EUROPEAN CHEMICALS AGENCY

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:

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PROPOSAL FOR A RESTRICTION

Summary

Based on the examination in the present report, the Dossier Submitter-ECHA concluded that the risk from lead compounds used as stabilisers in PVC articles is not adequately controlled. An analysis of possible risk management options (RMOs) including other REACH regulatory measures and other existing Union legislation concluded that a REACH restriction of lead compounds in PVC is the most appropriate risk reduction measure. Therefore, several restriction options were analysed to address the identified risk and to define the scope and conditions of the options. On the basis of a detailed analysis of the effectiveness, practicality and monitorability of the identified restriction options the following restriction is proposed:

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 and construction articles produced from recycled PVC (with a higher restriction limit of 1% w/w) and a 10-year derogation for PVC silica separators in lead acid batteries.

Table 1. 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 following article types containing recycled PVC for a period of 15 years from entry into force, if the concentration of lead (expressed as metal) does not exceed 1% by weight of the PVC material: - profiles and rigid sheets for building applications; - doors, windows, shutters, walls, blinds, fences, and roof gutters; - cable ducts; - fittings for tubes, furniture etc.; - pipes for non-drinking water, if the recycled PVC is used in a multilayer pipe and is entirely enclosed with a layer of virgin PVC in compliance with paragraph 1. Suppliers shall ensure before the first placing on the market of mixtures and articles containing recovered PVC that these are visibly, legibly and indelibly marked as follows: '*Contains recycled PVC' or with the following pictogram: (same as for entry 23..)*

	(b) PVC-silica separators in lead acid batteries for a period of 10 years. (c) Articles that can be placed in the mouth covered by paragraph 7 of Entry 63 of Annex XVII (d) Articles covered under existing legislation: - food contact materials covered by Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011 on plastic materials; - articles covered under Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive); - Directive 94/62/EC on packaging and packaging waste; - Directive 2009/48/EC on the safety of 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 proposed Annex XVII entry aims at restricting the placing on the market of articles in whose production lead compounds have been used as PVC stabilisers. These articles are most commonly produced of rigid PVC and are mainly used in building and construction relevant applications (making up 70-80% of PVC uses in the EU). Examples of such articles are window profiles, fittings, pipes and tubes, rolling shutters and gutters, wires and cables, roofing and flooring tiles.

Lead compounds cannot stabilise PVC in a satisfactory way at concentrations below approximately 0.5% (w/w) of the plastic material. Therefore, a restriction with the proposed concentration of 0.1% (w/w) would effectively end the intentional addition of lead-based stabilisers in the PVC compounding process. This would gradually eliminate the presence of lead in PVC articles manufactured or imported in the Union. A transitional period of 24 months after entry into force is proposed to allow use of existing stocks and to ensure that the information can be efficiently communicated within the relevant supply chains.

Following an assessment of ECHA's Call for comments (2016) and other available information, there appears to be a need to provide time limited derogations from the proposed restriction for:

(i) a higher lead restriction limit (of 1% w/w) in specific articles based on rigid and recycled PVC over 15 years, so as to allow recycling to continue serving as a viable waste management practice following the disposal of PVC articles;

(ii) PVC-silica separators in lead-acid batteries over 10 years, due to a lack of existing alternatives for this industrial application.

To be consistent with existing lead restrictions (Entry 63 of Annex XVII), derogations were provided for PVC articles already covered under specific Union legislation regulating lead as well as for the second hand market (i.e. the market for recycled PVC). The reasoning behind proposing these exemptions (along with information on technical/socioeconomic aspects) is elaborated in details in Section E.3 (restriction scenario) of Annex E to this report.

Summary of the justifications

Identified hazard and risk

Lead compounds are widely considered as a group of substances (the intrinsic properties of which are defined by the lead cation), which are hazardous for both human health and the environment. More specifically, all the lead compounds commonly used as PVC stabilisers have a harmonised CLP classification as:

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

(ii) environment: very toxic for the aquatic life (H 400 Aquatic Acute 1; H410 Aquatic Chronic).

It is well established that exposure to lead can result in severe neurobehavioral and neurodevelopmental effects, even at a low doses. Lead is considered a non-threshold neurotoxic substance associated with adverse impacts on the development of children's central nervous systems. In their scientific opinion, the CONTAM Panel of the European Food Safety Agency (EFSA 2010) concluded that there is no evidence for a threshold for a number of critical endpoints including developmental neurotoxicity and renal effects in adults. EFSA indicated that house dust and soil can be important sources of children's exposure to lead. They recommended that efforts should continue to reduce human exposure to lead from both dietary and non-dietary sources. One way of further reducing exposure to lead is the introduction of restrictions on the use of lead or lead compounds in applications, where there are suitable alternatives. The proposed restriction on the use of lead stabilisers in PVC targets one of the remaining consumer applications of lead.

In analogy to the approach used in REACH restrictions[1] for substances where it is not possible to establish a threshold (in line with Annex I of REACH, paragraph 6.5), a comprehensive exposure and risk characterisation of lead compounds used as PVC stabilisers has not been undertaken. Instead, releases of lead from PVC articles are used as a proxy for risk. To this end, the exposure assessment has focussed on estimating the amounts of lead released to the environment during the service and waste life-cycle stages of lead-stabilised PVC articles. Relevant direct (ingestion of dust) and indirect (consumption of food) exposure pathways for humans were then related to these releases. Because of the types of PVC articles covered (construction articles with a service life of 30-50 years), a key consideration of the exposure assessment is that, following disposal, releases of lead will occur until unknown time in the future. The use of lead compounds within a particular year will therefore not lead to immediate releases, but is associated with the potential for a particular quantity of lead release that will occur in the future.

Total lead emissions from PVC articles placed on the EU market in 2016 were estimated to be between 4.3 and 10.3 tonnes with a central estimate of 6.8 tonnes. Lead released during

[1] See e.g. the Annex XV restriction proposals for mercury, phenyl mercury, decaBDE, PFOA and related substances and D4/D5.

the disposal phase accounts for approximately 95% of emissions (the remainder being released during service life). Since the European PVC industry has already initiated the phase-out of lead compounds as PVC stabilisers, around 90% of the estimated lead emissions are attributable to PVC articles imported into the EU during 2016. Import data from Eurostat (2016) indicated that imports of relevant PVC articles have progressively increased (resulting in a 140% volume increase between 2010 and 2015) and are likely continuing to do so without a restriction in place. This highlights the need for Union-wide action to lower lead emissions to the European environment and to reduce human exposure to lead.

Based on the above, it is concluded that the identified risk to humans from lead stabilisers in PVC articles in the EU is not adequately controlled.

<u>Justification that action is required on a Union-wide basis</u>

The main reasons justifying that action is taken on a Union-wide basis are the following:

(i) A Union-wide restriction rather than dispersed national regulations of lead compounds in PVC articles would create a level-playing field for the PVC industry, while preventing market distortions resulting from different regulatory requirements. Importantly, an EU-wide restriction on placing on the market would not discriminate between PVC articles produced domestically and articles imported from third countries.

(ii) The remaining risk for humans exposed to lead via the environment resulting from placing lead-stabilised PVC articles onto the EU market is geographically not clearly delimited. Therefore, regulating the risk at Union level is likely to offer higher levels of protection of EU citizens than specific national legislations would do.

<u>Effectiveness and proportionality to the risk</u>

The proposed restriction is targeted at PVC articles produced using lead-based stabilisers that cause risks to human health, by contributing to overall lead exposure via various exposure pathways. The principal conceptual pathways for indirect exposure of humans to lead from PVC sources are outlined in Section 1.1.6 of this Annex XV report.

More specifically, the proposed restriction is expected:

- to strengthen the effectiveness of an existing voluntary action by the European PVC industry (the so-called Vinyl Plus agreement), aiming at a complete phase-out of lead-based PVC stabilisers in the EU.
- to further reduce human exposure to lead from PVC articles that are imported from non-EU countries. Imports of the main categories of articles covered by the proposed restriction (e.g. window frames, tubes, pipes, shutters, fittings etc.) have steadily decreased (Eurostat, 2016). Importantly, the majority of imports (~75-80%) originate from Asia where lead content in PVC articles is not regulated.

Therefore, this restriction proposal is making the voluntary agreement to phase out lead-based PVC stabilisers in the EU legally binding and furthermore prevents from lead stabilised PVC imports to enter the EU market

The proposed restriction will cost-effectively reduce human exposure to lead in the EU. The reduction in lead emissions to the environment was used as a proxy for the risk reduction capacity of the restriction. On the cost side, the cost of switching to an alternative as well as the enforcement costs of the restriction were considered.

Alternatives to lead stabilisers for the various PVC uses are already available and placed on the EU market. Notably, calcium-based stabiliser systems have been considered by industry to be the preferred and logical replacement of lead-based stabilisers. Overall, calcium-based stabilisers provide a technically and economically feasible alternative and considered to be safe for human health and the environment. Information provided by industry suggests that in some applications they may even offer better technical performance than lead-based systems. Price increases are marginal and since investments have been already made during the implementation of Vinyl Plus Agreement they will not affect the competitiveness of European PVC manufacturers.

As additional production costs are low and technical properties seem to be favourable, it is ECHA's expectation that the EU PVC industry would fully transition to calcium-based systems should the proposed restriction be adopted.

Based on a simulation of the total volume of lead-containing PVC articles placed on the EU market in 2016, the net compliance costs of the proposed restriction have been estimated to be in the range of €0.9 to 3.3 million per year with a central value of €2.1 million. The R&D costs for transitioning to the alternative as well the testing costs are anticipated to be insignificant and affordable for the EU PVC industry. A default value of €60 000 per year has been assumed for enforcing the restriction. This cost might even be an overestimate as the MS Competent Authorities have already set up the relevant infrastructures (sampling/testing methods) for the previous lead restriction provisions of Entry 63 of Annex XVII to REACH.

In conclusion, it is assumed that the total economic impact in 2020 (indicative year for the proposed restriction to enter into force) should be substantially lower than in 2016, but no quantitative assessment on the development of compliance costs was undertaken. In addition, no significant social impacts (e.g. loss of employment, or impact on consumers) are anticipated from the implementation of the proposed restriction.

The cost-effectiveness is estimated to be between € 100 and € 2 500 per kg of lead emissions avoided with a central cost-effectiveness estimate of roughly € 300 per kg of lead emissions avoided. With that, the cost-effectiveness of the proposed restriction for lead in PVC is in the same order of magnitude as previous restrictions under REACH.

As cost-effectiveness is not a welfare economic measure, an additional break-even analysis was performed based on the causal lead impairment model presented and discussed in Section E.5 of Annnex E. The break-even analysis suggested that the restriction breaks even if 1.24 g or more of the lead emitted per year would be ingested by humans.

Based on the cost-effectiveness and the break-even analysis, the proposed restriction is considered to be proportionate in reducing the identified risk.

The proposed restriction is implementable (technical feasible alternatives exist and a sufficiently long transition period for the supply chain is proposed), enforceable (appropriate analytical methods are available and the scope and the proposed derogations are clear) and manageable (the administrative burden for actors involved will be low with the proposed restriction making the existing voluntary agreement to phase out lead compounds in PVC

legally binding). Monitorability is ensured for both imported PVC based articles (via custom authorities' control and RAPEX system notifications) and EU produced articles (via projects of enforcement authorities and audit activities).
Thus, the proposed restriction is considered to be practical.

Stakeholder Consultations

In the preparation of this Annex XV restriction report, ECHA considered the outcome of various consultations (ECHA's Call for Comments/WTO notification in early 2016). MS competent Authorities were consulted on certain issues (enforceability/occupational exposure) and experts in water/waste policies (DG ENV/EEA) were consulted. In addition, information exchange meetings with key European industry stakeholders were held during the process (Analytical information is presented in Annex G).

1. The problem identified

1.1. The hazard, exposure/emissions and risk

1.1.1. Identity of the substances and physical and chemical properties

This restriction proposal concerns lead compounds used as PVC stabilisers in a variety of applications (window profiles, cable insulation, pipes and flooring etc.). The stabilisers allow the PVC to endure longer fabrication (heating) time and protect against photo-degradation, thereby prolonging the service life. The restriction mainly addresses effects to humans exposed via the environment. As detailed in Annex A, lead compounds have been historically used as PVC stabilisers; Table 2 lists the REACH registered lead compounds.

Table 2. List of registered (via REACH) lead compounds with a use as PVC stabiliser

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

The main physicochemical properties of the lead compounds used as PVC stabilisers have been extracted from the REACH Registration dossiers. An overview of the most commonly used lead stabilisers is given in Section B.1 of Annex B; no physicochemical properties are critical for the health effects of interest for this analysis.

1.1.2. Justification for targeting

Further to the nine lead compounds, already registered as PVC stabilisers in the EU, this restriction proposal targets all lead compounds. Such a group approach is deemed as essential as it is possible that additional lead compounds have the potential to be used as PVC stabilisers, especially in imported PVC articles. This grouping is also justified by the fact that there are not yet methods available to analyse all the specific (organic/inorganic) lead compounds in the relevant articles but only methods to determine lead.

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

The hazard profile of lead compounds, for both human health and the environment, depends on the intrinsic properties of their lead ions. An overview of the harmonised classifications of lead compounds, according to Annex VI of the CLP Regulation[2], is given below in Table 3 and is further discussed under section B.3 of Annex B.

Table 3. Harmonised classification and labelling of lead compounds according to Regulation 1272/2008

Hazard class and category codes	Hazard statement
Reprotoxic 1A, H360-Df	May damage the unborn child. Suspected of damaging fertility.
Aquatic Acute 1, H400	Very toxic to aquatic life.
Aquatic Chronic 1, H410	Vvery toxic to aquatic life with long lasting effects.
Toxic for organs, H373	May cause damage to central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion.

1.1.4. Human Health Hazard assessment

This report will focus on the human health effects of lead compounds. More specifically the exposure pathway under consideration concerns humans exposed to lead via the environment. This occurs mainly during the disposal phase of PVC articles (which is further elaborated in details in section 1.1.6 of this report).

1.1.4.1. Toxicokinetics

As discussed in section B.5.1 of Annex B, lead is most easily taken up into the body through inhalation or ingestion, whereas dermal uptake makes a negligible contribution to systemic lead levels (KEMI, 2012). 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. Of importance for this assessment, is that lead can become systemically available through soil, dust and hand-to-mouth behaviour is a possible route of exposure for both children and adults (Klein and Weilandics 1996) that come in contact with lead containing PVC articles, in particular in the interior of house (e.g. PVC flooring).

1.1.4.2. Neurotoxicity and neurodevelopmental effects

Of particular importance for the hazard assessment of the proposed restriction is the CLP classification of lead compounds as toxic to organs through prolonged or repeated exposure (H373). EFSA (2013), supported by RAC (2014), concluded that based on available human data, the most critical effects in relation to small increases in blood lead (PbB) levels are developmental neurotoxicity; effects on blood pressure, and chronic kidney disease. The

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

lead level in blood is often the best reflection of the lead exposure status of the individuals. (EPA-Denmark, 2014).

The focus of the hazard assessment in this report is on the non-threshold neurotoxic/neurodevelopmental effects of lead compounds related to children, which were the basis for the lead restrictions in Jewellery and in consumer articles that can be mouthed by children (Entry 63 of Annex XVII to REACH).

Children are identified as a vulnerable population regarding lead exposure. Following its absorption during pregnancy, lead is easily transferred to the foetus via the placenta (Carbone et al. 1998). The nervous system is the main target organ for lead toxicity and the developing foetus, and young children are the most vulnerable to lead induced neurotoxicity. High levels of lead exposure can have serious effects on the intellectual and behavioural development of individual young children.

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). JECFA (2010)[3] 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. 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.

In line with EFSA, ECHA's Risk Assessment Committee (RAC) while assessing the French proposal for restriction of lead in jewellery (RAC 2011)[4] 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. Despite some concerns with these calculations expressed by industry in the CSRs for lead compounds (2015), as discussed in section B.5.6.4 of Annex B, the observation that lead is non threshold and that current blood lead levels need to be lowered is not disputed. That was also the conclusion, of RAC, following the assessment of Sweden's proposed restriction for lead in consumer articles. With their recent scientific opinion (RAC 2014)[5], RAC highlighted that *neurotoxicity, specifically neurobehavioral and neurodevelopmental effects from repeated lead exposure are the key effects that this restriction is aimed at protecting against*.

In the frame of this assessment, ECHA has reviewed various recent studies suggesting effects additional to IQ losses, such as hyperactivity or attention deficit disorder (Kim et al.,2012; Apostolou et al., 2012) academic performance (Amato et al., 2012) or even linkages to autism (El-Ansary et al., 2011). A more analytical list of studies supporting

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

4 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

5 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)

linkages of lead exposure to these effects (or even contradicting to these findings) is discussed under the section B.5.6 of Annex B.

In general, although the mechanism(s) of neurotoxicity in children still need to be elucidated, studies of experimental animals suggest that lead can alter developmental and maturation processes that are important to cognitive function.

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.*

1.1.4.3. Other human health toxicity effects

Section B.5.1 of the Annex B presents an overview of the available literature on the various toxicity effects of lead compounds such acute toxicity, repeated dose toxicity and reproductive toxicity. Table 4 lists the most critical reported exposure values along with their sources for these (other than neurotoxicity) lead toxicity effects.

Table 4. ECHA compilation of information on lead exposure levels for various toxicity effects

Toxicity effect	Critical lead exposure levels
Repeated dose toxicity	**Haematological effects** *EFSA (2010):* Decreased haemoglobin production can be observed at blood Pb levels above 400 µg/L in children. Impacts on haemoglobin production sufficient to cause anaemia are associated with blood Pb levels of > 700 µg/L.
	Effect on blood pressure and cardiovascular effects *EFSA (2010):* data from 5 human studies concluded that blood led level of 36 µg Pb/L was associated to a 1% increase in systolic blood pressure. This corresponds to a daily lead exposure of 1.50 µg Pb/kg bw per day. *CSRs on lead compounds (2015):* weak positive association between blood Pb and blood pressure in general population with average blood Pb levels below 45 µg/dL.
	Kidney effects *EFSA (2010):* based on human data a blood Pb level of 15 µg Pb/L to be associated with a 10% increase of chronic kidney disease in the population. 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. *CSRs on the lead compounds (2015)*: NOAEL of 60 µg/dL, combined with >5 years of lead exposure for renal effects.
	Neurotoxicity/neurodevelopmental effects *(previously discussed)*
Acute toxicity	*TNO (2005):* Symptoms of acute Pb poisoning (e.g. headaches, diarrhoea, memory loss, altered mental state

	etc.) can occur at PbB levels of 800–1000 µg/L in children (USA): LOAEL value of 600–1000 µg/L related to colic in children as a result of Pb poisoning. *(ATSDR 2007):* OAEL of 800 µg/L and a NOAEL of 400 µg/L identified for acute effects in children.
Reproductive toxicity	**Male fertility** *Bonde et al. (2002):* cross sectional study of 503 men (occupational/ UK, Italy and Belgium) indicated a threshold for an effect upon semen quality at 45 µg/dL of concurrent PbB. As blood Pb levels increase above 50 µg/dL, a progressively greater impact on fertility can be expected. **Female fertility** Effects on female reproduction in animal studies are usually not apparent at the blood lead levels that impair male fertility; >> 50 µg/dL blood lead levels are generally needed to see an adverse effect on the fertility of females. In addition, human data are inconsistent and cannot be estimated with precision.

1.1.4.4. Conclusions on human health hazard effects

- All the lead compounds used as PVC stabilisers have a well-established hazard profile with toxic effects for both human health and environment as demonstrated by their most critical CLP harmonised classifications (for human health: Repr. 1A, H360Df, H373; for the aquatic environment H400).

- 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.

Therefore, this report does not present a quantitative hazard assessment but provides an overview of the various toxic effects for human health with focus on neurotoxic/neurodevelopmental effects on children. This non-threshold neurotoxic effect accounting for IQ deficits (that also served as the main health end point in recent REACH restrictions for lead in jewellery and consumer articles) offered the basis for lead subsequent exposure assessment and qualitative risk characterisation undertaken in the frame of this report.

1.1.5. Environmental hazard assessment

Lead compounds used as PVC stabilisers are all classified under the CLP Regulation for acute and chronic hazards to the aquatic environment. More specifically, they have the following harmonised classifications: 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).

Lead is present in the environment due to natural processes resulting in a background concentration of lead in all environmental compartments, including biota (LDAI, 2008). Information on the environmental fate and behaviour of lead is mainly based on monitoring data in water, soil, sediment, suspended matter and biota. Section B.4 of Annex B provides an overview of the environmental fate information for lead as described in the CSRs of registered lead compounds and in various risk assessment reports.

Due to the well-established hazard properties of lead, the release of PVC stabilisers into water compartments could also lead to a risk for aquatic organisms. In the LDAI (2008) risk assessment report, Predicted No Effect Concentrations (PNECs) have been derived for the following environmental compartments: water, sediment, soil as well as for sewage treatment plants. However, no further analysis of environmental risks has been undertaken in this Annex XV report since the focus of the assessment are the risks to human health, particularly through indirect exposure via the environment (including diet).

1.1.6. Exposure assessment

1.1.6.1. Indirect exposure of humans via the environment

1.1.6.1.1. Sources and releases of lead to the environment

Whilst it is acknowledged that human and environmental exposure to lead has decreased significantly over the last 20 to 30 years, exposure to the general population still exceeds the highest tolerable level with respect to the neurodevelopmental effects (KEMI, 2012). Releases of lead occur directly and indirectly to the atmosphere and water from numerous and 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).

Urban runoff and atmospheric deposition (via releases to air) are considered to be significant indirect sources of lead found in the aquatic environment. However, direct releases to aquatic environments are considered to be relatively small compared to the releases to soil via the atmosphere or the disposal of sewage sludge (EFSA, 2013).

PVC articles contribute to overall releases of lead to the atmosphere and water during both their service life (via degradation, abrasion and diffusion processes) and after disposal as waste (see 1.1.6.1.2).

In relation to the service life, 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. Overall, though, there is extensive data indicating that releases of lead do occur and will contribute to overall release of lead to the environment (and directly to humans via drinking water[6]). Dust in homes can contain lead from lead painted surfaces. 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 (ECHA 2014) during the assessment of the lead in consumer articles dossier. Some exposure from the degradation and abrasion of PVC profiles/frames and PVC based flooring is also expected, although there is no specific information available in the literature on the contribution to overall lead in dust from these articles. The OECD emission scenario document for plastics additives reports a release factor for the service life of plastic articles of 0.01%.

The disposal and treatment of PVC waste will lead to releases of lead to the environment (ARCHE, 2013; TNO, 2001). PVC articles disposed in landfill are considered to be relatively stable with limited potential for lead to be released 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[7] from municipal waste incinerators. Incinerator fly ash (also described as 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 from PVC that could be released to the environment. Stabilisation of fly-ash (e.g. with cement) prior to disposal in hazardous waste landfill can be successful in reducing the leading potential of lead (and other heavy metals). However, acceptance criteria for hazardous waste landfill allow wastes that have the potential for leaching (albeit at relatively low concentrations) to be disposed, implying that lead cannot be considered to be completely contained (over long time horizons) within stabilised hazardous waste.

These sources, amongst others (such as recycling of PVC articles and the re-use of incinerator bottom ash), are described quantitatively in the section B.9.3.2 of the Annex[8].

1.1.6.1.2. Pathways of human exposure to lead via the environment (lead in soil/food and drinking water/indoor environment)

In general, direct exposure of humans from the use of lead in PVC is not expected to be significant i.e. exposure of the general population through mouthing or via direct and prolonged contact with skin. However, certain types of articles 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). Ingestion of contaminated soil, dust and old lead-based paint as a result of hand-to-mouth activities are acknowledged to be an important source of lead intake in infants and young children (EFSA, 2010).

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6 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.

7 Where scrubbing water is treated in a wastewater treatment facility before release to the aquatic environment

8 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.

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). Therefore, human exposure to lead from PVC is considered to occur predominantly via the environment (including indoor environment) and diet (food and drinking water). Relevant pathways for human exposure include drinking water and food, indoor / outdoor air (including swallowing household dust or dirt containing lead) and soil.

An overview of the conceptual pathways by which lead from PVC articles can result in human exposure during service life and end of life are provided in Figure 1 and Figure 2 respectively.

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 to some extent 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)

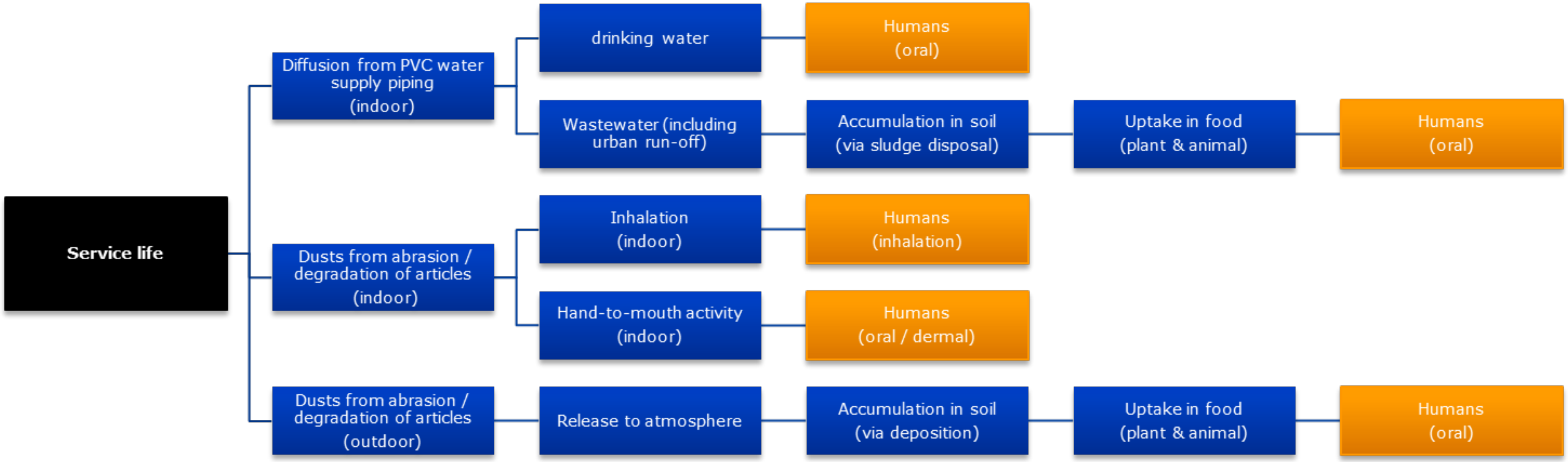

Figure 1. Conceptual exposure pathways for humans relevant to the service life of PVC articles

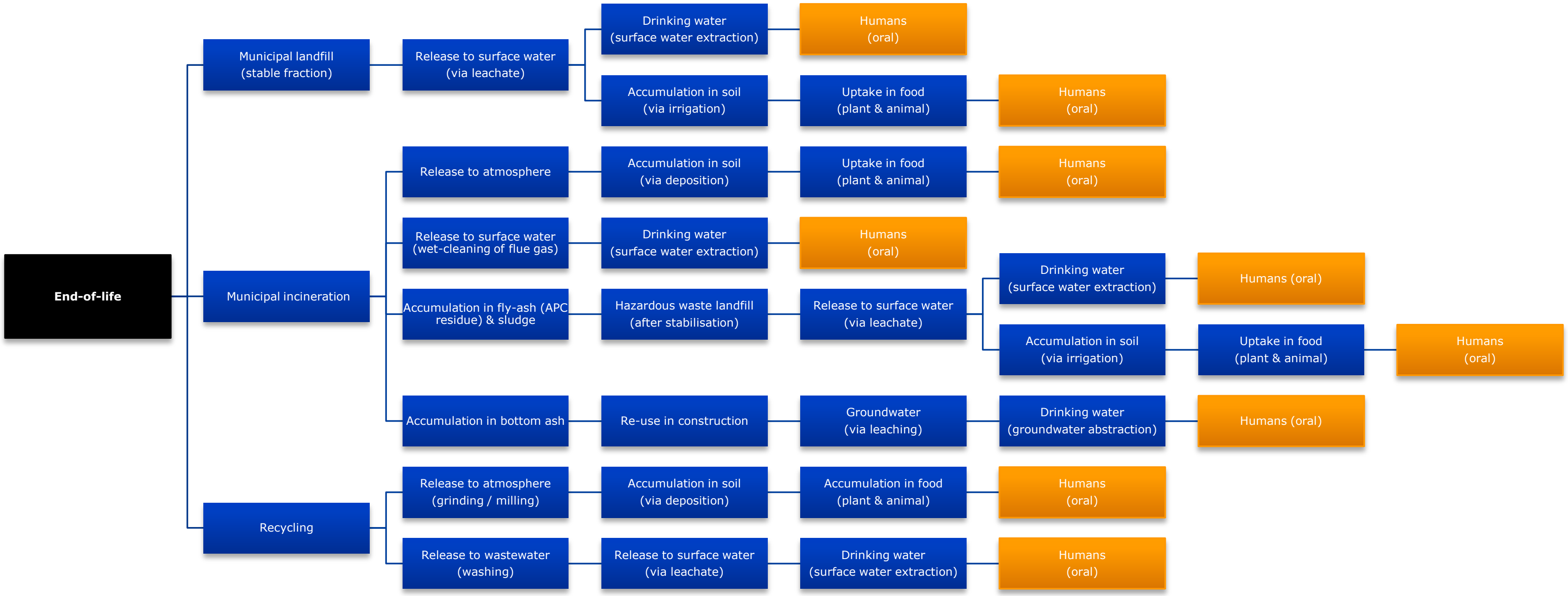

Figure 2. Conceptual exposure pathways for humans relevant to the end of life of PVC articles

1.1.6.2. Estimated releases of lead from PVC articles

As discussed in section B.9.3. of Annex B, this restriction proposal is based on the reduction of releases of lead to the environment during the service and waste life-cycle stages of PVC articles produced with lead-based stabilisers.

The aim of the assessment was 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. Estimates of lead releases are based on the assumption that all PVC articles produced using lead-based stabiliser will be subject to some form of disposal (e.g. recycling, landfill, incineration) at the end of their service life. Considering the extended service life of the PVC articles within the scope of this restriction proposal (which could exceed 50 years), a key consideration of the exposure assessment was that releases of lead are likely to occur at an unspecified time in the future, potentially more than 50 years after entering service. Thus, the 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 of. 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 model used for estimating releases is outlined in Figure 3. The model estimates releases from the service life and waste-life-cycle based on tonnage data (from industry) and release factors selected from the literature, ECHA guidance or empirically derived from measurement data.

As there are relatively large uncertainties in the input parameters for the model (e.g. the release factors to environment compartments, tonnage of lead stabiliser used, proportion of waste disposed via different routes in the future). Therefore, a probabilistic modelling approach (using Monte Carlo simulation) was adopted (a) to integrate the variability apparent in the input parameters and (b) to estimate the most likely releases from within the theoretical minimum and maximum extremes of the model. For example, the release factor to water from municipal landfill was reported to vary, dependent on the source of the factor, from 0.0001 to 0.032.

Lower and upper bound release factors for the exposure estimates were selected from ECHA R.18 guidance, a technical report (TNO 2001) and REACH registration dossiers (Arche, 2013). Upper and lower bound release factors are elaborated in Annex F. The model was re-run 100,000 times with different values for the input parameters selected from within the lower and upper bound ranges on each occasion. Estimates of releases are reported as the interquartile range of estimates and the median estimate. Theoretical minimum and maximum values are also reported in section B.9.3 of Annex B.

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 was selected from between 2025 to 2065, which corresponds to a proportion of PVC waste disposed in landfill, and going to incineration and recycling (based on industry predictions). The model was weighted such that a year of disposal is 10 times more likely to be from the later part of the range, than the earlier part, recognising that PVC articles have a relatively long service life and are therefore more likely to be disposed in 50 years, than in 10.

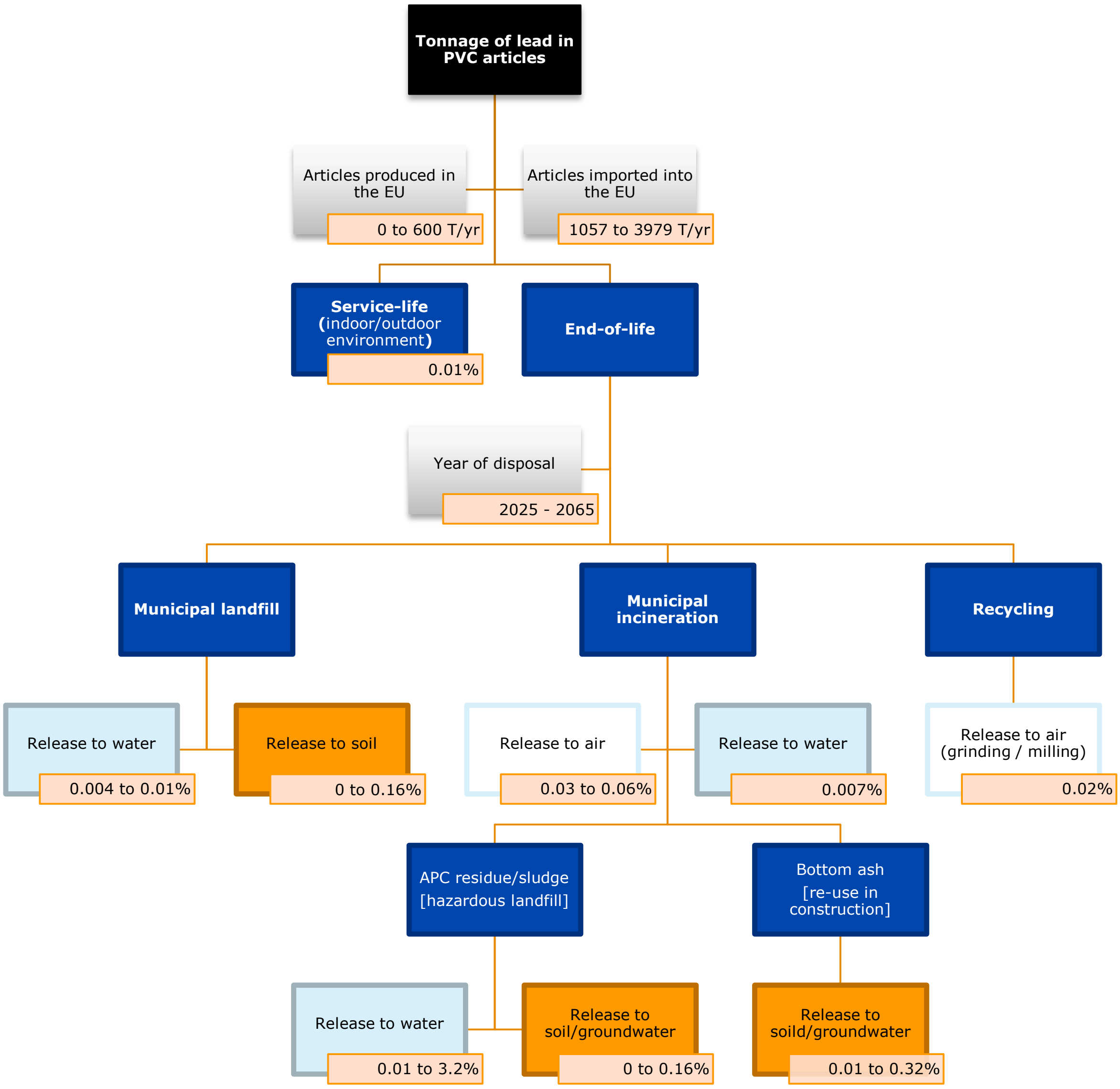

Figure 3. Overview of probabilistic model used to estimate release of lead to the environment

Estimated lead releases were found to be between 4.3 and 10.3 tonnes, with a median value of 6.8 tonnes (Table 5).

These values reflect total lead emissions expected to be released from PVC articles placed on the EU market for 2016 *(both EU manufactured and imported in the EU/from both service life and disposal stages)*

Table 5. Lead releases from PVC articles placed on the EU market in 2016 (estimated via Monte Carlo analysis)

Lead releases to the environment (tonnes) 2016 tonnage			
Life cycle stage	**25th percentile**	**Median**	**75th percentile**
Service Life	0.19	0.26	0.34
Recycling of articles	0.16	0.23	0.30
Municipal landfill	0.07	0.14	0.22
Municipal incineration[1]	3.29	6.11	9.88
Total[2]	**4.3**	**6.8**	**10.3**

1: Releases from municipal incineration include those associated with long-term disposal of fly-ash and from the re-use of incinerator bottom ash in construction projects.
2: Due to the characteristics of the Monte Carlo simulation the sum of the estimates for the different life-stages at 25th percentile, median and 75th percentile are not necessarily consistent with corresponding estimates of total releases

1.1.6.3. Other types of exposure from PVC articles

1.1.6.3.1. Consumer exposure

ECHA has reviewed a number of reports and risk assessments relevant for consumer exposure to lead from PVC articles, including the CSR for lead compounds (2015). An overview of the main consumer uses is given in section B.9.2.1. of Annex B. The following

Table 6 summarises the main conclusions of the relevant reports and studies:

Table 6. Main conclusions of studies relevant to lead consumer exposure from PVC

Report/Study	Main conclusion of relevance
Report prepared by the European Commission (2004) on the Life Cycle Assessment of PVC[9]	In PVC articles, the risk of consumer exposure is minimised by the PVC encapsulation effect that immobilises the lead stabiliser and prevents it from harming people (and the environment).
Voluntary Risk Assessment on Lead (LDAI 2008)	Degradation of exterior PVC surfaces is not expected to yield significant consumer exposure to lead due to slow release rates, removal of released lead due to weathering and low frequency of contact.
IOM (2006)[10]*, study on dermal lead exposures caused by direct skin contact (incl. and lead surface levels of PVC profiles)*	Levels of lead removed from lead stabilised PVC are low and dermal exposure of consumers is likely to be minimal.
KIWA (1998)[11] *on the long term leaching of lead from rigid PVC pipes.*	Pipes that have been in service for approximately 10 years show very low lead levels in the inner surface layer, indicating that no significant leaching of lead from within the wall of the pipe to the surface.

Overall, according to the available scientific evidence, lead in PVC articles is bound within the plastic matrix at the time of manufacture and has low inherent extractability during their service life.

In the exposure assessment of the current report it is assumed that lead stabilised PVC articles may release very <u>small quantities of lead</u> during their service life. An estimate of lead expected to be released during the service life of PVC articles placed on the EU market

9 European Commission (2004). Life Cycle Assessment of PVC and of principal competing materials (prepared by PE Europe GmbH; Institut für Kunststoffkunde und Kunststoffprüfung (IKP); Instituttet for Produktudvikling (IPU), DTU; RANDA GROUP.

10 The IOM (2005)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.

11 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 how various parameters (e.g. pH, rinsing with acids) may influence the leaching behaviour of lead.

during 2016 is provided through the exposure modelling and Monte Carlo Analysis (section 1.1.6.2). Although the contribution of service life to total lead emission from PVC articles if expected to be rather small, a restriction on lead stabilisers in PVC would in any case reduce this, thereby decreasing additional exposure for consumers to non-threshold neurotoxic lead (particularly harmful for small children and pregnant women).

1.1.6.3.2. Occupational exposure

The main aspects of occupational health exposure to lead from PVC manufacturing are discussed under the section B.9.1.3.2 of the Annex where the current maximum exposure concentration of lead compounds in the air (EU and national limits) are listed. The most recent sources of information/data on occupational exposure concern:

(1) A survey conducted by International Lead Association (ILA) (2009-2012) aiming to update the existing blood lead database on occupational exposure. Analytical data are presented in the CSRs of the lead compounds (2015) 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.*

(2) The industry voluntary risk assessment report (VRAR), specifically addressing occupational exposure to lead during PVC-production presents data from seven companies using lead stabilisers obtained between 1998 to 2006 (LDAI, 2008). *Analysis of the gathered data, indicated that no exceedance of blood lead concentration occurred during production of PVC articles.*

(3) Some further input was submitted by EuPC (December 2016) and included (i) 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; (ii) Sleeuwenhoek and Tongeren (2016) study on exposure of workers to lead *via* the dermal route and (iii) Vangeluwe et al. (2016) study in PVC compounding and converting sites (dermal exposure to lead). All these studies did not conclude significant health risk associated with lead exposure since they appear to be properly controlled by the specific requirements of the relevant Occupational Health and Safety acts.

In addition, implementation of various EU environmental legislations (listed in of the Appendix B3 of Annex) has been sufficient to reduce environmental exposure to lead from industrial sites. This conclusion is confirmed by:

- a greater than 85% reduction in lead releases of lead from industry, since 1990 reported by CSRs for lead compounds (2015);

- a greater than 90% decrease of lead industrial emissions between 1990 and 2013 according to a recent survey of the European Environmental Agency (EEA) on heavy metal emissions[12] across the EEA-33 countries.

1.1.6.4. Risk characterisation

Approach of this Annex XV report

A qualitative risk assessment has been carried out in this report according to REACH Annex I (para 6.5), since lead is a non-threshold neurotoxic substance and the risks to humans via the environment caused by its use in PVC cannot be adequately addressed in a quantitative way (e.g. by derivation of DNELs or PNECs). ECHA has, therefore, followed the same approach that has been used in previous reports for other such substances (e.g. PBT/vPvB substances, such as decaBDE, or the neurotoxic mercury compounds).

Overall, for the purpose of this assessment, lead emissions are used as a proxy for risk, and the reduction of lead emissions is used as an estimate of risk reduction capacity of the proposed restriction. Subsequently, lead emissions as risk proxy, are considered for estimating the cost-effectiveness and proportionality to the risk of the proposed restriction as will be discussed in the section 2.8 of this Annex XV report.

1.1.6.4.1. Human Health

The Section 1.1.4 of this report discusses the health effects of lead compounds. Overall it should be noted that:

- it is well established that repeated exposure to lead can result in severe neurobehavioral and neurodevelopmental effects, even at a low exposure. Lead is considered a non-threshold neurotoxic substance with adverse impacts on the development of children's central nervous systems (such as IQ loss);
- EFSA (2013) also concluded that there is no evidence for a threshold for renal effects in adults.

Therefore this restriction proposal addresses health effects of concern for the general population (although focus is on the neurodevelopmental effects on children)

Lead released to the environment from PVC articles will contribute to overall human exposure to lead though various pathways (see figures 1 and 2). The most significant source of lead exposure in humans in considered to be dietary uptake, through drinking water and food. 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 (EFSA 2013; CSR for lead compounds, 2015). EFSA also recommended that work should continue to reduce exposure to lead, from both dietary and non-dietary sources.

12 Available on : http://www.eea.europa.eu/data-and-maps/indicators/eea32-heavy-metal-hm-emissions-1/assessment-5

Section 1.1.6.1 has explained in detail that human exposure to lead via PVC articles mainly concerns indirect exposure via the environment with the following basic routes:

PVC articles -> service life -> aquatic compartment -> general population (food/drink/soil)

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

In the frame of this report, the total lead releases in the EU from PVC articles placed on the market in 2016 (both EU manufactured and imported) have been estimated. These are summarised in the following Table 7 indicating total lead emissions to the EU environment of approximately 7 tonnes (median value) to be released from PVC articles placed on the EU market in 2016.

Table 7. Median lead release from PVC articles placed on the EU market in 2016

Life cycle stage	**Median lead release to the environment (tonnes)**	**% of overall release**
Service Life	0.26	4
Recycling of articles	0.23	3
Municipal landfill	0.14	2
Municipal incineration	6.11	90
Total	**6.8**	**100**

Therefore, the main risk addressed in this restriction dossier is for humans (general population) exposed to lead emitted via the environment from PVC articles:

(a) mainly during the disposal phase of the PVC articles (recycling, landfilling and incineration) since associated lead releases cover >90% of the total releases;

(b) to a much lesser extent (3-5 % of total lead releases) during the service life of PVC articles, in particular in the interior of buildings as they gradually deteriorate releasing lead.

It has to be noted as well, that some lead is released from the formulation and processing stage ("production") of lead compounds (as discussed under the Section B.9.1 of the Annex) but such risk is expected to be sufficiently controlled by the risk management measures implemented in industrial installations.

In making the estimates of lead releases, ECHA has considered:

- The long service life of the PVC articles targeted by this restriction (10-50 years), and therefore 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 and a steady decline in landfill.

- ECHA's analysis also considered data submitted by Eurostat (May 2016) showing that imports of relevant PVC articles contribute significantly to the lead emissions (>90% of total). 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 (and since PVC imports are not covered by the industrial voluntary agreement

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.

1.1.6.4.2. Environment

Due to the well-established environmental hazardous properties of the specific lead compounds used as PVC stabilisers (Aquatic acute 1, H400; Aquatic chronic 1, H410) lead release into water compartments is also expected to cause risk for aquatic organisms.

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

1.2. Justification for an EU wide restriction measure

The primary reason to act on an EU wide basis is to ensure the functioning of the internal market by harmonising at a high level the protection of the public interests concerned, (Article 114 TFEU legislation) in this case primarily Human Health. It is securing the free movement of goods that gives the Union the power to intervene and protect Human Health and the Environment.

Lead is considered a non-threshold neurotoxic substance and lead compounds classified for their reprotoxic and aquatic toxic effects. An 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. Therefore, it would effectively reduce the human health and environmental risks caused by the use of lead compounds in PVC articles placed on the EU market.

As this health concern as well as the marketing of PVC articles are not geographically or nationally limited (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.* A Union wide restriction of lead compounds in PVC based articles 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.

1.3. Baseline

1.3.1. Problem definition

As discussed in more details in section 1.1 of this report:

(i) Lead is a non-threshold neurotoxic substance being of particular concern for the developing brains of young children as well as to unborn children through their mothers' exposure (VRAR 2008).

(ii) Lead can also accumulate in the environment and cause damage to the ecosystem.

EU wide restrictions on the various consumer uses of lead and its compounds have been imposed over many years with the aim to decrease the lead burden in the human population and the environment (e.g. jewellery and mouthable consumer articles) via the REACH Regulation and other legislation (electric and electronic devices, food contact materials and leaded gasoline).

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.*

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 supported as detailed in the section 1.1.6 of this report:

(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).

This restriction proposal for lead 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) such as (*indicative list*):

- Waste rigid PVC window and door profiles
- Rigid tubes, pipes and hoses
- PVC Floor coverings in rolls or tiles
- Shutters, blinds (incl. venetians and parts thereof)
- Fittings for furniture, coachwork and the like
- PVC cables and cable ducts

Based on this analysis, as explained in section E.7 of the Annex E, the proposed restriction covers the placing on the market of all PVC articles (based on soft and rigid PVC articles) for all uses (consumer, professional and industrial). It should be noted that 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) already covers some PVC articles (e.g. PVC prints in clothes, PVC based decorative items, garden hoses etc.). Such mouthable PVC articled are out of the scope of the proposed restriction[13].

1.3.2. How the situation would evolve without any regulatory measures

If no legislative action would be taken to restrict lead in PVC articles, the lead emissions from these article categories would keep accumulating to the total lead stock of the EU environment, even considering the current Vinyl+ voluntary agreement[14]. Therefore, in the absence of further restriction measures, the current (2016) levels of human (and environmental) lead exposure from PVC applications would – in theory – remain present and unchanged at Union level, in particular that level associated to PVC imports (that steadily increase in the last decade)

For the purpose of this assessment, it is important to distinguish between PVC articles manufactured in the EU and those imported to the internal market from non-EU countries. The reason for this has to do with the difference between the two markets of lead stabilised PVC in the current baseline situation. More specifically:

1.3.2.1. PVC manufactured articles

According to recent information from industry (ESPA, 2916) the ongoing Voluntary Commitment known as VinylPlus scheme[15], has successfully replaced lead-based stabilisers across the EU-27 by the end of 2015. In the Annex D of this report, the Union-wide substitution of lead-based stabilisers by existing alternatives (mainly Ca-based systems) over the period 2007-2016 is shown. Given this voluntary agreement, the contribution of the EU manufactured PVC articles to the overall lead exposure for humans will decrease with time.

In the absence of any further restriction measures, though, a complete phase out of lead stabilisers (to zero tonnes) on the EU internal market will not be achieved. ECHA's Call for comments demonstrated that in a few EU countries there are SMEs that still use (limited quantities) 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,

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13 A relevant exemption is proposed.

14 The Vinyl+ agreement only covers 95% of the EU manufacture and doesn't cover imports.

15 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).

some users of lead-containing PVC who have switched to an alternative stabiliser (via the VinylPlus agreement) might consider switching back to lead compounds (e.g. for cost or issues of technical feasibility in certain products).

1.3.2.2. PVC articles imported to the EU

Following ECHA's consultation with Eurostat (May 2016) the analysis of submitted data (annual tonnes of main rigid PVC articles imported in the period 2006-2015), indicated a steady increase of PVC imports from non-EU countries during the last decade. Since the majority of the PVC imports originate from Asia, where lead in PVC articles is not regulated, one may assume that a large part of imported PVC articles is stabilised by lead. This assumption is further supported by the information received during consultation with TBT countries in early 2016 (e.g. Thailand, Philippines) for their manufacturing of lead stabilisers and exports of PVC articles to Europe.

Based on the information collected by ECHA (and assumptions presented in details in section B.9 of Annex B and section F.1 of Annex F), the following Table 8 gives a broad picture (in ranges) of the lead contained in the articles placed on EU market for 2016.

Table 8. Estimated total tonnes of lead contained in PVC articles covered by this proposal and placed on the EU market during 2016.

Category of articles	**Tonnes in PVC articles (2016)**	
	Lower bound	*Upper bound*
EU manufactured PVC	0	283
EU imported PVC	1057	3980
Total	1057	4263

1.3.2.3. Conclusion of baseline analysis

Given the above considerations for the business-as-usual scenario, it can be assumed that in the years to come (2016 onwards) 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.

In the absence of a Union-wide restriction of lead in PVC, lead containing PVC material and articles would still be available in the world market (*mainly through the increased PVC imports*). Therefore, there is no compelling justification to assume that a complete phase out of lead emitted from PVC applications would be achieved in the baseline scenario (despite the downward trend of lead in the EU and the voluntary agreement).

2. Impact Assessment

2.1. Introduction

The impact assessment presented in this document employs a semi-quantitative approach to estimating the benefits and costs of the proposed restriction on lead compounds in PVC. The analysis includes an examination of the compliance costs of the proposed restriction and its cost-effectiveness. In addition, a break-even analysis was performed to demonstrate the presence of health benefits from the proposed restriction was likely.

The boundaries of the assessment were defined to capture the main impacts of the proposed restriction, the actors impacted and the timeframe these impacts are likely to occur. Specifically, these were defined as follows:

- **Geographic:** The focus of the assessment is on EU28, as the final decision on whether or not to implement a restriction focuses mainly on weighting the costs and benefits for the EU society of the proposed measure. The impacts of the proposed restriction on actors in other jurisdictions are also considered, e.g., producers and suppliers of articles in the scope of the proposed restriction, insofar these result in impacts to EU actors, such as importers, wholesalers, retailers and consumers.
- **Temporal**: The temporal scope of the proposed restriction was selected despite its limitations: while the costs of the restriction will likely begin to approach zero by already by 2020 (indicative year of entry into force for the purpose of this analysis) many of the benefits of the restriction would continue further into the future. For the purpose of comparing the benefits and costs of the restriction, all monetised values are based on assumptions about the 2016 values (EU produced and manufactured volume of lead stabilisers/tonnes of PVC articles).
- **Supply chain:** The focus of the analysis is on EU producers and importers of articles in the scope of this proposed restriction and their upstream and downstream supply chains, from substance manufacturers to end-users to recyclers.

2.2. Risk Management options

2.2.1. Proposed options for restriction

ECHA has prepared this restriction dossier on the basis of a request by the Commission to assess the risk to human health and the environment of lead released from PVC articles and the need for European Union-wide action beyond any measures already in place. The scope of the proposal is limited to the various lead compounds used as PVC stabilisers. As already discussed in Section 1.1.6 of this report (and further detailed in Annex B), *the conclusion of this examination is that the risk for humans exposed to environmental lead releases from PVC articles is not adequately controlled*. Therefore, ECHA conducted an analysis of diverse risk management options (RMOs) to identify the most appropriate measure to address these risks and to define its scope and conditions.

In a first step, existing EU legislation of relevance to the proposed restriction was carefully examined (detailed in section B.9.1.). Subsequently, other possible Union-wide RMOs (non-legislative measures; legislation other than REACH; other REACH processes) were assessed 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. However, these were assessed as not appropriate to address all the article categories contributing to risk as described in section E.1.3. of the Annex.

Since we concluded that a restriction under REACH is the most appropriate RMO to address the risks from lead stabilisers, the following three restriction options were investigated:

Restriction option 1: A Restriction on lead and its compounds in all PVC articles with a concentration limit of 0.1%, 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.

Restriction option 2: A restriction on lead and its compounds in all PVC articles with a concentration limit of 0.1% 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.

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 can be assumed to at approximately 0.5%-at least for some uses e.g. pipes as- indicated in section A.2.1 of Annex A) . As discussed under section E.1.2, such a limit would potentially be assumed high enough to avoid a need for derogating PVC recycling.

Each of these options was assessed against the main criteria for restriction or other risk management measures: effectiveness, practicality and monitorability (as discussed under the Section E.3.2). As a result of this assessment, the following option is proposed since it was found to overall better meet the criteria for restriction in comparison to the other evaluated options.

2.2.2. Proposed restriction, conditions and justification for the selection scope

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 and construction *articles 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.*

The details of the proposed restriction are given in the Summary section of the report and section E.1.1.1 of Annex E. It restricts the placing on the market of articles or parts thereof produced from PVC if the concentration of lead (expressed as metal) is equal to or greater than 0.1% by weight of the PVC material.

It is important to note that:

- The scope of the proposed restriction covers all the uses (consumer, industrial and professional) of lead compounds in PVC;

- The proposed restriction covers PVC articles placed on market in the EU (both manufactured in the EU and imported into the EU). 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.
- 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.

Concerning the conditions of the proposed restriction, the following aspects have been assessed and concluded:

(I) Restriction limit: 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, gradually eliminating the presence of lead in PVC articles manufactured in or imported into the EU.

(II) Transition period: The proposed restriction foresees a transition period of 24 months. Following discussions with the stakeholders and considering the comments received through the stakeholders' consultation, this specific transitional period was concluded to allow:

- Remaining producers of EU articles made with PVC to achieve a full transition to alternatives;

- EU importers to communicate to their international suppliers the requirements for lead content in PVC articles. Although, the supply chains of many of the articles in scope could be complex, it is anticipated that two years would be sufficient time as industry already has experience with moving to the alternative;

- Non-EU manufacturers to switch to alternatives for the purpose of manufacturing PVC articles intended for placement on the EU market. Given the availability of a similarly priced alternative, two years is considered sufficient time for non-EU entities to comply with the proposed restriction;

- All actors to deplete existing supplies of lead stabilised articles produced under current EU regulatory requirements.

(III) Derogations: During the development of the proposed restriction option, and following the outcome of the ECHA' Call for comments and information exchange with the stakeholders, it was concluded that derogations from the proposed restriction were justified:

- For certain building and construction products manufactured by use of recycled PVC for 15 years, if their lead concentration does not exceed 1% w/w.
- PVC-silica separators in lead-acid batteries for 10 years, due to the lack of existing alternatives for this industrial application.
- PVC articles already covered by specific Union legislation, regulating lead content or migration.
- PVC articles covered by the paragraph 7 of Entry 63 of Annex XVII to REACH.
- Second hand articles.

The reasoning and justification for these derogations, following consideration of the available technical and socio-economic information are summarised in the next Section 2.3.3 (and detailed in Section E.3.2 of the Annex).

Overall, the wording of the proposed restriction was prepared on the basis of brief consultation with an enforcement authority (see Annex G, Stakeholder consultation).

2.3. Restriction scenario (s)

2.3.1. Behavioural responses

The proposed restriction of lead compounds in PVC is based on the assumption that the market will be able to comply with the restriction within 24 months of its entry into force as previously discussed. For the purpose of this analysis, it is assumed that this would take place around the year 2020. This should give sufficient time for all actors to adapt as substantial substitution of the lead compounds has already occurred due to *Vinyl Plus*; this information would also have permeated other non-EU regions.

2.3.2. Transition to alternatives

A number of stabilisers for PVC have been traditionally used in the EU and worldwide in the various PVC applications, such as: cadmium compounds; tin compounds; liquid mixed metal stabilisers etc. An overview is given in Section E.2.1 of the Annex. According to comments submitted from associated EU industry in the various consultations, *calcium-based systems are the logical replacement for the lead stabilisers*. More specifically:

- ESPA (2016) stated that for the most common rigid PVC applications (e.g. window frames), a typical composition contain mainly calcium-based stabiliser systems at a concentration of approximately 3.5% (w/w).
- ECVM (2016)[16] noted that the use of calcium-based stabiliser systems has been the most common in the rigid PVC applications for the last years in the EU**.**

No alternative technologies have been reported to ECHA as appropriate for lead substitution. Therefore, by considering the information on the various alternative systems *ECHA has decided to focus its further assessment for potential alternative to lead stabilisers* *<u>exclusively on the calcium based-systems</u>.*

Detailed information on the typical composition and PVC applications of calcium-based stabilisers is given in the section E.2 of Annex E. The most important aspects of their risk

16 More info available on: http://www.pvc.org/en/p/calcium-zinc-stabilisers

profile and technical/economic feasibility are presented below in this section of the Annex XV report.

2.3.2.1. Health & environmental risk profile

A number of technical reports and Risk assessments (e.g. REACH Registration dossiers, Eurotox 2007, EFSA scientific opinions) have been reviewed by ECHA to assess the human health and environmental hazards from use of calcium-based systems in PVC.

The following Table 9 summarises the available information for the health profile of the main ingredients present in a calcium-based stabiliser system along with the related sources of information. Similarly, ECHA has screened the available information from EU environmental risk assessment and reports of relevance for the calcium-based systems.

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 health and environmental toxicity;
- calcium-based systems have a much lower hazard profile (non-classified) than the lead compounds used as PVC stabilisers which as discussed in section 1 are non-threshold neurotoxic for human health and toxic for aquatic organisms.

Table 9. Screening of the health profile of the main components in a calcium-based system (ECHA compilation of available data)

Component	**Summary of info**	**Sources**
Fatty acids C16-18	The fatty acid moiety (a) is not considered to be hazardous to human health since fatty acids natural constituents of the human body and of human nutrition (b) generally judged as not representing a risk to human health exclusion from REACH registration requirements.	REACH Registration dossiers for calcium stabilisers.
Calcium	Essential nutrient, integral component of the skeleton. Its deficiency reduction in bone mass leads to osteopenia and osteoporosis, and an associated increased risk of fracture.	EFSA (2015)[17] scientific opinion on dietary references values for calcium / REACH Registration dossiers for calcium stabilisers.
Zinc	Essential nutrient for growth and development, neurological function. Clinical manifestations of	EFSA (2014)[18] Scientific Opinion on dietary

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

18 EFSA's 2014 Scientific Opinion on dietary references values for zinc (available on: https://www.efsa.europa.eu/en/efsajournal/pub/3844)

	zinc deficiency are (i) growth retardation, (ii) delay in sexual maturation or (iii) increased susceptibility to infections impact to human health only at very high doses.	references values for zinc (Berg, 1990)/ REACH Registration dossiers for calcium stabilisers.
Zeolites	Given their wide applications zeolites have been assessed under other legislative frameworks. It needs to be noted that (i) no-significant health risks are identified (ii) natural Zeolite (Clinoptilolite) is an EU authorised feed additive.	HERA, 2004[19]/ SCHER (2006)[20]/(EGTOP, 2011).[21]
Phenolic antioxidants	Natural substances, commercially available for use as EU approved food additives. Their use as co-stabiliser in calcium-based systems is not expected to pose any significant risks for human health.	EFSA (2013) scientific opinion on various phenolic compounds as well for phenol.[22]
Polyols	The most commonly used polyols are sorbitol (E 420), mannitol (E 421), isomalt (E 953) etc. chemically assessed by the European Commission. They are also acceptable for use as food additives, therefore safe for use in PVC stabilisers.	(NCBI, 2016)[23] /(SCF, 2003)[24].

2.3.2.2. Technical and economic feasibility

Following consultation with the producers of European Stabilisers Producers Association (ESPA, 2016) it was highlighted that stabiliser systems are generally supplied as a "one-

19 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

20 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)

21 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

22 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)

23 More information is available on http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4017274/

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

pack", including not only the main alternative substance (i.e. the stabiliser) but also other additives such as lubricants and co-stabilisers.

By using this one-pack approach, *a calcium-based system is to be compared versus a lead-based system in assessing total "cost/performance".*

The technical characteristics of calcium-based systems are discussed in more details in Section E.2.4. In summary, the calcium-based systems are reported to give products, which have:

- a high degree of clarity,
- good mechanical and electrical properties,
- good resistance to weathering capable of covering the whole area of PVC
- low migration, low odour, low VOC emissions,
- good initial colour and excellent transparency, especially in plasticised PVC.

According to the industry, the presence of metal salts (e.g. calcium, zinc, magnesium) in calcium based systems accounts for their improved technical characteristics compared to lead stabilisers on the following aspects:

- wider applicability for a wider range of PVC applications;
- better stabilisation effect; and
- better colour stability in artificial and natural weathering.

The above-indicated concept of one-pack should be considered in the assessment of economic feasibility of the calcium-based systems. Therefore, further to the price, *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. It is important to note, that in principle, switching from Pb-based to Ca-based stabiliser, the percentage dosage of the stabiliser is decreased, not increased, as a result of enhancing the performance of the systems developed in the last 10 years.

Via a practical example developed and presented in Section E.2.4 *(lead substitution by calcium-based system in window profiles)* the following observations were made:

- The cost/performance of a calcium-based system is at least equivalent to a lead-based one (as the dosage is similar in both cases), therefore there is no significant impact on the price of a window frame.
- Although the calcium-based system is slightly more expensive (+0.7 €/kg), the cost contribution of the PVC stabiliser to the cost of the whole window is very low, typically tens of Euro cents.

Overall, the cost/performance difference between a lead formulation and a calcium-based system is negligible.

General conclusion

From the above analysis, the available information/studies (detailed in Section E.2 of the Annex) and considering the current industrial trends and practices (massive substitution of lead by calcium-based stabilisers, over the last decade in the EU) it can be broadly concluded that: *The calcium-based systems in the various PVC applications offer a better technical performance than the lead stabilisers at comparable costs.*

2.3.3. Proposed derogations

ECHA's Call for evidence yielded a number of comments from stakeholders on certain applications of lead PVC stabilisers that would be adversely affected by the proposed restriction. ECHA's assessment has been presented in details in the Section E.3.2 of the Annex E. An overview of the main issues and conclusions is presented below.

2.3.3.1. Higher lead restriction limit for recycled PVC

Industry (ESPA, EuPC, ECVM) noted that a higher lead limit of 1% w/w should be provided for recycled PVC (rather than the generic 0.1% w/w) due to lead legacy currently present in the PVC waste. *Overall, PVC recyclers/converters highlighted in order to comply with a limit of 0.1%, only 10% of an article could be made from (the cheaper) recycled PVC, therefore, PVC recycling would no longer be economically viable and would have to stop (because of the fixed and variable costs needed to co-process and operate the extruders).*

Not granting of a higher limit would result according to the industry to a number of adverse effects (Tauw IA, 2013), including:

(i) socioeconomic effects (e.g. closing of approximately 130 recyclers; loss of approximately 800 jobs; loss of more than 7 billion euros until 2050 for the recyclers)

(ii) environmental effects: (e.g. higher energy and raw materials consumption; global warming potential etc.)

ECHA has carefully considered the information submitted by industry and available data in relevant technical reports and literature. A further assessment was performed by ECHA assuming that: if *PVC recycling would not be possible after 2020 (i.e. no derogation from the proposed restriction would be granted), PVC articles at the end of their service life would be then disposed via other prevalent waste management practices (i.e. landfilling, incineration and export).* The main conclusions of ECHA's assessment on the various aspects (risks-emissions; socioeconomic effects; scope & enforceability) are summarised in the following overview Table 10 (along with the Annex sections where analytical data/estimates are provided):

Table 10. Overview of ECHA's analysis on PVC recycling

ECHA's analysis	**Results/Conclusions**	**Section/Table (Annex E)**
Risk /lead emissions	If PVC recycling would stop (2020 onwards) ECHA, estimated the additional lead releases to the EU environment (from incineration and landfilling of PVC waste that could not be recycled) would be approximately 23 tonnes (*between 9-43 tonnes considering the 10-90 percentile*). This net increase in lead	Estimates/assumptions Presented in Section E.3.2.1.4, & Table E.7

	releases to be used as proxy of increased risk.	
Socio-economic effects	(i) Additional costs for society If PVC recycling would stop (2020 onwards), ECHA estimated that the additional annual costs for disposal of PVC waste would be approximately €57.6 million in total (€*15.6* million *for incineration and €42.0* million *for landfill*). These are significant costs (probably still an underestimation) and would be borne by society in general. (ii) 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 (virgin PVC would be more expensive). ECHA has developed an example for window profile estimating that termination of PVC recycling from 2020 onwards would result into a price increase of 5.3-9.2 % for average PVC window profiles (compared to current prices).	Estimates/assumptions Presented in Section E.3.2.1.3, & Table E.5 Estimates/assumptions Presented in Section E.3.2.1.3, & Table E.6
Conditions and scope	(i) Restriction limit ECHA concluded that a threshold concentration of 1% (w/w) lead in the PVC of) would ensure continuation of PVC recycling. This could be re-assessed approximately 10 years after the restriction had entered into force. (ii) Re-evaluation period A 15 year period has been chosen following an assessment of the projected concentration of lead in recycled PVC from 2020 and 2040, and the costs of disposing of recyled PVC. This time period would also allow a re-evaluation of the situation in the future to check if the projected lead concentrations are being met and to make any necessary changes. (iii) Scope Following consultation with Industry and enforcement Authorities, ECHA concluded that a potential derogation with a higher lead limit should be granted for certain	Estimates/assumptions Presented in Section E.3.2.1.2, & Figure E.4 Estimates/assumptions Presented in Section E.3.2.1.1, & Figure E.4 More details (+proposed wording) are presented in Sections E.3.2.1.2,

	(not all) types of rigid PVC articles, based on recycled material by considering: - Health concerns related certain types of PVC articles (e.g. PVC flooring) see Section E.3.2.1.4 (); - Alignment with the existing relevant provisions of Annex XVII (see Entry 23). (iv) Enforceability To enable enforceability of the proposed derogation ECHA has recommended that: • *Producers of PVC articles* should clearly indicate the percentage of recycled PVC in their products (as well as where it is used in the article); • *Importers of PVC articles* could be asked to provide documentation (from their suppliers/contractors); • An additional requirement, specifying that PVC articles containing recycled PVC are visibly, legibly, and indelibly marked in analogy to entry 23 of Annex XVII to REACH).	& E.3.2.1.6 More details (+proposed wording) are presented in Sections E.3.2.1.5, & E.3.2.1.6

2.3.3.2. Assessment of other (than PVC recycling) comments concerning potential derogations (or higher transition period) from the proposed restriction

ECHA has carefully assessed the comments and information provided from stakeholders during ECHA's Call for evidence (and other contacts/email exchanges etc.) on other PVC uses where lead stabilisers claimed to be still essential. The outcome of this assessment is detailed in the Sections E.3.2.2. The following Table 11, provided an overview of the derogations proposed (or not) based on information submitted in the ECHA's call for evidence.

Table 11. Overview of ECHA's assessment on comments for potential derogations

ECHA's assessment	**PVC applications** (comments via ECHA's Call for evidence)	**ECHA's conclusion/section of Annex**
Proposed derogations from the restriction of lead in PVC	*PVC recycling* (higher lead limit 1% w/w)	As previously presented in Table 9 (analysis in Section E.3.2.1)
	PVC silica separators in lead-acid batteries (lead content ~2%/ approximately 20 tonnes of lead stabilisers per year in the EU).	A temporary derogation of 10 years from the proposed restriction of lead in PVC would be justified.This period would allow industry to develop technically and econmically feasible alternatives to tetralead trioxide sulphate (More info on technical/socioeconomic aspects in Section E.3.2.2).
	Second hand PVC articles (EU market in 2015 accounts for approximately 25000 tonnes of PVC articles)	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 mainly for enforceability reasons and alignment with the existing lead restrictions. (More info in Section E.3.2.3).
	PVC articles covered by other EU specific legislation regulating lead (food contacts/RoHS/Toys/Packaging mouthable consumer articles)	An exemption for these type of PVC articles should be justified for alignment with the existing lead restrictions. (More info in Section E.3.2.4).
Not proposed derogations from the restriction of lead in PVC		
	PVC electrochemical sensors in In-Vitro Diagnostics Equipment. (Lead content is 1.5%/approximately 15 kg of lead per year.	Given the time frame of lead substitution for this use (within the next 2-3 years) there is no need for derogation *as restriction would not enter into force earlier than 2020. (*More info in Section E.3.3.1).

	PVC insulation cables and wires (lead monoxide or lead tetraoxide at a concentration between 0.3 to 0.9% w/w).	No clear from available info why available alternative do not work (or even why these uses are not covered by RoHS). *ECHA concludes that PVC wires and cables should not be exempted, in the absence of more concrete information that would possibly justify a need for a derogation.* (More info in Section E.3.3.2).

2.4. Economic impacts

The proposed restriction will cause some economic impacts. Substitution costs are expected to be incurred between €0.8 – 3.3 million with a central value of €2.0 million for 2016. Enforcement costs are estimated at about €60 thousand per year. Investment/development and testing costs are assessed as being negligible. Potential costs to the recycling sector, and from the selling of second hand market goods are avoided by the inclusion of appropriate derogations to the proposed restriction. No costs related to any unsold stocks are considered since it is assumed that industry will have time to deplete all stocks during the transition period of 24 months (prior to the entry into force of the proposed restriction).

2.4.1. Substitution costs

Based on recent information from industry it appears that the targets of the voluntary phase out were met (ESPA, 2016). As such, it is only the quantity of stabilisers not covered by ESPA members, which needs to be substituted, together with the amount of Pb- based stabilisers coming into the EU via imports. It is assumed that the total tonnage of Pb-based stabilisers is replaced by Ca-based stabilisers (see section 2.3.2) and that the price of the Ca-based stabiliser if 0.7 €/kg more expensive than the price of the Pb-based stabiliser. Finally, a smaller quantity of Ca-based stabiliser is required to achieve the same level of stabilisation (the dosage ratio of Ca-based to Pb-based is 0.88). Using the above assumptions substitution costs are estimated to be between €0.9 – 3.3 million with a central value of €2.1 million for 2016 (Table 12). The majority of the tonnages to be substituted comes from imports. It is assumed that the corresponding substitution costs will be incurred by EU entities (producers of stabilisers, producers of PVC articles, other actors in their supply chain, or EU consumers) and are therefore, costs of the restriction to EU society.

Table 12. 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)	1 321	2 322	**3 142**	3 921	4 974
Pb stabilisers produced in the EU28 (t/year)	0	72	**165**	295	354
Total amount of Pb stabilisers (t/year)	1 321	2 394	**3 308**	4 216	5 328
Dosage ratio Ca stabiliser/Pb stabiliser			**0.88**		
Equivalent amount of Ca stabilisers needed for substitution (t/year)	1 163	2 107	**2 911**	3 710	4 688
Price difference between Ca stabilisers and Pb stabilisers (€/kg)			**0.7**		
Substitution costs (€ million /year)	0.9	1.5	**2.1**	2.6	3.3

Figures might not agree due to rounding.
Note: the values are assuming that substitution costs are fully passed onto the EU consumers and therefore the costs corresponding to non-EU produced PVC (via imports) are included in the calculations. Alternatively, it could be assumed that a portion of these costs is borne by EU PVC producers (and remove these costs from the calculation, see Annex E.4.1).
Source: Section E.4 and ESPA (2016)

2.4.2. Testing costs and investment/development costs

Testing costs incurred by industry to comply with the restriction are considered to be negligible. These costs would concern companies that supply, retail or import PVC articles and would need to make sure that these do not contain lead based stabilisers. According to the available information, companies rely mostly on contractual procedures with their suppliers (contract requirement for the supplier to comply with EU legislation), or simply on supply chain communication, rather than conducting tests (see Annex E.4.2). In addition, no investment or development costs by the EU industry are expected to be needed. Although the Ca-based stabilisers are not simple drop-in alternatives, the corresponding development costs have already been absorbed by the manufacturers and converters during the voluntary phase out by industry (see Annex E.4.3).

2.4.3. Enforcement costs

The average cost incurred by Member State enforcement authorities to ensure that EU28 economic actors comply with the restriction are of approximately €60 thousand per year on average (in 2014 values). This figure is considered as illustrative of the order of magnitude of the potential costs (see Annex E.4.4).

2.4.4. 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 (with a central value of €2.1 million (see Table 13). Regarding imports, it is expected that 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 are expected to gradually move out of this market (through switching to alternatives).

Overall, it is therefore assumed that the total compliance costs in 2020 should be lower than in 2016, but no quantitative assessment on the development of compliance costs was undertaken. Moreover, it is also expected 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 13.

Table 13. 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	
Substitution costs	€0.9 – 3.3 million (€2.1 million central value)
Investment costs	Not estimated, likely negligible
Testing costs	Not estimated, likely negligible
Enforcement costs	0.06

2.5. Human Health and environmental impacts

The human health and environmental impacts that would be avoided with the implementation of the proposed restriction are briefly described below. It is also considered that the transition to calcium-based alternatives will not bring any additional impacts to human health or the environment (see section 2.3.2 of this report). The reductions in lead emissions, which are associated with the avoided human health and environmental impacts, are estimated in section 1.1.6 of this report.

2.5.1. Human Health impacts

2.5.1.1. Neurotoxicity

The impact assessment for this restriction proposal focuses on neurodevelopmental effects on children. Lead exposure, at levels commonly observed in the EU today, can impair the neurodevelopment and can affect cognition and behaviour. Early-life exposure to lead is related to neurologic deficits, leading to reduced cognitive ability. The latter can be measured with standardised IQ tests. A small reduction in IQ can in turn have a significant population effect in terms of reduced lifetime earnings. In order to quantify this effect, the model of Grosse et al. (2002) can be used. This model links the amount of lead ingested (from the environment) to the corresponding blood lead level in children and the resulting neurodevelopment effect (IQ loss). The IQ score can then be linked to the expected (loss of) earnings of an individual during the working life (see Annex E.5.1.1). In the present report, an IQ loss with a value equal to the compliance costs of the proposed restriction is used to estimate the portion of the emissions that would need to be ingested by children to balance the costs of the restriction (see section 2.8.2).

2.5.1.2. Other impacts

The proposed restriction is expected to have positive health impacts both on workers and on the general population. Examples are workers in the construction and in the recycling sector and inhabitants of areas, which are close to incinerators and/or landfills. These impacts are not quantified in this restriction report (see Annex E.5.1.2).

2.5.2. Environmental impacts

Lead has detrimental effects on soil, plants, microorganisms and animals. 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 (see section B and Annex E.5.2) 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 have been linked to potential failure of WFD objectives (section B.9.2.2.1). 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.

2.6. Other impacts

2.6.1. Social impacts

This section presents an overview of potential impacts of the proposed restriction on various relevant actors. More details are provided in Annex E.6.1.

<u>PVC convertors/recyclers</u>

Producers of PVC products are commonly called convertors. The proposed restriction will not affect convertors who manufacture articles out of virgin PVC. In addition, the restriction contains a derogation for recycling activities. No major impact is expected on this category of actors.

<u>Producers of stabilisers</u>

The majority of EU producers, representing approximately 95% of former Pb-stabiliser production (ESPA, 2015), have already voluntarily phased out lead and switched to Ca-based stabilisers in the context of the VinylPlus agreement. No major impact is expected on this category of actors. The impact on the lead stabiliser producers which are not part of the voluntary agreement is taken into account in the calculation of the substitution costs (section 2.4.1). Finally, the producers of lead-based stabilisers can still export to non-EU countries as manufacturing is not included in the scope of the proposed restriction. ESPA (2016) informed that there is currently only one European company producing lead stabilisers for export to non-EU countries.

Importers of PVC articles

Importers of PVC articles stabilised with lead will not be able to place these articles in the EU market after the entry into force of the proposed restriction. The costs for moving to alternatives were taken into account in the substitution costs of the proposed restriction. It was assumed that all costs related to imported articles are fully passed on to EU entities (section 2.4.1), although the distribution of these costs between the different actors (EU producers of articles, importers of articles, or consumers) is not known.

In addition, a fraction of these costs could also be borne by non-EU entities (e.g. non-EU producers of PVC articles).

PVC exporters

The proposed restriction bans the placing of PVC articles containing lead stabilisers 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. If recycling would no longer be possible in the EU (in case no derogation was granted), exports of PVC waste might even increase (see Annex E.3.2).

Impacts on SMEs

The majority of actors in the PVC supply chain are SMEs. However, any effect of the proposed restriction should be limited as alternatives are already available (ESPA, 2015). There is also no evidence that SMEs would be more affected than other companies. Many SMEs are active in the recycling sector, however any impact on these companies is mitigated by the proposed derogation on recycling activities (see Annex E.3.2).

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). The use in silica separators is covered by a specific derogation, whereas no need to derogate was identified for the use of PVC in vitro diagnostics as the substitution to alternatives is bound to happen before entry into force of the proposed restriction.

2.6.2. Wider economic impacts

The proposed restriction would have minor impacts on article prices; therefore, international trade flows are likely to remain unchanged and no substantial wider economic impacts can be anticipated as a result of the restriction (see Annex E.6.2).

2.6.3. Distributional impacts

Any negative impacts on manufacturers of lead-based stabilisers, producers of PVC articles and importers of PVC articles stabilised with lead are anticipated to be offset by gains by manufacturers, producers and importers of lead-free alternatives. As substitution has already taken place for most of the tonnage concerned, these distributional impacts are expected to be limited (see Annex E.6.3).

2.7. Practicality, enforceability and monitorability

More details about ECHA's assessment on the "practicality" aspects of the proposed restriction are presented in the section E.7. Overall, *ECHA concluded that the proposed restriction is practical because it is implementable, enforceable and manageable, whereas monitorability is feasible based on existing practices.*

The following Table 14 gives an overview of the main considerations:

Table 14. Justifications of the practicality of the proposed restriction of lead in PVC (ECHA's assessment)

Practicality/enforceability/ monitorability	Justifications
Implementability (alternatives, conditions, familiarity of supply chain)	• High degree of familiarity in the supply chains regarding PVC articles that may contain lead and its compounds. Information is available to downstream users and consumers via provisions in REACH (e.g. Article 7). • Technically feasible alternatives (mainly calcium-based systems) with lower risk are currently available at similar prices. • The proposed transition period gives sufficient time to the impacted supply chains to transition to alternatives. • Limit value of 0.1% sufficient to exclude intentional use of lead (>0.5%) and cover the presence of potential impurities.
Enforceability (testing methods, clarity of scope)	• Testing (e.g. XRF, wet chemical methods) and sampling methods exist for lead in PVC articles. Both industry and enforcement authorities have experience applying them (similar to the ones applied for the existing restriction provisions for lead in entry 63 of Annex XVII). More info in section E.7.2.3. • The scope of the proposed restriction is clear and unambiguous and covers the all the uses (consumer and professional) of lead compounds in PVC.
Manageability (administrative burden for actors)	• Implementation of the current voluntary scheme (Vinyl Plus) for the phase out of lead PVC stabilisers in the EU. • Availability of information regarding which PVC articles may be stabilised by lead.

	• Stakeholders' experience with regulatory action on lead (from already existing restriction provisions of Annex XVII).
Monitorability	• For EU produced PVC articles, monitoring: i) can be done by ECHA and national enforcement authorities (ii) can be facilitated by the audit activities scheduled by Industry for the Vinyl Schemes. • For imported PVC based articles, the compliance control can be accomplished by custom authorities and notifications of any violation of the restriction can be reported in the RAPEX system. • Furthermore, it is possible to monitor the result of the implementation and the effectiveness of the proposed restriction via biomonitoring studies.

2.8. Comparison of cost and benefits

2.8.1. 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 (see section 2.4). The compliance costs for 2016 are estimated to be in the range of € 0.9 to 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 € 1.5 – 2.7 million (Table 15). 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 (Table 15). All calculations assume that compliance costs are fully passed onto EU consumers and therefore incorporate non-EU produced PVC sold to EU consumers via imports. If it is assumed that some of the costs are taken on by the EU producers, the compliance costs of the restriction diminish and the cost-effectiveness estimates further improve, yielding even lower values of cost-effectiveness (see Annex E.8.1).

Table 15. Cost effectiveness for articles placed on the market in 2016

	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* (M€/year)	0.87	1.53	**2.09**	2.65	3.34
Cost effectiveness (€/kg emission avoided)**	2 484	356	**308**	258	99

** Compliance costs include substitution and enforcement costs*

*** Cost effectiveness = Compliance costs / Pb emissions*

Figures might not agree due to rounding.
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)

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 for a PBT-like substance 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 lead emission reduced is in the same order of magnitude as, or lower than, the cost-effectiveness of reducing emissions of other PBT (-like) substances (Figure 4).

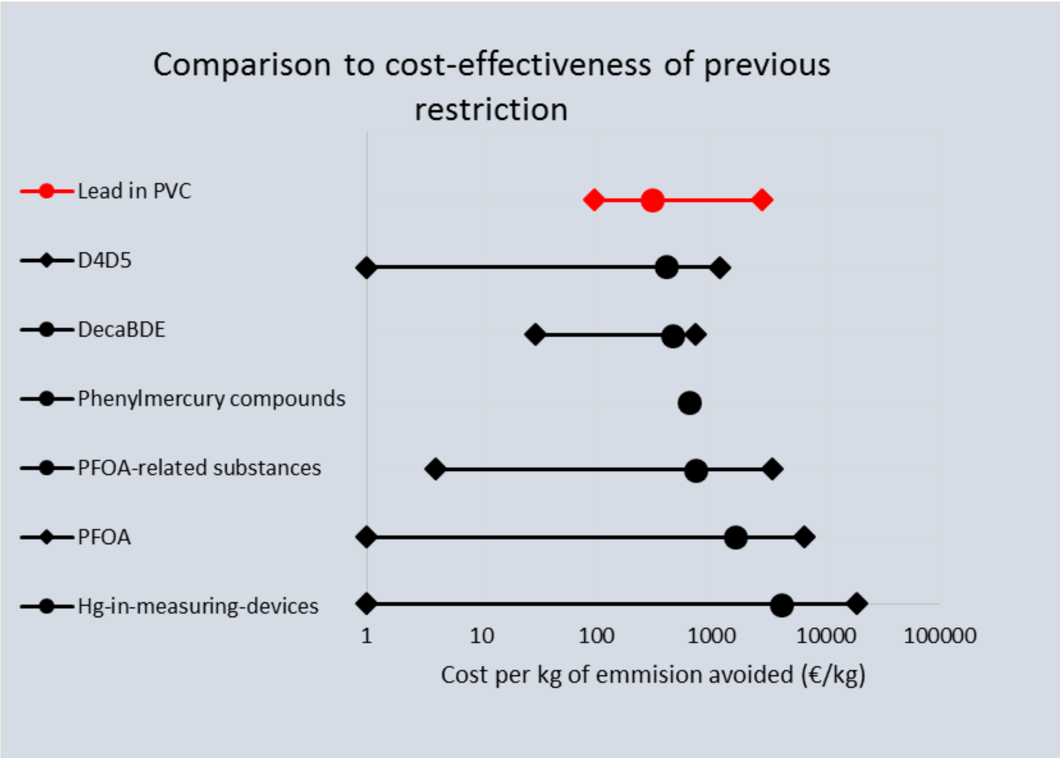

Figure 4. Comparison to the cost-effectiveness values of previous restrictions under REACH(with points representing central values and diamonds representing confidence intervals. *(Source: Table E.14 of Annex E.8.1)*

2.8.2. Cost-benefit considerations (break-even analysis)

The compliance costs of the proposed restriction (switching plus enforcement costs) for the volumes of lead-stabilised PVC placed on the EU market in 2016 range from € 0.9 to 3.3 million with a central estimate of € 2.1 million (section 2.4) These cost estimates are conservative in that they presume the total additional production cost will be fully passed on to EU consumers. If it is considered that one IQ point has a value of € 10000 it is found that annually 209 IQ points need to be prevented from being lost due to Pb exposure in order to break even (see Annex E.8.2).

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. 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 lead 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):

$$1.08\,\frac{\frac{\mu g}{kg\ BW}}{day}\text{per IQ point} * 365\,\frac{day}{year} * 15kg\text{ average BW} * 209\text{ IQ points} = 1.24\ g/year$$

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 1.1.6 to range from 0.35 to 33.8 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 (see also Figure 5).

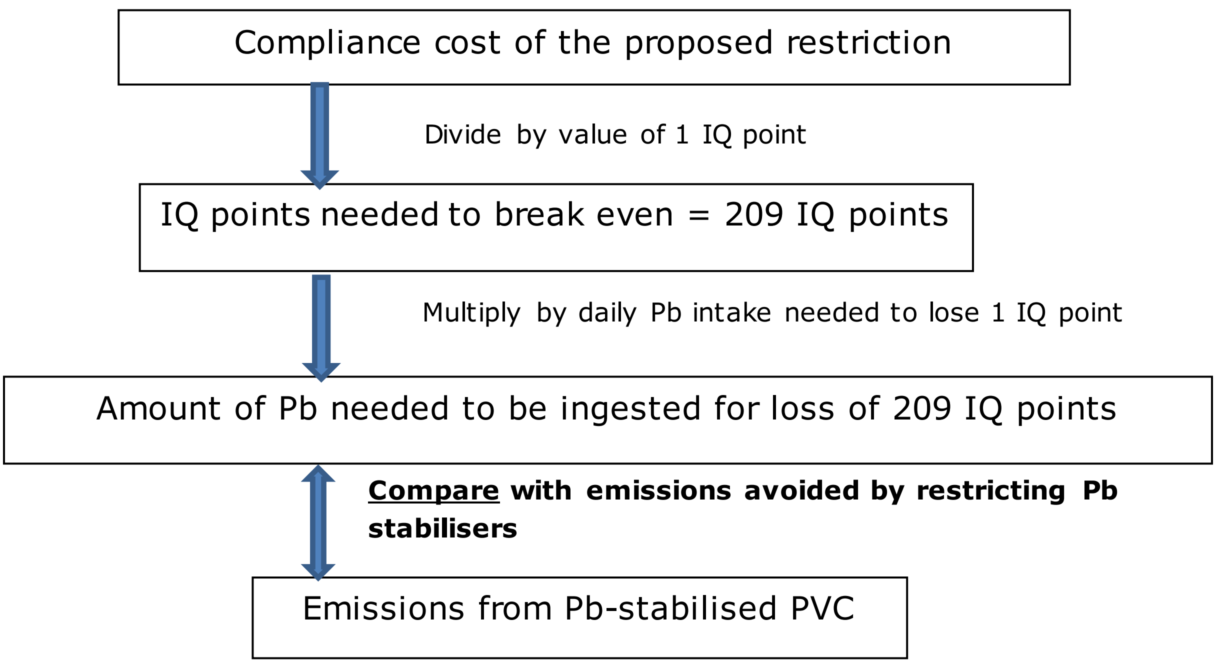

Figure 5. Schematic view of the break-even analysis model

3. Assumptions, uncertainties and sensitivities

This section discusses the key assumptions and uncertainties used in the development of this restriction proposal. These relate to both the exposure assessment (lead emissions) and cost/benefits estimates as also discussed under Annex F of this restriction dossier.

3.1. Uncertainty in the exposure assessment

Section F.1 of Annex F elaborates on the estimation of tonnes of lead, which were used as input values in the exposure assessment of this report to calculate environmental emissions of lead. These input values were derived by application of the various assumptions used in this analysis when applied to:

i. the expected tonnes of lead stabilisers used to produce articles in the EU for 2016 (consultation with ESPA, 2016) and
ii. the tonnes of PVC articles containing lead imported into the EU in 2016 (Eurostat, 2016).

Certainly, these selected values of annual tonnages (based on data received from Industry or Eurostat) do have an inherent uncertainty (*since they are a forecast for 2016 given the current trends*) and therefore are expressed as a range (upper/lower bound). Table 16 lists the main assumptions applied. It has to be noted that uncertainties and assumptions are also inherent to the estimates of releases of lead from PVC articles during their service life and disposal.

Table 16. List of ECHA assumptions applied on tonnes of lead stabilisers/PVC imported articles to derive input parameters (tonnes of lead) for the exposure assessment

Tested parameter	Assumption (AS)	Used value (or range)
Tonnes of lead stabilisers used to produce articles in the EU for 2016 *(0-600 tonnes)* *Source: ESPA (2016)*	**AS-1** Number of companies that participate in VinylPlus	5% of European producers of lead PVC stabilisers, mainly SMEs companies, are not ESPA members and do not participate to VinylPlus) *(ESPA, 2015)*
	AS-2: Share of lead stabilisers for exported PVC items	30% was set as an average value to reflect the share of lead stabilisers used to *stabilise* PVC articles exported from EU in 2016. *(ESPA, 2016)*
	AS-3: Share of PVC articles covered by the proposed restriction	70-80% of the total PVC uses (analytically discussed under Annex A) are covered by the current assessment that mainly targets the building/construction applications *(ECVM, 2015)*
	AS-4: Conversion from tons of lead stabilisers to tons of metallic lead	0.8 was estimated as the conversion factor by relating the molecular weights of metallic lead vs the average of the most commonly used stabilisers (which are presented under section B.1)*(ECHA estimate)*
Tonnes of in PVC articles imported into the EU in 2016. *Source: Eurostat (2016)*	**AS-5:** A share of PVC imported in the EU in 2016 is lead stabilized	20-60% of the PVC imports are stabilised by lead compounds (indicated as "lower (LO) Pb bound" and "upper (UP) Pb bound" respectively). *(ECHA estimate)*
	AS-6: The average lead concentration in the imported PVC articles	1.5 % can be considered as the average lead concentration, based on information communicated by ESPA (May 2016)

Based on the above-mentioned assumptions and sensitivity analysis, the tonnes of lead contained in the selected PVC articles (imported into the EU in the years 2015/2016) were further estimated in Table F.4 of Annex F. Furthermore, ECHA has selected emission factors, from a number of available values in the literature (listed in the Table F.5), as the most relevant ones to enable estimations of lead emission from different PVC waste practices (e.g. incineration, landfill, re-use).

3.2. Uncertainty in the cost-benefit assessment

As also discussed in section F.2.1 of Annex F, the assumptions, uncertainties and sensitivity analysis reported in the exposure assessment section of this report are also of relevance for the cost estimates and in particular for the cost-effectiveness estimations (that take into account both cost and emissions values). 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.

The following Table 17 provides an overview of the main key assumptions that have a certain impact on the cost aspects of the proposed restriction and potentially to the Cost/Benefit ratio (C/B).

Table 17. Summary of uncertainties impacting the benefit-cost (B/C) ratio of the proposed restriction

Impact	Description	Direction B/C ratio is likely affected
Human health impacts to be avoided (general population)	Break-even analysis currently only incorporates neurotoxicity but ignores other health endpoints associated with Pb exposure. Inclusion of these health endpoints would result in a higher B/C ratio.	++
Other human health impacts to be avoided (worker exposure)	Not estimated. Their estimation would increase the value of benefits, resulting in a higher B/C ratio of the proposed restriction.	+
Environmental benefits: e.g., effects on aquatic species	Not estimated. Their estimation would increase the value of benefits, resulting in a higher B/C ratio of the proposed restriction. An indication of their value is provided in section	+
Substitution costs	Likely lower than estimated, leading to lower overall costs of the proposed restriction, resulting in an improved B/C ratio of the proposed restriction (see section E.4.1 of Annex E)	+
Testing costs	Not estimated in main restriction scenario. Their inclusion would lead to higher total restriction costs, reducing the B/C ratio of the proposed restriction (section E.4.2 of Annex E)	-
Enforcement costs	Unlikely to occur as assumed annually throughout the study period. Considering the overestimation would reduce the total restriction costs, resulting in a higher B/C ratio of the proposed restriction (see section E.4.4 of Annex E)	+
Costs to PVC compounders (i.e., on producers of PVC in primary forms)	Cost to compounders using lead are assumed to be fully passed on to downstream users; i.e., they are included in the estimated substitution costs. The potential gains to compounders using alternative stabilisers (e.g. calcium systems) are not estimated.	+
Costs to manufacturers	Not estimated. It is likely that the gains of manufacturers of alternatives (e.g. calcium stabilisers) are larger than the costs to manufacturers of lead stabilisers. This would result in higher benefits and hence in a higher B/C ratio of the proposed restriction.	+
Costs to SMEs	Not estimated. It is possible that some SMEs have higher costs to transition to alternatives (see section E.6.1.2).	-

Social impacts	Not estimated. It is assumed that employment losses of lead manufacturers are offset by employment gains of alternatives manufacturers (see section E.6.1).	+/-
Impacts of higher quality of the PVC articles containing alternative stabilisers	Not estimated but likely positive, leading to lower total restriction costs and a higher B/C ratio of the proposed restriction.	+
Wider economic impacts	Not estimated, likely to be negligible (see section E.6.2)	+/-
Distributional costs	Not estimated, 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.	+/-

Legend:
Direction in which the B/C ratio is affected: "+" denotes an improvement and "-", a deterioration of the B/C ratio of the restriction
Degree of improvement/deterioration of B/C ratio: "+/-" denotes minor, "++/--": moderate and "+++/---": significant improvement/deterioration.

4. Conclusion

As elaborated in Section 1.1.6, the general population is primarily exposed to the non-threshold neurotoxic substance lead through diet (food and beverage consumption, including drinking water) although non-food sources (dust, soil etc.) also contribute to overall exposure. Further reduction of lead releases from lead stabilised PVC articles is likely to have beneficial effects on human health, particularly in specific target populations (e.g. avoid IQ loss in children). In analogy to the approach used in other REACH restrictions for substances where it is not possible to derive a threshold (in line to Annex I of REACH, paragraph 6.5), a comprehensive exposure and risk characterisation for the lead compounds used as PVC stabilisers has not been undertaken and releases of lead from PVC articles are used as a proxy for risk.

The total quantity of lead expected to be released from PVC articles placed on the Union in 2016 (following their disposal) was estimated to be between 4.3 and 10.3 tonnes with a median estimate of 6.8 tonnes. Approximately 90% of the estimated lead emissions during 2016 are expected to be released from PVC articles imported into the EU.

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

The costs of the proposed restriction are currently (2016 values) estimated at €2.1 million annually (median value). Overall, it is therefore assumed that the total economic impacts in 2020 (indicative year for entry into force of the proposed restriction) should be substantially lower than in 2016, but no quantitative assessment on the development of compliance costs was undertaken. In addition, no significant social impacts (e.g. loss of employment, or impact on consumers) are anticipated from the implementation of the proposed restriction**.**

The cost effectiveness of the proposed restriction for lead in PVC was estimated at central value of 308 €/kg of Pb emissions avoided, in the same order of magnitude (or lower) as previous restrictions under REACH on, mercury and its compounds (i.e. phenyl mercury). A break-even analysis was also performed to provide an indication of the expected impacts on human health from the proposed restriction that breaks even if 1.24 g of the lead emitted per year would be ingested by humans.

Overall, the proposed restriction is considered to be a balanced justified and cost effective measure which (i) targets to the exposures and is capable of reducing the identified risks within a reasonable period, thereby leading to human health and environmental benefits; and (ii) is affordable for the impacted supply chains with human health benefits that outweigh the risks. The proposed restriction is a practical and monitorable measure for industry and enforcement authorities. It builds on the existing industry compliance and Member State enforcement practices on lead in PVC. It is implementable, enforceable and manageable.

In conclusion, the restriction dossier demonstrates that an action is required on a Union-wide level and the proposed restriction is the most appropriate measure. This conclusion is reinforced when uncertainties are taken into account.