtures with virgin PVC) is currently in the range 40 - 100%.

According to the baseline, by 2020 PVC articles produced using recycled PVC will be able to meet a 1% concentration limit (if less than 95% of recyclate is used). ECHA is of the opinion that a threshold concentration of lead in the specific PVC articles produced from recycled PVC of 1% (w/w) would ensure continuation of PVC recycling, with only minor costs if 100% recyclate was previously used. However, since the concentration of lead in PVC waste is expected to progressively decline within the EU over time (as lead is no longer used as a stabiliser), it may be that a lower limit (i.e. lower than 1% w/w lead) could be applied in the future without adversely affecting the sustainability of PVC recycling Therefore, the threshold concentration of lead in recycled PVC could be re-assessed at an appropriate time in the future after the restriction had entered into force.

Justification of the appropriate time frame for re-assessment of the PVC recycling derogation

ECHA has considered the data provided by Tauw IA (2013) on the projected lead concentrations in several articles (window frames, pipes and fittings) produced using recycled PVC over the next few years. For the purpose of this analysis, though, window frames have

been selected as representative of the whole category of rigid PVC articles and since have been historically produced by the highest concentrations of lead stabilisers (>1.5%)The Tauw projected data on *new window frames* are presented in the Table E4. These data are based on the assumption that following the successful implementation of VinylPlus Schemes the use of lead stabilisers in window frames (and other applications of rigid PVC) will be completely phased out from 2016. Therefore, only legacy lead from recyclate will be present in new window frames. According to Figure E4, it is expected that lead concentrations in post-consumer PVC waste will decrease slowly over a long period of time.

Table E4. Projected lead concentration in new window frames produced with recycled PVC[75]

Year	Indicative lead concentration in new window frames (w/w)			Reduction in lead concentration (compared to central value)
	40% recyclate (min)	70% recyclate (max)	*Central value*	
2020 (baseline year)	0.45	0.75	0.60	
2025	0.40	0.70	0.55	<10%
2030	0.35	0.65	0.50	20%
2035	0.25	0.45	0.35	40%
2040	0.15	0.30	0.23	>60%

The time periods in the table have been examined to determine if it is appropriate to introduce a time limited derogation. An unconditional derogation has some disadvantages (see enforceability) and will provide no incentive to reduce the concentration in PVC as quickly as possible to meet a 0.1% limit. Ensuring that PVC recycling remains a viable waste management practice while at the same time reducing emission levels of lead as a particular hazardous for human health and environment chemical are both targets to achieve on the way to implementation of the Circular Economy Package[76].

According to these estimates, the legacy lead content in new window frames made with recycled PVC will decrease only slowly in the first few years from 2020 (entry into force). For instance, it would take at least 10 years until a 20% decrease (2030) would be detected. However, a faster decrease is expected to occur 15 or 20 years after the entry into force (approximately 40-50% reduction in lead content from 2020 level). Therefore, by 15 years after entry into force, it seems reasonable to assume that the lead concentration in recycled PVC waste will have decreased significantly. We assume that around 2035-2040 industry could

[75] ECHA has derived lead concentrations in new window frames, produced 5, 10, 15 and 20 years after the entry into force of the proposed restriction based on data of Figure E1.

[76] The Circular Economy Package consists of an EU Action Plan for the Circular Economy that establishes a concrete and ambitious programme of action, with measures covering the whole cycle: from production and consumption to waste management and the market for secondary raw materials: http://eur-lex.europa.eu/resource.html?uri=cellar:8a8ef5e8-99a0-11e5-b3b7-01aa75ed71a1.0012.02/DOC_1&format=PDF

already meet the generic limit of 0.1% lead. This is because a significant level of legacy lead in PVC waste will have been phased out- by co-extruding higher proportions of recycled PVC with virgin PVC in the production of new PVC articles. It is understood though that this may still incur some costs for industry as for some recycled streams a higher proportion of virgin PVC may need to be used.

In addition, it is possible that the projected decrease is higher or lower than estimated, therefore before this stage is reached 10 years (after the entry into force) it might be the appropriate time frame for a re-assessment of the situation, in particular concerning the efforts of industry to reduce the lead concentration in recycled PVC waste. Focus of this assessment would be to assess:

(i) whether the projected (by EuPC/Tauw) reduction of lead concentration in the derogated articles prepared by recycled PVC actually occurs;

(ii) whether the limit of 1% of lead in recycled PVC for these specific PVC articles can be adjusted (e.g. downwards?);

(iii) or if there was no improvement, perhaps to re-consider the justifications behind the granted derogations.

Further to window frames, ECHA has also checked the Tauw data and relevant graph for new pipes and fittings based on recycled PVC. It must be noted that for the most common concentrations of recyclates in PVC articles (40% for window frames, 65% for pipes/fittings) the projected lead concentrations at around 2035-2040 are pretty similar at the level of approximately 0.25% w/w. Therefore the above-mentioned conclusion for 15 years initial period of derogation and re-assessment after 10 years are additionally substantiated by these data.

E.3.2.1.3. Economic and social impacts if the concentration limit of 0.1% immediately applied to recycled PVC

Information submitted via Stakeholders Consultations

According to Tauw (2013), and based on the input of European recyclers, the following socio-economic impacts are expected to occur if a derogation for recycled PVC would not be granted from a proposed 0.1% concentration limit in a EU restriction of lead in PVC:

- Closing down of approximately 130 recycling companies. This estimate is based on the average size of a recycling company and the amount of recycled PVC waste per year (the number of recycling companies in Europe was estimated to 154 in 2013). ECVM (2016) additionally noted that if PVC cannot be recycled anymore not just recyclers will be affected, but convertors as well, as this would substantially increase the cost of raw materials, moving thereby manufacturing outside EU;
- A loss of approximately 800 jobs. This reflects the number of losses of jobs in PVC recycling and converters' sectors;
- A loss of more than € 7 billion as added value from 2015 to 2050 for the PVC recycling sector. This loss mainly concerns the fact that recycling activities would have to stop until approximately 2050 (when levels of Pb in post-consumer PVC expected to approach the threshold concentration of 0.1% w/w). According to the Industry, it would be extremely difficult and highly uncertain that recycling companies would re-start again and go back to business due to the significant investments needed and the loss of

know-how.

According to ECHA's assessment there could be indeed, some adverse economic impacts for the recycling industry if there is no derogation for PVC recycling. However, the aggregated estimates of impacts to companies (e.g. closure of companies/loss of jobs) are difficult to assess. From the information provided by industry it is not clear if ceasing of PVC recycling would lead to a total or partial shutdown of each individual company. In addition, some of the losses might be regained in other sectors of the PVC industry e.g. by selling the excess recycled PVC to 3rd countries where there is demand. Finally, lost profits is a more appropriate indicator to estimate losses to industry instead of total added value.

ECHA assessment/Further analysis on socio-economic justifications

ECHA carried out an additional assessment by considering more recent data and information exchanges with stakeholders. ECHA's analysis was based on an assumption that PVC recycling would not be possible after 2020 (i.e. no derogation from the proposed restriction would be granted) and PVC articles at the end of their service life would be disposed via other prevalent waste management practices (i.e. landfilling, incineration and export). ECVM (2016) confirmed to ECHA that no granting of the derogation would result into stopping all recycled of post-consumer waste from long life applications. In ECHA's opinion, though, this could still be considered, though, as a worst case scenario.

Further ECHA's assessment has therefore focused on estimates of:

- Costs due to a need for greater incineration or landfill disposal (based on gate fees). However, the need for further capital investment to meet demand for capacity was not considered;
- Price increases for PVC products (if the cheaper-compared to virgin material- PVC recyclate could no longer be used for their production after 2020);
- Lead release to the environment (as risk proxy) due to incineration or landfilling of the PVC waste that could not be recycled after 2020.

Changes in PVC waste management practices (if a derogation for recycling would not be granted)

According to RIVM (2016), 450 000 tonnes of PVC waste were recycled in 2015 of which approximately 60% (300 000 tonnes) concerns rigid PVC applications (e.g. window frames, fitting and pipes).

The goal of the PVC sector is 800 000 tonnes of PVC waste to be recycled in the year 2020, therefore approximately 500 000 tonnes of PVC waste would be produced from the disposal of rigid PVC articles within the scope of this proposed derogation (as previously discussed).

Should a derogation not be granted, approximately 500 000 tonnes of PVC waste per year could not be recycled any more from 2020 onwards and therefore would need to be disposed through other waste management practices and virgin PVC production would increase by 500 000 tonnes per annum. ECHA has used this value as basis for the subsequent emission and cost estimations.

EuPC (Tauw 2013) has projected the PVC waste management distribution for the next few decades. According to their prognosis, in 2020 out of the total PVC waste: approximately 20% will be recycled, approximately 20% would be landfilled, approximately 45% would be incinerated, and approximately 15% would be exported outside the EU (see Appendix E, Figure

E8). If PVC recycling ceases after 2020 the tonnage of PVC waste that would have been recycled are projected to be proportionally disposed among the other three practices, leading to the following modified distribution of wastes to the three waste management practices:

- Approximately 56% of PVC waste would go for incineration (45% initial prognosis);
- Approximately 25% of PVC waste would go for landfilling (20% initial prognosis);
- Approximately 19% of PVC waste would be exported outside of the EU (15% initial prognosis).

This modified post 2020 distribution for PVC waste management are presented in the next section in Table E5, where total annual cost estimates are also derived.

Estimated costs (based on gate fees) for landfill/incineration if no PVC recycling is possible after 2020

For the further assessment the average values of €125 per tonne for landfilling and € 150 per tonne for incineration were selected. Based on these average cost values and the projected PVC waste management for 2020, in the absence of a derogation (as estimated above), ECHA has produced estimates of the annual incurred costs for landfill/incineration as presented below in Table E5.

Industry experts (ECVM/EuPC 2016) highlighted that:

(i) The cost figures (euros/tonne) presented in the Table E16 of Appendix E are estimates of the gate fee plus landfill tax, i.e. only the actual costs. They do not include the value of the lost opportunity cost of selling the waste for recycling;

(ii) The information from industry indicates there to be is an excess of incineration capacity in some countries as a results of the economic slowdown and new capacity coming on-stream. This however does not take into account the fact that a lead restriction that would seriously constrain recycling might overwhelm incineration capacity, probably resulting in cost increases;

(iii) export of PVC waste is overall a loss of resources for the European industry and its long-term viability is not assured. The current assessment therefore excluded PVC exports in the cost estimation, since this may not be reasonably considered as a longer-term option.

Table E5. Total annual costs for incineration and landfill of the PVC waste that could not be recycled from 2020 in the event that a derogation for lead in PVC recycling would not be granted (ECHA's 2016 estimates based on best available data from IND/literature)

	Landfill	**Incineration**	**Export**
Volume of PVC waste (tonnes) in 2020 that could no longer be recycled *(Source VinylPlus 2015)*	500 000		
% of PVC waste in 2020 that would be disposed via other-than recycling-practices *(Modified from Tauw, 2013)*	25%	56%	19%
Tonnes of PVC waste that would be disposed via other-than recycling-practices	125 000	280 000	95 000
Average price per tonne for the waste management practice in the EU *(ECVM 2016,* Annex Table-1*)*	€125	€150	Not estimated
Total costs for the year 2020 (as indicative "baseline" year of entry into force)	€15.6 million	€42.0 million	Not estimated
	Total cost: €57.6 million		

According to these estimates (and additional information from industry) it can be concluded that: the additional annual costs for disposal of PVC waste (approximately € 57.6 million in total for incineration and landfill) are significant costs (and probably reflect an underestimation). These costs would be borne by society in general.

Impact on the price of PVC products

The proposed restriction without a derogation for lead in PVC recycling is likely to increase prices of PVC articles that can no longer use the cheaper recycled PVC material. An example of such extra costs is presented below in Table E6.

Applying some sensitivity analysis (40-70% recyclate in the PVC mixture) it was estimated (see Table E6 below) that not granting a derogation for PVC recycling from 2020 onwards would result into a price increase of 5.3-9.2% for average PVC window profiles[77] (compared to current prices).

[77] If price increases need to be calculated on the price of the window unit (around 400 euro), these are approximately 10 times lower than for the price of profiles, therefore between 0.5-0.9%.

Overall, if no derogation for PVC recycling would be granted, the companies affected would need to use (more expensive) virgin PVC (in principle, lead free), which would incur higher raw material costs (Tauw IA, 2013). For SMEs (e.g. importers of PVC profiles) it would probably be difficult to absorb these price increases, which would eventually be passed on to downstream users or consumers.

Table E6. Price difference for window profiles if no recycling would be possible after 2020 (baseline situation vs 2020)

Mass of PVC in the profile constituting the frame of a standard PVC window unit (1.23 x 1.48 m) (ESPA, 2015)	Approximately 15 kg	
Price difference between PVC recycling (cheaper) and virgin PVC[78] (ECHA-phthalates dossier, 2016)	€350 /tonne (in general)	
Example (from a consumer perspective)		
	Price increase per window frame (€)	% increase of price of PVC window profile (€40 average price)
Baseline scenario where profiles produced by **40% recycled PVC** (which should be replaced by virgin PVC 2020 onwards)	2.1	5.3
Baseline scenario where profiles produced by **70% recycled PVC** (which should be replaced by virgin PVC 2020 onwards)	3.7	9.2

E.3.2.1.4. Environmental risks and impacts associated with a derogation for PVC recycling

Information submitted via Stakeholders Consultations

The following environmental impacts were identified in the Tauw IA (2013):

- Higher energy consumption. When material is recycled or incinerated, the use of primary energy is prevented because the production of virgin material is not necessary and less electricity and heat has to be generated using primary fuels. If a derogation for recycling was not granted there would be a decrease in prevention of primary energy;
- Higher raw materials consumption. If PVC waste is going to incineration and landfilling (rather than recycling) the process would demand a higher raw materials (crude oil, salts etc.) consumption. This has been estimated at approximately 1 800 kilo tonnes

[78] As indicated in the ECHA Annex XV restriction proposal for phthalates (ECHA 2016), the cost difference between the low quality PVC recyclates (made out of post-consumer PVC waste, which would still contain some legacy lead) and virgin PVC material is assumed to be €350 per tonne of raw material.

oil/gas/condensate/coal/lignite and approximately 930 kilo tonnes of salts;

- Global warming potential. In general, waste processing recycling reduces the emission of greenhouse gasses. As recycling prevents the production of new PVC and incineration prevents burning of fossil fuel, total emissions [of CO2-equivalent] are negative.

The magnitude of the impacts described by industry are, however, difficult to for ECHA to corroborate.

In addition, industry provided (December 2016) a recently performed risk assessment of lead migration during the service life of PVC articles manufactured using recycled PVC (Vangheluwe et al., 2016).

This study used the lead migration and release data from the FABES study to develop exposure scenarios for consumers and the environment from widespread uses of recycled PVC (such as pipes and fittings, window frames, roller shutters, road furniture, roofing tiles, garden hoses, etc.).

The report includes the following conclusions:

- Health risks: No risks via dermal or oral exposure (via mouthing of articles) to lead migrating from PVC articles made from recycled PVC were identified. This was on the basis that although leaching occurs dermal absorption of lead is very low (negligible) and there is an absence of irritating or sensitizing effects on skin. No mouthing of articles was considered likely. However, the potential for 'hand to mouth' exposure was not explicitly considered.
- Environmental risks: Releases to environmental compartments were estimated based on the anticipated surface area of certain PVC articles within a standard town of 10,000 people together with assumptions on the frequency and duration that these articles would be in contact with water, the length of service life and leaching rates. All releases were assumed to pass through a municipal waste water treatment plant prior to discharge to the aquatic environment. The environmental exposure assessment indicated that the contributions due to the leaching of Pb from the uses of recycled PVC considered were <1% of the regional lead background concentrations for water, sediment and soil from other sources. The environmental risk characterisation reports RCR values of <1 for all environmental compartments against the PNEC values derived for the REACH registration dossier and the water framework directive EQS. As the authors consider that the contribution from these uses was <1% of background concentration from other sources they also conclude that uses of recycled PVC do not pose any additional risk to humans indirectly exposed to lead via the environment (e.g. via diet).

ECHA's further analysis for environmental risk/emissions justifications

As already discussed in the previous sections, PVC recycling is forecast to increase in the future. Therefore, PVC containing lead stabiliser (legacy lead) will remain in circulation incorporated into new articles. As there is always some loss of materials during recycling operations and some of the PVC waste will be disposed of via other waste management routes (incineration or landfill), the concentration of lead in new articles made from recycled PVC will progressively decline over time.

According to Industry data, no lead-based stabiliser will be intentionally added during the recycling or production of PVC articles in the EU after 2016 (via the VinylPlus Initiative). There

will continue to be some addition of lead to the EU stock through imports. However, this can be assumed to reduce over time as a consequence of the proposed restriction. In this context, if there was a derogation for lead in articles produced using recycled PVC, and PVC recycling rates would continue as forecast, a progressive reduction of human and environmental exposure to lead (and thereby relevant risk) would take place.

However, as discussed and estimated in Section E.3.2.1.3 if there was no derogation for re-use of recycled PVC in the specific applications based on rigid PVC, the PVC waste that could be recycled in 2020 (approximately 500 000 tonnes) would be either landfilled (approximately 125 000 tonnes) incinerated (approximately 285 000 tonnes) or exported from EU (approximately 85 000 tonnes).

To explore the implications of a derogation from the perspective of environmental releases, the probabilistic model used to estimate releases of lead to the environment from lead-stabilised PVC articles (section B.9) was used to estimate releases of lead to the environment from the disposal of the PVC waste arising in 2020. The model was modified to investigate scenarios including and excluding PVC recycling.

Overall releases of lead (which will occur over many years for some pathways) from the disposal of approximately 2 000 000 tonnes of PVC waste in 2020 (RIVM, 2016) (with PVC recycling still in place) were estimated to be 44 to 185 tonnes (10^{th} to 90^{th} percentile range). The absence of recycling (disposal via other routes) resulted in a net increase of lead releases to the environment of between 9 and 43 tonnes (10^{th} to 90^{th} percentile range); equivalent to a relative increase of releases of ~20% (see Table E8.)

These estimates were based on a waste PVC tonnage of 2 000 000 tonnes (lead content assumed be 1–2%) and the assumptions on the relative proportion of PVC waste going to different waste management options outlined in Table E7.

Table E7. Waste management practice under "derogation" and "no derogation" environmental release scenarios.

Waste management option prevalence (% of waste by weight)				
Scenario	Recycled	Incinerated	Landfill	Export
Derogation	20	45	20	15
No derogation[1]	-	56	25	19

Table E8. Net increase in environmental releases under a "no recycling" waste management scenario

Net increase (tonnes) in Pb release to the environment in absence of derogation				
Min	10^{th} percentile	Median	90^{th} percentile	Max
1	**9**	**23**	**43**	66

The additional lead releases to the EU environment (from waste disposed in 2020) are due to additional releases from incineration and landfilling of PVC waste that could not be recycled (including re-use of incinerator bottom ash). This net increase in releases can be used as a proxy of increased risk against the baseline scenario (lead emissions from PVC waste disposal in 2020 with recycling).

ECHA also notes, further to section E.3.2.1.1, that a derogation with a wider scope (covering all PVC articles) may raise concerns from a risk perspective. PVC flooring containing lead (which according to Industry - see

Figure E3 – accounts for one of the main applications of PVC recyclate), for example, could result in relatively greater exposure of humans to lead, than other PVC articles used in construction. This is because its deterioration over time (via physicochemical processes, including photo degradation, and wear and tear) can be reasonably foreseen to result in releases of lead to the indoor environment (in the form of dusts) potentially leading to exposure via inhalation or through hand to mouth activities. Certain PVC articles stabilised with lead that were used in the home have been linked with the formation of lead containing dusts in the past (e.g. case-study of vinyl mini [venetian] blinds in the US[79]). In addition, certain populations, i.e. young children and infants, may also have potential for exposure to lead in PVC flooring via direct and prolonged contact with skin (including hand-to-mouth exposure).

In addition, industry (EuPC, 2016) have informed us about a new proposed EU harmonised standard 14041 (CE mark) that foresees a limit of 0.1% Pb in all for flooring products to be placed on the European market. The standard which is currently under development (and is subject to formal vote in CEN) covers floor coverings: carpets and laminates. We therefore expect that during the upcoming Public Consultation (in early 2017) on this Annex XV dossier more information will be submitted. Since the standard is expected to cover all types of flooring (based on either virgin or recycled PVC), its implementation would provide:

i. an additional risk reduction measure for lead emission from these type of indoor products, and

ii. would thereby make redundant the insertion of PVC flooring in the list of the items derogated from the proposed restriction as based on recycled PVC

On the contrary, other construction applications (e.g. window profiles, pipes), which are commonly installed by professionals (quite often on external parts of buildings), are unlikely to raise similar concerns since these uses are not expected to lead to direct exposures to humans during their service life.

E.3.2.1.5. Enforceability aspects of a derogation in PVC recycling

A derogation for recycling may raise enforceability issues concerning scope and traceability (in particular of imported PVC articles that are claimed by importers to be produced using recycled PVC). As previously discussed, in order to facilitate the enforceability aspects of the derogation, ECHA recommends that:

- Not all PVC articles, but rather an exhaustive list of rigid PVC articles, should be

[79] See: https://www.cpsc.gov/content/cpsc-finds-lead-poisoning-hazard-for-young-children-in-imported-vinyl-miniblinds

derogated. As previously discussed, such list should include PVC articles that would not be expected to lead to significant human exposure to lead during their service life (e.g. via dust inside the buildings or direct and prolonged contact);

- Producers of PVC articles should be obliged to 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[80]);
- Importers of PVC articles could be asked to provide documentation (from their suppliers/contractors) proving that articles were produced using PVC recyclate (with any essential details on% recycled PVC; location of recycled material, etc.);
- In addition, there could be an additional requirement, specifying that PVC articles containing recycled PVC are visibly, legibly, and indelibly marked as follows (contains recycled PVC) in analogy to the labelling requirement for recycled PVC containing cadmium (entry 23 of Annex XVII to REACH).

E.3.2.1.6. Conclusion/proposed wording

Based on the assessment of the available technical and socioeconomic information, it can be concluded that a derogation from the proposed restriction should be provided for specific types of PVC articles, *if the concentration of lead (expressed as metal) does not exceed 1% by weight of the PVC material.*

Overall, the decision to exempt only specific types of PVC articles rather than those defined by CPR Regulation (proposed by Tauw 2013) or all PVC articles (request from industry during Public consultation) was mainly based on the following considerations:

- Consultation with a MS Authority on the wording of the proposal revealed that it would be clearer for enforcers to implement this derogation while checking for a specific list of PVC articles.
- The list has been drafted in consistency to entry 23 of Annex XVII (under paragraph-4) where also an exemption for certain rigid PVC articles based on recycled PVC articles is foreseen.
- The list of articles contains the main categories of rigid PVC articles that have been historically produced by lead stabilisers in the EU. However it does not contain indoor PVC articles (e.g. PVC flooring) which could lead to human exposure (e.g. via dust).

Therefore, after also considering the enforceability aspects discussed under the Section, E.3.2.1.5., the following wording is recommended:

5. *By way of derogation, paragraph 1 shall not apply to the <u>following article types containing recycled PVC</u> 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:*

(a) profiles and rigid sheets for building applications;

(b) doors, windows, shutters, walls, blinds, fences, and roof gutters;

(c) cable ducts;

(d) fittings for tubes, furniture etc.

[80] As a reminder, PVC pipes/profiles can be produced using coextruded layers, with lead usually present within an inner layer of recycled PVC (such articles are partly covered by the lead in consumer articles restriction, if mouthable).

(e) 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 above.

Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time that these are visibly, legibly and indelibly marked as follows: '*Contains recycled PVC' or with the following pictogram: (same as for entry 23).*

A re-assessment of the derogation at approximately 10 years after the entry into force of the proposed restriction would be recommended to (i) verify the current prognosis for reduction of legacy lead in new articles produced from recycled PVC (ii) to check the validity of the current justifications (risk/cost relevant aspects) behind the granting of this derogation.

E.3.2.2. Derogation for PVC silica separators

E.3.2.2.1. Technical considerations

Information was submitted in ECHA's call for comments by a European company claiming that the effect of a potential restriction on lead would particularly impact manufactures of microporous plastic (PVC) separators in lead-based batteries. They highlighted that, at Union level, they are the only European company (and SME) that they use lead stabiliser (tetralead trioxide sulphate) for these PVC separators applications.

The company informed that:

- in the production of a PVC-silica separator an amount (< 2.5% w/w) of tetralead trioxide sulphate is incorporated to help maintain the integrity of the plastic component in the lead-acid battery. The tonnage used for this application is below 20 tonnes of lead stabiliser per year;
- in a lead-acid battery, these separators are used inside the battery to prevent any short-circuits between electrodes. This item is a very important component as it plays a critical role on the entire battery performance and life.

The company highlighted the following:

- The tetralead trioxide sulphate is not used as a traditional PVC stabiliser, as a unique process is applied to produce the separator at low temperatures, as opposed to the melting of PVC during traditional extrusion with use of the substance as a PVC stabiliser;
- This separator is only used for industrial lead-based batteries (such as batteries for forklift application or critical infrastructure backup). Such batteries are always enclosed and are recycled at more than 99% efficiency.

Industry claimed that several alternatives to tetralead trioxide sulphate have been tested without success up to now. Due to the particular nature of these products, there are only very few possible alternatives for battery separators for lead-based batteries. The company informed that:

- accelerated tests in the lab to simulate 20 years of battery life in real operation take nearly 3 years and further validation by customers is required;
- customers also request field tests which typically last 5 years before final approval of formulation changes.

Therefore, the company highlighted that although they are working to find alternatives to the substance with highest priority and urgency, it may take around 10 years to develop and fully replace lead compounds in their application.

E.3.2.2.2. Socio-economic considerations

The company noted that, in case PVC microporous separators in lead batteries were not derogated, they will have to cease production because the technical performance of the separator in the battery will not be maintained. Their customers (final user of the separators and manufacturers of lead-acid batteries, ~28 000 firms in the EU) would be deprived from a product contributing to a more efficient use of resources.

The company also informed that:

- Cost of research and development in order to find the suitable alternative or substitution costs are relatively high for an SME of their size, but the main points that their product is unique and all the ideas tested up to now were not successful;
- It is difficult to estimate the price of suitable alternative(s) since none has been identified yet. Although the price of alternatives is higher the fact that stabilisers are used at very low amounts may not cause big changes in the price of the final product.

Conclusion: After carefully considering the submitted information (via follow-up exchanges between ECHA and the company), and considering the nature of this PVC application (industrial use in closed system), ECHA has concluded that a temporary derogation of 10 years from the proposed restriction of lead in PVC would be justified for PVC silica separators in lead-acid batteries. This period would allow industry to develop technically and economically feasible alternatives to tetralead trioxide sulphate.

E.3.2.3. Derogation for second hand articles

In the course of ECHA's Call for comments (2016), the association of European Stabilisers Producers (ESPA) submitted a comment requesting that "*articles made from recycled PVC shall be out of scope of a restriction, just as 2nd hand articles…"* In addition, the European Plastic Converters (EuPC) informed that there is an important market for second hand use in the EU for the PVC articles in the building applications. For the window profiles, for instance, the second hand market accounts for approximately 2 800 tonnes (through extrapolation at EU level: approximately 25 000 tonnes).

It should be noted that an exemption for second hand market articles was granted for the recent restriction of lead and its compounds in consumer articles (entry 63, par 10), which was imposed via the Regulation (EU) 2015/628 (entry 63 of Annex XVII to REACH). As mentioned in the recital 12: Economic operators should be allowed a transitional period to adapt their manufacturing to the restriction laid down by this Regulation and to dispose of their stock not yet placed on the market; The restriction should not apply to second hand articles which were placed on the market for the first time before the end of that transitional period as that would give rise to considerable enforcement difficulties.

As mentioned in the Background Document for lead in consumer articles (ECHA 2014), the resources of REACH Competent Authorities for carrying out inspection activities are general limited for articles placed on the primary market. Additional inspection activities concerning the second-hand market would therefore neither be easily implementable nor be manageable for

the authorities. The additional costs for carrying out inspections would not be proportionate to the achieved risk reduction.

ECHA has concluded that an exemption for used PVC articles (and therefore for articles placed on the market before 24 months after entry into force of the restriction) should be justified taking into account the considerations above.

E.3.2.4. Derogation for other EU legislation

Articles already covered by specific Union legislation regulating lead content or migration should be exempted for reasons of consistency with the recent REACH restriction provision (lead in jewellery/lead in consumer articles). The types of articles covered by these specific legislative frameworks are presented below in Table E9. below.
In addition, PVC articles which are covered by paragraph 7 of entry 63 (mouthable articles for consumer use) are excluded from the scope of the proposed restriction.

Table E9. Article types which are exempted from the proposed restriction when covered by European Union legislation specifically regulating lead

Type of articles	*EU specific legislation*
Articles intended to come in to contact with food (e.g. kitchen utensils, ceramic articles for food/drinking use etc.) when covered by the specific EU legislation.	Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
Electrical and electronic articles, such as bulbs, light sources etc.	Directive 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
Toys	Directive 2009/48/EC on the safety of toys.
Packaging materials	Directive 94/62/EC on packaging and packaging waste.
PVC mouthable articles	Paragraph 7 of entry 63 of Annex XVII to REACH

E.3.3. Potential derogations not included in the proposed restriction

In addition, to the derogations proposed by ECHA above, other information was submitted in ECHA's call for comments on specific impacts on industry but where ECHA has assessed a derogation is not required. These are elaborated below.

E.3.3.1. Lead PVC stabilisers for electrochemical sensors for in vitro diagnostic equipment

A comment was submitted by a company concerning the use of lead thermal stabiliser in PVC applied for electrochemical sensors in In-Vitro Diagnostics Equipment.

The following information was communicated to ECHA:

- Lead content is 1.5% corresponding to an annual use of less than 15 kg of lead;
- The equipment is used by professionals wearing gloves at hospitals and the waste stream is highly regulated as biohazardous waste;
- The company conducted two substitution attempts without success for most of the sensor types. Final approval of a potential alternative would require at least two additional years of verification and stability tests.

Industry noted that:

- they have a large base of installed equipment with an expected lifetime of 20+ years, executing globally more than 100 million tests per year at intensive care units.
- 1000+ number of employees are involved in the production and support of this equipment.

The company requested *'a transition period of at least 5 years due to difficulties in substitution'.* Through a follow up exchange between ECHA and the company, the timeframe of opinion and decision making process was explained: (~two years until potential adoption of the restriction on top of which a transition period of 12-24 months is commonly granted before entry into force that facilitates the implementation as well as the depletion of stocks, etc.).

Following this clarification it was agreed that if a transition period of 24 months would be granted for this restriction there would be no need to derogate this specific application *(since substitution of lead PVC stabilisers should take place within the next 2-3 years).*

E.3.3.2. Uses of lead-based stabilisers in insulation cables and wires

A comment was received by a EU-based company, informing that some *PVC insulation cables and wires* are still stabilised with lead compounds (lead monoxide or lead tetraoxide at a concentration between 0.3 to 0.9% w/w).

- The company sent only some generic information, noting that: if lead is restricted in PVC, it may be difficult for specific cable applications to meet customers' specifications;
- employees working in lead compounding operations use personal protective equipment and are subject to periodic medical checks including blood tests;
- although no direct information on societal effects is available, a longer transition period or an exemption from the restriction may be necessary for these PVC applications.

Although ECHA requested more specific technical details (on non-feasibility of substitutes) for these PVC uses, no further information was submitted that would enable further assessment.

Another comment submitted to ECHA's Call, (ESPA 2016) highlighted, however, that *(…in the flexible PVC segment, lead stabilisers were already no longer used in the EU for electrical cables, also for compliance with the RoHS directive).* ESPA's input is in line with the information received through consultation with EU Plastics industry (VinylPlus reports). Therefore, in the absence of any more concrete information of technical and socioeconomic nature that would possibly justify the need for a derogation, ECHA concludes that PVC wires and cables should not be exempted from a proposed restriction of lead compounds in PVC articles.

E.4. Economic impacts

E.4.1. Substitution costs

With regard to substitution costs, some generic information is available on prices and quantities of the different stabilisers contained in PVC and on the concentrations with which they are used to stabilise PVC (see section E.2.4.2). However, detailed information on R&D and investments costs has not been made available to ECHA.

The economic impact assessment focuses on substitution to calcium-based systems, which are assumed to be the primary replacement for lead-based stabilisers. In consequence, the calculation of substitution costs is based on the price differential between Ca-based and Pb-based stabilisers (the actual price per kg of the two stabilisers was claimed confidential) and the relative amounts needed to achieve satisfactory stabilisation.

To calculate the substitution costs, it is assumed that the entire quantity of Pb-based stabilisers would be replaced by Ca-based stabilisers. For the purpose of estimating the substitution costs, the price of the Ca-based stabiliser is assumed to be €0.7/kg more than that of the Pb-based stabiliser (ESPA 2015).

ESPA[81] represents more than 95% of the PVC stabiliser industry across Europe. According to ESPA (2016), all its members replaced the Pb-based stabilisers with Ca-based stabilisers by the beginning of 2016. Consequently, the current manufacturing of Pb-based stabilisers in the EU is expected to be done by companies who are not part of ESPA's voluntary commitment to phase out Pb-based stabilisers. Therefore, it is considered that from 2016 onwards a range of 0 - 5% of the tonnage of Pb-based stabilisers produced in 2015 would annually be placed on the EU market. For the purpose of this analysis, Pb-stabilised PVC entering the EU via imports are assumed to remain stable over the period 2016-2020 (therefore, the 2015 values were used for the analysis). This could be an underestimation since Eurostat data suggests a significant increment in total annual imports of rigid PVC during the last decade.

Based on the reported 2016 figures of annual sales of Pb-stabilised PVC in the EU 28 and the estimated amount of Pb-based stabilisers imported in PVC articles the substitution cost for 2016 is estimated to be between € 0.9 – 3.3 million with a central value of €2.1 million (see **Error! Reference source not found.**, 0 provides a robustness check of this cost analysis). This represents the baseline situation in the absence of a restriction.

For the purpose of this report it is assumed that from 2016 onwards the annual substitution costs will remain relatively stable until the entry into force of the proposed restriction (around 2020). This is further elaborated under the section E.4.5.

According to ESPA (2015), switching from a Pb-based to Ca-based system saves the expenses linked to risk reduction measures specific to the use of lead. Therefore, the medical monitoring which is necessary when Pb-based stabilisers are used (blood-Pb level control), reduces the cost difference between Pb-based and Ca-based systems.

Based on the cost estimations presented in this section and the emission estimations of section B.9.3 values of Cost-effectiveness are given and discussed under the section E.8 of this Annex.

[81] See: http://www.stabilisers.eu/wp-content/uploads/2016/01/ESPA-stabilisers_update_January-20161.pdf

Table E10. 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).

	min	25th	**50th**	75th	max
Pb stabilisers imported in articles (tonnes/year)	1321	2322	**3142**	3921	4974
Pb stabilisers produced in the EU28 (t/year)	0	72	**165**	295	354
Total amount of Pb stabilisers (t/year)	1321	2394	**3308**	4216	5328
Dosage ratio Ca stabiliser/Pb stabiliser			**0.88**		
Equivalent amount of Ca stabilisers needed for substitution (t/year)	1163	2107	**2911**	3710	4688
Price difference between Ca stabilisers and Pb stabilisers (€/kg)			**0.7**		
Substitution costs [a] (M€/year)	0.9	1.5	**2.1**	2.6	3.3

Note: assuming that substitution costs are fully passed onto the consumers and therefore incorporating them also for non-EU produced PVC (via imports) sold to EU consumers.
Source: Data provided by ESPA (2016)

E.4.2. Testing costs

All European companies that supply, retail or import PVC articles will have to ensure that their articles are in compliance with the new restriction provisions of lead in PVC.

In determining the likely cost of ensuring compliance, the findings of a recent compliance control survey that examined to what extent European industry employs the following strategies to ensure compliance of their articles with EU regulations (ECHA's restriction dossier on phthalates in consumer articles, 2016) are relevant:

- Contractual procedures, i.e., explicitly specified in the purchase contract requirements for the international supplier to comply with EU legislation and/or the importer's internal chemical policies.
- Provision of information to suppliers regarding the requirements to meet EU legislation or the importer's chemical policies.
- Monitoring and control procedures. These are varied and may include: a requirement the supplier to sign a declaration of compliance and/or to provide test documentation, spot tests, audit/supervision, etc. carried out by an EU buyer (importer) to their international suppliers.

The survey revealed that contractual obligations in combination with information provision are the most frequent compliance management strategies used by respondents. This is consistent with previous surveys on compliance control costs, e.g., ECHA (2014a). Actual testing is less frequently used and the majority of respondents rely on the provision of a declaration of compliance (with EU regulations or a list of restricted substances prepared by buyers).

ECHA presumes that the findings of this survey should be also applicable for the present restriction case, especially as it is also related to PVC. Therefore, it is expected that the majority of downstream users or importers would rely on the provision of a declaration of compliance of their suppliers as result of their contractual obligations. It should be noted that according to ESPA (2016) the associate companies regularly assess the lead content of PVC articles in the framework of technical service/formulation development. That means that the necessary information (e.g. presence of lead in PVC articles) should be anyway available to the distributors/downstream users. It also means if any texting is carried out on PVC articles after entry into force of the restriction, it may not be specifically for the purposes of compliance.

According to the above analysis, the presence of lead in PVC articles should be traceable along the supply chain. Whenever such information will not be available from suppliers, though, the remaining option will be to test article samples.

Section E.7 of this dossier summarises the current technical information on the available analytical methods for lead testing in PVC articles. In addition, some information concerning the cost of the analytical methods was communicated by industry (ESPA, 2016) and concern:

(1) The wet chemical methods (AAS/ICP-MS). Their cost (including sample preparation) can be estimated to be in the range of €70-140 per sample (in-house) to achieve the required accuracy. Overall, the cost could drop significantly for processing (regular batches of) samples in an external lab, in particular for simpler pass/fail checks for enforcement purposes.

(2) X-ray fluorescence (XRF) spectroscopy. For XRF screening, RPA (2009) reports a cost of €15 and KEMI (2012) a range from €25-40. All these costs are lower than the corresponding costs for wet chemical analysis, as reported by the same laboratories. Overall, XRF method is cheaper than the wet chemical methods since it is non-destructive and does not require sample preparation.

In the scope of this assessment, ECHA has considered the above mentioned recent information and statements from industry on the testing costs of existing analytical methods. It should be noted that no safe precise estimations on the numbers of PVC articles manufactured or imported into the EU can be made (since Eurostat data refers to total tonnes of PVC articles). Therefore, quantitative estimations of total costs at EU level for testing of lead in PVC articles were not deemed purposeful. *Overall, no significant testing costs for industry are expected from to implementation of an EU restriction of lead in PVC articles.*

E.4.3. Investment/Development costs

As discussed in details under section E.2, alternatives to Pb-based stabilisers at a marginally higher cost (and with similar or even better technical characteristics) are widely used by European industry. A corresponding estimate of the potential substitution costs was provided in section E.4.1.

Whether the switch to alternative substances for lead stabilisers (e.g. Ca-based systems) results in any investment costs was investigated by ECHA through addressing a specific question in ECHA's Call for evidence (Appendix G). This consultation did not result in any specific feedback or figures from stakeholders on this issue. ESPA (2015), however, informed ECHA that although the most commonly used alternatives (Ca-based systems) are not simple "drop in" replacements for lead based formulations, the development costs of new formulations had already been absorbed by the manufacturers and converters.

In the absence of more specific information, ECHA concludes that:

(a) At EU level, no additional substitution costs are anticipated for the switch-over from Pb-based stabilisers to the alternative Ca-based systems, as these costs were already incurred by EU manufacturers and converters they can be seen as a sunk cost here ;

(b) The proposed restriction is not expected to result in a need for increased investment (e.g. for research & development activities). Substitution has already been carried out widely in the EU during the last decade. Therefore, producers already are expected to know how to produce lead-free PVC articles.

E.4.4. Enforcement costs

Enforcement costs are administrative costs incurred by Member States enforcement agencies to ensure that economic actors on the EU28 market comply with the EU regulations. By evaluating data reported from European studies on inspection/enforcement costs of REACH restrictions (Milieu, 2012; RPA, 2012), ECHA assessed the administrative burden of enforcement for new restriction proposals. ECHA concluded that based on data reported by Member States, the average administrative cost of enforcing a restriction is approximately €55 600 per year.

This value is estimated based on numbers of controls over the period 2010-2014 reported by Member States (reporting under REACH art. 117 / CLP art.46). The calculation is based on an average cost per control (inspection) and an average number of controls per restriction. ECHA notes that while the average enforcement costs may remain fairly similar over time, as they are driven by budgetary constraints, the costs for individual restrictions would likely vary. It is often the practice that enforcement campaigns focus on newer restrictions or high-risk restrictions considered a priority by Member States, and fewer resources are allocated to restrictions industry is already familiar with.

For the purpose of the current assessment, the value of €55 600 per year, should be seen as only illustrative in terms of the order of magnitude of the cost. It has to be noted that the Member State Competent Authorities have generally established the infrastructures and experience in enforcing other lead restrictions (.e.g. in consumer articles, jewellery) so that the new restriction of lead in PVC may not significantly add to the existing administrative costs. Therefore, the ECHA general established value for the annual administrative burden of enforcing a new restriction is most likely an overestimate for this proposal.

Overall, the proposed restriction is not expected to bring any major additional administrative burden on public authorities in terms of cost for inspection and enforcement.

E.4.5. Conclusion on economic impacts

The net annual compliance costs of the proposed restriction to EU society are estimated to be in the range of €0.9–3.3 million (see Table E11.). The contribution of imported articles to the total substitution costs is assumed to remain broadly stable during the period 2016-2020 (or even decrease, in spite of the increasing trends of PVC imports into the EU indicated under section A.1.4). This is a reasonable hypothesis as the signal of an upcoming EU legislative restriction (even if this would enter into force after 2020) would be echoed outside the EU, resulting in an increasing proportion of imported PVC being lead-free. In the meantime, non-ESPA members producing Pb-stabilised PVC (in 2015 these constituted approximately 5% of the PVC market in Europe) are expected to gradually move out of this market (through switching to alternatives).

Overall, it is assumed that the total compliance costs in 2020 should be substantially lower than in 2016, but no quantitative assessment on the development of compliance costs was undertaken. Moreover, it is also assumed that enforcement/administrative costs may gradually decrease as soon as the infrastructure for the implementation of the restriction will be established. A summary of the economic impacts is given below in the Table E11.

Table E11. Summary of economic impacts of the proposed restriction based on the use of Pb-based stabilisers 2016 (total values reflecting EU manufactures and EU imported articles.

Cost estimates for 2016 and after (in € million)	
Substitution costs	0.9–3.3 (central value 2.1)
Investment costs	Not estimated, likely to be negligible
Testing costs	Not estimated, likely to be negligible
Enforcement costs	0.06

E.5. Human health and environmental impacts

Lead exposure is detrimental to humans even at relatively low levels. Infants and young children are particularly susceptible because their growing bodies absorb more lead than adults and their neurodevelopmental systems are more sensitive to the damaging effects of lead. These adverse health effects of lead for human health have been detailed under the section B.5 of this report.

Moreover, infants and young children tend to be more exposed to lead as they often mouth objects that can contain lead or ingest dust or soil (Etchevers et al., 2015). The latter served as the basis for the preparation of the restriction proposal (KEMI, 2012) covering the consumer articles that can be mouthed by small children (paragraphs 6-10 of Annex XVII) (ECHA' guideline for lead in consumer articles, 2016). Children and adults may be exposed to lead by ingesting food or water containing lead, inhaling lead dust from lead-based paint or lead-contaminated soil, or from playing or working with items containing lead. Lead exposure during pregnancy is of particular concern because it can harm the developing baby.

Lead release to the environment is also of concern. As discussed in section B.3, lead compounds used as PVC stabilisers are toxic for aquatic organisms (classified by CLP Regulations as Aquatic Acute 1 and Aquatic Chronic 1). Under certain physico-chemical conditions changes to lead speciation can affect its solubility, bioavailability and/or toxicity.

Lead contamination is a global problem (see Figure E6). In a recent review, Clune et al. (2011) identified more than 50 human exposure hotspots worldwide with mean or median blood lead levels (BLL) ≥ 10 µg/dL measured in children (<18 years). Throughout Europe, the authors counted 23 well-documented cases of lead exposure in children with BLL ranging from 0.02 µg/dL to 42.5 µg/dL. As such exposure studies have mostly been carried out where heightened BLL are to be expected, it may be assumed that many more communities within Europe are affected by low-to-moderate levels of lead exposure.

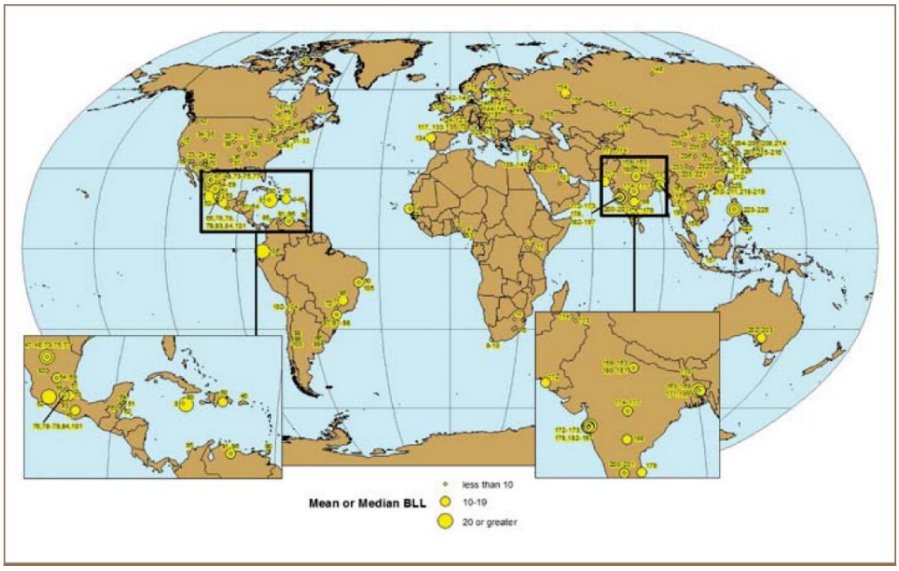


Figure E6. Global hot-spots of lead contamination (Clune et al., 2011)

At levels of lead exposure commonly observed in Europe today, the primary health concern is subtle impairment of neurodevelopment with small but measurable effects on cognitive and behavioural outcomes (Grosse et al. 2002). The best-established relationship between early-life lead exposure and neurologic deficits is reduced cognitive ability as measured with standardised IQ tests. Since cognitive ability affects school performance, educational attainment, and success in the labour market, even small reductions in IQ may have a significant population effect in terms of reduced lifetime earnings. This approach served as the basis for the monetisation of some lead health impacts (converting IQ losses to productivity loss) in the restriction proposal of lead in consumer articles (KEMI, 2012).

This diffuse population impact is at the centre of the current restriction proposal. Below, the relationship between lead exposure and lifetime earning losses is described and quantified in more detail. Other harmful impacts of lead exposure to human health and the environment are described only qualitatively because the causal relationship between lead exposure and these impacts is less certain and/or their costing is more controversial.

E.5.1. Human health impacts

Lead may affect almost every organ and system in the human body. As mentioned above, young children are particularly susceptible to the effects of lead and even low-level during childhood may result in a number of adverse health impacts (U.S. EPA 2013):

- Lower IQ and hyperactivity;

- Behaviour and learning problems;
- Impaired growth;
- Auditory and visual function impairment;
- Motor function impairment.

As lead is stored in bones along with calcium, it may accumulate in humans over time. During pregnancy, lead is released from bones as part of maternal calcium to help form the bones of the foetus. Lead may also cross the placenta l barrier exposing the foetus to lead, which may result in reduced growth of the foetus and premature birth. In non-pregnant adults, lead exposure may induce reproductive problems, decrease kidney function and cause cardiovascular diseases. Impacts related to acute lead exposure include dizziness, fatigue, irritability, nausea and, in more severe cases, paralysis, convulsions and cancer.

E.5.1.1. Beneficial impacts of the proposed restriction on neurotoxicity

For the purpose of this restriction proposal, neurodevelopmental population effects are of primary concern. The causal model of Grosse et al. (2002) is widely used to quantify and monetise such effects (see Figure E7). For example, versions of the model have been applied to assess changes in exposure to lead (e.g. Grosse et al., 2002; Dockins et al., 2002) and mercury (e.g. Rice et al., 2010; Rheinberger and Hammitt, 2012).

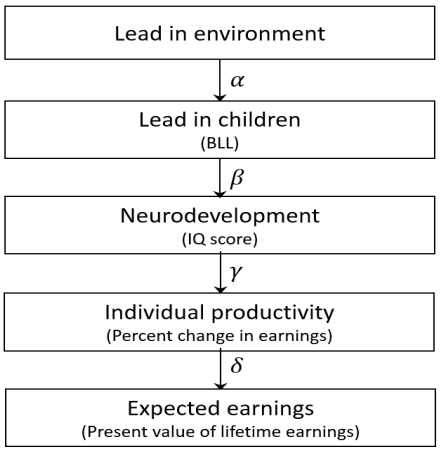


Figure E7. Causal model of lead exposure and economic productivity (Grosse et al., 2002).

The causal model depicted in Figure E7 is based on a set of parameters that allows exposure to lead in children to be converted into expected lifetime earning losses. Assuming non-zero background exposure, the dose-response relationship between a child's IQ response (ΔIQ) and lead exposure (ΔPb) is assumed to be linear with slope parameters α (environmental exposure to BLL parameter) and β (BLL to IQ parameter):

$$\Delta IQ = \beta \Delta BLL;\ \Delta BLL = \alpha \Delta Pb. \quad (1)$$

The effects of neurotoxicity are commonly valued by the present value of the change in lifetime earnings (ΔE) expected from a change in IQ (ΔPV_E).

The valuation model proposed by Rheinberger and Hammitt (2012) can then be used to estimate the present value per IQ-point lost as:

$$\Delta PV_E = \Delta IQ \int_{age\ 20}^{age\ 65} e^{-\delta\tau}\, \Delta E\, d\tau;\ \Delta E = \gamma E, \qquad (2)$$

where γ is the percentage change in lifetime earnings from a permanent one-point IQ change in a typical child and E denotes inflation-adjusted average annual earnings of an EU citizen, which are discounted at the discount rate δ over a typical work life of 45 years.

It remains to specify the conversion parameters $(\alpha, \beta, \gamma, \delta)$ of the model. Seeking consistency with earlier restrictions on lead in consumer articles and lead in jewellery, the values reported in Table E12. are used to populate the causal model of Figure E7. In the break-even analysis presented in E.8, the inverse of each conversion parameter is then used to convert the IQ-point equivalent of the compliance costs estimated in section E.4 into a burden of child lead exposure.

Table E12. Conversion parameters to populate the causal model by Grosse et al. (2002)

Symbol	Definition	Units	Central value	Variability	Source
α	Intake to BLL parameter	µg/dL BLL µg Pb ingested/kg BW/day	1.804	Alternative value of 1.597 corresponding to a 1-IQ point change per 1.22 µg Pb ingested/kg BW/day	Lead in consumer article restriction
β	BLL to IQ parameter	IQ points gained per µg/dL BLL reduction	1.948	Could go down to 0.6, see Budtz-Jorgensen et al. (2013)	Lead in consumer article restriction
γ	IQ to productivity parameter	Percent points per IQ point	See restriction on lead in consumer articles	Rates imply a range b/ 8 000 – 12 000 Euro per point.	See Lin et al. (2016)
δ	Discount rate	percent	4%	-	SEA restriction guidance

E.5.1.2. Other beneficial impacts of the proposed restriction

Although difficult to quantify, the proposed restriction on lead-based PVC stabilisers is likely to have positive health impacts on adults as well (as discussed in details in Annex B, section B.5) e.g. installers who trim raw PVC material when fitting window frames may no longer be exposed to lead; recyclers may less often come into contact with lead-containing PVC when scrapping old window frames or pipes; people living in the vicinity of landfills or incinerators may be less exposed to lead via the atmosphere, or via drinking water and food. While a detailed assessment of these health benefits is not feasible, it is noted that these benefits exist and that they might be substantial in individual cases.

E.5.2. Environmental impacts

As outlined in section B.9.3.1.1, releases of lead occur directly and indirectly to the atmosphere and water from numerous diverse sources, including:

- metal production and processing (steel, iron and lead),
- manufacturing industries,

- electricity / heat production,
- old (legacy) lead-based paint systems,
- use of lead ammunition,
- automotive applications (lead-acid batteries), including during recycling.
- Lead-water distribution systems (and fittings), and
- PVC articles (including water distribution systems).

Most of the lead released into the environment will remain near the source. However, a fraction of up to 20 percent might be widely dispersed (with the size of particles governing how far lead moves from the source). Studies show, for example, that measured lead levels in Greenland increased and reduced with the rise and decline of use of leaded petrol in North America and Eurasia over the past century (Rosman et al. 1993). The environmental fate of lead and its relationship with the human exposure is discussed in Annex B: (sections B.4 and B.9).

In the next sections, the effects of lead on soil, plants, micro-organism and larger animals will be briefly described and the primary benefit of the proposed restriction on lead-based PVC stabilisers will be outlined.

E.5.2.1. Detrimental effects of lead on terrestrial and aquatic ecosystems

Lead accumulates in the upper layers of the soil surface, particularly in soils with a high organic content. Organic matter in these upper layers retains lead in the soil where it will affect micro-organism and grazing food chains. The uneven distribution of lead in ecosystems might displace other metals from the binding sites on the organic matter (U.S. EPA 2013). Moreover, lead may hinder the chemical breakdown of inorganic soil fragments so that lead in the soil becomes soluble and can be taken up by plants.

Plants absorbing lead from the soil retain most of it in their roots, but some lead may also be stored in the plant foliage where it becomes available to grazing animals. At high atmospheric levels, lead suppresses plant growth and may kill the plant by reducing its rate of photosynthesis, inhibiting respiration, and causing pre-mature cell aging. Lead concentrations that correspond to those found in plants growing near to smelters or roadsides lead may even affect population genetics.

At greater concentrations (10 000 – 40 000 ppm dry weight), lead can eradicate populations of bacteria and fungi on leaf surfaces and in soil (U.S. EPA 2013). As many of these micro-organisms are an essential part of the food chain, this may have a significant impact on higher animals as well. In invertebrates, mammals and birds, lead affects the central nervous system and inhibits the synthesis of red blood cells. Plant-feeding animals are exposed to lead: i) directly through their intake of forage and feed contaminated by airborne lead, and ii) indirectly through feeding on plant roots. Predatory animals are exposed through feeding on prey that accumulates lead.

Hunting and fishing gear (lead ammunition and lead weights) can have a severe effect on individual organisms and are a particular concern in wetlands and other aquatic ecosystems. Observations on waterfowl suggest that three to 10 days after ingesting lead, it will be distributed throughout major organs eventually causing mortality (U.S. EPA 2013). Whilst birds

and fish primarily accumulate organic forms of lead, other aquatic organisms may also accumulate inorganic lead species through transfers of lead from water and sediments, increasing the bioavailability of lead in aquatic systems.

Lead is identified as a Priority Substance (PS) under the Water Framework Directive (WFD - 2000/60/EC)[82]. The annual average environmental quality standard (EQS) for lead in European freshwaters is currently 7.2 µg/L. A revised limit of 1.2 µg/L bioavailable lead in freshwaters was proposed in January 2012, as part of a wider package of revisions to WFD EQS.

E.5.2.2. Beneficial impacts of the proposed restriction

Whilst it is difficult to explicitly link releases of lead from PVC articles to any specific environmental benefit it is clear that because of extensive adverse effects of lead in the environment (outlined above and in section B of this report) reducing the overall burden of lead to the environment will be beneficial to wildlife and the functioning of ecosystems.

In particular, lead releases from point and diffuse urban sources to the aquatic environment has been linked to potential failure of WFD objections (section B.9.2.1.1). A reduction in the lead released from PVC articles (either during service life or after disposal) will contribute to achieving WFD objectives in urban water bodies.

E.6. Other impacts

E.6.1. Social impacts

E.6.1.1. General information

Under section E.3.2, the potential impacts (loss of jobs, closure of companies, price differences in PVC products) of not derogating the recycling of lead-containing PVC waste have been assessed and discussed. This section will therefore focus on other conceivable impacts to society caused by the general EU restriction of Pb-based stabilisers in PVC.

As indicated by Tauw IA (2013), and based on information from the stakeholders, it is considered that in case of a EU restriction on Pb-based stabilisers in PVC applications:

- Prices of PVC articles (i.e. consumer goods) are not or only marginally affected and the restriction is unlikely to have an impact on the overall number of articles sold or bought. In other words, the price elasticity of articles does not need to be assessed as changes therein are conjectured to be negligible;
- No major cost to consumers (or other entities of society) are expected since alternatives are already marketed at a competitive price. This conclusion was confirmed by ESPA in writing (November 2015), noting that producers rather than consumers would "absorb" the price differences associated with the switching from Pb-based to Ca-based stabilisers.

[82] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy [OJ L327 of 22.12.2000].

E.6.1.2. Information on potential impacts to various European actors

This section presents available information of the potential impacts on various relevant actors. The analysis is based on information provided by Tauw IA (2013) and by stakeholders in response to various ECHA consultations (see Annex G: Stakeholder consultations).

Impact on PVC convertors/recyclers

Producers of PVC products are commonly called convertors. A reduction of lead in PVC articles would not affect convertors who manufacture articles out of virgin PVC. However, convertors of articles that contain recycled PVC would be directly affected by the proposed restriction as they could no longer recycle use lead-containing PVC. These convertors would have no other option than switching to virgin (i.e. lead free) PVC, which has a higher price than recycled PVC. This would result in economic and social impacts as discussed in section E.3.2.1. Similarly, if lead were restricted in recovered PVC waste, this would constrain or prevent subsequent use of PVC recyclates in new articles and thereby reduce the market for recycled PVC in Europe. Overall, such a development would likely have a significant negative impact on the recycling industry (Tauw IA, 2013).

Stabiliser producers

As reported by Tauw IA (2013) and confirmed by ESPA (2016), since lead stabilisers have been phased out by the end of 2015 via the VinylPlus agreement, the EU stabiliser producers have already taken steps to gradually switch to other stabiliser systems. Therefore, a restriction of lead in PVC articles would have hardly an effect on EU stabiliser producers and processors. In addition, lead stabilisers might still be manufactured and exported to other jurisdictions. ESPA (2016) informed that there is currently only one European company producing lead stabilisers for export to non-EU countries.

Importers of PVC articles

Following the examination of Eurostat (2016) data (presented and analysed in section A.1.4), ECHA noted that imports of PVC articles used for building/construction applications from outside the EU (mainly from Asian countries) have steadily increased in volume over the last decade. For the purpose of this dossier, ECHA assumed, as detailed out in section F.1.2, that a significant share of imported PVC (20-60%) may contain lead, since until today no legislative restriction measures for lead in PVC have been imposed on producers outside the EU. Therefore, it is conceivable that some PVC importers may be affected by a potential EU restriction, since they would not be able any longer to import lead-stabilised PVC articles into the EU. Most probably, though, those effects would be only temporary because non-EU producers should be able to quickly switch to lead-free alternatives as well. This may require importers to modify contractual obligations with non-EU PVC suppliers (as discussed under testing costs), which could entail some additional administrative burden in particular on importing SMEs. During ECHA's call for comments (2016) no specific information or data were submitted that would enable a quantitative estimation of the potential cost to importers. Moreover, whilst ESPA (2016) stated that there might be impacts on importers, they also indicated that no specific information is available.

PVC exporters

The proposed restriction bans the placing of PVC articles containing lead stabilisers in PVC on the EU market. Therefore, the export of such articles is *not* affected by the restriction, as the

production processes are not specifically included in the scope of the proposed restriction. Furthermore, no significant impacts on exporters of PVC waste are expected due to the restriction of lead in PVC. Actually, if recycling would no longer be possible in the EU (in case no derogation was granted), exports of PVC waste might even increase (see section E.3.2).

Impacts on SMEs

The proposed restriction is expected to impact various actors within the PVC supply chain, the majority of which are SMEs. However, as indicated by ESPA (2015), the effect should be limited as suitable alternatives are already available. There is no evidence that a certain type of companies, e.g. SMEs, would be more affected than others except for the case that no derogation would be granted for PVC recycling. In this case, European SMEs in the recycling sector could be severely impacted by the proposed restriction.

Because of the restriction, importers, which are most commonly SMEs, will have to control the quality of imported PVC products also in relation to the content of lead compounds. However, since the necessary testing methods are well established and relatively cheap (see section E.4.2), testing is unlikely to cause a significant cost burden.

During ECHA's Call for evidence, technical and socioeconomic information was submitted by specific SMEs that asked for a potential exemption from the proposed restriction for their specialised (industrial/professional type) PVC applications (e.g. for PVC in vitro diagnostics or in silica separators in lead acid batteries). From these reactions, ECHA concludes that it may be possible that specific SMEs would be adversely impacted by the proposed restriction if no derogation would be granted for their specific applications (more details are provided in section E.3.1).

Economic impacts in terms of administrative burdens that affected companies, in particular SMEs, would meet because of the proposed restriction are mainly related to obtaining knowledge about the scope of the restriction and about the actions to be taken in order to comply with the restriction.

E.6.1.3. ECHA's general conclusion on social impacts

Based on the information provided during ECHA's consultations with stakeholders as well as in relevant studies and reports:

- There is no reason to assume any negative social impacts in terms of temporary unemployment or redeployment of staff or any other adjustment cost as a result of the restriction proposal; it is assumed that any negative impacts on employment in the supply chain are offset by positive impacts (e.g. employment gains) in other PVC sectors such that these impacts are distributional in nature;
- The proposed restriction is not expected to have any adverse impact on the free movement of goods, services, capital and workers inside the Union;
- There is no reason to assume that there will be any significant impacts on consumers or the general public within the EU in terms of changes in availability or quality or price of consumer products;
- Although the social impacts on third countries have not been assessed in this dossier, it seems reasonable to assume that the proposed restriction of lead in PVC will result in

positive net social impacts in third countries producing PVC articles of better quality that are safer for their citizens and their environment.

E.6.2. Wider economic impacts

Based on information from industry (ESPA, 2016), ECHA concludes that the proposed restriction would have marginal impacts (if any) on article prices. Therefore, international trade flows are likely to remain unchanged and no substantial wider economic impacts can be anticipated as result of the restriction. No wider impacts on the economic growth or development, changes to competition within the EU or direct impacts on the macro-economic stabilisation have been identified by ECHA for the case that the proposed restriction was implemented. In addition, there is no single member state, region, or sector that will be affected beyond measure by the proposed restriction.

E.6.3. Distributional impacts

The proposed restriction would potentially have a negative impact on some actors in the supply chain, including manufacturers, producers, and importers of lead-containing PVC articles. On the other hand, other actors in the supply chain, namely providers of alternative articles (e.g. providers of calcium-based stabiliser systems), would likely benefit.

Most of the affected actors are SMEs. Companies that are not already importing or using alternatives to lead-stabilised PVC products have to adapt their business model if a restriction is introduced. This will involve some negative impacts for these companies in the short run. During the preparation of this restriction proposal no information has indicated that this adaption of businesses would result in severe negative impacts on employment.

European citizens are most likely to benefit from the restriction proposal in terms of their reduced exposure to lead (which is likely to reduce the burden of neurotoxicity in children). Other actors that will benefit from the proposed restriction are companies that already have substituted lead in their PVC articles and especially those companies that have reliable information and data verifying that their articles are lead-free (e.g. companies that participated in the voluntary phase-out of Pb-based stabilisers).

No further information concerning distributional impacts on the market have been submitted that could occur if the proposed restriction was implemented. Based on the available information and data it could not be established that a specific sector or part of society or geographical area would be more affected by the proposed restriction than any other.

E.7. Practicality and monitorability

E.7.1. Implementability and manageability

As demonstrated in section E.2, the replacement of lead-based systems in PVC applications with alternative lead-free stabilisers seems to be economically and technically feasible. Consequently, actors involved in the supply chain marketing PVC articles should be able to comply with the proposed restriction simply by switching to lead-free stabilisers (e.g. calcium-based systems). With the exceptions mentioned below, the market actors consulted during the consultation process have not indicated any foreseeable difficulties in complying with the proposed restriction on lead in PVC. No major changes in production techniques, machinery, or training of staff are anticipated.

Altogether, the proposed restriction is easily understandable for all affected parties and access to the relevant information is relatively easy. Thus, the proposed restriction option is considered to be implementable and manageable for all parties affected.

E.7.2. Enforceability

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 limit value that can be subject to supervision mechanisms. To be implementable within a reasonable time frame, the appropriate analytical methods should be available and the restriction should also be designed so that an existing supervision mechanism exists and is practically workable for enforcement authorities. As discussed below, the proposed restriction has been structured to meet all of the above requirements.

E.7.2.1. Scope and transition period of the restriction

Clarifications on the scope of the restriction

The scope of the proposed restriction is clear and unambiguous and covers all the uses (consumer and professional) of lead compounds in PVC. As discussed under the Section E.1.1, the restriction covers the placing on the market of articles or parts thereof produced from polymers or copolymers of vinyl chloride (PVC) with concentrations of lead (expressed as metal) equal to or greater than 0.1% by weight of the PVC material.

Therefore, PVC articles manufactured in the EU and placed on the EU market and PVC articles imported into the EU are covered by this restriction. It should be noted, however, that since the proposal does not restrict the manufacturing of lead stabilisers, it does not impose any restriction to the exporting of PVC lead stabilisers outside the EU.

It should be also noted that:

- The proposed restriction—although mainly targeted at rigid PVC articles for building—covers all kind of PVC articles (either soft or rigid) for all kind of uses (consumer, professional and industrial applications);
- The scope is delineated by the proposed derogations, the justifications of which are given in Section E.3. All estimations presented in Annex E take these derogations already into account (cf. Section F.1 of Annex F);
- PVC consumer "mouthable" articles covered by paragraph 7 of entry 63 of Annex XVII to REACH, in particular, are excluded from the scope of the proposed restriction to prevent these from being overregulated. If a PVC article of the same type exists as both mouthable and non-mouthable types (e.g. garden hoses[83]), then non-mouthable types are covered by this proposed restriction.

Transition period of the restriction

EuPC (2016) informed ECHA that certain types of PVC articles, e.g. fittings for pipes, may remain in the convertors' stock for long periods before being sent to distributors and that stock depletion may take some years. EuPC is of the opinion that a total period of 4 years should be

[83] The scope of the restriction for lead containing mouthable consumer articles has been clarified via an ECHA guideline (2016), available under: https://echa.europa.eu/documents/10162/13563/lead_guideline_information_en.pdf

envisaged as a transition period for this restriction to allow the depletion of current stocks. ECHA clarified that since a derogation from the restriction (which links to the transition period) will be granted for 1st placing on the market, and stocks are not considered as placing on the market, a transition period in the range of what is commonly granted for restriction (1-2 years) would not be problematic for the depletion of the stocks.

Based on information that ECHA received during stakeholder consultations there are concerns that actors in the PVC supply chain may need some time to become fully informed about the restriction and make the necessary adaptions. This need may be more important for importers which will have to communicate the new restriction to their non-EU suppliers, which, in turn, will need a period of time for switching to lead-free alternatives. ECHA's Call for evidence yielded two comments from SMEs indicating that they will need approximately 2-5 years (from now) to substitute Pb-based stabilisers in their specific applications. The proposed restriction therefore foresees a transition period of 24 months to facilitate the dissemination of information throughout the PVC supply chain and thereby the full transition to lead-free PVC stabilisers in these remaining PVC applications.

E.7.2.2. Restriction limit

As indicated by Tauw IA (2013), lead compounds cannot stabilise PVC in a satisfactory way at concentrations below approximately 0. 5%. Therefore, the proposed limit (0.1% w/w) will ensure that lead compounds are not intentionally added to products (and thereby gradually eliminate the presence of lead in EU-manufactured and imported PVC articles) since concentrations below this limit will not achieve PVC stabilisation. As indicated above, it has to be noted that compliance with the restriction limit (0.1% w/w/) should be checked by determining the lead concentration of the PVC material/part of the corresponding article.

Currently, 0.1% w/w is the limit that triggers the notification requirement under article 7(2) of REACH and the information requirement under article 33 of REACH and has been used as a default restriction thresholds in many restrictions. This limit is assumed sufficient to cover the presence of potential impurities (due to accidental presence and unintentional use). However, as already discussed in section E.3.2.1 (derogation for PVC recycling), a higher restriction limit of 1% PB w/w has been proposed for articles produced from recycled PVC. The latter limit of 1% (w/w) has been proposed by Tauw IA (2013) and should ensure that any presence of legacy lead will not create problems of compliance with the restriction threshold. Therefore, PVC recycling will continue to take place as a waste management practice.

E.7.2.3. Analytical methods

According to KEMI (2012), numerous analytical standards exist for the determination of lead and other elements in raw materials such as metal alloys, rubber, paints and polymers. These methods include European standards, ISO methods, and corresponding ASTM standards (USA) etc.[84]

[84] Analytical reference to these standards and methods for determination of lead content is given in the Background Document for lead in consumer articles, (table 45) available under: https://echa.europa.eu/documents/10162/ab0baa9c-29f8-41e2-bcd9-42af796088d2

ECHA consulted industry on the availability of analytical methods for the determination of lead in PVC. ESPA (2016) informed that their members regularly assess the lead content of PVC articles in the framework of technical service/formulation development.

For the determination of lead content in various articles, the following analytical methods exist:

E.7.2.3.1. Wet chemical methods

These mainly concern Atomic Absorption Spectroscopy (AAS) and (ICP-MS) which are destructive methods and are used for a reliable determination of the full lead content. Both the actual determination methods and the methods for sample preparation (microwave digestion and dry ashing) are widely available and employed by virtually all commercial laboratories. There should be no need for further standardisation or method adaptation to enforce the restriction, which enables its immediate implementability.

Concerning the sample preparation, industry informed that a fragment of the PVC article is shredded and digested in strong oxidising mineral acids during up to a couple of hours to ensure quantitative extraction. The lead content of the resulting solution is then determined by ICP-AES or –AA. The quantification limit is low enough to assess lead contents well below 0.1%. Information on the cost aspects of the method is discussed in section E.4.

E.7.2.3.2 X-ray fluorescence (XRF) spectroscopy

XRF can be used to detect elements in the relevant matrices and is already applied for screening purposes by European enforcement agencies to enforce e.g. the RoHS directive and the Toy Safety directive. In the US, hand-held XRF guns appear to be used on a routine basis to scan for the presence of lead paints before renovation works etc. The cost of a gun seems to be around 20 - 30 US dollars.

The XRF method has several advantages:

- It is non-destructive, gives immediate answers, and also does not require sample preparation. This facilitates the enforcement process significantly and supports manufacturers' internal control of compliance.
- It is considerably cheaper than other methods and field-portable XRF instruments have already been purchased by several European enforcement agencies for the purpose of enforcing other regulations. This allows for a cheap and efficient in-house testing.

At the same time, though, the XRF method has the following technical drawbacks (KEMI, 2012):

- It does not allow for an analysis of the interior of the articles, but only the surface layer;
- It is not appropriate for use on soft and low-density materials as it requires a certain hardness and density;
- Its resolution can be questioned. Thus, in case an article has a lead content close to the restriction limit, a wet chemical analysis will be required to determine the compliance of the article.

For these reasons, the XRF method cannot completely replace wet chemical methods, but can be used as a means of screening (and hence reduce the number of destructive wet chemical

analyses). Actually, ESPA highlighted that for determination of lead in PVC, their members rely on wet chemistry which achieves the accuracy required for their purpose.

As an overall conclusion, testing of lead content is already carried out widely both by industry actors (for compliance) and by authorities (for enforcement). The methods are widely available, commonly used and provide a non-destructive, immediate-answer screening method. No modification of existing analytical methods is anticipated from this restriction option. It can therefore be implemented rather quickly. It can also be noted that the methods for lead content analysis can be used for the simultaneous enforcement of other restrictions in REACH, which makes enforcement cheaper and more efficient. These restrictions include the ones of lead and its compounds in jewellery/mouthable consumer articles (entry 63), and that of cadmium in various applications, including many plastic materials (entry 23).

Altogether, the combination of XRF and wet chemical methods and the opportunity to enforce various regulations simultaneously and thus decrease the incremental cost and workload of this specific restriction, makes a lead restriction based on content in PVC articles fully appropriate in terms of enforceability.

E.7.3. Monitorability

Monitoring may cover any means to follow up the effect of the proposed restriction in reducing the exposure. This may include the monitoring of blood lead levels in children to see if the exposure decreases following the restriction (KEMI, 202). However, the 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.

Another means to follow up this restriction option is 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. This means of monitoring is essentially identical to enforcement, but can also comprise:

- Actions undertaken by industry actors to comply with the proposed restrictions (or their voluntary schemes, e.g. VinylPlus); and
- Measurements carried out by independent test institutes, media, or green and consumer groups. Unlike the measurement of blood lead levels, this means of monitoring will be directly related to this restriction.

The monitoring of the proposed restriction will be therefore done through enforcement. No additional monitoring activities are envisaged. In addition to national reporting of enforcement success, notifications of any violation of the restrictions should be reported to the RAPEX system, which in that way would support monitoring of the implementation of the proposed restriction.

No additional costs for monitoring are anticipated.

E.8. Comparison of costs and benefits

E.8.1. Cost-effectiveness of the proposed restriction

The compliance costs used in the assessment of the cost-effectiveness of the proposed restriction include both substitution and enforcement costs (for details, see section E.4). The compliance costs for 2016 are estimated to be in the range of €0.9–3.3 million with a central value of €2.1 million. The interquartile range of compliance costs corresponding to the simulated market volumes of lead-containing PVC is €1.53–2.65 million (see **Error! Reference source not found.**). The central value of cost-effectiveness is 308 €/kg of Pb emissions avoided, with a range of 99 to 2 484 €/kg; the corresponding interquartile range is 258 to 356 €/kg (see Table E13.).

All calculations reported above and in Table E13 assume that compliance costs are fully passed onto EU consumers and therefore incorporate non-EU produced PVC sold to EU consumers via imports. However, it is possible that some of these costs are born by non-EU producers. In that case, the welfare cost to the EU of implementing the restriction would further reduce and its cost-effectiveness would become even more favourable. If one assumes, for example, that 50% of the costs are born by non-EU actors, then the central cost-effectiveness estimate drops from 308 €/kg to 165 €/kg (see Table E14).

Table E13. Cost-effectiveness for articles placed on the market in 2016, including imported articles.

	min	25th	**50th**	75th	max
Pb production (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*
NOTE: the emission factors used (Pb emissions divided by Pb production) vary across the scenarios. The scenario corresponding to the lowest Pb-based stabiliser production (min), applies also a low emission factor (lower emission factor scenario). The scenario corresponding to the highest Pb-based stabiliser production applies a high emission factor (highest emission factor scenario). This results in different cost-effectiveness values across the different scenarios.
Source: Data based on information exchange with ESPA (2015)

Table E14. Cost-effectiveness for articles placed on the market in 2016: change in the central cost-effectiveness estimate when different percentages of restriction-induced costs would be passed on to EU consumers.

% of import-related cost passed on to EU consumers	0%	50%	100%

Amount of Pb stabiliser to be substituted (tonnes/year)	3 308	3 308	3 308
Equivalent amount of Ca stabiliser needed (tonnes/year)	2 911	2 911	2 911
Substitution costs (€ million/year)	0.1	1.1	2.0
Pb emissions (tonnes/year)	6.8	6.8	6.8
Compliance costs* (€ million /year)	0.16	1.13	2.09
Cost effectiveness (€/kg emission avoided)**	**23**	**165**	**308**

** Compliance costs include substitution and enforcement costs*
*** Cost-effectiveness = Compliance costs / Pb emissions*
Source: Table E13

When looking at the data available, the cost-effectiveness of measures taken under REACH are of relevance. Even if it is not straightforward to establish benchmarks for an acceptable level of costs per tonne of emission avoided, the cost-effectiveness estimates can be used to support the assessment of proportionality. Especially the information on the cost-effectiveness of previous restrictions under the REACH Regulation is considered relevant here, as it indicates the level of costs that has been considered acceptable in the context of REACH. This does not exclude the possibility, however, that higher cost-effectiveness estimates could be considered proportionate. It can be concluded that the estimated cost-effectiveness of € 308/kg of Pb emission reduced is in the same order of magnitude, or lower than, as the cost-effectiveness of reducing emissions of other substances restricted under REACH (Table E15.).

Table E15. Comparison of the cost-effectiveness of the proposed restriction and previous restrictions under REACH.

Restrictions under REACH	**Central value**	**Range**	**Remarks**
Proposed restriction (€/kg of emission avoided)	308	99 – 2 484	
Mercury-in-measuring-devices (€/kg of Hg **used**)	4 100	0 – 19 200	If the calculations were done for Hg emitted, the value of the cost-effectiveness would be higher.
Phenylmercury compounds (€/kg of emission avoided)	649	n/a	
DecaBDE (€/kg of emission avoided)	464	30 – 756	
PFOA(€/kg of emission avoided) PFOA-related substances (€/kg of emission avoided)	<1 649 734	0 – 6 551 4 – 3 533	SEAC considered that the changes proposed to the scope improved the cost-effectiveness of the restriction.
D4D5 (€/kg of emission avoided)	400 - 430	<0 – 1 200	The central values were estimated for a compliance period of 2 and 5 years respectively.

Source: Table E13 and https://echa.europa.eu/previous-consultations-on-restriction-proposals

E.8.2. Cost-benefit considerations

It is well known that cost-effectiveness is not a welfare measure, as the socially optimal level of Pb emission reductions is unknown. Whilst it is difficult to reliably quantify the expected impacts on human health and the environment of the proposed restriction with the information at hand, it is possible to conduct a break-even analysis by inverting the causal model presented in Figure E7.

Starting point for doing so are the compliance cost obtained in section E.4. Any potential benefit of the restriction accruing to EU-based companies are ignored; instead the cost indicated by ESPA (2015) for switching from Pb-based to Ca-based stabilisers is taken forward. According to **Error! Reference source not found.** the compliance costs (switching plus enforcement costs) for the volumes of lead-stabilised PVC placed on the EU market in 2016 range from €0.9-3.3 million with a central estimate of €2.1 million. These cost estimates are conservative in that they presume the total additional production cost will be fully passed on to EU consumers.

Further assumptions need to be made on the social value per IQ point, which is taken to range from €8 000 (as in the restriction on lead in consumer articles) to €12 000 (Lin et al. 2016) in 2014 €. After inflation adjustment a meaningful central value of one IQ point gained through the proposed restriction is €10 000. Applying these assumptions, it is found that annually 209 IQ points need to be prevented from being lost due to Pb exposure in order to break even, assuming that imported volumes would remain on their 2015 level.

Consistent with the lead in consumer articles restriction, it is assumed that one IQ point corresponds to a BLL change of 1.948 µg/dL, which in turn corresponds to a daily lead intake of 1.08 µg/kg BW/day. (Sensitivity assessments on these values could be done but the re-analysis of the Lanphear dataset by Budtz-Jorgensen et al. (2013) suggests that one would not expect a higher dose to be required for observing a one point IQ change.)

The target population consists of children aged 6 years or younger. The average weight among this age group is assumed to be 15kg. Based on these assumptions, 209 IQ points can be reconverted into the total amount of Pb that needs to end up in humans to make the proposed restriction break even (note that no assumption is made about the total number of individuals who would benefit from the restriction):

$$1.08 \frac{\frac{\mu g}{kg\ BW}}{day} \text{per IQ point} * 365 \frac{day}{year} * 15 kg \text{ average BW} * 209 \text{ IQ points} = 1.24 \text{ g/year}$$

This quantity can then be compared to the lead emissions that correspond to the annual volumes of Pb-stabilised PVC placed on the EU market. For 2016, these were modelled in section B.9 to range from 4.3 to 10.3 tonnes with a central estimate of 6.8 tonnes. One may therefore conclude that for the central estimates the restriction breaks even if 1.24 g of the lead emitted per year would be ingested by humans. In other words, ~0.18 ppm of the total lead estimated to be released needs to accumulate in the target population per year to allow the proposed restriction to break even.

Appendix E

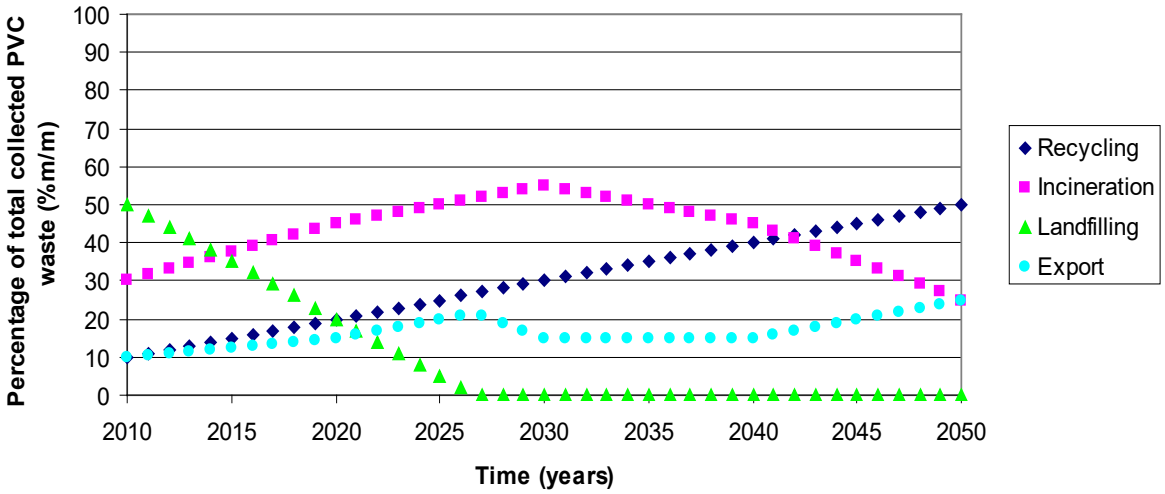


Figure E8. Prognosis for the relative contribution of different PVC waste management options over time (Tauw IA, 2013)

Table E16. Summary of data on landfill/incineration costs per tonne in the EU (ECVM/EuPC, 2016)[85]

Cost of waste practice (Euros /tonne, €/tonne)		**Source of data (+type of PVC waste applied)**
Cost of landfilling	Cost of incineration	
(A) 50 – 200	100-300	**VITO (2009) report** "Study on the cadmium content of recycled PVC waste" (*relevant to mainly rigid PVC waste*)
(B) 90-200	100	**RPA (2012).** "Socio-Economic Assessment of the Impact of Potential Restrictions on Four Phthalates on the Recycling of PVC Waste. (*relevant to mainly soft PVC waste*)
(C) 125	175	**RPA (2013).** Socio-economic study for the application for authorization of formulation and use or recycled PVC containing DEHP.
125	**150**	**Industry expert judgement** for a realistic average value (ECVM, 2016)

[85] ECHA contacted EuPC/ECVM (2016) for available data on the cost of landfill and incineration of PVC waste in the EU. Industry responded with recent data from various sources highlighting, in parallel, the variations from one country to another and the fact that the gate fee depends on the type of waste.

Annex F: Assumptions, uncertainties and sensitivity analysis

This Annex discusses the key assumptions and uncertainties used when developing this restriction proposal. These relate to the tonnage stabiliser used to produce articles in the EU as well as the tonnage of PVC articles containing lead imported into the EU. Uncertainties and assumptions are also inherent to the estimates of releases of lead from PVC articles during their service life and disposal as well as to the estimates of substitution costs, cost-effectiveness and human health benefits. Sensitivity analysis of these uncertainties, where performed, is described.

F.1. Estimates of lead release from PVC articles

F.1.1. Tonnage of lead stabiliser for PVC applications produced and used on the EU market in 2016

As already discussed under section A.2.3, ESPA has reported a range of 8000-12000 tonnes of lead stabilisers sold on the EU market during 2015 by ESPA Members for the various PVC applications. Industry also informed that a significant share of the lead compounds is used to stabilise PVC articles that are exported from the EU.

For the purpose of this assessment, a forecast for the tonnage of lead stabilisers used in the EU in 2016 was made, comprising an upper and lower bound, as follows:

- **Zero tonnes (lower bound)** reflects a completion of lead phase out via the successful implementation of VinylPlus targets by ESPA members (*This has been confirmed by ESPA, following the outcome of an audit by KPMG for the 1st half of 2016*);
- **632 tonnes (upper bound)** is the maximum estimate for the tonnage of lead stabilisers sold in the EU market in 2016 by companies that are not members of ESPA (and therefore do not necessarily participate in the VinylPlus scheme). This value is based on the maximum reported ESPA tonnage in 2015 (12 000 tonnes) and an assumption that approximately 5% European producers of lead based stabilisers, mainly SME companies, are not ESPA members (12 000 / 0.95 = 12 632).

Several further assumptions (AS) were applied to this tonnage range and are described below and summarised in Table F1.):

***AS-1**: Share of lead stabilisers for exported PVC items*

A value of 30% was used to estimate the tonnage of lead stabilisers produced in the EU that are used in PVC articles that are subsequently exported from EU (and thereby do not directly contribute to exposure in the EU during service life or waste disposal).

Therefore, the tonnage range was modified by a factor of 0.7 (CF1). This results in a refined tonnage range of approximately **0-442 tonnes (V2)** of lead stabilisers used in EU in 2016.

***AS-2**: Share of PVC articles covered by the proposed restriction*

The reported quantities of lead stabilisers in 2015 apply to all PVC uses in the EU 28, a few of which (e.g. packaging/electronic applications etc.) are outside of the scope of the proposed restriction). As discussed in section A.1.2, the current restriction proposal targets building/construction applications (which according to ECVM account for approximately 70-

80% of the total PVC uses). Therefore a factor 0.8 (CF3) was applied to V2 values from step AS-1, resulting in **0-354 tonnes (V3)** of lead stabilisers used in 2016 to stabilise PVC articles (produced and used in the EU 28) within the scope of the proposed restriction.

AS-3*: Conversion to metallic lead*

A further factor was used to convert the tonnage estimates for lead stabiliser to the tonnage of metallic lead. A factor of

0.8[86] (CF4) was applied to the V3 value estimated under AS-2 resulting in approximately **0-283 tonnes of lead (V5)** contained in PVC articles (manufactured and used in the EU 28) which are covered by the proposed restriction.

Table F1. List of assumptions/correction factors used to estimate lead contained in PVC articles (produced and placed on the EU market in 2016) which are targeted by the proposed restriction.

Value (V)	**Assumption (AS) / Correction factor (CF)**	**Corrected value**
(V1: 0-632 tonnes)	***AS-1:*** *Share of lead stabilisers for exported PVC items:* (V2 corrected by a CF2=0.7)	**V3: 0-442 tonnes** of lead compounds that stabilised PVC articles produced and used in EU in 2016
(V3:0-442 tonnes)	***AS-2:*** *Share of PVC articles covered by the proposed restriction.* (V3 corrected by a CF3=0.8)	**V4: 0-354** tonnes of lead compounds used in 2016 to stabilise PVC articles produced and used in the EU 28, covered by the proposed restriction
(V4: 0-354 tonnes)	***AS-3:*** *Conversion to metallic lead* (V4 corrected by a CF4: 0.8)	**V5: 0-283 tonnes of lead** contained in lead stabilised PVC articles (produced and used in the EU 28 in 2015)

[86] The conversion factor of 0.8 was estimated by relating the molecular weight of metallic lead to the average molecular weights of the most commonly used lead stabilisers (which are presented under section B.1 of this Annex.

F.1.2. Tonnes of lead emitted in the EU waste stream from imported PVC articles into the EU market in 2016

ECHA contacted Eurostat in May 2016 to request data on EU imports of the main PVC article categories of relevance for this restriction proposal.

Eurostat provided data for 2006-2015 on imports to the EU of the main types of articles considered in this restriction proposal (pipes, tubes, frames, fittings etc.). These articles are mainly produced from rigid PVC for building/construction related applications. The data comprised the total annual quantities imported *(expressed in thousand tonnes)* and the total annual value *(expressed in million euros)* and are presented in Table A2 and Table A3, respectively, of Annex A:.

For the purpose of this analysis (emission and cost estimates for the year 2016), the 2015 reported data was used under the assumption that these figures will not change significantly between consecutive years. However, given the apparent upward trend in PVC imports during the last decade, the 2016 values would be expected a bit marginally greater. Therefore 2016 estimates (substitution costs/lead emissions) may be considered as underestimations.

Eurostat data for PVC imports was focused on the main article categories targeted by the proposed restriction (articles for building construction applications as discussed under the section B.9.3). It must be noted, thought, there is some uncertainty on the reported total values (tonnes of imported PVC articles in the EU). This relates to the fact that a few of the analysed article types (e.g. rigid tubes, pipes, window frames) are reported as made of PVC, whereas others (e.g. fittings, shutters etc.) as made of plastic material (which could be PVC or other plastic material). This is clearly indicated below in

Table F2. where:

- Rows 1-3 concern items which are exclusively based on PVC articles,
- Rows 4-6 items that are based in plastics (which may include other plastic articles, in addition to PVC).

To account for this uncertainty, a sensitivity analysis was performed by establishing **"**lower" and "upper" PVC bounds considering that:

- by adding the annual tonnes of imported articles in rows 1-3, an estimation of the lower (LO) PVC bound is derived (under the assumption that all the items presented in rows 4-6 are produced by other than PVC plastic materials);
- by adding the annual tonnes of imported articles in rows 1-6 an estimation of upper (UP) PVC bound can be derived (under the assumption that all articles are based on PVC material).

Table F2. EU imports (annual quantities in thousand tonnes) for main PVC article categories for building/construction applications (Eurostat, 2016).

ARTICLE TYPE / YEAR	**2006**	**2008**	**2010**	**2012**	**2013**	**2014**	**2015**
1. Rigid tubes, pipes and hoses/**(PVC)**	7.9	9. 7	7.7	11.7	11.3	13.3	15.5
2. Doors, Windows and their frames/ **(PVC)**	22.5	30.8	31.5	37.4	41.9	67.8	67.3
3. Floor, wall and ceiling coverings (in rolls or tiles) /**(PVC)**	36.4	59.8	73.4	121.9	170.0	219.6	270.5
4. Fittings (joints, elbows, flanges, for tubes) /**(plastics)**	31.9	36.2	37.2	38.9	39.4	44.5	46.5
5. Shutters, blinds (incl. venetians and parts)/**(plastics)**	21.1	18.3	17.5	14.9	16.0	18.4	18.2
6. Fittings for furniture, coachwork etc./**(plastics)**	12.9	18.9	15.7	15.8	18.9	24.3	25.0
TOTAL (LO) PVC bound) *(1-3 rows)*	**66.7**	**100.0**	**112.6**	**170.1**	**223.1**	**300.6**	**352.4**
TOTAL (UP) PVC bound) *(1-6 rows)*	**132.5**	**173.5**	**182.9**	**240.5**	**297.4**	**378.8**	**442.1**

According to

Table F2, for 2015 a range of **352.4 (LO-PVC bound) -442.1 (UP-PVC bound)** thousand tonnes of PVC articles were imported in the EU within the categories targeted by the proposed restriction.

Further to these estimates of the tonnage of PVC articles, the following assumptions (AS) were made used to calculate the tonnage of lead in the imported PVC items (that could subsequently be released during service life or waste stage):

AS-1: A range of 20-60% of the PVC imports are stabilised by lead compounds (indicated as "lower (LO) Pb bound" and "upper (UP) Pb bound" respectively). In a recent contact with Industry, ESPA noted that lead compounds are still widely used outside the EU as PVC stabilisers, therefore this range seems realistic.

AS-2: The average lead concentration in the imported PVC articles is 1.5% (w/w). This is based on the information communicated by ESPA (May 2016) that the lead concentration in the remaining rigid PVC used (stabilised by lead compounds in the EU) is ~1.5-2%.

Based on the above-mentioned assumptions and sensitivity analysis, the lead tonnes contained in the selected PVC articles (imported into the EU in the years 2015/2016) were further estimated in the following

Table F3. Lead (tons) in the total quantity of selected PVC articles imported into the EU in 2015 *(analysis of Eurostat 2016 data)*

1. Estimation of tonnes of lead stabilised PVC imported in the EU in 2015/2016 *(based on AS-1: 20-60% lead stabilised PVC)*		
	LO-PVC bound (based on 352.4 tonnes of PVC)	**UP-PVC bound** (based on 442.1 tonnes of PVC)
LO-Pb bound (20% of Pb-PVC stabilised)	70 500	88 400
UP-Pb bound (60% of Pb-PVC stabilised)	211 400	265 300
2. Estimation of tonnes of lead in lead stabilised PVC imported into the EU in 2015/2016 *(based on AS-2, 1.5% lead as average content in PVC)*		
LO-Pb bound (20% of Pb-PVC stabilised)	1 057	1 330
UP-Pb bound (60% of Pb-PVC stabilised)	3 170	3 980

Therefore, lead was estimated to be present in the selected PVC articles (imported in the EU 28 in 2015) in a range between **1 057-3 980 tonnes**. *(By using the factor of 1/0.8, these tonnes of metallic lead can be converted to quantities of lead stabilisers in a range between 1321-5327 tonnes to be used for the substitution cost estimations)*

An overview of the above indicated results (estimates of lead present in PVC articles) is given in the following Table F4. and will offer the input for the lead emissions.

Table F3. Lead (tons) in PVC articles placed on the EU market in 2016 *(ECHA analysis)*

	Low Pb	*Upper Pb*
EU produced PVC	0	283
Imported PVC	1 057	3 980
Total	**1 057**	**4 263**

F.1.3. Lead releases from PVC during waste disposal and re-use

Release (to environmental compartments) and distribution (between fly ash, bottom ash and water treatment sludge after municipal incineration) factors were selected from those reported by Arche (2013), TNO (2011), ECHA Guidance and the OECD Emission Scenario Document for plastics additives (OECD, 2009).

Table F4. Lead emission factors used for this analysis

Source and compartment		Value[1] (dimensionless)	Reference
MW incineration	F_{air}	0.0003 - 0.0006	Lower bound = ECHA R.18 default of 0.03%; Upper bound = 0.06% factor from ARCHE 2013 (based on EU-27 measurements); TNO 2001 value of 0.02% - all values possibly underestimates as based on tonnage of total municipal waste, rather than PVC waste only, as discussed in TNO 2001.
	F_{water} (scrubber systems)	0.00007	From wet-cleaning facilities only; 0.007% factor from ARCHE 2013 (based on EU-27 measurements)
	F_{sludge}	0.006	0.6% factor from ARCHE 2013 (based on EU-27 measurements) - fraction subsequently disposed to hazardous landfill
HW landfill	F_{air}	0	ARCHE 2013: P.26 - emissions via air from landfill activities are deemed negligible, lead has a reported boiling point of 1 740 ^{o}C)
	F_{water} (fly ash and incineration sludge only)	0.0001 - 0.032	Lower bound = 0.0001 from OECD ESD service life emission for plastic additives used as heat stabilisers; upper bound = 3.2% ECHA R.18 default (p.99); 0.23%/yr used in TNO 2001 for fly ash (4.6% over 20 years)
	F_{soil}	0 – 0.0016	Lower bound = 0 from ARCHE 2013: P.27 - metals are not expected to pass through the landfill body; upper bound = 0.16% ECHA R.18 default (p.99)
MW landfill	F_{air}	0	ARCHE 2013: P.26 - emissions via air from landfill activities are deemed negligible, lead has a reported boiling point of 1 740^{o}C)

Source and compartment		Value[1] (dimensionless)	Reference
	F_{water}	0.00004 - 0.0001	Lower bound = 0.004% from ARCHE 2013 (based on EU-27 measurements of Pb conc in leachate and leachate volume modelling for 20 years); upper bound from ARCHE 2013 (based on EU-27 measurements of Pb conc in leachate and leachate volume modelling for 20 years); default service life emission factor from OECD ES is also 0.01%
	F_{soil}	0 - 0.0016	Lower bound = 0 from ARCHE 2013: P.27 - metals are not expected to pass through the landfill body; upper bound = 0.16% ECHA R.18 default (p.99)
RW (shredding / milling)	F_{air}	0.0002	[(0.1*0.015)*0.15 = 0.0002]; based on ECHA default release of dusts from plastic material of 0.1 during shredding/milling further corrected for average conc (1.5%) of lead in PVC article and effectiveness of RMMs (90% of dusts captured and 95% efficiency of filter = 85.5%) – outlined in Appendix R.18-7; section 7.4; Factor of 0.0015 proposed by ARCHE 2013 for shredding activity based on an ECHA default approach for metals - not plastics;
Article service life (degradation and abrasion)		0.0001	0.01% from OECD emission scenario document for plastics additives – heat stabilisers
Re-use in road construction (for incinerator bottom ash fraction) - consistent with ERC 10a		0.0001 - 0.0032	Lower bound = service life - solids (degradation and abrasion) - OECD emission scenario document; upper bound ECHA R.18 defaults for release to soil and water (2 x 0.0016)
Fraction of lead subject to municipal incineration incorporated in fly-ash		0.37	ARCHE 2013
Fraction of lead subject to municipal incineration incorporated in bottom ash		0.63	ARCHE 2013

Notes: MW – municipal waste; HW: hazardous waste; RW: recycled waste; 1: upper and lower bound range used in probabilistic assessment of releases reported in B.9.3.2.

The probabilistic release model described in section B.9.3.2 uses information on the percentage of PVC waste that is estimated to be disposed via different waste management options in the future.

Table F5. Estimated proportion of PVC waste disposed via different routes in between 2025 and 2065

Year of disposal	Recycling (%)	Incineration (%)	Landfill (%)	Probability of selection in simulation
2025	25	50	10	0.10
2026	26	49	10	0.12
2027	26	49	10	0.14
2028	27	48	10	0.16
2029	28	47	10	0.18
2030	29	47	9	0.20
2031	29	46	9	0.22
2032	30	46	9	0.24
2033	31	45	9	0.26
2034	32	44	9	0.28
2035	32	44	9	0.30
2036	33	43	9	0.32
2037	34	42	9	0.34
2038	35	42	8	0.36
2039	35	41	8	0.38
2040	36	41	8	0.40
2041	37	40	8	0.42
2042	38	39	8	0.44
2043	38	39	8	0.46
2044	39	38	8	0.48
2045	40	37	8	0.50

Year of disposal	Recycling (%)	Incineration (%)	Landfill (%)	Probability of selection in simulation
2046	41	37	7	0.52
2047	41	36	7	0.54
2048	42	36	7	0.56
2049	43	35	7	0.58
2050	44	34	7	0.60
2051	44	34	7	0.62
2052	45	33	7	0.64
2053	46	32	7	0.66
2054	47	32	6	0.68
2055	47	31	6	0.70
2056	48	31	6	0.72
2057	49	30	6	0.74
2058	50	29	6	0.76
2059	50	29	6	0.78
2060	51	28	6	0.80
2061	52	27	6	0.82
2062	53	27	5	0.84
2063	53	26	5	0.86
2064	54	26	5	0.88
2065	55	25	5	0.90

F.2. Costs and benefits

The assumptions, uncertainties and sensitivity analysis discussed under the section F.1 are also of relevance for the cost estimates derived for the purpose of this analysis. Therefore in the calculation of 2016 substitution costs the tonnes of lead PVC stabilisers placed on the EU market (as previously discussed) were used as main input parameters.

Overall, it can be said that the following key assumptions have a certain impact on the cost aspects & cost-effectiveness of the proposed restriction.

- Baseline assumptions regarding the forecast of future tonnages of lead stabilisers placed on the EU28 market in the absence of the proposed restriction.
- Testing costs, whose magnitude is highly uncertain (due to diverse industry practices), and are likely largely not attributable to the proposed restriction (due to existing practices to monitor the presence of lead in articles under regulatory obligation or voluntary policies)
- Substitution costs, to give an indication of the costs of the combined factors (restriction and public awareness). Furthermore, the following assumptions were considered for the estimation of costs:
  - approximately € 0.7 /kg price difference between calcium and lead stabiliser "packs" (calcium more expensive). ESPA (2106) clarified that this mainly reflects material costs, rather than redesign/research costs which have already been absorbed by associated companies during the last few years.
  - dosage ratio from lead to calcium stabilisers at approximately 0.88 (ESPA, 2015) to be used for estimating the tonnes of Calcium stabilisers required for the substitution of the lead stabilisers placed on the EU marker in 2016.

Since lead stabilisers have been fully substituted in the EU28 (by end of 2015) in all PVC applications in scope of this restriction proposal, the cost differential for their alternatives is likely also approaching zero. Therefore, it maybe that the lower bound cost scenario also overestimates the increase of material costs due to substitution and provides some buffer for minor costs such as R&D and testing costs which might occur in the short run.

The Annex XV report of this dossier, in Table 17, presents the main key assumptions that have certain impact on cost aspects of the proposed restriction and potentially to the cost/benefit (C/B) ratio.

Annex G: Stakeholder information

During the work for this dossier, ECHA have maintained an open and interactive dialogue with a broad circle of interested parties to ensure that different views were accounted for the assessment. Stakeholder contacts included Member States Competent Authorities, other EU institutions (EEA, JRC and associated Commission services), and industry actors at different levels of the supply chain/sector organisations.

Several methods have been used in the consultation; targeted telephone calls and emails to selected stakeholders, stakeholder meetings, and written consultation including targeted periods for specific consultation with stakeholders on certain issues. More information is presented below.

G.1. ECHA's Call for evidence

A Call for evidence was advertised on the ECHA website from 16/12/2015 to 15/02/2016 and focused on certain topics such as:

- Information on PVC articles containing lead as stabiliser which are used or imported into the EU (e.g. description and number of articles, lead concentration (w/w)).
- Size or potential for human exposure of lead associated with use of lead stabilisers in the PCV compounding and conversion to PVC articles as well as in the service life (or waste stage) of these PVC articles.
- Size or potential for environmental exposure associated with emissions of lead to air, water, and soil during the service life (or waste stage) of lead based PVC articles.
- Foreseen impacts (positive or negative) to various industry actors (manufacturers, distributors or importers) due to a potential restriction of lead in PVC applications. Focus was on any information/data on (i) potential substitution/testing/reformulation costs (ii) potential societal impacts (loss of employment, issues for SMEs?)
- Any uses of lead in PVC for which substitution may not be possible, thereby derogation may be needed.
- Any issues on the enforceability aspects of the potential restriction of lead in PVC applications (e.g. restriction limit/transition period/second had items).

The background note for the Call for evidence (http://echa.europa.eu/addressing-chemicals-of-concern/restriction/previous-calls-for-comments-and-evidence/-/substance-rev/7902/term) gives more information and lists the specific questions of technical and socioeconomic nature which were addressed to stakeholders. In addition, the complete questionnaire addressed by ECHA to stakeholders is presented in the Appendix G.

The Call for evidence yielded 7 comments (1 confidential) from Member States, companies, industry or trade associations. The respondents submitted helpful

information (including requests for derogations or transition periods) which was considered by ECHA in the various parts of this analysis. Follow-up email contacts with stakeholders were performed by ECHA to clarify on the requested exemptions as well on other issues essential for this assessment

G.2. Consultation with Associated Industry

G.2.1. Direct contact with stakeholders

Besides the Call for evidence, bilateral contacts have also been made, by email or phone calls, with companies and organisations that have knowledge in specific areas. A constructive interaction was established with the most relevant European associations (ESPA, EuPC, ECVM). This collaboration has proven to be crucial in clarifying certain technical issues (e.g. derogations) and collecting updated information which was subsequently used in various parts of this assessment.

Issues discussed included:

- Availability of lead-free alternative systems materials and experience from their use;
- Future market trends on uses and disposal of related PVC products
- Testing methods and costs
- Recent and ongoing studies (e.g. on PVC recycling, lead migration from PVC etc.)
- Impacts (technical and economic)
- Derogations from the proposed restriction

G.2.2. Participation in "targeted" meeting with stakeholders

In addition, ECHA has participated in the following meetings with Industry so as to carry out "targeted" discussion on specific topics of interest for this dossier:

(a) **ESPA meeting in (Antalya, Turkey, 16-18 November 2015).** At an early stage of the work for this dossier, ECHA attended the Conference of the European Stabilisers Producers Association-ESPA (November 2015, Antalya) and liaised with their experts for information on the availability of alternatives/technical and economic feasibility.

(b) **Information exchange meeting between IND associations, ECHA and Commission services (Brussels, 16/09/2016).** A meeting between ECHA/Commissions services and the key industry associations (ESPA, EuPC, ECVM-Vinyl) was hosted by DG GROW in order to exchange further information on a few remaining issues of importance for the preparation for this Annex XV report such as: (1) conditions of the restrictions (second hand market, transition period) (2) Updated results of FABES study on lead migration from PVC (3) reflection on PVC imports and requested derogations (with focus on PVC recycling).

G.3. Consultation with international organisations and non-EU Countries

To assist with the understanding of the impact of this work in non-EU countries, the Commission contacted WTO (World Trade Organisation) during mid December 2015 to mid-March 2016 with a specific questionnaire for their Members so as:

(i) to inform about a potential future restriction of lead compounds in PVC;

(ii) to gather information on future trends in their use, additional uses not yet identified, lead content in articles, information on risk or migration, information on alternatives,

(iii) to identify any existing legislation of lead in PCV articles outside the EU.

The consultation led to a number of helpful responses, mainly from Asia. Information included market trends on lead PVC stabilisers (Thailand); Lead risk assessment reports (Japan), information on lead and alternative PVC stabilisers and analytical standards (Philippines) etc.

G.4. Consultation with other EU services and institutions

ECHA has contacted experts of DG-ENV (on Water and Waste Framework Directives) as well as of the European Environmental Agency (EEA). Through email exchanges (and a teleconference) information and ideas were exchanged and data were submitted to ECHA (e.g. monitoring data from WFD implementation) that were mainly considered for the purposes of the exposure assessment (section B.9) of the Annex.

G.5. Consultation with Member State Competent Authorities

To assess the enforceability of the proposal, the draft Annex XVII entry was shared with the Finnish enforcement authority (Tukes). The advice received was mainly regarding the wording of the proposal and scope of the derogations. In addition, the German Authorities (BAuA) were consulted in Annex B of the report given their expertise in the preparation of the analysis of the most appropriate risk management option for lead compounds in PVC products (2012).

Appendix G: Question addressed to ECHA's Call for Evidence (16-12-15/15-12-16)/specific information requests

1. Do you have information on PVC articles containing Pb as stabiliser which are used or imported into the EU? The following are examples of relevant information: description of the article, concentration of Pb in the article (w/w), number of articles/volume of Pb in PVC articles manufactured or imported in the EU per year.

2. Do you have information on the size or potential for human exposure of Pb associated with (i) the use of lead stabilisers in the PCV compounding and conversion to PVC articles (ii) the service life (or waste stage) of PVC articles containing Pb as a stabiliser Any data on exposure from possible migration of these compounds through other sources or contamination such as dust would be also relevant.

3. Do you have information on the size or potential for environmental exposure associated with emissions of Pb to air, water (including sediment/wastewater) and soil during the service life (or waste stage) of PVC articles containing Pb as a stabiliser (volumes, emissions, treatment method etc.).

4. Are there any foreseen impacts (positive or negative) to your industry (as manufacturer, distributor or importer) due to a potential restriction of lead in PVC applications? More specifically:

   i. Any available qualitative and/or quantitative information/data on potential substitution/testing/reformulation costs?

   ii. Any potential societal impacts (loss of employment, issues for SMEs?)

   iii. Any uses of lead in PVC for which substitution may not be possible, thereby derogation may have to be requested?

5. Any issues on the enforceability aspects of a potential restriction of lead in PVC applications? (E.g. restriction limit/transition period/second had items-stocks?)

6. Any other info that would be relevant for the preparation of this Annex XV report?

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