EUROPEAN CHEMICALS AGENCY

ANNEX XV EVALUATION REPORT

Evaluation related to the recovered PVC containing cadmium to enable the Commission to conduct the required review of the existing derogation in paragraph 4 of entry 23 of Annex XVII to REACH

SUBSTANCE NAMES: Cadmium and its compounds

IUPAC NAMES: Cadmium and its compounds

EC NUMBERS: 231-152-8 (Cadmium)

CAS NUMBERS: 7440-43-9 (Cadmium)

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The European Commission requested ECHA to prepare an evaluation report to assist the Commission with its review of the derogation in paragraph 4 of entry 23 of Annex XVII to REACH for cadmium and its compounds in mixtures and articles containing recovered polymers or copolymers of vinyl chloride (PVC). The Commission asked ECHA to determine the current quantities and average cadmium concentration of post-consumer rigid PVC waste and of the recovered PVC obtained from it, related to certain applications, and to review the hazards associated with cadmium (human health and the environment) as well as the risks associated with the use of recovered PVC containing cadmium. Based on this evaluation, the Commission will consider whether to request ECHA to prepare an Annex XV dossier in accordance with Article 69(1) to launch the procedure to amend the derogation granted in paragraph 4 of entry 23.

ECHA investigated the derogation in place for the restriction of cadmium and its compounds in products containing recycled PVC. The restriction includes a generic concentration limit value of 0.01 % weight by weight for cadmium compounds (as cadmium). However, certain mixtures and articles (see footnote 4 below) containing recycled PVC are allowed to be placed on the market with a higher cadmium concentration (concentration limit value of 0.1 w/w).

The overall conclusion of the evaluation is that the current limit value associated with the derogation for recovered PVC articles could be reduced, for example to 0.08 % w/w, without major impacts on current recycling rates nor costs to industry. However, reducing the limit would not significantly improve product safety nor environmental protection, and that any potential decline in recycling - as a result of a tighter limit - could actually lead to an increase in releases of cadmium to the environment as greater quantities of PVC are disposed of as waste, rather than being recycled.

During the preparation of this report, the European Parliament adopted a resolution related to a restriction proposal on lead in PVC objecting to the adoption of the draft restriction (P9_TA(2020)0030). This resolution raises several issues that are applicable to the assumptions made during the current investigation on cadmium in PVC. ECHA notes that many issues related to the recycling of PVC containing lead apply equally to the current investigation. The main difference being that the recycling derogation in the current cadmium in PVC measure already exists and is not time limited. The recently proposed restriction of lead in PVC contained a derogation for certain types of rigid PVC articles to have a higher concentration limit value for lead, similar to the existing approach to cadmium in Entry 23 of Annex XVII. Aligning the list of articles derogated under the cadmium restriction with those of the lead restriction (if adopted) could simplify compliance for operators and enforcement by authorities.

Background

This investigation report concerns the presence of cadmium in PVC and its potential to pose a risk to human health or the environment that is not controlled. The report focuses on the risk associated with cadmium present in recovered PVC[1] as a legacy impurity. Cadmium and

[1] Recovered PVC is also referred to as recycled PVC.

eight cadmium-containing substances are included in the candidate list of Substances of Very High Concern.

During the development of this report, there was also considerable work done on lead in PVC.[2] The outcomes of that work affect the conclusions here; one of the main ones being that recycling can be considered to be a risk management measure in itself as long as service-life releases are minimised (as previously agreed by ECHA's Committee for Risk Assessment (RAC) in relation to their evaluation of the proposed restriction of lead in PVC). Subsequently, greater overall risks to the environment and human health may occur should recycling rates fall. Some parts of this report were revised to account of the information available from the lead in PVC restriction.

Large quantities of waste PVC arise per year in the EU, which are forecast to increase. Cadmium is currently regulated by entry 23 of Annex XVII to REACH[3]. Paragraph 4 in the entry contains a specific derogation for mixtures and articles used in certain applications containing recovered PVC (from waste), which are allowed to contain a higher concentration of cadmium (0.1 % w/w) than is otherwise allowed (0.01 % w/w). This is not a time limited derogation. Based on a review clause within paragraph 4, the derogation needs to be reviewed, in particular with a view to the feasibility of reducing the concentration limit value for cadmium in recovered PVC and to reassess the scope of the articles included in the derogation.

The European Commission therefore requested ECHA to prepare an evaluation report in order to assist them with the review the derogation[4] for cadmium and its compounds in mixtures and articles containing recovered PVC[5]. The Commission asked ECHA to determine

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[2] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180a40af7

[3] Directive 91/338/EEC (subsequently enacted as entry 23 of Annex XVII of REACH).

[4] In its request, the Commission requests ECHA to:

(i) determine, based on the most up-to-date data available, the current quantities and average cadmium content of post-consumer rigid PVC waste and of recovered PVC obtained from it, related to the applications referred to in points (a) to (e) of that paragraph ["*profiles and rigid sheets for building applications; doors, windows, shutters, walls, blinds, fences and roof gutters; decks and terraces; cable ducts; pipes for non-drinking water if the recovered PVC is used in the middle layer of a multi-layer pipe and is entirely covered by a layer of newly produced PVC in compliance with paragraph 1 above*"].

Estimations of cadmium content and projections of cadmium content in recovered rigid PVC which served as a basis for the existing derogation [VITO report 2009/TEM/R/189] should be reviewed and updated, together with a targeted impact assessment which should address different lower maximum cadmium limit values in recovered PVC down to the full elimination of the derogation.

(ii) review the hazards associated to cadmium as well as the risks associated to the use of recovered PVC containing cadmium. The review should be based on the available information from studies conducted in the EU or abroad, including reports from industry.

[5] https://www.echa.europa.eu/documents/10162/13641/echa_rest_proposals_rubber_granules_en.pdf/1a8a254c-bd4a-47b1-a091-99ae4a94a8c2

the current quantities and average cadmium concentration of post-consumer rigid PVC waste and of the recovered PVC obtained from it, related to certain applications, and to review the hazards associated with cadmium (human health and the environment) as well as the risks associated with the use of recovered PVC containing cadmium.

The presence of cadmium in post-consumer PVC waste arises because of legacy uses of cadmium-containing substances as stabilisers and pigments that are, with few exceptions[6], no longer permitted. Under current EU legislation, PVC waste can either be recycled, incinerated or disposed of via (typically municipal) landfills. Recycling is increasing and is forecast to increase further into the future. A proportion of PVC waste is also exported from the EU[7]. The presence of legacy cadmium affects PVC waste handling, particularly the quantity that is recycled.

As the volume of PVC waste arising each year is not currently fully recycled, the remainder is disposed of via incineration or landfill, resulting in releases of cadmium to the environment. Conventional mechanical recycling techniques can be used to recycle PVC multiple times before disposal becomes necessary.

As the service-life of PVC articles is relatively long (particularly in construction applications where current recycling activities are focussed), recycling waste PVC into new PVC articles postpones end-of-life releases of cadmium (as well as other hazardous substances e.g. lead). Service-life emissions of cadmium from certain types of articles made of rigid recycled PVC can be expected to be very low, particularly where encapsulation of recycled material occurs (such as in window profiles and pipes for non-drinking water). As such, using recycled PVC in these articles can be considered as a risk management measure. As the relatively long lifecycle of PVC articles used for construction (50 years is not uncommon) maintains cadmium in material cycles, this will allow sufficient time for society to devise more sustainable ways of dealing with legacy materials in waste PVC, including cadmium, for example through decontamination or chemical recycling[8].

The dual-challenge facing industry and regulators is therefore how to optimise recycling of PVC (and plastics more generally) to maximise societal benefit (including resource efficiency), whilst ensuring a high level of protection for human health and the environment from hazardous legacy substances (such as cadmium).

Analysis

The principal risk of cadmium addressed in this review is that of toxicity to the kidney, especially to the proximal tubular cells where cadmium accumulates over time and may cause renal dysfunction. Cadmium can also cause bone demineralisation, either through

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[6] For instance, exemption under paragraph 3 (articles coloured with mixtures containing cadmium for safety reasons.) See QA ID: 0825:.Q&As - ECHA (europa.eu) .

[7] UK used to have quite a high recycling rate among the EU member states. At this point, it is unclear how the UK's withdrawal from the EU affects the exports/imports of PVC waste.

[8] According to CEFIC's position paper, 'Chemical recycling is not yet a widely deployed option for the recycling of plastic waste. Scale-up requires innovation, harmonised policies, recycling-chains and clear pathways to "valorise" plastic waste that is currently incinerated, landfilled or wasted.' https://cefic.org/app/uploads/2020/03/Cefic-Position-Paper-on-Chemical-Recycling-1.pdf

direct bone damage or indirectly as a result of renal dysfunction. Data on human exposure to cadmium in the general population have also been statistically associated with increased risk of cancer such as in the lung, endometrium, bladder and breast. Generally Cadmium is considered as a threshold substance, however, this is not always clear in case of carcinogenicity, as mentioned in section 3.6. EFSA (2009) acknowledged that human and environmental exposure to cadmium has decreased significantly over the last 20 to 30 years and that the risk for adverse effects on kidney function at an individual level at dietary exposures across Europe is now very low. Despite this, the EFSA CONTAM Panel recommended that exposure to cadmium at the population level should be reduced.

The need for the derogation in the entry 23 of Annex XVII to REACH was supported, at the time when the regulation was adopted, by estimates of the cadmium concentration and projections of the cadmium concentration in recovered rigid PVC [VITO report 2009/TEM/R/189]. Given the request by the European Commission in 2016, ECHA contracted VITO to review and update the original report, here referred to as 'updated cadmium in recovered PVC study' or VITO 2017 study.

The updated cadmium in recovered PVC study provides contemporary data on the past, current and future quantities and average cadmium concentration in post-consumer PVC waste and of the recovered PVC obtained from it. Contrary to expectations, the quantity of legacy cadmium in materials to be recycled has not decreased since the implementation of the derogation. This is largely because, the underlying data used in the modelling has changed significantly since 2009 as new expert estimates suggest that the concentration of cadmium in recovered PVC is actually 75% greater than estimated by industry experts at the time the derogation was developed[9]. However, the divergence in the estimates is overshadowed by a large increase of cadmium-free waste originating from products put on the market after 1996. As a result, the overall estimated cadmium concentration in articles is similar to that estimated in the 2009 study. It was noted during the preparation of this report that little in the way of measured data was available on concentrations on cadmium in recyclate.

In line with the 2009 study, and with the scope of this review, VITO also performed a targeted impact assessment, based on updated data on PVC waste arisings and product markets (and projections for both) provided by EuPC/VinylPlus[10].

To check the robustness of the calculations of cadmium concentrations in new PVC products VITO also undertook a sensitivity analysis on each of the basic parameters (being historic cadmium use concentration, consumption and average lifetime).

The sensitivity analysis identified that the length of article service life and the concentration of cadmium used (in original articles) have the most impact on the cadmium concentrations

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[9] In December 2019 EPPA provided some information on monitoring of cadmium content in the recycled PVC core of PVC windows. The information is in form of tables and covers a few of the most recent years, and its representativeness is uncertain (EPPA 2019: EPPA Monitoring on Cadmium in rPVC of PVC Windows, Brussels, November 27th).

[10] EuPC is the EU-level Trade Association, based in Brussels, representing European Plastics Converters (sometimes called "Processors"). VinylPlus is a voluntary sustainable development programme of the European PVC industry.

of new window profiles containing recovered PVC. The impact of increased consumption of window profiles is very limited.

To aid the review of the present derogation, four potential future derogation options (scenarios) were defined using different concentration limit values for cadmium in various PVC products, as follows:

- Scenario A: Retain the current derogation, with the same limit value (0.1% w/w);
- Scenario B: Remove the derogation – as a result the 0.01% w/w limit applies for all uses, including uses of recovered PVC;
- Scenario C: Retain the current derogation, with a lower concentration limit value (0.08% w/w) for specific PVC products[11] made from recovered PVC;
- Scenario D: Retain the current derogation, with a lower concentration limit value (0.05%) for specific PVC products[12] made from recovered PVC, except for window profiles (retain the current limit value of 0.1% w/w)

The use of non-standard/non-mechanical recycling techniques such as feedstock recycling (i.e. the breakdown of PVC into other components followed by e.g. gasification, pyrolysis, dechlorination etc) or non-conventional mechanical recycling[13] (estimated to be able to handle 100 000 tonnes of PVC by 2020) are not considered further in this report as they do not produce PVC with cadmium (Cd) content <1% for recycling. These would lead to additional primary PVC to be produced for replacement (with additional high energy costs[14]).

In addition, the impact of a time-limit to the derogation has also not been considered (as this was not requested) but this would encourage industry to find solutions to reduce the amount of cadmium in recycled PVC over time.

Scenario A focusses on prolonging the current situation and retaining the existing derogation, with the same limit value (0.1% w/w). In Scenario B, the derogation is abandoned, and the generic cadmium limit value (0.01% w/w) applies to all products, including those made from recovered PVC. In Scenario C, the concentration limit value for products containing recovered PVC is reduced from 0.1% (w/w) to 0.08% w/w, a concentration which, would not affect current recycling rates (which would remain similar to

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[11] The scope may need to be reconsidered, e.g. whether to align the list of articles with the list of articles in the lead in PVC restriction.

[12] See the previous footnote concerning the Scenario C. The same applies to Scenario D.

[13] VinylPlus differentiates between the conventional and non-conventional technologies and explains that conventional technologies consist of sorting and shredding separate components within the waste streams, whereas non-conventional technologies precede these steps with a chemical processing or pre-processing in order to remove all non-PVC waste from more complex or contaminated waste streams.

[14] The amount of CO_2 that is generated manufacturing 1 tonne of PVC varies across the European PVC Industry. One example is Hydro Polymers Ltd that emits around 640 kg of CO_2 for every 1 tonne of polymer produced in the manufacturing chain (Jason Leadbitter *PVC and sustainability* Prog. Polym. Sci. 27 (2002) 2197–2226).

those in Scenario A). In Scenario D, the concentration limit value for window profiles containing recovered PVC would remain at 0.1% w/w, whereas for other PVC products containing recovered PVC the concentration limit value would be reduced to 0.05% w/w. Again, because of the concentration of cadmium reported in articles, this scenario would not directly affect recycling rates, which would remain similar as in Scenario A.

The defined scenarios were analysed in a targeted impact assessment. The key issues considered included:

- The extent to which the different scenarios affect recycling and cadmium exposure/releases;
- The extent to which the scenarios require legislative changes, and the administrative and implementing complexity of such changes;
- Whether the scenarios reduce, maintain or improve the overall environmental impact;
- Potential impacts of the scenario on competitiveness;
- Social impacts such as employment.

Conclusions

The main conclusion of the analysis is that the maintenance of scenario A or the adoption of the more stringent concentration limits defined in Scenarios C and D would not affect current recycling activities as industry appears to be able to structure its use of recyclate such that the recycled products could stay within of the limits proposed in scenarios C and D As such, they allow exploitation of the currently installed recycling infrastructure for using recyclate with only limited associated releases of cadmium. The adoption of Scenario B (with the 0.01% limit value) would set notably more stringent requirements for recovered PVC. The scenario would have limited effects of service-life exposure but would result in a greater volume of post-consumer PVC waste being disposed of via landfill or municipal incineration, with consequent increase in the release of cadmium to the environment compared to the same quantity being recycled.

The modelling undertaken by VITO was based on average concentrations of PVC in waste and does not take into account the variability in cadmium concentration resulting from different origins and ages of waste. As the limit imposed by a restriction has to be complied with under all circumstances, adoption of a more stringent concentration limit value for recovered PVC may necessitate the need to use more costly approaches for sorting, storing, re-mixing or other such activities (such as determining the cadmium concentration). The simplified analysis based on average concentrations overlooks these factors, which in practice would increase the cost of recycling and may therefore lead to more material being disposed of rather than recycled.

To support this assessment, the potential release of cadmium to the environment that would occur with and without current levels of recycling of post-consumer PVC was estimated. Modelling of releases demonstrated that recycling of PVC, at current levels, prevents (or at worst delays) approximately 20% of the releases of cadmium that would otherwise occur if no recycling took place. These releases would not occur during the subsequent service life of articles made from recycled PVC (or during their manufacture) and would continue to be prevented for as long as the material is stopped from entering conventional end of life disposal (e.g. via landfilling or incineration).

Eventual disposal of articles made of recycled PVC (feasibly after several article service lives) could potentially result in releases (in which case recycling delays rather than prevents releases), but this would be dependent on the waste treatment technologies in place at the point in time of final disposal and the effectiveness of the risk management measures to prevent releases to the environment at that time. Assuming relatively long article service lives (which is not unreasonable for PVC construction products to which the derogation is applied), decontamination or chemical recycling technologies, that can remove legacy hazardous substances from post-consumer waste PVC, are likely to have reached maturity.

In summary, compared to the current limit values, the concentration limits associated with the derogation could feasibly be reduced (to either of those outlined in Scenarios C or D) without major impacts. This is because sufficient amount of recovered PVC with adequately low legacy cadmium concentration is currently available on the EU market. Potential additional costs, if any, arising under scenarios C and D would be limited to those from e.g. additional sorting and surveillance by recyclers to ensure compliance with the lower limit. As long as the material would stay within the lower limits, without major extra effort, no additional costs to industry would result.

Reducing the concentration limit (too low) could theoretically drive industry to reject more potentially recyclable material (as there is less tolerance of variability), increasing the cost of recycled material and (perversely) increasing overall emissions from waste PVC (as a greater proportion of post-consumer waste PVC is disposed of by landfill and incineration). However, as Scenarios C and D appear to simply reflect current industry practice, industry is expected to have limited compliance costs. However, although costs would be minor so would the benefits for the environment or to human health from lower concentration limits as releases are minimised by maximising recycling into articles with low service life release rather than reducing the concentration of cadmium in articles.

From a regulatory perspective, the modification of the restriction to include stricter limits (Scenarios B, C and D) appear to be an implementable, but (administratively) costly measure, that would be unlikely to significantly improve the safety of articles made out of recovered PVC but which may lead to reduced recycling (and thus increased releases of cadmium in the shorter term and higher resource use in general). The effect is more profound the tighter the limit is.

Greater overall risks to the environment may occur should recycling rates fall as recycling can be considered to be a risk management measure in itself as long as service-life releases are minimised (agreed by RAC in relation to the lead in PVC restriction). Furthermore, the greater the reduction in the limit value, the greater is the potential (unintuitive) environmental risk (administrative cost staying closely the same).

It should also be considered how to create incentives to industry to gather and make available information concerning the cadmium concentration in waste PVC and recyclate, such as a requirement to make regular measurements of cadmium concentrations. The lack of such information hindered drawing conclusions from this and the VITO (2009) study. Such data should also be useful for the enforcement of the current legislation (with the derogation). In addition, a time limit to the exemption could also be considered.

Effects of other potential risk management measures (e.g. labelling) were not assessed as this study focuses strictly to use of the derogation following the request by the Commission.

During the preparation of this report, the European Parliament adopted a resolution related to a related restriction proposal on lead in PVC objecting to the adoption of the draft restriction (P9_TA(2020)0030). This resolution raises several issues that are applicable to the assumptions made during the current study on cadmium in PVC. Many issues related to the recycling of lead in PVC apply equally to cadmium in PVC. The main difference here is that the recycling derogation in the current cadmium in PVC measure already exists and is not time limited.

In terms of the scope of articles to be included in the derogation, ECHA notes that the recently proposed restriction of lead in PVC contained a derogation for certain types of rigid PVC articles to be made from recycled PVC. The basis for this list was the existing restriction on Cd on recycled PVC, but was extensively revised during the development of the proposal and subsequent opinion-making to limit the scope of permitted articles to those with minimal potential for exposure during service life; principally by requiring the encapsulation of recycled PVC by another material or by excluding articles from the inhabited parts of buildings (requiring their use in service areas/voids). This was to ensure a high level of protection for human health. Should the restriction of lead in PVC be adopted it would appear sensible to align the list of articles derogated under the cadmium restriction with those of the lead restriction. This would simplify compliance for operators and enforcement by authorities.

Report

1. Introduction

Historically there were two main uses of cadmium compounds in PVC: use as a stabiliser and use as a pigment.

There are two basic types of PVC where cadmium compounds were used as a stabiliser: flexible (or plasticised PVC, which is sometimes referred to as pPVC) and rigid PVC (or unplasticised PVC, which is sometimes referred to as uPVC).

Both flexible and rigid PVC formulations require stabilisers to prevent heat and light mediated degradation of the molecular structure of the polymer chain (particularly those that occur during manufacture), accompanied by release of hydrogen chloride, discolouration and embrittlement.

The cadmium compounds used as pigments in PVC include: cadmium zinc sulphide yellow, cadmium sulphoselenide red and cadmium sulphoselenide orange.

The presence of cadmium in post-consumer PVC waste arises because of legacy uses as stabilisers and pigments that are, with few exceptions, no longer permitted. Cadmium is not restricted in PVC and other plastic materials where it is used for safety reasons[15].

The presence of legacy cadmium affects PVC waste handling, particularly recycling. PVC waste can be recycled, incinerated or disposed of via (typically municipal) landfills. A small proportion is currently also exported from the EU.

As the volume of PVC waste arising each year is not currently fully recycled, a portion of PVC waste containing cadmium is diverted to incineration or landfill. These waste treatment techniques are associated with releases of cadmium to the environment. All cadmium containing post-consumer PVC waste will, unless recycled, have to be disposed of.

As the service-life of PVC articles is relatively long (particularly in constructions applications where recycling activities are focussed), recycling waste PVC into new PVC articles postpones end-of-life releases of cadmium (and other hazardous substances e.g. lead) to the environment (in reality for many hundreds of years[16]). As such, recycling can be considered as a type of risk management, as long as risks during the service-life of the new articles produced from recyclate have been minimised.

The challenge facing industry and regulators is therefore how to optimise recycling, whilst ensuring that the risks from the presence of cadmium in recycled articles are minimised. There is also a need to decide on the relative importance of recycling vs production of new PVC.

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[15] ECHA's Q&A on this subject states that there are two safety aspects in relation to this derogation. The first relates to the use of a specific colour or pigment with certain properties which is necessary to prevent accidents. The second relates to the use of a specific colour or pigment with certain properties in safety equipment.

[16] Information received during the lead in PVC restriction discussions

Directive 91/338/EEC (subsequently enacted as entry 23 of Annex XVII of REACH) limited the use of cadmium in PVC (and other synthetic organic polymers) articles to a concentration of 0.01% by mass of the plastic material. The restriction derogated mixtures produced from PVC waste (recovered PVC) and mixtures and articles containing recovered PVC if the concentration of cadmium does not exceed 0.1% (w/w) in the following rigid PVC applications:

a) Profiles and rigid sheets for building applications;
b) Doors, windows, shutters, walls, blinds, fences, and roof gutters;
c) Decks and terraces;
d) Cable ducts;
e) Pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC.

This is not a time limited derogation but entry 23 also requires that the derogation for recovered PVC is reviewed by 31 December 2017 in particular with a view to reducing the concentration limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e).

The use of cadmium in PVC as a stabiliser was discontinued as a result of Directive 91/338/EEC as it cannot perform its function at concentrations <0.01 % w/w and other suitable alternatives existed. Registrations for the relevant cadmium pigments cover the use of these substances as colouring agents and pigments.

On 1 June 2016[17], ECHA received a request by the European Commission to:

(i) determine, based on the most up-to-date data available, the current quantities and average cadmium content of post-consumer rigid PVC waste and of recovered PVC obtained from it, related to the applications referred to in points (a) to (e) of that paragraph ["profiles and rigid sheets for building applications; doors, windows, shutters, walls, blinds, fences and roof gutters; decks and terraces; cable ducts; pipes for non-drinking water if the recovered PVC is used in the middle layer of a multi-layer pipe and is entirely covered by a layer of newly produced PVC in compliance with paragraph 1 above"].

    Estimations of cadmium content and projections of cadmium content in recovered rigid PVC which served as a basis for the existing derogation [VITO report 2009/TEM/R/189] should be reviewed and updated, together with a targeted impact assessment which should address different lower maximum cadmium limit values in recovered PVC down to the full elimination of the derogation.

(ii) review the hazards associated to cadmium as well as the risks associated to the use of recovered PVC containing cadmium. The review should be based on the available information from studies conducted in the EU or abroad, including reports from industry.

Based on this evaluation, the Commission will consider whether to request ECHA to prepare an Annex XV dossier in accordance with Article 69(1) to launch the procedure to amend the

[17] https://echa.europa.eu/documents/10162/13641/echa_rest_proposals_rubber_granules_en.pdf

derogation granted in paragraph 4 of entry 23, in particular with a view to reducing the limit value for cadmium and/or to revoke the derogation for one or all of the applications listed in points (a) to (e) of that paragraph.

In addition to cadmium and its compounds being restricted in Annex XVII, cadmium and eight of its salts (carbonate, nitrate, hydroxide, chloride, fluoride, oxide, sulphide, arsenate) are included on the candidate list as Substances of Very High Concern due to their carcinogenicity and specific target organ toxicity.

For the preparation of this report, ECHA contracted VITO NV[18] to update a 2009 study on the cadmium content of recycled (recovered) PVC waste that VITO NV completed for VinylPlus (subsequently referred to as 'the 2009 study').

The study undertaken for ECHA updates the data on past, current and future situation of quantities and average cadmium content of post-consumer PVC waste and of recovered PVC obtained from it, related to the applications mentioned below. Furthermore, a limited targeted impact assessment is performed addressing different scenarios supporting the phase-out of cadmium in PVC products.

2. The problem identified

2.1. Manufacturing

Cadmium stabilisers are no longer produced for use in the EU; the manufacturing of cadmium pigments is not covered in this document.

Prior to the UK withdrawal from the EU the registrants for the cadmium pigments were located in the UK. Since April 2021 all registrations where a transfer to the EU was started were finalised, and the registrations for which no transfer was started (which became legally void on 1 January 2021) have been revoked in REACH-IT. The current status of the registrations previously belonging to UK companies, i.e. either transferred to the EU/EEA or revoked, can be found in the REACH-IT.

2.2. Use of cadmium compounds in PVC

The use of cadmium compounds in PVC was discontinued in 2001, as a result of Directive 91/338/EEC. In that Directive a derogation was given to mixtures produced from PVC waste (recovered PVC) if the concentration of cadmium in mixtures and articles containing recovered PVC (expressed as cadmium metal) does not exceed 0.1 % by weight of the plastic material in the following rigid PVC applications:

(a) profiles and rigid sheets for building applications;

(b) doors, windows, shutters, walls, blinds, fences, and roof gutters;

(c) decks and terraces;

(d) cable ducts;

(e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC in

[18] VITO NV - Boeretang 200, BE-2400 MOL, Belgium

compliance with paragraph 1 above.

The main field of application for recovered PVC articles is the building sector (windows, pipes, flooring, cables and membranes). PVC is often used in these types of articles due to its stability and long lifetime, as it requires minimum care and maintenance during the use phase.

Two main uses of cadmium compounds in PVC have been identified: use as a stabiliser and use as a pigment. Both these uses can be expected to contribute to the cadmium content of recovered PVC.

2.2.1. Cadmium stabilisers

There are two types of PVC compounds and articles where cadmium was used as a stabiliser: flexible (or plasticised PVC, which is sometimes referred to as pPVC) and rigid PVC (which is sometimes referred to as unplasticised PVC or uPVC).

Both flexible and rigid PVC formulations required the addition of stabilisers to prevent heat and light mediated degradation in the molecular structure of the polymer chain (particularly during manufacture), accompanied by release of hydrogen chloride, discolouration and embrittlement. Stabilisers have been usually added at a concentration of between 1 % and 8 % by mass of compounded resin, depending on the particular application[19].

Cadmium-based stabilisers are one specific group of stabilisers for PVC articles that were used in the past.

Cadmium stabilisers were used for PVC stabilisation in liquid form (e.g. cadmium-2-ethylhexanoate) or in solid form (e.g. cadmium-stearate, cadmium-laurate). Liquid stabilisers were used primarily in flexible PVC, while solid stabilisers were used primarily for producing rigid profiles[20]. Other cadmium compounds than those reported here could also have been used as stabilisers.

It is not clear what quantities of cadmium stabilisers were used per year. Prior to 2001, the tonnage of cadmium-based stabilisers was already in decline (expressed as cadmium metal) in the EU-15[21]:

- 1997: 104 tonnes
- 1998: 51 tonnes
- 1999: 31 tonnes

In the absence of more precise values, it is believed that the annual consumption of cadmium-based stabilisers, being incorporated in PVC articles in Europe, could have peaked for several years at greater levels (around 3 000 tonnes of cadmium annually).

It should be noted that electrical cables and pipes were never stabilised with cadmium compounds.

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[19] In Adams et.al., AEAT, 2000

[20] based on Billiet, J. and Hamilton, A., 1996

[21] Vinyl 2010 Progress Report, 2001 – page 9

2.2.2. Cadmium pigments

The cadmium compounds used as pigments in PVC include: cadmium zinc sulphide yellow, cadmium sulphoselenide red and cadmium sulphoselenide orange.

According to Eurocolour, the three pigments (mentioned above) are used in the following polymers:

- low-density polyethylene (LDPE);
- styrene acrylonitrile resin (SAN); and
- polyamides;

In addition, for signal colours and security applications all kinds of polymers are used.

The applications include: wall anchors and joining elements for the building sector, cramps for the electric sector, plastic cages for the textile sector, parts for rescue boats for ships, parts for security equipment for outdoor applications, seats, reels and diverse technical parts for outdoor applications.

In total about 4.1 tonnes of these pigments are used annually for safety critical applications in plastics in the EU; the amount specifically in PVC is not known. The concentration of the pigment in the final article is approximately 0.5% w/w.

2.2.3. End-of-life

Compared to many other plastics articles, PVC articles are durable. This applies particularly in building and construction applications, which are central to this study. Therefore, such PVC articles typically reach the end of their service life only after many years (up to 50 years).

The disposal of PVC waste will contribute to releases of cadmium to the environment. PVC articles disposed in landfill are considered to be relatively stable with limited potential for cadmium 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 may contribute to the releases of cadmium to air and water from municipal waste incinerators. Best available techniques are set to limit the amount of cadmium permitted to be released in fly ash to 0.005–0.02 mg/m^3 and to receiving water to 0.005–0.03 mg/ml[22]. However, cadmium is also present in bottom ash after incineration of PVC and this is then subject to waste legislation. If the concentration of cadmium in bottom ash is >0.1% (as it is a category 1B carcinogen) it should be treated as hazardous waste but there is anecdotal evidence this is not the case, especially when it is produced in municipal incinerators. Therefore it is assumed for the purposes of this assessment that the majority of bottom ash either goes to normal landfill or for other uses e.g. in construction activities. Therefore a restriction at source on cadmium is important to limit the effect of these latter activities.

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[22] Frederik Neuwahl, Gianluca Cusano, Jorge Gómez Benavides, Simon Holbrook, Serge Roudier (2019); Best Available Techniques (BAT) Reference Document for Waste Incineration; EUR 29971 EN; doi:10.2760/761437

Recycling of PVC articles reduces the amount of cadmium going to waste (e.g. landfills or incineration). Emissions of cadmium during the recycling PVC are assumed to be low as the cadmium is fixed in the PVC matrix, but may occur via the formation of dusts during mechanical grinding and milling. Exposures to workers will be minimised under occupational health legislation. However, measured data is not easily available in the literature to check this.

Recycling increases the length of time that cadmium will be present in PVC products. However, the cadmium concentration in recycled articles will progressively decline over time reflecting the fact that the concentration of cadmium in PVC recyclate will also gradually reduce as end of life articles (the feedstock) will steadily contain less cadmium (as it is no longer used).

In the PVC categories of interest in this report (profiles and pipes), the quantity of products containing cadmium grew steeply from the 1950s until 2007-2008, after that the production volumes declined and stabilised on generally lower lever (as described in the graphs later below). Volumes of waste arisings follow the changes in use with a lag depending on the duration of their use. For instance, waste arisings from cadmium containing window profiles are expected to start to decrease as of 2040 whereas waste arisings from other profiles are expected to decrease earlier due to a shorter article service life. Waste arisings from (non-pressure) pipes (the articles with the longest service lives) are expected to peak only after 2050.

3. Hazard, exposure / emissions and risk

3.1. Identity of the substance(s)

Table 1. An overview of the typical substances used as stabilisers (previous use) and pigments

Substance	EC number	CAS number	Registration status	Use in PVC (current or previous)[23]
Cadmium bis(2-ethylhexanoate)	219-346-0	2420-98-6	Not registered	Stabiliser
cadmium dioctadecanoate (cadmium distearate)	218-743-6	2223-93-0	Not registered	Stabiliser
cadmium didodecanoate (cadmium dilaurate)	220-017-9	2605-44-9	Not registered	Stabiliser
barium cadmium tetrastearate	214-740-9	1191-79-23	Not registered	Stabiliser
cadmium	220-650-0	2847-16-7	Not	Stabiliser

[23] Uses of substances other than as a stabiliser or a pigment in PVC are not covered

didecanoate			registered	
cadmium carbonate	208-168-9	513-78-0	10 - 100 tonnes per annum	Stabiliser?
cadmium oxide	215-146-2	1306-19-0	1 000 - 10 000 tonnes per annum	Stabiliser?
cadmium sulfoselenide red	261-218-1	58339-34-7	100 - 1 000 tonnes per annum	Pigment[24]
cadmium zinc sulfide yellow	232-466-8	8048-07-5	100 - 1 000 tonnes per annum	Pigment
cadmium sulphoselenide orange	235-758-3	12656-57-4	Not registered.	Pigment

3.2. Classification and labelling

Table 2. Classification and labelling information for the typical substances used as stabilisers and pigments

Substance	**Classification Hazard Class and Category Code(s)**	**Hazard phrases**	**Group entry if relevant**	**C&L notifications (additional)**
Cadmium bis(2-ethylhexanoate) cadmium dioctadecanoate (cadmium distearate) cadmium didodecanoate (cadmium dilaurate) barium cadmium tetrastearate cadmium didecanoate	Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H302 H312 H332 H400 H410	Cadmium compounds, with the exception of cadmium sulphoselenide (xCdS.yCdSe), reaction mass of cadmium sulphide with zinc sulphide (xCdS.yZnS), reaction mass of cadmium sulphide with mercury sulphide (xCdS.yHgS), and those specified elsewhere in this Annex	Acute Tox. 1 H330 Acute Tox. 3 H301 Repr. 1A H360 Repr. 2 H361 Muta. 1B H340 Carc. 1B H350 STOT RE 1 H372 Aquat. Acute 1 H400 Aquat. Chronic 1 H410
Cadmium carbonate	Muta. 1B Carc. 1B Acute Tox. 4*	H340 H350 H332	None	-

[24] It is likely that the registered amount mostly is used for other purposes that as a pigment of plastics.

	Acute Tox. 4* Acute Tox. 4* STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H312 H302 H372 (kidney, bone) H400 H410		
Cadmium oxide	Acute Tox. 2 * Muta. 2 Carc. 1B STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1 Repr. 2	H330 H341 H350 H372 ** H400 H410 H361fd	None	-
Cadmium chloride	Muta. 1B Carc. 1B STOT RE 1	H340 H350 H372 (kidney, bone)	None	Acute Tox. 1 H330 Repr. 1A H360 Acute Tox. 3 H301
Cadmium sulfoselenide red	Not classified		None	There are C&L notifications for: Acute tox. 4 (H302, 312, 332), Skin irritant 2 (H315), STOT SE 3 (H335).
Cadmium zinc sulfide yellow	Not classified		None	-
cadmium sulphoselenide orange	Not classified		None	-

3.3. Environmental effects

3.3.1. Environmental fate properties

3.3.1.1. Cadmium stabilisers

The EU RAR on cadmium metal and cadmium oxide (ECB 2007) provides a comprehensive review of the available data on fate properties of cadmium and cadmium compounds. In the RAR and the REACH registration dossiers for most inorganic cadmium substances, it is assumed that the toxicity of the cadmium-compounds is related (mainly) to the Cd^{2+} ion.

For checking the potential of metal substances to release ions in the environment, a specific test, the transformation/dissolution (T/D) (OECD Series on Testing and Assessment No. 29; OECD, 2001) has been proposed for classification purposes. This test has been performed for metallic cadmium and some cadmium compounds.

Table 3. Examples of transformation/dissolution results for different cadmium compounds.

	Dissolved cadmium (µg Cd/l)	Loading (mg/l)	pH	Duration (days)	Reference
Cd metal	135-192	1-100	+/- 8	7	ECB 2007
CdO	95-227	1-100	+/- 8	7	ECB 2007
CdTe	19	1	6	28	ECHA 2013a
CdTe	15	1	6	7	ECHA 2013a
CdTe	213	10	6	7	ECHA 2013a
CdS	5.75	1	6	28	CSR CdS (Lead registrant 2012)
CdZnS	0.18-0.61	1	6	7	ECHA 2013a
CdZnS	0.98-1.97	1	6	28	ECHA 2013a
CdSSe	< 0.1- 0.24	1	6	7	ECHA 2013a
CdSSe	0.14 -0.23	1	6	28	ECHA 2013a

3.3.1.2. Degradation

Cadmium is not degradable but can occur in different forms. For inorganic cadmium compounds, dissolution and transformation between different forms are the important processes for the fate and availability of cadmium.

3.3.1.3. Environmental distribution

Distribution in the aquatic environment

Cadmium enters the aquatic environment from numerous sources, e.g. via the atmosphere, wash-off from agricultural land, and from mining residues (zinc ores), solid wastes and wastewater discharges.

Once in the aquatic environment, cadmium is highly mobile.

Distribution in soil

In soil, cadmium is distributed between the following fractions (Lead registrant 2013a):

- Dissolved in pore water (which includes many species):
- Exchangeable, bound to soil particles
- Exchangeable, bound to organic ligands (of which a small part in the dissolved fraction and the major part in the solid fraction)
- Present in secondary clay minerals and metal oxides/hydroxides
- Present in primary minerals

Cadmium in soil particles is almost invariably present at the $Cd(^{2+})$ oxidation state (Smolders and Mertens 2013) where it adsorbs to various reactive soil surfaces, such as soil organic matter, oxyhydroxides of iron, aluminium and manganese and clay minerals.

The soil pH and the redox potential are important parameters that affect the speciation and the distribution of the Cd species between the particulate matter and soluble forms in soil pore water. In general cadmium tends to be more adsorbed and complexed at higher pH (pH > 7) than at lower pH. (Smolders and Mertens, 2013, ECB 2007). The pH of the soil not only determines the degree of complexation and adsorption of cadmium, but also the solubility of the various cadmium minerals.

The redox potential of the soil is also of importance for the solubility of cadmium compounds, for example, sulphides that form in strongly reduced soil may precipitate cadmium ions as cadmium sulphides. Lower solubility is predicted for cadmium substituted in the mixed sulphides than for cadmium in pure cadmium sulphide. (Barret & McBride, 2007, Gustafsson 2013, Smolder & Mertens 2013).

3.3.1.4. Adsorption/desorption

Adsorption and desorption processes can have a large influence on the long-term fate of cadmium emitted to the environment, since adsorption may gradually lower cadmium availability. However, according to Smolders and Mertens (2013), laboratory studies have shown that cadmium sorption in soil reaches equilibrium within hours and that sorption is reversible, even after >1 year "ageing" after adsorption. The authors conclude that ageing reactions which make the cadmium in soil less available with time, are not likely relevant in the environment, except at high pH. As mentioned in the previous section, the adsorption/desorption behaviour of a metal strongly depends on prevailing environmental conditions. Many different algorithms have been proposed for K_D as a function of different soil parameters such as pH , content of organic matter/organic carbon; cation exchange capacity, content of metal oxides and clay etc. (e.g. reviews in ERM 2000, ECB 2007, Smolders & Mertens 2013, Sternbeck et al. 2011).

3.3.1.5. Bioaccumulation

Numerous data on bioconcentration and bioaccumulation of soluble cadmium compounds in the aquatic environment were reviewed in the EU RAR on cadmium (ECB 2007).

In EFSA (2009) it is summarised that cadmium accumulation has been reported for grasses and food crops, poultry, cattle, horses and wildlife. In general, cadmium accumulates in the leaves of plants and for plants grown in the same soil accumulation decreases in the order: Leafy vegetables[25]> root vegetables > grain crops. EFSA also conclude that although some data indicate increased cadmium concentrations in animals at the top of the food chain, the data available on biomagnification are not conclusive. Because of this, increase in meat due to increased soil concentrations cannot be assumed. Nevertheless, uptake of cadmium from soil by feed crops may result in high levels of cadmium in beef and poultry (especially in the liver and kidney).

Among the bioaccumulation data reported by the registrants, a study considered uptake in plants was cited (Ma, 1987)[26]. This field study on pasture collected at a contaminated site (cadmium concentration in soil between 0.3 and 9.2 mg/kg dw) and a control site (cadmium concentration in soil was 0.1 mg/kg dw). The measured BCFs (plant to soil, dry weight) was 21 in the uncontaminated site while it varied between 0.22 and 5.3 at the contaminated sites, with the lowest BCFs measured at the locations with highest concentrations in soil. This supports the EFSA findings.

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[25] Cadmium in air may also be adsorbed onto or taken up into the leaves, see chapter B.9.7.

[26] This study was considered as reliable with restrictions by the registrants.

Smolders and Mertens (2013), who reviewed a number of experimental studies, concluded that studies where cadmium is administered as a Cd^{2+} salt show that uptake increases linearly with soil cadmium, provided that all other soil properties remain constant. However, they also observed that bioavailability varies largely and that observed total soil cadmium concentrations in different soils poorly predict cadmium uptake in crops. Total soil cadmium typically explains less than 50% of the variance of crop cadmium concentrations in surveys. This means that total soil cadmium concentrations are poor predictors of cadmium concentrations in crops.

3.3.1.6. Secondary poisoning

Not relevant for this proposal.

3.3.1.7. Cadmium pigments

Cadmium pigments, such as cadmium sulfoselenide red and zincsulphide yellow, are usually highly insoluble in water according to standardised water solubility tests, which may give them different properties from the more soluble cadmium compounds.

The transformation/dissolution results shown in Table 3 may indicate that the dissolved cadmium available from the pigments is lower than other, more soluble cadmium compounds, but differences in initial loading complicate this conclusion.

This means that for the less soluble substances (CdS, CdZnS, CdSSe) much lower concentrations of available cadmium forms will be present in ecotoxicity tests compared to more soluble compounds (CdO, CdTe), and it is concluded by the registrant that the former substances have a lower toxicity than the latter.

However, if these substances are released into the environment and different environmental conditions and processes (pH, redox potential, the presence of electron acceptors, water logging etc.) are acting on the compound for years to decades, the solubility, availability and hence toxicity of cadmium in these compounds may change considerably (see below). The information on fate of different cadmium compounds in such long-term perspectives is however scarce. Information on the effect of waste-treatment processes, such as landfilling and, particularly, incineration on the fate of cadmium pigments is not available.

3.3.1.8. Availability in soil of cadmium from pigments

Availability of cadmium in pigments compared to other sources

The concentration of cadmium in arable soils is a key determinant of cadmium in crops, although the uptake also depends on e.g. pH, organic matter and crop specific factors. Gustafsson (2013) demonstrated that cadmium sulphides and selenides in pigments are thermodynamically unstable in the surface horizon of agricultural soil. The presence of oxygen and trivalent iron (Fe 3+) will lead to gradual dissolution of these compounds. Sulphide-bound cadmium can persist in soils over a time scale of years only if there is an excess of sulphide–bound zinc. From the data assembled in the review it was concluded that cadmium pigments probably will dissolve completely in soils over a time-frame of years to decades. It is hence likely that, within a time frame of a couple of years to decade/-s, cadmium from pigments has a similar solubility and bioavailability as an easily soluble cadmium salt such as cadmium chloride. This is supported by other data submitted in the Cadmium in artist’s paints restriction public consolation (Smolders E and Koos D. (2014)). A concern that the Gustafsson study may only be relevant for Swedish soils was also not supported by the above study. This was supported by the RAC opinion on cadmium in artist paints (ECHA 2014). In addition, there is also some evidence that photochemical degradation could play a role in making cadmium more available in the environment (Liu, Huiting, et al (2017)).

It will therefore be assumed in this report that all of the cadmium in pigments will be available to plants over the long-term.

Cadmium in sludge compared to cadmium in soil

Cadmium is recognised as one of the most mobile trace elements, being more weakly bound to soil constituents compared to many other metals. Cadmium adsorption in soil is strongly controlled by soil pH and soil organic matter, but is also influenced by a range of soil constituents like clay minerals and manganese, aluminium, and iron oxides and hydroxides (Bergkvist et al, 2005). As a source of plant nutrients and organic matter, sewage sludge is a beneficial soil amendment, especially for arable soils low in organic matter. Sludge also contains adsorptive organic and inorganic components which may influence the solubility of the added metals in sludge amended soils in a long-term perspective. Bergkvist et al (2005) investigated the influence of long-term (41 years) sewage sludge addition on cadmium sorption and solubility in batch experiments performed on samples taken from sludge amended as well as control treatments in a clay loam soil. They found that cadmium sorption and solubility was unaltered, or even slightly reduced in the sludge amended soil, compared to the control treatment. They concluded that no “sludge protection” had occurred in these soils. Other studies performed in sandy soils have shown that sludge application resulted in increased sorption of cadmium (reviewed in Bergkvist et al. 2005). Bergkvist et al. therefore concluded that mixing sludge with soil may result in long-term increases or decreases in cadmium sorption and solubility or no change at all, depending on the affinity for cadmium of the sludge itself compared to the native soil and accounting for competition effects with other sludge borne metals. Smolders and Mertens (2013) also concludes that increasing organic matter by adding biosolids such as sewage sludge does not immobilise cadmium strongly, unless in soils where the organic matter content is extremely low.

3.4. Environmental hazards

3.4.1. Cadmium stabilisers

All the relevant cadmium stabilisers are classified as Aquatic Acute 1 H400 and Aquatic Chronic 1 H410.

Table 4. Summary of PNEC information for cadmium stabilisers

Compartment	Data	PNEC	Reference
Aquatic	Median HC5 value (Aldenberg and Slob, 1993) from 44 chronic NOEC values. Data are derived from 19 tests with fish/amphibians, 22 tests with aquatic invertebrates and 8 tests with primary producers, and represent 28 species in total. All tests belong to data quality group RI 1-3. The NOEC values were obtained from laboratory based, single species studies and refer to the dissolved fraction. An assessment factor of two is applied to the HC5.	The PNECwater is = 0.19 µg Cd L-	ECB 2007
Terrestrial	The PNECsoil is based on the 5th percentile (HC5) of a log-logistic distribution fitted to 21 NOECs of microbial processes (5 different processes). The HC5 of the microbial processes almost equals the HC5 values based on the fauna and plant data (54 different tests) and the HC5 of the whole data set of reliable tests (derived from 75 different tests with 20 different species and 5 different soil microbial processes). The NOEC data are derived from terrestrial toxicity tests with Cd2+ salts. The HC5 is 2.3 µg g-1. There is currently no justification for higher toxicity of Cd salts in the field then in the laboratory. Therefore, a PNEC can be proposed as the median HC5 with an additional assessment factor ranging from 1 to 2.	PNECsoil = 1.15-2.3 µg Cd/gdw	ECB 2007
Sediment		PNECsediment = 2.3 mg Cd/kgdw	ECB 2007
Atmospheric	Not relevant		
Sewage Treatment plants		PNECmicro-organisms = 20 µg Cd/L	ECB 2007

3.4.2. Cadmium pigments

3.4.2.1. Registration dossiers

In the registration dossiers, the data for cadmium sulfoselenide is read-across from the data set for CdTe:

> *CdSSe is a highly insoluble Cd-compound. This is demonstrated by the transformation-dissolution tests, where after 7 days shaking at pH6 only 0.026% of the Cd in the substance goes into solution; after 28 days of testing, dissolution was still very low: 0.028% of total Cd contained in the substance. For this reason, the ecotoxicity results obtained on soluble Cd-compounds are considered not relevant for CdSSe. Reference is made to standardised testing, applied on CdTe, another Cd-compound with limited solubility in water. The solubility of CdTe is however higher than the one of CdSSe, so this dataset on CdTe can be considered as a worst case for the CdSSe.*

For cadmium zinc sulphide, a similar approach as for CdTe is taken; most data come from CdTe (e.g. all aquatic and terrestrial data) but for some endpoints more data is reported (e.g. aquatic and terrestrial bioaccumulation) and there are differences in e.g. PNECterrestrial.

> *CdZnS is a highly insoluble Cd-compound. This is demonstrated by the transformation-dissolution tests, where after 7 days shaking at pH6 only 0.06% of the Cd in the substance goes into solution; after 28 days of testing, dissolution was still very low: 0.23% of total Cd contained in the substance. For this reason, the ecotoxicity results obtained on soluble Cd-compounds are considered not relevant for CdZnS. Reference is made to standardised testing, applied on CdTe, another Cd-compound with limited solubility in water. The solubility of CdTe is however higher than the one of CdZnS, so this dataset on CdTe can be considered as a worst case for the CdZnS.*

In summary, the assessments in the CSRs for these pigments are based on experimental ecotox studies with CdTe; CdTe PNEC derivation is copied from Cd metal/CdO and ENV classification is based on CdTe ecotox data. The other two pigments then read-across ecotox data from CdTe; PNEC derivation is again based on Cd metal/CdO. However, no classification is proposed based on insolubility of the pigments.

Table 5. Summary of PNEC information for Cadmium Telluride

Compartment	Data	PNEC	Reference
Aquatic	Fish OECD 203 test for fish acute toxicity available. LC_{50} results and the LOEC are higher than the solubility level of the test item in the test medium. No acute effects were seen at a concentration of 1g CdTe/L. Daphnia Tests performed according to OECD 202 standard test protocol for Daphnia acute immobilisation test. The LC_{50} was determined at 0.4 mg CdTe/L. Algae EC_{50} of 3.1 mg CdTe/L was found.	-	CdTe registration dossier.
Terrestrial	Earthworm OECD Guideline 207 (Earthworm, Acute Toxicity Tests). Solid CdTe is not acute toxic to earthworm when mixed into soil substrate up to concentrations of 2.1 g/kg Cd Te or 1g/kg of cadmium. Terrestrial arthropods CdTe had no effect on reproduction of adult springtails (Folsomia candida) at 10 mg/kg dw (NOEC). The NOEC for mortality was 1000 mg/kg dw. Terrestrial plants Solid CdTe is not acute toxic to plants when mixed into soil substrate up to concentrations of 2.1 g CdTe/kg DW (or 1 g Cd/kg DW).		CdTe registration dossier.

3.4.2.2. Compliance check on cadmium telluride

Cadmium telluride, as previously stated, is used by the registrants to read-across for the environmental (and health) hazards of the cadmium pigments of interest. However, the current hazard profile of this cadmium telluride has been questioned.

ECHA has initiated a compliance check on cadmium telluride for certain of its environmental and human health endpoints and decided to request certain studies[27].

[27] https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status/-/dislist/substance/100.013.773

The tests being requested in the compliance check are:

- Short-term toxicity testing on aquatic invertebrates (test method EU C.2./OECD TG 202);
- Growth inhibition study aquatic plants (test method EUC.3./OECD TG 201);
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method OECD TG203);
- Pre-natal developmental toxicity study (test method OECDTG 4L4) in a first species (rat or rabbit), oral route;
- Long-term toxicity testing on aquatic invertebrates (test method EU C.2O./OECD TG 211); and
- Long-term toxicity testing on fish (test method OECD TG210)

The registrant will then need to update their dossier for cadmium telluride as will the registrants of the pigments.

3.5. Health effects

According to Annex VI of the CLP Regulation (EC) No 1272/2008, cadmium and certain cadmium compounds are classified as category 1B carcinogens (for all routes of exposure), category 2 mutagens and category 2 reproductive toxicants. However, most of the substances indicated as use for cadmium-based stabilisers are only classified for acute toxicity category 4 (for all routes of exposure). The cadmium pigments are not classified at all.

EFSA reported that there is high concern regarding the toxicity of cadmium and their assessment shows that certain subgroups of the EU population, such as children and vegetarians, are significantly exceeding the tolerable intake of cadmium and that exposure to cadmium at population level should be reduced (EFSA, 2009).

Under Regulation 793/93/CEE, an extensive risk assessment (RAR) on cadmium metal and cadmium oxide was made by the Belgian authorities (ECB 2007); this information is assumed to be relevant for the cadmium stabilisers. In addition, the information in the RAR is also relevant for the cadmium compounds used in pigments, since the toxicity of all Cd-compounds is related to the Cd^{2+} ion. However, the cadmium pigments are much less soluble, this affects their bioavailability and their toxicity.

The end-point specific summaries below are to a large extent based on the EU RAR on cadmium metal and cadmium oxide, the risk assessment of cadmium from EFSA (2009) and an updated review of cadmium (Swedish Chemicals Agency 2011). Some newer studies, not included in the RAR, were assessed for bone toxicity and carcinogenicity. However, a comprehensive literature review for all endpoints was not carried out.

Cadmium and eight cadmium compounds are currently included in the candidate list as Substances of Very High Concern.

Substance	Date of inclusion in candidate list	Reason for inclusion
Cadmium	20/6/2013	Carcinogenic (Article 57a) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)
Cadmium carbonate	15/01/2018	Carcinogenic (Article 57a) Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)
Cadmium chloride	16/06/2014	Carcinogenic (Article 57a) Mutagenic (Article 57b) Toxic for reproduction (Article 57c) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)
Cadmium fluoride	17/12/2014	Carcinogenic (Article 57a) Mutagenic (Article 57b) Toxic for reproduction (Article 57c) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)
Cadmium hydroxide	15/01/2018	Carcinogenic (Article 57a) Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)
Cadmium nitrate	15/01/2018	Carcinogenic (Article 57a) Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)
Cadmium oxide	20/06/2013	Carcinogenic (Article 57a) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)
Cadmium sulphate	17/12/2014	Carcinogenic (Article 57a) Mutagenic (Article 57b) Toxic for reproduction (Article 57c) Specific target organ toxicity after repeated exposure (Article 57(f) -

		human health)
Cadmium sulphide	16/12/2013	Carcinogenic (Article 57a) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)

3.5.1. Toxicokinetics (absorption, metabolism, distribution and elimination: ADME)

3.5.1.1. Cadmium stabilisers

According to the Swedish Chemicals Agency (2011), the gastrointestinal absorption of cadmium ranges between 1 and 10 % depending on the individuals' iron status; those with low iron stores and iron deficiency are in the higher range. Newborns and small children may have an even higher absorption, independent of iron status.

Lung absorption is higher; 25-50 % may be absorbed from fumes and 10-30 % from dust, depending on the particle size. Dermal uptake is considered to be low, likely significantly less than 1 %. Cadmium can cross the placenta but at a low rate. (ECB 2007).

After absorption, cadmium is transported in the blood to the liver, forms a complex with–metallothionein and is transported in the blood to the kidneys. In the kidneys, cadmium–metallothionein is rapidly degraded in the tubules to release cadmium. Cadmium accumulates in kidney tubules and causes damage to tubular cells, especially in the proximal tubules. Absorbed cadmium is excreted very slowly, and the amounts excreted into urine and faeces are approximately equal. In humans, half-life estimates have been reported to be in the range of 7–16 years (IARC 2012). According to other references (Swedish Chemicals Agency 2011) it is even longer (10-30 years) and in a recent study the biological half-time of cadmium in the kidney was calculated to be between 18 and 44 years, depending on the model used (Åkerström et al. 2013).

Cadmium in urine is mainly influenced by the body burden of cadmium and is generally proportional to the concentration in the kidney. In adults, there is a close relationship between the cadmium concentrations in urine and kidneys (correlation coefficient 0.88) based on living kidney donors, and these recent data indicate that 25 mg/kg in the renal cortex roughly corresponds to a urinary cadmium concentration of 0.4 µg/g creatinine (cr) (Åkerström et al. 2013). This indicates that the concentrations in urine correspond to considerably higher concentrations in the kidney cortex than previously observed at autopsy. Because the half-life of cadmium in the body is very long, urinary cadmium (U-Cd) is highly dependent on age, in adults (Swedish Chemicals Agency 2011). A large recent study from Belgium show that urinary cadmium is high during childhood followed by a decrease during adolescence and a progressive rise until the age of 60 years, where urinary cadmium concentrations level off (Chaumont et al. 2013).

The significance of U-Cd as an exposure marker in situations of very low exposure has been questioned (Chaumont 2012, Akerstrom 2013). The associations between U-Cd and urinary proteins at very low exposure may not be due to Cd toxicity, and the clinical significance of slight proteinuria may also be limited.

3.5.1.2. Cadmium pigments

The registrants for CdZnS and CdSSE argue that the toxicokinetics of the cadmium pigments differ from more soluble cadmium compounds, principally as a result of their limited solubility. Absorption via inhalation is considered to be limited based on experimental studies investigating relative absorption of soluble and highly insoluble cadmium pigments with rats. After inhalation, insoluble cadmium pigments are appear to be transported by mucocilliary clearance to the gastrointestinal tract leading to excretion via faeces with minimal systemic absorption. In terms of ingestion, the Registrants report that uptake from cadmium pigments after ingestion in rats is only 0.41 % (for cadmium red) and 0.31 % (cadmium yellow) of the absorption observed in $CdCl_2$. These data are supported by *in vitro* bio accessibility testing.

3.5.2. Acute toxicity

3.5.2.1. Cadmium stabilisers

Cadmium compounds used as stabilisers are classified as Acute tox category 4 for all routes of exposure, except cadmium oxide that is classified as Acute tox 2 for inhalation.

LD_{50} values are available in animal studies for the oral route (890, 2,330 mg /kg for Cd metal), but no experimental details are available. LD_{50} oral values range from 72 to 300 mg CdO/kg for CdO (63-259 mg Cd/kg) and from 50 to 400 mg Cd/kg for other water-soluble compounds. No clear dose-effect (response) relationship for CdO administered by the oral route could be determined (ECB 2007).

Acute inhalation exposure of animals to cadmium oxide aerosols was found to produce pulmonary inflammation and oedema. Concentrations above 5 mg/m³ have caused clear pulmonary damage (destruction of lung epithelial cells, resulting in pulmonary oedema, tracheo-bronchitis, and pneumonitis).

The lowest observed adverse effect level (LOAEL) reported to cause mild pulmonary damage (hypercellularity indicative of hyperplasia) was an 3-hour exposure to 0.5 mg/m^3 CdO fumes, and is considered as reliable data although methods used were not totally conform with ER 67/548/EEC, Annex V and OECD guidelines.

No information on skin exposure could be retrieved neither for CdO nor for Cd metal.

3.5.2.2. Cadmium pigments

In the registrations for some cadmium pigments (ECHA 2013a) read-across from data on cadmium telluride, a substance with higher water solubility compared to the cadmium pigments, were used to assess the acute oral toxicity. No deaths occurred in two groups of three rats treated at a dose level of 2000 mg/kg cadmium telluride. Therefore the LD_{50} of the pigments is > 2000 mg/kg. In addition, the LC_{50} of CdTe is > 2.87 mg/L air.

3.5.3. B.5.3 Irritation

3.5.3.1. Cadmium stabilisers

Skin

No studies were located regarding irritation effects in animals after exposure to cadmium oxide and/or metal.

No studies were located regarding dermal effects in humans after exposure to cadmium oxide and/or metal.

Eye

No studies were located regarding eye irritation effects in animals after exposure to cadmium oxide and/or metal.

No studies were located regarding ocular effects in humans after exposure to cadmium oxide and/or metal.

Respiratory

Based on the data after acute and repeated exposure, it seems however possible that cadmium oxide/metal (as fumes) are irritant for the respiratory tract in animals as in humans.

3.5.3.2. Cadmium pigments

In the registrations for some cadmium pigments (ECHA 2013a) read-across from data on cadmium telluride, a substance with higher water solubility compared to the cadmium pigments, were used to assess skin and eye irritation. The effects observed do not require classification as an eye or skin irritant.

3.5.4. Corrosivity

3.5.4.1. Cadmium stabilisers

No studies were located regarding corrosive effects on the skin, the eye and the respiratory tract in humans after exposure to cadmium oxide and/or cadmium metal.

3.5.4.2. Cadmium pigments

The cadmium pigments are not considered corrosive.

3.5.5. Sensitisation

3.5.5.1. Cadmium stabilisers

Skin sensitisation

No studies were located regarding sensitisation effects in animals after exposure to cadmium oxide/Cd metal.

No studies were located regarding a sensitisation effect of cadmium oxide/Cd metal. However, a few studies in humans show positive patch tests to cadmium.

Respiratory sensitisation

No studies were located regarding respiratory sensitisation in animals after exposure to cadmium oxide/Cd metal.

No studies were located regarding sensitisation effects on the respiratory tract in humans after exposure to cadmium oxide/Cd metal.

3.5.5.2. Cadmium pigments

In the registrations for some cadmium pigments (ECHA 2013a) read-across from data on cadmium telluride, a substance with higher water solubility compared to the cadmium pigments, were used to assess skin sensitisation. Using the Magnusson-Kligman method, no signs of contact sensitisation were detected in guinea pigs.

3.5.6. Repeated dose toxicity

3.5.6.1. Cadmium stabilisers

Both cadmium carbonate and cadmium chloride are classified as STOT RE 1 H372 with the target organs of kidney and bone. The other cadmium substances used as stabilisers are not classified for these endpoints.

This classification is supported by ‘a substantial body of information available indicating that the lung, kidney and bone are the target organs upon repeated exposure to CdO in occupational settings (mainly by inhalation). Environmental exposure to Cd (generic, not specifically CdO), mainly by the oral route, is associated with bone and kidney toxicity.’ EU RAR (2007).

Lung toxicity

The EU RAR (ECB 2007) indicates that long-term inhalation exposure of experimental animals to CdO results in similar effects as seen upon acute exposures, i.e. pneumonia accompanied by histopathologic alterations and changes in the cellular and enzymatic composition of the bronchoalveolar fluid. Prolonged inhalation of fumes or dust containing cadmium by humans can give rise to chronic pulmonary disorders, characterised by obstructive changes, decreased lung function and emphysema. Chronic obstructive airway disease has been reported to lead in severe cases to an increased mortality. Lung effects are not expected after oral exposure to cadmium via food.

Bone toxicity

In the EU RAR of cadmium metal and cadmium oxide (ECB 2007) it was concluded that bone tissue constitutes a target organ for the general and occupational populations exposed to cadmium compounds. In humans, the mechanism of bone toxicity is not fully explained and types of bone lesions associated with cadmium exposure are not clearly identified. The most severe form of cadmium toxicity is Itai-itai disease, which comprises severe signs of osteomalacia and osteoporosis associated with renal disease in aged women. In workers exposed to cadmium compounds (not specifically CdO or Cd metal), clinical bone disease has been described but the number of cases is limited.

In the scientific opinion from EFSA (EFSA 2009) it is concluded that *“the studies evaluated indicate a range of urinary Cd for possible effects on bone effects starting from 0.5 µg/g creatinine, which is similar to the levels at which kidney damage occurs.”*

There is evidence that Cd has a direct toxic effect on bone. Cd accumulates in osteocytes, the periosteum, and bone marrow but not in the hydroxyapatite (Lindh et al. 1981). Experimental studies demonstrate skeletal effects of Cd in vitro, as well as in vivo in animals displaying no nephrotoxicity (Bhattacharyya 2009; Nordberg et al. 2007). Osteoclasts in culture are particularly sensitive to low Cd concentrations (Bhattacharyya 2009). In support of this, cross-sectional investigations have found a positive association between U-Cd and markers of bone resorption (Åkesson et al. 2006; Schutte et al. 2008) (Table 6), even in children (Sughis et al. 2011). As a consequence of increased release of calcium from bone to the circulation, the excess is excreted into urine. Because U-Cd was inversely associated with levels of parathyroid hormone (Åkesson et al. 2006; Schutte et al. 2008), the Cd-associated calciuria is most likely a result of increased bone resorption, rather than decreased tubular reabsorption, which would instead have resulted in a compensatory increase in parathyroid hormone.

Even in the absence of Cd-induced renal tubular dysfunction, low-level environmental exposure to Cd seems to mobilise bone minerals from the skeletal tissue. Effects on bone mineral density, osteoporosis, and increased fracture risk are reported to occur at U-Cd as low as 0.5–2 µg/g cr (Åkesson et al. 2006; Alfvén et al. 2000, 2004; Engström et al. 2011; Gallagher et al. 2008; Nawrot et al. 2010; Schutte et al. 2008; Staessen et al. 1999; Wu et al. 2010). Similar associations have been observed at corresponding dietary intake levels (Engström et al. 2012; Thomas et al. 2011). Such associations were also observed in studies where tobacco smoking could not be the cause (Åkesson et al. 2006; Engström et al. 2011, 2012; Thomas et al. 2011). The bone effects at high exposures do not appear to be reversible (Chen et al. 2009).

The effect of Cd on the skeleton has been reported to be irreversible upon cessation of exposure. A longitudinal study from contaminated areas in China examined individuals living in areas with moderate (0.51 mg/kg) and heavy (3.7 mg/kg) exposure after their cessation of consuming Cd-polluted rice (Chen et al. 2009). The decrease in wrist bone mineral density in women over a period of 8 years was larger when baseline U-Cd and B-Cd were high compared with low-exposure groups.

Osteoporosis is characterised by low bone mass and microarchitectural deterioration of the skeleton, leading to fragility and increased risk of fractures (hip, spine and forearm). Established or suggested risk factors for osteoporosis and fractures are female sex, old age, low body weight, early menopause, family history of osteoporosis, deficiency of Vitamin D and calcium, smoking, excessive consumption of alcohol, inactivity, several medical disorders and certain drugs. According to a more recent risk assessment (Swedish Chemicals Agency 2011), the data supporting an adverse effect of the present exposure to cadmium in Sweden on the risk of osteoporosis have increased substantially during the last few years. Irrespective of whether the studies employed a decrease in the bone mineral density, increased risk of osteoporosis or increased risk of fractures, these changes seem to occur at very low urinary cadmium concentrations. Both the new Swedish Mammography Cohort (SMC) and the new American National Health and Nutrition Examination Survey (NHANES) studies (see Table 6. Studies on bone effects of cadmium ((Swedish Chemicals Agency 2011)) suggest that even a urinary concentration from around 0.5 µg/g creatinine is associated with increased risk of osteoporosis and fractures. There are increasing data suggesting that the effect of cadmium on bone is independent of kidney damage and recent data support that these effects occur even before the kidney damage. In addition, the Swedish studies showed an increased risk of osteoporosis and fractures even among those who never smoked. This finding suggests that dietary cadmium alone contribute to the risk (Swedish Chemicals Agency 2011; Engström et al. 2012).

Several epidemiological studies have observed an association between cadmium and bone mineral density (for a review see Swedish Chemicals Agency 2011). However, only few published studies have so far considered fracture incidence.

Table 6. Studies on bone effects of cadmium ((Swedish Chemicals Agency 2011)

<table>
<tr><th rowspan="2">Study</th><th rowspan="2">Study type</th><th colspan="2">Results</th><th rowspan="2">Reference</th></tr>
<tr><th>Women</th><th>Men</th></tr>
<tr><td>CadmiBel</td><td>Prospective cohort of 506 subjects.</td><td>Observed risk ratios associated with doubled urinary cadmium concentrations: 1.73 (95% CI 1.16–2.57; P = 0.007) for fractures.</td><td>Observed risk ratios associated with doubled urinary cadmium concentrations: 1.60 (95% CI 0.94–2.72, P = 0.08) for height loss in men.</td><td>In: Swedish Chemicals Agency 2011</td></tr>
<tr><td>OSCAR</td><td>Fracture incidence was assessed retrospectively in the Swedish OSCAR study.</td><td colspan="2">Fractures occurring after the age of 50 years (n = 558, 32 forearm fractures), the fracture hazard ratio, adjusted for sex and other relevant covariates, increased by 18% (95% CI 1.0–38%) per unit urinary cadmium (1 nmol/mmol creatinine; ~ 1 µg/g creatinine).

When subjects were grouped in exposure categories, the hazard ratio reached 3.5 (90% CI 1.1–11) in the group of subjects with urinary cadmium concentrations between 2 and 4 nmol/mmol creatinine and 8.8 (90% CI 2.6–30) in the group of subjects with urinary cadmium concentrations greater than or equal to 4 nmol/mmol creatinine (mainly men).</td><td>Alfvén et al. 2004</td></tr>
<tr><td>Swedish Mammography Cohort</td><td>Cross-sectional</td><td colspan="2">For any first fracture (n=395) the odds ratio (OR) was 1.16 (95% CI, 0.89-1.50) comparing urinary Cd ≥0.5 µg/g creatinine with lower levels. Among never-smokers, the ORs (95% CIs) were 2.03 (1.33-3.09) for any first fracture, 2.06 (1.28-3.32) for first osteoporotic fracture, 2.18 (1.20-3.94) for first distal forearm fracture and 1.89 (1.25-2.85) for multiple incident fractures. Similar risks were observed when dietary cadmium was used instead of urinary cadmium in the same women from the Swedish Mammography Cohort. The individual dietary cadmium exposure was estimated using a food frequency questionnaire</td><td>(Engström et al. 2011)</td></tr>
</table>

Study	**Study type**	**Results**		**Reference**
		Women	***Men***	
		together with national data on cadmium in all foods. Comparing the women's dietary cadmium exposure above the median (13 µg Cd/day) to that below was associated with OR 1.31 (1.02-1.69) of fractures in all women and OR, 1.54 (1.06-2.24) in never smokers. In an analysis where women with high both dietary and urinary cadmium were contrasted against the women with low exposure, the association with fractures was more pronounced OR 1.46 (1.00-2.15) in all women and 3.05 (1.66-5.59) in never-smokers		
Cohort of Swedish Men	Population-based prospective cohort study. Individual cadmium intake estimated using a food frequency questionnaire.	Average intake 19 µg Cd/day), dietary cadmium was associated with a statistically significant 19 % higher rate of any fracture comparing the highest cadmium intake tertile with the lowest tertile.		Thomas et al. 2011
	Study the association between hip fracture risk and cadmium in erythrocytes (Ery-Cd) was investigated. Prospective samples from a Swedish biobank were used for 109 individuals who later in life had sustained a low-trauma hip fracture, matched with two controls of the same age and gender.	The mean concentration of Ery-Cd (±SD) in case samples was 1.3 ± 1.4 versus 0.9 ± 1.0 µg/L in controls. The odds ratio (OR) was 1.63 [95 % confidence interval (CI) 1.10-2.42] for suffering a hip fracture for each microgram per liter increase in Ery-Cd. However, when taking smoking into consideration (never, former, or current), neither Ery-Cd nor smoking showed a statistically significant increase in fracture risk. Using multiple conditional logistic regression with BMI, height, and smoking, the estimated OR for a 1-µg/L increase in Ery-Cd was 1.52 (95 % CI 0.77-2.97). Subgroup analysis showed an increased fracture risk among women (OR = 1.94, 95 % CI 1.18-3.20, for a 1 µg/L increase), which also remained in the multiple analysis		Sommar et al. 2013b

Study	**Study type**	**Results**		**Reference**
		Women	***Men***	
		(OR = 3.33, 95 % CI 1.29-8.56).		

In addition, the following information is available:

Study	**Study type**	**Results**		**Reference**
		women	***men***	
Osteoporotic Fractures in Men (MrOS) study		The study population consisted of 936 men aged 70 to 81 years at inclusion (years 2002 to 2004). A number of potential confounders and other risk factors were included in the models. Significant negative associations between U-Cd and BMD were found. In addition, positive associations between U-Cd and incident fractures were found, especially non-vertebral osteoporosis fractures in the fourth quartile of U-Cd, with hazard ratios of 1.8 to 3.3 in the various models. U-Cd as a continuous variable was significantly associated with nonvertebral osteoporosis fractures (adjusted hazard ratio 1.3 to 1.4 per µg Cd/g creatinine), also in never-smokers, but not with the other fracture groups (all fractures, hip fractures, vertebral fractures, and other fractures). Relatively low cadmium exposure through diet and smoking increases the risk of low BMD and osteoporosis-related fractures in elderly men.		Ohlsson, C. and Mellström, D. (2016),
Malmö Diet and Cancer Study	The aim was to investigate a perceived association between low levels of blood cadmium (B-Cd) at baseline and risk of first incident fracture.	998 first incident fractures occurred in women during a follow-up lasting 20.2 years (median) (12.5–21.2 years) (25th–75th percentile). Women in Cd-Q4 were more often current smokers than in Cd-Q1 78.4 vs. 3.3% ($p < 0.001$) and the number of cigarettes smoked per day correlated with B-Cd ($r = 0.49$; $p < 0.001$). The risk of fracture was not associated with baseline B-Cd in adjusted models. The hazard ratio (HR) Cd-Q4 vs. Cd-Q1 was 1.06 (95% confidence interval (CI) 0.89–1.27). Overall mortality		Moberg, L., Nilsson, P.M., Samsioe, G. et al (2017).

Study	**Study type**	**Results**		**Reference**
		women	***men***	
		was significantly higher for women with high B-Cd, HR 2.06 (95% CI 1.57–2.69).		
4th Korea National Health and Nutrition Examination Survey, 2008-2009	Association between cadmium exposure and bone mineral density (BMD) in young and middle-aged men.	1275 adult men aged 20–64 years were analyzed. BCd was measured by atomic absorption spectrophotometry and renal function was assessed by the estimated glomerular filtration rate (eGFR) with CKD-EPI formula. The risk of lower bone density was increased according to the increase in BCd levels after adjusting for eGFR and covariates, in which a significant interaction between BCd and eGFR existed. Significant negative associations between BCd and BMD were found: beta (*p*-value) were −0.03 (0.02), −0.04 (0.004) and −0.03 (0.04) in total femur, lumbar spine and femoral neck, respectively, which were limited to the people with eGFR ≤ lower 25%. Although, a causal relationship could not be determined because of a cross-sectional design in the present study, the results suggest low level Cd toxicity to bone via low eGFR and that measures to reduce environmental Cd exposure may be helpful to prevent bone loss in men.		Eunae Burm et al (2015)
-	-	The presumed relationship between bone density and the dietary intake of cadmium, lead and mercury were studied in healthy premenopausal women. The median predicted dietary cadmium intake among the 158 women studied was 25.29 µg/day (18.62–35.00) and 2.74 µg/kg body weight/week (bw/w) (1.92–3.83). We did not detect any relation between FFQ-derived dietary exposure estimates of cadmium and bone density in the sample of healthy premenopausal Spanish women.		Lavado-García et al 2017.

In summary, data from relatively large prospective cohorts from the general population in Sweden (males and females) show that individuals in the upper half of the exposure range of cadmium via food have a significantly higher risk of having bone fractures compared to those in the lower half of the exposure range. It should be noted that the cadmium exposure where this effect is observed is at the level of the common exposure to cadmium via food within EU. The median exposure in the cohort of females (Reference study A1) was 13 µg/day ag, which assuming a body weight of 60 kg, corresponds to a weekly intake of 1.5 ug Cd per kg body weight (bw). For a comparison, the average intake in adults (males and females) in EU is approximately 1.8 µg/kg bw per week (range1.5-2.2) with Sweden in the middle of this range (EFSA 2012). The median urinary cadmium concentration in the cohort of almost 2700 women (reference study A1) was 0.34 µg/g creatinine; 23 % had urinary cadmium concentrations >0.5 µg/g creatinine (Engström 2011b). The population attributable risk of dietary Cd for osteoporotic fractures was estimated to be about 7% and 13% in women and men, respectively (Engström et al. 2012; Thomas et al. 2011) in Sweden, where the exposure to Cd is at the low end in a global perspective (Hruba et al. 2012; Pawlas et al. 2013; Wennberg et al. 2006).

In addition, Åkesson et al (2014) found that exposure to low concentrations of Cd is associated with effects on bone, including increased risk of osteoporosis and fractures, and that this observation has implications for the health risk assessment of Cd. Other effects associated with Cd should also be considered, in particular cancer, although the information is still too limited for appropriate use in quantitative risk assessment. They concluded non-renal effects should be considered critical effects in the health risk assessment of Cd.

The potential for bone effects from inhalatory cadmium exposure was further demonstrated in an experimental foetal and neonatal development study in mice with cadmium oxide (Blum et al 2012). Following exposure to 100 µg CdO/m^3 during day 4.5 to 16.5 post coitus in pregnant mice decreases in foetal length and delayed neonatal growth were recorded as well as increased levels of cadmium in maternal organs. However, there were no specific measurements of skeletal and bone development. In a review of the toxicity of cadmium during pregnancy (Jacobo-Estrada et al 2017), an insight was given into the possible mechanisms involved in the multiple organ toxic effects in foetuses after exposure to cadmium. It was suggested in this review that insufficient data has been generated on the relationship between cadmium exposure and calcium homeostasis in both the dam and the foetus and that this could have a major influence on the risk of the mother and foetus to develop osteomalacia or osteoporosis due to cadmium exposure. The existence of this calcium homeostasis pathway is also supported in a review of several elements on bone metabolism (Dermience et al 2015). The effects on bone via effects on calcium homeostasis is termed a “direct” pathway and the effects on bone toxicity as a consequence of the effects of cadmium on the kidneys reducing the efficiency of intestinal calcium absorption is termed an “indirect” pathway.

In a study designed to investigate vascular dysfunction in the aorta of genetically modified mouse strain for atherosclerosis (ApoE$^{-/-}$), 28-day exposure to cadmium chloride in the drinking water was found to decrease cytoplasmic levels of nitric oxide and increase superoxide anions, hydrogen peroxide and peroxynitrite (Oliveira et al 2018). Such findings are suggestive of an effect of cadmium on oxidative stress within the bone marrow, which may provide mechanistic evidence for the bone toxicity of cadmium.

Kidney toxicity

The kidney is another target organ for cadmium (not specifically CdO or Cd metal) toxicity following repeated exposure by the oral or inhalation routes. Numerous studies in animals have indicated that exposure to cadmium compounds administered orally or by inhalation causes kidney damage. In workers occupationally exposed to cadmium, a Cd body burden corresponding to a U-cd of 5 µg/g creatinine constitutes a LOAEL based on the occurrence of LMW proteinuria. There is consensus in the literature concerning the health significance of this threshold because of the frequent observation of irreversible tubular changes above this value and in view of its association with further renal alteration. In the general population (mainly exposed by the oral route), based on studies conducted in Europe, it appears that renal effects can be detected for Cd body burdens below 5 µg Cd/g creatinine and even from 2 µg Cd/g creatinine (LOAEL). It is plausible that the lower LOAEL in the general population exposed by the oral route is the reflection of an interaction of Cd exposure with pre-existing or concurrent renal diseases that are less prevalent in mainly healthy young individuals in occupational settings.

In the EU RAR of cadmium metal and cadmium oxide (ECB 2007) it was concluded that there is ample and robust evidence of the nephrotoxic potential of cadmium. The main issue was therefore to define the dose-effect/response relationships for this endpoint as well as the health relevance of the endpoints used to establish these relationships. For workers occupationally exposed to cadmium (mainly by inhalation), a LOAEL of 5 µg Cd/g creatinine in urine was considered to constitute a reasonable estimate. The health significance of this threshold was justified by the frequent observation of irreversibility of tubular changes above this value and its association with further renal alteration. Further, it was considered plausible that the lower LOAEL (2 µg Cd/g creatinine in urine) in the general population exposed by the oral route could be the consequence of an interaction of cadmium exposure with pre-existing or concurrent renal disease. It was emphasized that the interpretation of the LOAELs and the margin of safety should take into account the long half-life of cadmium and the uncertainties regarding the present hazard assessment.

A scientific opinion on “Cadmium in food” from an EFSA panel (EFSA 2009) concluded that *“it seems reasonable that minor changes in renal markers are associated with urinary Cd around 1 µg/g creatinine”*, at the same time recognizing that *“the identification of a reference point for deriving a health based guidance value is difficult and depends on several study-specific factors, including the size of the study”.*

According to a later risk assessment (Swedish Chemicals Agency 2011), a number of studies, including the Swedish general population, show significant associations between cadmium in urine and/or blood and markers of impaired kidney function, mostly impaired tubular function, where the risk starts to increase already below 1 µg/g creatinine. It should, however, be noted that associations between low-molecular-weight proteins and cadmium in urine at very low environmental exposure levels should be interpreted with caution, given the unspecific nature of the tubular reabsorption of proteins. The close relationships between low-molecular-weight proteins and cadmium in urine might simply reflect intra- and inter-individual variations in the tubular reabsorption capacity. Moreover, the clinical significance of slight proteinuria may also be limited. Thus, doubts have recently been raised regarding the justification of basing the risk assessment on this relationship at very low cadmium exposure.

Reversibility: According to the EU RAR on cadmium and cadmium oxide (ECB 2007) some controversy exists as to the reversibility of renal effects of cadmium both in the general population and in workers. The (ir)reversibility of tubular proteinuria after reduction or cessation of exposure depends on the intensity of exposure and/or the severity of the tubular damage. It was concluded that, as for inhalation exposure, incipient tubular effects associated with low cadmium exposure in the general population are reversible if exposure is substantially decreased. Severe tubular damage (urinary leakage of the proteins retinol-binding protein (RBP) or Beta-2 microglobulin (ß2M) > 1 000-1 500 µg/g creatinine) is generally irreversible.

A longitudinal study on 74 inhabitants from a cadmium-polluted area in Japan (Kido et al. 1988) showed irreversible and even progression of renal dysfunction 5 years after cessation of cadmium exposure. Likewise, a study from China indicates that the negative effects on bone still remain 10 years after the population abandoned ingestion of cadmium-polluted rice (Chen et al. 2009).

The biological half-life of cadmium in humans is extremely long and the body burden of cadmium therefore increases, mainly via accumulation in the kidney, during the entire life span of an individual. Unless exposure is substantially decreased kidney, and bone, effects therefore tend to be irreversible due to the continued internal exposure from stored cadmium. In that respect cadmium behaves in a way that resembles substances that are persistent and bioaccumulating in the environment.

Long-term health effects of kidney damage: Although there is strong evidence that elevated levels of several biomarkers of renal dysfunction and/or associations between cadmium burden and these biomarkers occur in populations environmentally exposed to cadmium, there is less agreement about the significance of these changes. In addition to the reversibility issue (see above) there are data indicating an increased mortality risk in subjects having urinary ß2M levels only slightly above normal levels. Cadmium may also potentiate diabetes-induced effects on the kidney (EFSA 2009). There are also indications that environmental and occupational exposures to cadmium affect the development of end-stage renal disease, measured as need for renal replacement therapy (Hellström et al. 2001). In a recent population based prospective case-referent study in Sweden erythrocyte-Cd tended to be related to an increased risk of end-stage renal disease, but confounding by lead and mercury could partly explain this finding (Sommar et al. 2013a).

Recent literature is showing that the association between Cd and protein excretion probably represents normal variability in renal physiology resulting is a temporarily increased or decreased excretion, independent of kidney cadmium concentration (Akerstrom et al (2013)).

Other

Evidence for cardiovascular toxicity resulting from oral and inhalation exposure to CdO and other Cd compounds (chloride, acetate) in animals is suggestive of a slight effect on blood pressure. Overall, the weight of evidence suggests that cardiovascular effects are not a sensitive end point indicator for CdO toxicity.

Exposure to cadmium compounds can cause liver damage in animals but generally only after high levels of exposure. There is little evidence for liver damage in humans exposed to cadmium (including CdO or Cd metal).

Evidence from experimental systems indicates a potential neurotoxic hazard for cadmium (not CdO or Cd metal specifically) in adult rats. In humans, heavy occupational exposure to cadmium dust has been associated with olfactory impairments and studies performed on a limited number of occupationally-exposed subjects are suggestive of an effect of Cd on the peripheral and central nervous system but no firm conclusions were reached.

Overall, based on the concurrence of epidemiological studies indicating both kidney and bone effects in the general population at body burden below 5µg Cd/g creatinine, a single LOAEL of 2 µg/g creatinine has been considered for the risk characterisation in the EU RAR. It should be recognised, however, that uncertainties remain as to the accuracy of this value.

3.5.6.2. Cadmium pigments

For these substances a read –across has been made with cadmium telluride.

No information on long-term effects is available.

The current compliance check has requested a developmental toxicity study (Pre-natal developmental toxicity study) to be carried out which may mean an update on the hazard of the pigments is required.

3.5.7. Carcinogenicity

3.5.7.1. Cadmium stabilisers

CdO is carcinogenic in animals, especially lung tumours in rat inhalation studies (ECB 2007).

The possibility that, in humans, cadmium might cause a risk of lung cancer by inhalation is suggested by several epidemiological studies but the possible contribution of confounding factors (mainly co-exposure to other carcinogens) could not be clearly defined. Overall, however, the weight of evidence collected in genotoxicity tests, long-term animal experiments and epidemiological studies leads to the conclusion that CdO has to be considered at least as a suspected human carcinogen (lung cancer) upon inhalation exposure. There is no indication or evidence that CdO acts as a carcinogen in the general population exposed by the oral route (ECB 2007).

Like other toxic effects caused by cadmium compounds, carcinogenic effects are most likely caused by the cadmium ion. Some cadmium compounds have a harmonised classification for carcinogenicity: cadmium (metal), cadmium oxide, cadmium sulphide, cadmium chloride, cadmium sulphate and cadmium fluoride are classified as carcinogenic category 1B, whereas cadmium formate, cadmium cyanide, cadmium fluorosilica and cadmium iodide are classified as carcinogenic category 2. No route of exposure is specified so it is assumed it is carcinogenic by all routes.

Cadmium is **classified by IARC** as a cancer-causing agent in humans based on three lines of evidence:

1) Several but not all studies showed a positive association between occupational exposure to cadmium and risk of lung cancer. Occupational exposures have historically been through inhalation. The IARC Working Group reaffirmed the classification of cadmium and its compounds as “carcinogenic to humans” (Group 1) with sufficient evidence for the lung and limited evidence for prostate, and kidney in 2009. Studies involved complex occupational exposures to the metal and its compounds, making it impossible to separately assess their carcinogenicity. In a

meta-analysis which summarises occupational cohorts, the combined estimate showed a 20% statistically significant increased risk as compared to non-exposed.

2) Data in rats show that the pulmonary system is a target site for carcinogenesis after cadmium inhalation.
3) Several *in vitro* studies have shown that most likely, cadmium induces cancer by multiple mechanisms, the most important being aberrant gene expression, oxidative stress, inhibition of DNA damage repair and inhibition of apoptosis, possible also epigenetic effects. Also*, in vitro* and *in vivo* studies provide evidence that cadmium may act as an estrogen mimic.

In addition to the lung cancers, there have been concerns raised if $cadmium^{2+}$ can cause other cancers and by other routes:

Prostate cancer

The previous evidence with regard to prostate cancer has not been regarded as convincing, but the available human studies have limited ability to detect an effect. A recent case-control study (40 cases and 58 hospital-based controls from two provinces in southern and northern Italy) showed a relation between the toenail cadmium concentration and prostate cancer risk. An excess cancer risk in subjects in the third and fourth (highest) quartiles of toenail cadmium concentration (odds ratio 1.3 and 4.7, respectively) compared with subjects in the bottom quartile was observed. Results were basically unchanged when limiting the analysis to each province or entering toenail cadmium concentrations as continuous values in the regression model (P=0.004). Despite the limited statistical stability of the point estimates, these findings appear to support the hypothesis that cadmium exposure increases prostate cancer risk, but these types of case control studies must be interpreted with caution because the result is dependent on how the cases and controls were selected. Also the relevance of cadmium in toenails as a marker of exposure is less clear.

A recent meta-analysis (of three studies) showed no statistically significant association with cancer risk (relative risk (RR) = 1.10; 95% cancer incidence (CI): 0.99–1.22, for highest vs. lowest dietary cadmium group) . However, there was strong evidence of heterogeneity, and subgroup analyses were conducted using the study design, geographical location, and cancer type. In subgroup analyses, the positive associations between dietary cadmium intake and cancer risk were observed among studies with Western populations (RR = 1.15; 95% CI: 1.08–1.23) and studies investigating some hormone-related cancers (prostate, breast, and endometrial cancers) (Cho et al. 2013).

A prospective cohort study from Belgium assessed the association between environmental exposure to cadmium and cancer incidence. This study was a prolongation of the Flemish part of the CadmiBel study including 6 districts with high cadmium exposure close to zinc smelters and 4 districts with low exposure. In total, 994 subjects were included at baseline. Occupationally exposed were not excluded, but a sensitivity analysis was performed based on environmentally exposed alone. The population-attributable risk of **lung cancer** of 67 % (95 % CI 33-101) in a high-exposure area, compared with that of 73 % (38-108) for smoking. In total 19 lung cancer cases occurred whereof 18 in the high exposure area. For lung cancer, the adjusted RR was 1.70 (95 % CI, 1.13-2.57: p = 0.011) for a doubling of the 24-hour urinary cadmium excretion. The corresponding results for a doubling of cadmium concentration in soil was 1.57 (95 % CI, 1.11-2.24 : p = 0.012). The RR for residence in the high-exposure area versus the low exposure area was 4.17 (1.21-14.4: p = 0.024). Overall cancer (N = 70) was also increased in the high-exposure group, but a clear excess was seen only with regard to lung. The median urinary cadmium excretion in this study was 0.8 µg/g creatinine, and the 25th and 75th percentiles were about 0.5 and 1.4 µg/g creatinine. As the exposure might have been caused by both inhalation and ingestion, the exact relevance for dietary cadmium exposure is not clear.

Bladder cancer

A Belgian case–control study of bladder cancer (172 cases and 359 population controls) showed an OR of 5.7 (95% CI 3.3–9.9) for bladder cancer comparing highest tertile of blood cadmium (≥1 µg/L) with lowest (<0.2 µg/L) after adjustments for sex, age, smoking status (current/non-current), number of cigarettes smoked per day, number of years smoking and occupational exposure to polyaromatic hydrocarbons or aromatic amines.

Endometrial cancer

The significance of the oestrogen-mimicking effects such as the well-characterized estrogenic responses of the endometrial lining (hypertrophy and hyperplasia) observed in animals exposed to environmentally relevant doses of cadmium, was further explored in humans. In a large population-based prospective cohort among Swedish postmenopausal women (n = 32 210) the association between dietary cadmium intake and endometrial cancer incidence, the cancer form most suited to explore potential estrogenic effects, was assessed. This is the first study exploring health effects in relation to the dietary cadmium intake, which is in contrast to smaller studies where cadmium has been monitored in urine. Thus, based on the construction of a food-cadmium database in the cohort, a large study population was utilized and the incidence was assessed prospectively. This design reduces the selection bias that often occurs in case-control studies, but is on the other hand, dependent on the assumption that estimated dietary cadmium intake is a valid reflection of the internal dose. The average estimated cadmium intake was 15 µg/day (1.5 µg/kg bw per week). During 16 years of follow-up, 378 cases of endometroid adenocarcinoma were ascertained through computerized linkage to the Swedish Cancer Registry with virtually no loss to follow-up. The highest versus lowest percentile of cadmium intake was associated with risk of endometrial cancer, RR 1.39 (95 % CI) 1.04-1.85; P for trend 0.02). To reduce the influence of endogenous oestrogen exposure, analyses were stratified by body mass index and by use of postmenopausal hormone use. Analyses were also stratified by smoking status because an anti-estrogenic effect of cigarette smoking is shown on circulating oestrogen concentrations due to increased metabolic clearance, a reduction in relative body weight, and an earlier age at menopause. Among never-smoking, non-overweight women the RR was 1.86 (95 % CI 1.13-3.08; P for trend 0.009). A 2.9-fold increased risk (95 % CI 1.05-7.79) was observed with long-term cadmium intake consistently above the median intake in both 1987 and in 1997 in never-smoking women with low available oestrogen (non-overweight and non-users of postmenopausal hormones). Although the data support the hypothesis that cadmium may exert estrogenic effects and possibly increase the risk of hormone-related cancers this needs to be confirmed by other studies.

In a recent thesis from the Karolinska Institutet (Ali 2013) investigations on the oestrogen-like effects of cadmium as well as possible involvement of classical/non-classical oestrogen receptor signaling was studied in mice, and these mechanisms were further scrutinized in cell-based models. Furthermore, associations of biomarker of cadmium exposure with endogenous circulating sex hormones were evaluated in a population-based study of women. The data collectively suggests that cadmium-induced oestrogen-like effects do not involve classical oestrogen receptor signalling but rather appear to be mediated via membrane-associated signalling. The activation/transactivation of GPR30/EGFR-Raf-MEK-ERK/MAPKs and Mdm2 represent a general mechanism by which cadmium may exert its effects. Since EGFR, ERK and Mdm2 are all known key players in cancer promotion, cadmium-induced activation of these and disturbance in the oestradiol/testosterone balance in women may have implications for the promotion/development of hormone-related cancers.

Breast cancer

In the same study population as for the study on endometrial cancer incidence (Swedish Mammography Cohort; a population-based prospective cohort; see above), the association between dietary cadmium exposure and risk of overall and oestrogen receptor defined (ER+ or ER-) postmenopausal breast cancer was assessed (Julin et al 2012a). In 55 987 postmenopausal women who completed a food frequency questionnaire at baseline in 1987 a total of 2112 incident cases of invasive breast cancer were ascertained during an average follow-up of 12.2 years. Information on ER status was available for 1916 cases (1626 ER+ and 290 ER-). The mean estimated energy-adjusted cadmium intake in the cohort was 15 µg/day. After adjusting for confounders, including consumption of whole grains and vegetables (which account for 40% of the dietary exposure, but also contain putative anticarcinogenic phytochemicals), dietary cadmium intake was positively associated with overall breast cancer tumors, comparing the highest tertile (>16 µg/day; median=17 µg/day) with the lowest (<13 µg/day; median=12 µg/day) [RR, 1.21; 95% CI, 1.07–1.36; P_{trend} =0.02]. Among lean and normal weight women, statistically significant associations were observed for all tumors (RR, 1.27; 95% CI, 1.07–1.50) and for ER_+ tumours (RR, 1.25; 95% CI, 1.03–1.52) and similar, but not statistically significant associations, were found for ER_- tumours (RR, 1.22; 95% CI, 0.76–1.93). Overall, these results suggest a role for dietary cadmium in postmenopausal breast cancer development. This is said to be in line with earlier case-control studies based on biomarker of cadmium exposure. Expressed as a continuous risk, dietary cadmium was associated with a RR of 1.18 (95% CI, 1.08-1.29), per continuous 5 µg/day increment, for overall breast cancer, which equals a 3.6 % increased risk per µg Cd/day (exposure via food). The association was tested for non-linearity, but no support of a non-linear relationship was indicated (Julin 2012b).

Four case-control studies have explored the association between urinary cadmium and breast cancer, all showing statistically significant increased odds with increasing U-Cd (Gallagher et al. 2010; McElroy et al. 2006; Nagata et al. 2013). Including 246 breast cancer cases, McElroy et al. (2006), observed a multivariable-adjusted OR of 2.29 (95% CI 1.3–4.2), comparing the highest quartile of U-Cd (>0.58 µg/g cr) with the lowest (<0.26 µg/g cr). Based on 153 breast cancer cases, Nagata et al. (2013) observed an OR of 6.05 (95 % CI 2.90-12.62) comparing the highest tertile of U-Cd (>2.6 µg/g) to lowest (<1.7 µg/g). Similar results were observed in two other case-control samples from the USA, consisting of 100 and 98 cases, respectively (Gallagher et al. 2010). Data on premenopausal mammographic density, a strong marker of breast cancer risk. However, conflicting evidence was later presented by the same author (Adams et al 2016) in an epidemiological study evaluating the relationship of cadmium exposure, evaluated by urinary cadmium levels, and the incidence of invasive breast amongst a large cohort of postmenopausal women in a Women's Health Initiative study of bone mineral density. In this study no association was observed between urinary cadmium and breast cancer risk in any subgroup examined, including those who had never smoked and women with body mass index[28] less than 25. A recent meta-analysis (of four studies) showed a statistically significant positive association between dietary cadmium intake and breast cancer risk, RR= 1.15 (95% CI 1.04-1.28) (Cho et al 2013).

Epidemiological studies have also reported Cd exposure associated with the development of breast cancer (Larsson et al. 2015; Nagata et al. 2013; Strumylaite et al. 2014). Moreover, chronic Cd exposure is closely related to tumor progression, invasiveness, and metastasis (Achanzar et al. 2001; Waalkes et al. 2000). Diet and tobacco smoking are the main source of Cd intake in non-occupational–exposed people. In a prospective cohort study, dietary Cd exposure was positively associated with postmenopausal breast cancer (Julin et al. 2012). Breast cancer risk was increased with Cd burden in blood, urine, and breast tissue of humans (Larsson et al. 2015; Peng et al. 2015; Strumylaite et al. 2011).

Another meta-analysis also suggests that a high cadmium exposure may be a risk factor for breast cancer (Larsson SC et al (2015) and another case-control case study that cadmium is a risk factor for breast cancer, especially for both ER+ and HER2 cancer patients (Strumylaite L et al (2015). A further *meta*-analysis studies showed a significant increase in breast cancer risk in women exposed to higher cadmium levels (Lin J et al (2016)).

Skin cancer

In a systematic review of epidemiological studies linking exposure to trace elements and the risk of skin cancer (Matthews et al 2019), it was concluded that elements such as arsenic and selenium were associated with increased risk of keratinocyte carcinoma but the data on the association between cadmium and the risk of skin cancer remains too sparse to draw any conclusions. The potential for skin toxicity to arise from cadmium exposure was determined in a recent 30-day study in rats which demonstrated that cadmium deposition occurs in the skin following oral exposure (Tucovic et al 2018). In addition, skin inflammation in the form of oxidative stress changes was observed at both the cadmium doses evaluated as were dose dependent structural changes in the skin with the presence/activation of innate immunity cells. Increases in inflammatory cytokines (IL-6, TNF and IL-1β) were also detected. It was considered that these data may be relevant in attempting to explain a potential link between dietary cadmium intake and the risk of skin pathologies.

Conclusion: Cadmium is classified as a human carcinogen by IARC, mainly based on lung cancer among occupationally exposed people. In EU many cadmium compounds have a harmonised classification for cancer (Carc. Cat 1B or 2) but without any indication on a route of exposure. More recent studies suggest an association based on dietary cadmium exposure. Results from experimental and epidemiological studies clearly raise concern that cadmium might act as a metalloestrogen and possibly increase the risk of hormone-related cancers in humans. Additionally, the potential role of cadmium in tumour angiogenesis has been considered and remains uncertain (Wei et al 2017).

[28] Bod Mass Index (BMI) = weight (kg)/height (m)^2

3.5.7.2. Cadmium pigments

For these substances a read –across has been made with cadmium telluride.

No data are available on carcinogenicity. Cadmium telluride is non-genotoxic and therefore no classification is proposed for carcinogenicity. The data for CdTe is considered to provide information as a worst case scenario for CdSSe (much lower bioaccessibility of Cd from CdSSe), therefore no classification proposed for CSSe.

3.5.8. Mutagenicity

3.5.8.1. Cadmium stabilisers

Like other toxic effects caused by cadmium compounds, genotoxic effects can be assumed to be caused by the cadmium ion. Some cadmium compounds have a harmonized classification for mutagenicity. Cadmium chloride, cadmium sulphate and cadmium fluoride are classified as Muta. Cat 1B, whereas cadmium (metal), cadmium oxide and cadmium sulphide are classified as Muta. Cat 2. The general entry for cadmium compounds not classified elsewhere (Index number 048-001-00-5) does not include mutagenicity.

The conclusion in the EU RAR of cadmium metal and cadmium oxide (ECB 2007) was that *“although the available data on the cadmium compounds of concern (Cd metal and oxide) are scarce and the results with water-soluble compounds conflicting, it is concluded that it cannot be excluded that cadmium metal and oxide can exert genotoxic effects in vivo.”* Further, it was stated that *“while, water solubility does not necessarily reflect in vivo solubility, it can be assumed that Cd/CdO will to some extent be solubilised in vivo, especially in the lung, and data obtained with soluble Cd compounds may be considered relevant to assess the possible genotoxic potential (hazard) of cadmium oxide.”*

Experimentally, using molecular and cytogenetic assays, cadmium chloride has been shown to cause chromosomal aberrations in the femoral bone marrow of rats following a single intraperitoneal dose which also caused chromosomal band number alterations in liver and kidney cells (Aly et al 2018).

3.5.8.2. Cadmium pigments

For these substances a read –across has been made with cadmium telluride.

Three recently made (2010-2013) in vitro studies with cadmium telluride, were all negative.

3.5.9. Toxicity for reproduction

3.5.9.1. Cadmium stabilisers

Some cadmium compounds have a harmonised classification for reprotoxicity. Cadmium chloride, cadmium sulphate and cadmium fluoride are classified as Repr. Cat 1B, whereas cadmium (metal), cadmium oxide and cadmium sulphide are classified as Repr. Cat 2.

Developmental toxicity

Neurotoxicity and child development

The risk assessments of Cd and CdO performed according to the Existing Substances Regulation (ESR) concluded that “*information is needed to better document the possible neurotoxic effects of Cd suggested in experimental animals, especially on the developing* *brain. The collection of this additional information should, however, not delay the implementation of appropriate control measures needed to address the concerns expressed for several other health effects including repeated dose toxicity and carcinogenicity*." (ECB 2007).

A few small cross-sectional epidemiological studies indicate an adverse effect of cadmium exposure on child development, supported by experimental studies showing cadmium-induced neurotoxicity. Although available data does not allow quantitative health risk assessment, these effects should be kept in mind (Swedish Chemicals Agency 2011).

A recent investigation in U.S. children, using National Health and Nutrition Examination Survey (NHANES) data on approximately 2 200 individuals, suggests that low-level environmental cadmium exposure in children may be associated with adverse neurodevelopmental outcomes (Ciesielski et al. 2012). Median urinary cadmium (µg/L) ranged from 0.078 (age 6-7 yrs) to 0.146 (age 14-15 yrs). When comparing children in the highest quartile of urinary cadmium with those in the lowest quartile, adjusted odds ratios were 3.21 (95% CI: 1.43-7.17) for learning disabilities, 3.00 (95% CI: 1.12-8.01) for special education and 0.67 (95% CI: 0.28-1.61) for attention deficit hyperactivity disorder (ADHD). The urinary cadmium levels in U.S. children are probably similar to what can be expected within EU. For example, the median urinary level in young (age 20-29 yrs) non-smoking women in Sweden is approximately 0.1-0.2 µg/g creatinine, corresponding roughly to 0.1-0.2 µg/L[29].9

A study on early-life low-level cadmium exposure in rural Bangladesh also indicates effects on child development, showing lower child intelligence, particularly in girls (Kippler et al. 2012).

3.5.9.2. Cadmium pigments

For these substances a read –across has been made with cadmium telluride.

A non-guideline study for reproductive toxicity is available for CdTe, (28 days), no reproductive effects were seen. For developmental toxicity, a non-guideline study with CdTe is available (28 days), no developmental effect seen.

Due to the lack of a suitable test reported for reproductive toxicity a pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route is included in the decision towards the registrant. If this is positive then this would need to be considered in terms of the read-across with the cadmium pigments.

3.5.10. Other effects

3.5.10.1. Cadmium stabilisers

Overall mortality

Two recent studies from Belgium and USA indicate associations between cadmium and increased mortality, which is alarming. Both studies are of high quality (prospective) and

[29] 9 For urinary cadmium levels in Sweden, see the following link: http://www.imm.ki.se/Datavard/Tidsserier/Cadmium%20in%20urine.htm.

the Belgian study has even included repeated measurements of exposure. Still, it is difficult to judge whether the results could be due to confounding factors. For instance, low urinary creatinine excretion is associated with all-cause mortality and cardiovascular disease. Thus, adjusting a urine-based exposure marker by creatinine may result in falsely high associations between exposure and disease or mortality. It is noteworthy that the Belgian study employed urinary cadmium per 24 hours and blood cadmium. Nevertheless, these data clearly add to the concern that cadmium might exert severe effects on human health (Swedish Chemicals Agency 2011).

3.5.10.2. Cadmium pigments

Not relevant

3.5.11. Derivation of DNEL(s) / DMEL(s)

The current restriction proposal covers cadmium and cadmium compounds. The toxic effects of these substances are caused by the cadmium ion and all cadmium compounds contribute to the concentration of cadmium ion that can be found in different media.

Most previous risk assessments have been based on kidney toxicity, for example the risk assessment by EFSA in 2009. In that case the Tolerable Weekly Intake (TWI) set (2.5 µg per kg body weight per week) was calculated from a urinary Cd level of 1 µg/g creatinine at 50 years of age.

The DNEL for workers used by industry in the registrations of several different cadmium compounds is based on the IOEL (4 µg/m^3 in air, measured as the respirable fraction) suggested by SCOEL (final draft Feb 2009). A biological limit value was also calculated by SCOEL, 2 µg Cd/ g creatinine. These values were considered to protect workers from kidney (and bone) toxicity and local lung effects, including lung cancer. Whether this value is also protective against cancer in other tissues was not assessed. According to a paper from the Austrian Workers' Compensation Board (Püringer 2011), the German Committee on Hazardous Substances (AGS) has recently endorsed a limit value of 16 ng Cd/m^3 based on the acceptable cancer risk of 1 : 25 000, i.e. a value 250-fold lower than the IOEL suggested by SCOEL.

According to a more recent risk assessment (Swedish Chemicals Agency 2011), the data supporting an adverse effect of the present exposure to cadmium (in Sweden) on the risk of osteoporosis have increased substantially during the last few years. Only a couple of under-powered studies failed to show any association between cadmium and low bone mineral density. Moreover a few studies were considered inconclusive. Irrespective of whether the studies employed a decrease in the bone mineral density, increased risk of osteoporosis or increased risk of fractures, these changes seem to occur at very low urinary cadmium concentrations. Both the new Swedish (SMC) and the new American (NHANES) studies suggest that even a urinary concentration around 0.5 µg/g creatinine is associated with increased risk of osteoporosis and fractures. There are increasing data suggesting that the effect of cadmium on bone is independent of kidney damage - and recent data support that these effects occur even before the kidney damage. Furthermore, the Swedish studies showed very clear increased risk of osteoporosis and fractures even among those who never smoked. This finding suggests that dietary cadmium alone contribute to the risk (Swedish Chemicals Agency 2011; Engström et al. 2012). Further, in the scientific opinion from EFSA (EFSA 2009) it is concluded that *"the studies evaluated indicate a range of urinary Cd for* *possible effects on bone effects starting from 0.5 µg/g creatinine, which is similar to the levels at which kidney damage occurs."*

In recent years more data on cancer effects have also become available. For dietary cadmium intake, meta-analyses have shown statistically significant associations between dietary cadmium and some hormone-related cancers, i.e. prostate, breast and endometrial cancers (Cho et al. 2013).

Since a quantitative link between cadmium emissions from PVC articles and human exposure may be difficult to establish, the approach that can be taken is to claim that any (part of the) release of cadmium to the environment should be controlled and reduced, because for a significant part of the population, the current level of exposure is critical in regard of the effects on kidneys and bone.

3.6. Exposure information

3.6.1. Introduction

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

(i) during service life of articles produced from recycled PVC (consumer and environmental exposure);

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

The main downstream uses allowed for recycled PVC containing cadmium are the applications allowed in entry 23 of Annex XVII of REACH:

a) Profiles and rigid sheets for building applications;
b) Doors, windows, shutters, walls, blinds, fences, and roof gutters;
c) Decks and terraces;
d) Cable ducts;
e) Pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC.

As discussed in the section (manufacture/uses/base-line), the cadmium content varies across the different applications (window profiles 0.35%).

3.6.2. Service life

3.6.2.1. Consumer exposure

Various studies and assessments agree that cadmium in PVC articles is bound within the plastic matrix at the time of manufacture and has low inherent extractability during the service life of the main downstream uses. A report prepared by the European Commission (2004) on the Life Cycle Assessment of PVC and of principal competing materials, concluded that 'metals like lead and cadmium used in additives and stabiliser systems are immobilised'.

However, whilst leaching behaviour is acknowledged to be limited, losses of plastic additives during article service-life can occur as a result of abrasion and polymer degradation. The

OECD emission scenario document for plastic additives establishes a default release factor for heat stabilisers during article service life of 0.01% (w/w).

Overall, on the basis of the available data, it can be concluded that PVC articles containing cadmium release only small quantities during their service life, particularly if they are not exposed to environments that would promote polymer degradation or result in abrasion.

3.6.2.2. Environmental emissions of cadmium (during service life of PVC articles)

Water Framework Directive

The key objective of the Water Framework Directive (WFD) is to achieve good status for all water bodies by 2015. This comprises the objectives of good ecological and chemical status for surface waters and good quantitative and chemical status for groundwater. Cadmium and its compounds are identified as a Priority Substance (PS) under the WFD (Directive 2000/60/EC)[30], as well as Directive 2008/105/EC on environmental quality standards (EQS[31]), and Directive 2006/118/EC on the protection of groundwater against pollution and deterioration[32]. The annual average environmental quality standard for cadmium in freshwaters is currently 0.08 – 0.25 µg/L (depending on water hardness).

As part of the implementation of the WFD, the European Commission (DG ENV) developed “source screening sheets” for priority substances (PS) and priority hazardous substances (PHS), including cadmium[33]. These sheets were developed to identify relevant sources of PS or PHS to the water environment, particularly highlighting those that could contribute to potential failure of WFD objectives (e.g. EQS threshold values). Sources were classified into one of three categories:

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

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

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

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

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

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

[33] Revised source screening of priority substances under the WFD: Results for Cadmium (Cd) (priority hazardous substance) Version: 2 Date: October 2010

Various sources of cadmium that could be associated with uses as a PVC stabiliser or pigment were considered as Category 1 sources i.e. to result or contribute to the failure of WFD objectives (Table 7). For example, "discharges in sewage effluents or storm water as a result of run-off from buildings and constructions in paved urban areas". This could include losses of cadmium (via degradation / weathering) from the external parts of buildings where ridged PVC materials are often used (e.g. in roofing, guttering and rain water downpipes). Similarly, emissions from "waste disposal and treatment areas" are also identified as potentially affecting WFD objectives.

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

Table 7. Table of sources of cadmium (aquatic and atmospheric emissions) most relevant to PVC applications of this assessment (Source: Revised source screening of priority substances under the WFD: Results for Cadmium (Cd) (priority hazardous substance) 2010)

Source category (area/code)	*Classification*
Discharges to surface waters by point sources	
- S6 Release from materials and constructions in non sewered areas	Category 3
- (S7) Discharges in sewage effluents or storm water as a result of run off from buildings and constructions in paved urban areas (roofs, paints)	Category 1
- (S8) Discharges in sewage effluents or storm water as a result of households, consumer use (water pipes; fittings).	Category 2
Emissions to atmosphere	
- (A3) From buildings	Category 3
- (A5) From industry IPPC categories	
o Fossil fuel combustion	Category 1
- (A7) From waste disposal/treatment areas (landfill and others)	Category 1

Migration of cadmium from PVC

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

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

The results of this investigation for cadmium are shown in Table 8. It can be concluded from these data that cadmium migrates to water from both rigid and flexible PVC granules under the conditions of the study and that diffusion would appear to be appreciably greater from flexible PVC than from rigid PVC.

A supplementary study (2nd FABES study) was conducted in September 2015 to further investigate diffusion rates of cadmium in rigid and flexible PVC. Summary details of this study, including results, were made available to ECHA by VinylPlus during the development of this Annex XV report (see Table 9). The results and conclusions of this investigations have also been reported by Mercea et al. (2016). In this study four samples of rigid PVC and four samples of flexible PVC were maintained in distilled water in glass vials at 30 and 70°C, respectively, and the cadmium concentration in solution measured after 28, 42, 56 and 70 days.

As observed in the first study, diffusion coefficients were greater for flexible PVC than for rigid PVC. Equally, greater diffusion was observed at 70°C than at 30°C. Diffusion coefficients for cadmium in rigid PVC samples were confirmed to be in the range of 10^{-16} cm^2/s that was observed in the first FABES study, which is considered to be fairly typical diffusion co-efficient for a substance in rigid PVC. Diffusion co-efficients are relatively greater for the same substance in other types of polymers e.g. PET, PS, PA, PP< HDPE, LDPE

Table 8. Migration of cadmium from rigid PVC (1st FABES study, 2016)

Parameter	**Rigid PVC**	**Flexible PVC**
Diffusion coefficients derived from measurements (cm^2/s)	$6*10^{-16}$	$4-10*10^{-14}$
Partition coefficients derived from measurements (g/cm^3)	2 000	7 400 – 15 000
Diffusion coefficients used for modelling (cm^2/s)	10^{-15}	10^{-13}
Partition coefficients used for modelling	1 000	10 000
Concentration in water (µg/L)	0.013	0.53

Table 9. Migration of cadmium from rigid and flexible PVC (2nd FABES study, 2016)

Sample		Diffusion coefficients (cm^2/s) x 10^{-17}	
		30°C	70°C
Rigid	1	-	-
	2[34]	50	65.0
	3	-	-
	4	-	-
Flexible	5	-	-
	6	0.8	1.1
	7	17.0	800.0

Note: only results from one sample of rigid sample and two samples of flexible PVC were available.

3.6.3. Indirect exposure of humans via the environment through end of life of PVC waste.

The principal risk addressed in this restriction report is that of toxicity to the kidney, especially to the proximal tubular cells where it accumulates over time and may cause renal dysfunction. Cadmium can also cause bone demineralisation, either through direct bone damage or indirectly as a result of renal dysfunction. Data on human exposure to cadmium in the general population have been statistically associated with increased risk of cancer such as in the lung, endometrium, bladder, and breast. (EFSA, 2010) and in previous REACH restriction reports (e.g. cadmium in artists paints, KEMI 2014).

It is acknowledged that human and environmental exposure to cadmium has decreased significantly over the last 20 to 30 years, the risk for adverse effects on kidney function at an individual level at dietary exposures across Europe is very low. However, the CONTAM Panel recommended that the current exposure to cadmium at the population level should be reduced (EFSA, 2009).

Cadmium and its compounds, in terms of its kidney and bone effects, are considered as threshold substances (see section 3.5). However, the possible carcinogenic properties may well be non-threshold. Due to the lack of data on exposure of cadmium from recycled PVC

[34] This is compared to lead that had diffusion co-efficients of 1.5 (30°C) and 3.0 (70°C) x 10^{-17}

an approach similar to that lead compounds used as PVC stabilisers has been undertaken for this report. This approach (based on the requirements of Annex I of REACH, where a threshold cannot be determined) uses estimation of emissions as a proxy of the risk of a substance and the reduction is emissions as a proxy for the risk reduction capacity of the measure. No qualitative assessment has been carried out due to the difficulties in assessing the exposure to individuals from the releases under consideration.

It should also be considered that cadmium pigments have a much lower bioavailability than the cadmium substances historically used as stabilisers. However, there is evidence that they do eventually breakdown in the environment to form more soluble cadmium ions and are then available for uptake into plants or humans. In addition, the behaviour of cadmium pigments during incineration is not well known.

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

In general, “direct” human exposure from the use of cadmium in recycled [or recovered] PVC (service-life exposure) is expected to be limited i.e. exposure of the general population through mouthing or via direct and prolonged contact with skin as the uses allowed are all in construction products.

Therefore, potential human exposure is considered to occur predominantly via the environment (including indoor environment) and diet (food and drinking water). Relevant conceptual pathways for human exposure to cadmium associated with service-life and end-of-life are outlined below.

PVC articles contribute to overall releases of cadmium to the atmosphere and water during both their service life (via degradation, abrasion and [limited] migration/leaching processes) and after disposal as waste.

The disposal and treatment of PVC waste will lead to releases of cadmium to the environment (ARCHE, 2012). PVC articles disposed in landfill are considered to be relatively stable with limited potential for cadmium 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 cadmium to air and water[35] from municipal waste incinerators. Incinerator fly ash (also described as air pollution control residue) is acknowledged to be heavily contaminated with unstable (potentially mobile) cadmium, which can be readily released from the fly-ash matrix through leaching. Thus, fly-ash is a long-term reservoir of cadmium from PVC that could be released to the environment.

Stabilisation of fly-ash (e.g. with cement) prior to long-term disposal in hazardous waste landfill or prior to re-use (in construction applications) can reduce the leaching potential of cadmium (and other heavy metals). However, acceptance criteria for hazardous waste landfill (or re-use) allow some leaching to occur (albeit at relatively low concentrations), implying that cadmium cannot be considered to be completely contained (over long time horizons) within stabilised fly-ash.

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

For the general population, which is not occupationally exposed, food and water are considered to be the most important sources of exposure to cadmium (EFSA, 2009). Therefore, human exposure to cadmium 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 cadmium) and soil.

Cadmium is commonly present in food (EFSA, 2009). EFSA (2009) assessed dietary cadmium exposure in the European population across the aggregated food categories specified in the EFSA concise European Food Consumption database.

Foodstuffs are the main source of cadmium exposure for the non-smoking general population. Cadmium absorption after dietary exposure in humans is relatively low (3–5 %) but cadmium is efficiently retained in the kidney and liver in the human body, with a very long biological half-life ranging from 10 to 30 years. A health based guidance value for cadmium of 7 µg/kg body weight (bw) per week. House dust can be an important source of exposure for children.

The mean exposure for adults across Europe is close to, or slightly exceeding, the tolerable weekly intake (TWI) of 2.5 µg/kg bw Subgroups such as vegetarians, children, smokers and people living in highly contaminated areas may exceed the TWI by about 2-fold. Although the risk for adverse effects on kidney function at an individual level at dietary exposures across Europe is very low, the CONTAM Panel concluded that the current exposure to Cd at the population level should be reduced.

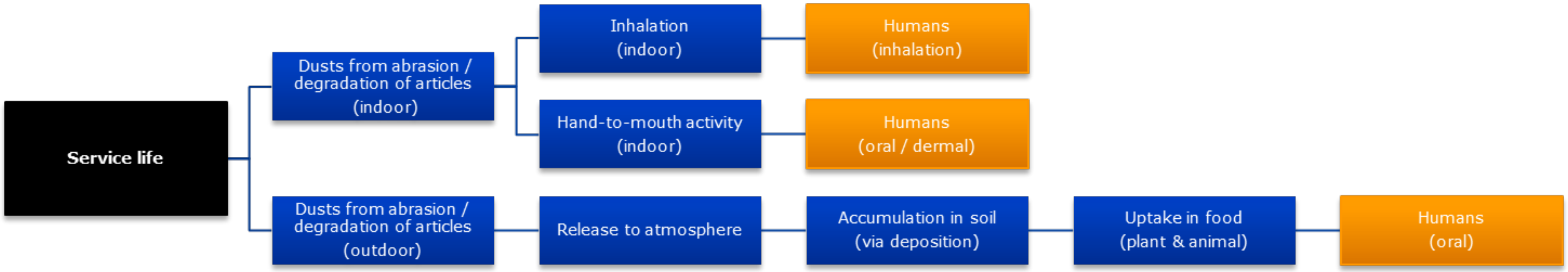

Figure 1. Conceptual cadmium exposure pathways for humans relevant to the service life of articles containing recycled PVC

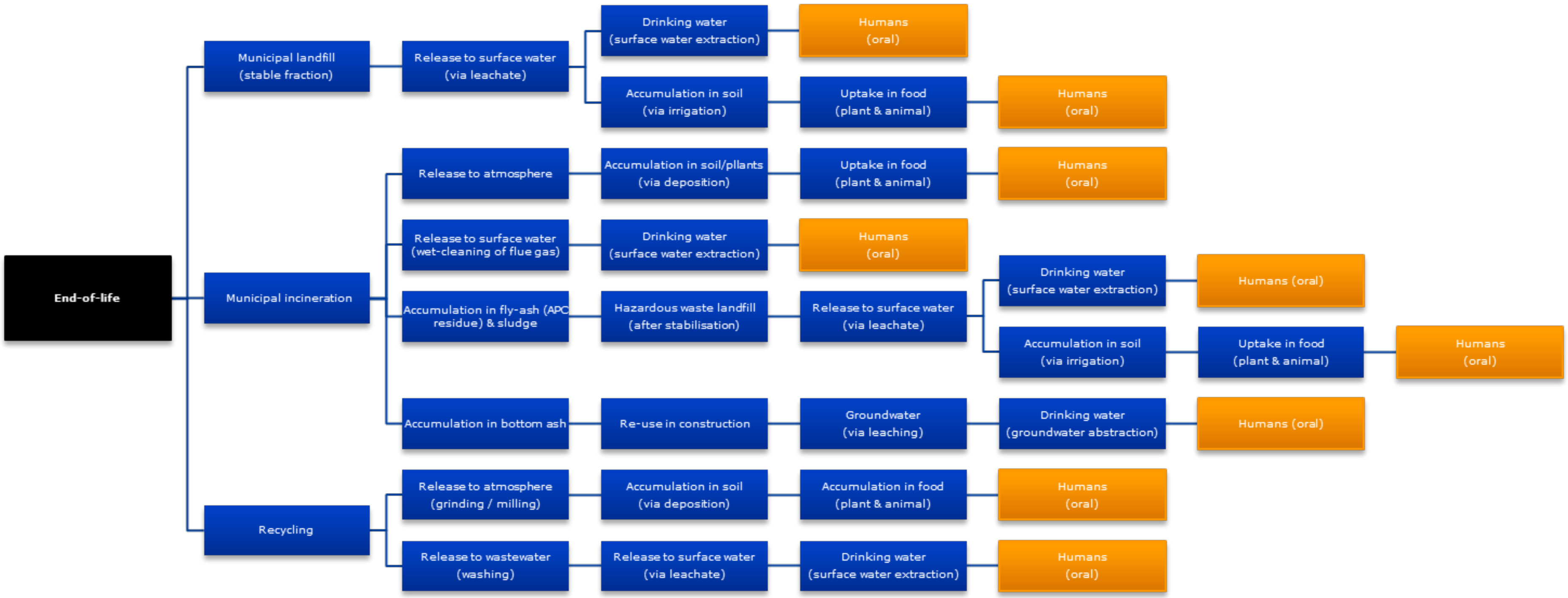

Figure 2. Conceptual cadmium exposure pathways for humans relevant to the end of life of articles containing recycled PVC

3.6.3.2. Cadmium in waste PVC – results of environmental mass-flow modelling

As outlined in section 3.6.6.2, the recycling of PVC waste will avoid any releases of cadmium (and other substances e.g. lead) associated with the disposal via landfilling or incineration. PVC can be recycled numerous times. As such, as long as risks during the recycling process and the subsequent service life of articles containing recovered PVC are adequately-controlled, the recycling of PVC can be considered as a form of risk management for legacy cadmium (and lead) in PVC.

The influence of PVC recycling on end-of-life releases of cadmium (the efficiency of risk management) were assessed using a mass-flow model. The difference between estimated releases to the environment with and without recycling taking place can be used to illustrate the effect of recycling on cadmium mass-flows and environmental releases, relative to other waste-management techniques.

Estimates of cadmium releases are based on the assumption that all PVC articles produced using recycled PVC will be subject to some form of waste handling (e.g. recycling, landfill, incineration) at the end of their service life (which could be up to 50 years after the start of their service life). A further key consideration is that associated releases of cadmium after disposal could occur at an unspecified time in the future, particularly if waste PVC is disposed of in a landfill. Thus, the disposal of an article containing recycled PVC in a particular year may not lead to immediate releases but can be associated with the potential for releases in the future. This concept was also central to the exposure assessment of the flame retardant decaBDE, a PBT substance, and lead in PVC where releases were distributed across both the service life and waste disposal life cycle stages.

The mass-flow model used was based on the model developed by ECHA for the proposed restriction on the use of lead-based stabilisers in PVC (ECHA, 2016). The model was used to estimate releases to different environmental compartments based on the mass-flow (tonnage) of waste PVC directed to various waste-treatment techniques, including municipal landfill, municipal incineration, recycling and waste export.

The model also estimated releases to environmental compartments from disposal or re-use of 'waste resulting from municipal incineration, such as incinerator air pollution control [APC] residue (fly-ash), wastewater treatment sludge and bottom-ash. The releases from these materials are estimated on a generic basis irrespective of any use that could occur[36].

The recycling element of the model estimated releases to the environment that would occur from the mechanical grinding and milling of plastics that takes place during recycling (as

[36] The use of municipal incinerator fly-ash within the construction industry is practised in some Member States. The range of release factors proposed for this are assumed to be sufficiently wide to account for the range of likely releases that could occur dependent on the potential long-term fate of this material in different Member States i.e. hazardous landfill, long-term storage, use in construction as road fillers. An analysis of potential releases from building material produced using stabilised incinerator fly-ash in the UK during the opinion-making of the lead stabiliser in PVC dossier supported this assumption.

dusts) as well as releases associated with a single subsequent service life of an article produced using recyclate containing cadmium (via abrasion and degradation of PVC matrix). The exposure and emission from recycling are assumed to be low based on default values from ECHA R.18 Guidance (0.006%). However, measured data to support default values are not available in the literature. When recycling was excluded from the model the portion of PVC waste subject to recycling was reallocated to other waste-management options in proportion to the relative tonnage of PVC waste treated by the remaining techniques.

Release factors to environmental compartments for each waste treatment option were identified either from an assessment of environmental releases included in Registration dossiers for cadmium substances (ARCHE, 2012) or, where these were absent, default values from ECHA R.18 guidance. As a range of release factors were reported for some compartments, or release factors for some parts of the model were particularly uncertain, a probabilistic approach (Monte Carlo simulation, using Oracle Crystal Ball Software) was used to integrate this variability and estimate overall releases in terms of a 'most likely' range.

Mass flow data (waste arisings [tonnes] and proportion of waste subject to different waste treatment techniques) estimated for 2020 were used to parametrise the model (VITO, 2017; IA TAUW, 2013). The concentration of cadmium in waste PVC was taken from VITO (2017). The model was re-run on 10 000 occasions with results reported below as a range, summarised in terms of theoretical minimum and maximum values as well as median and interquartile range, which are indicative of 'most likely' releases. A sensitivity analyses of the relative variability introduced by each of the model parameters was also undertaken

Table 10. PVC waste profile in 2020 (After VITO, 2017)

Waste type	Waste arising [t]	Cadmium conc. [% ww]	Cadmium content [t]
Window profiles	286 724	0.0478	13 705
Other profiles	546 785	0.0707	38 658
Pipes	527 296	0.00853	4 498
Total	**1 360 805**		**56 861**

Table 11. Percentage of PVC waste treated by different techniques in 2020, with and without recycling scenario

Scenario	Recycling	Incineration	Landfill	Export
Recycling[1]	20	45	20	15
No recycling[2]	-	56	25	19

Notes: 1: After IA TAUW (2013); 2: Recycled material reallocated to different waste management techniques in proportion to relative volume treated in 2020 with recycling

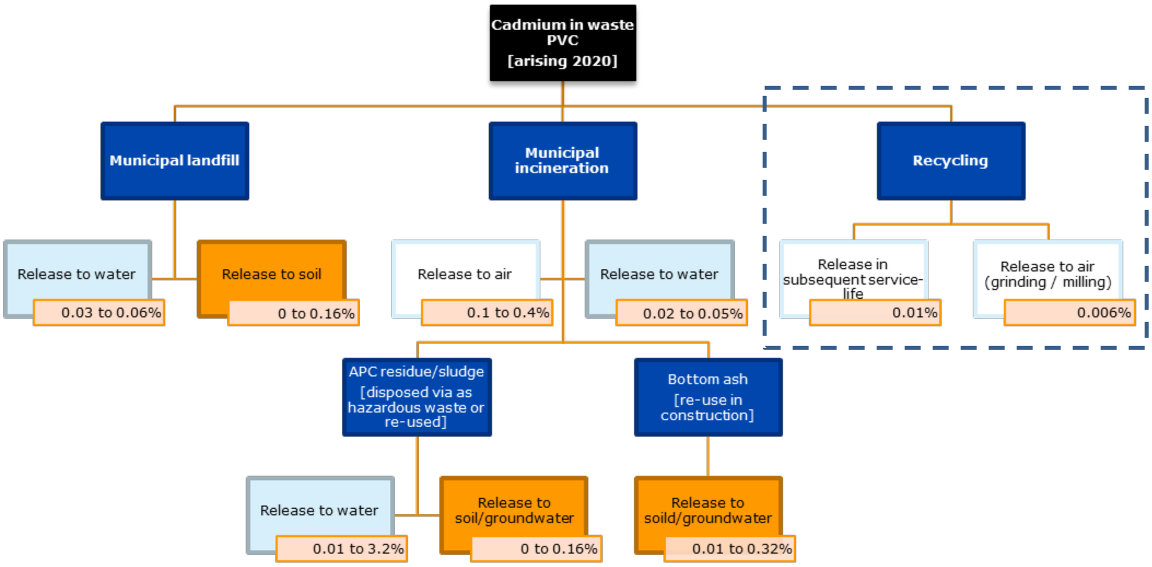

Figure 3. Conceptual basis of mass-flow environmental release model for cadmium in waste PVC.

Results

According to VITO (2017) PVC waste arisings in 2020 will be 1 360 805 tonnes. The corresponding tonnage of cadmium in this waste will be 56 861 tonnes. The 'most likely' (interquartile range) resulting cadmium releases associated with the end of life disposal of this waste where recycling continues according to industry forecasts are 292 to 652 tonnes. Where recycling does not take place (and waste is diverted to other treatment techniques) most likely releases are estimated to be between 353 and 802 tonnes. These releases are associated with the waste arising in a given year, but some will occur over a longer time period than others. For example, releases to air from incineration or recycling will occur at the point of treatment, whilst releases from municipal landfill or those associated with the disposal or re-use of fly-ash will occur over much longer time horizons after initial disposal. These releases should be controlled by relevant environmental measures.

This corresponds to a most likely relative increase in releases of between 60 and 150 tonnes when recycling does not take place, which is equivalent to a net increase in overall releases of between 17 and 19 percent. The cadmium release associated with recycling, which incorporates releases during recycling and subsequent releases during a single article service life, are estimated to be between 0.3 and 0.6 percent of overall releases associated with the disposal of PVC waste arisings in 2020.

The overall release factor associated with waste PVC treatment was calculated for the two scenarios (with / without recycling) based on the volume of PVC waste arising and the volume of cadmium released to the environment. In both scenarios the release factor is relatively low. However, the overall release factor assuming recycling was 20% lower than when recycling does not take place.

Table 12. Release of cadmium to the environment from PVC waste arising in 2020

Release	Min	25%ile	Median	75%ile	Max
Total cadmium release [tonnes] (with recycling)	38.5	292.0	471.4	652.0	898.7
Total cadmium release [tonnes] (no recycling)	39.4	353.0	575.9	802.0	1105.1
Increase in release [tonnes]	0.9	59.7	104.3	149.5	206.4
Net increase in releases [%] with no recycling	2.4	16.9	18.1	18.7	18.7
Cadmium release associated with recycling [%]	0.2	0.3	0.4	0.6	4.7

Table 13. Cadmium release factors for end-of-life treatment of waste PVC waste arising in 2020

Release factor (PVC waste)	Min	25%ile	Median	75%ile	Max
No recycling	0.00069	0.0062	0.01	0.014	0.019
With recycling	0.00068	0.0051	0.0083	0.011	0.016

Derivation of release factors for different environmental compartments

Release (to environmental compartments) and distribution (between fly ash, bottom ash and water treatment sludge after municipal incineration) factors were selected from those reported by Arche (2013), TNO (2011), ECHA Guidance and the OECD Emission Scenario Document for plastics additives (OECD, 2009).

Table 14. Cadmium release factors used for mass-flow modelling

Source and compartment		Value[1] (dimensionless)	Reference
MW incineration	F_{air}	0.001 - 0.004	Lower bound = ECHA R.18 default of 0.001; Upper bound = 0.004 from ARCHE 2012 (based on EU-27 measurements);
	F_{water} (scrubber systems)	0.0002 – 0.0005	From wet-cleaning facilities only; lower bound 0.0002 from ECHA R18; upper bound 0.0005 from ARCHE 2012 (based on EU-27 measurements)
	F_{sludge}	0.02	0.02 from ARCHE 2012 (based on EU-27 measurements) - fraction subsequently sent to hazardous landfill
HW landfill	F_{air}	0	Emissions via air from landfill activities are deemed negligible for cadmium, with a reported boiling point of 767 °C (ARCHE, 2012)
	F_{water} (fly ash and incineration sludge only)	0.0001 - 0.032	Lower bound = 0.0001 based on OECD service life emission (consistent with ECHA approach); upper bound = 3.2% ECHA R.18 default (p.99)
	F_{soil}	0 – 0.0016	Lower bound = 0 metals are not expected to pass through the landfill body (ARCHE, 2012); upper bound = 0.16% ECHA R.18 default (p.99)
MW landfill	F_{air}	0	Emissions via air from landfill activities are deemed negligible for cadmium, with a reported boiling point of 767 °C (ARCHE, 2012)
	F_{water}	0.0003 - 0.0006	Lower bound = 0.0003; upper bound = 0.0006 both based on EU-27 measurements of cadmium concentration in leachate and leachate volume modelling for 20 years (ARCHE, 2012).

Source and compartment		Value[1] (dimensionless)	Reference
	F_{soil}	0 - 0.0016	Lower bound = 0 metals are not expected to pass through the landfill body (ARCHE, 2012); upper bound = 0.16% ECHA R.18 default (p.99)
RW (shredding / milling)	F_{air}	0.00006	[(0.1*0.004)*0.15 = 0.00006]; based on ECHA default release from plastic material corrected for average conc (0.4%) of cadmium in waste PVC and effectiveness of RMMs (90% of dusts captured and 95% efficiency of filter = 85.5%)
Article service life (degradation and abrasion)		0.0001	0.01% from OECD emission scenario document for plastics additives – heat stabilisers
Re-use in road construction (for incinerator bottom ash fraction) - consistent with ERC 10a		0.0001 - 0.0032	Lower bound = service life - solids (degradation and abrasion) - OECD emission scenario document; upper bound ECHA R.18 defaults for release to soil and water (2 x 0.0016)
Fraction of cadmium subject to municipal incineration incorporated in fly-ash		0.85	ARCHE (2012)
Fraction of lead subject to municipal incineration incorporated in bottom ash		0.13	ARCHE (2012)

Notes: MW – municipal waste; HW: hazardous waste; RW: recycled waste; 1: upper and lower bound range used in mass-flow analysis

3.6.4. Risk characterisation

The purpose of this report is to assess the current derogation for cadmium in recycled plastic.

The major exposure to cadmium would be associated with end of life when the PVC articles are disposed of (and not recycled). If the tonnage of PVC that is currently recycled was instead disposed of as waste this was estimated to result in an additional 104.3 tonnes of cadmium being released in 2020 (from 59.7 to 149.5 tonnes, most likely interquartile range) rather than being retained within the PVC matrix. As the potential emissions from PVC recycling process and the service life of articles made from PVC recyclate are considered to be negligible (<1% of overall releases), recycling can be seen as a measure to reduce annual exposure to the environment.

3.7. Justification for an EU wide restriction measure

This review concentrates on risks associated to the use of recovered PVC containing cadmium. Cadmium is regulated by Entry 23 of the REACH Annex XVII. Paragraph 4 in the entry contains a specific derogation for mixtures and articles used in certain applications containing recovered PVC, and a review clause stating that the derogation needs to be reviewed with a view to reducing the limit value for cadmium and to reassess the scope of the articles included in the derogation.

The existing Entry 23 Paragraph 4 applies across the EU, and there is no information available suggesting the reconsideration of the EU-wide basis. Any potential modifications to the entry, including any modifications to derogation(s), clearly need to be made on a Union-wide basis.

The practical 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 concentrating on Human Health. Secondly, there is a need to assess and balance any consequences of cadmium regulation with (EU wide) activities promoting recycling of PVC materials and circular economy.

A tightening of the current derogation would potentially decrease the rate of recycling of PVC materials, which generally means increased use of other resources. As a result, more cadmium tainted material would need to be managed in alternative ways (i.e. incinerated, stored at a landfill). This in turn, would increase, however little, annual environmental and human exposure to cadmium. Therefore, the effects need to be simultaneously assessed and balanced EU wide. A Union wide restriction of cadmium compounds in PVC based articles creates a level playfield for trade and prevents the market distortions resulted from national regulations. It does not discriminate between PVC articles produced in the EU and articles imported from third countries, and it does not hinder commercial relations on the internal market.

3.8. Baseline

In line with the Vito 2009 study and the current scope ECHA has arranged an update of the relevant data on average cadmium content and a targeted impact assessment. The work is based on updated data on waste arisings and product markets (and projections for both) provided by EuPC/VinylPlus following a similar approach as in the Vito 2009 study.

The 2009 study focussed on 5 major applications of PVC construction and building articles:

- Profiles (window and other profiles);
- Pipes;
- Flooring;
- Roofing and weatherproofing membranes;
- Electric cables.

The updated study focusses on the applications mentioned in paragraph 4 of entry 23 of Annex XVII to REACH and is based on the data provided by EuPC and VinylPlus.

Using similar calculations as in the 2009 study, all relevant tables and figures on waste amounts and cadmium content from the 2009 study have been updated.

The resulting information is used to update estimations of cadmium content and projections of cadmium content in rigid PVC, including a targeted impact assessment, which serves as a basis for reviewing the existing derogation. The main emphasis has been to assess effects of potential modification of the current derogation on cadmium in recovered PVC.

3.8.1. Update of data and calculations

The following paragraphs provide the basic information needed to be able to assess several scenarios enabling a cadmium phase out in PVC profiles and pipes. The data is structured as follows:

- Correspondence of product categories
- Data and characteristics on PVC profiles and pipes production
- Information on waste from PVC profiles and pipes
- Insights in PVC waste recycling into new products (profiles and pipes)

3.8.1.1. Product categories

The following rigid PVC applications are listed in paragraph 4 of entry 23 of Annex XVII of REACH:

- Profiles and rigid sheets for building applications;
- Doors, windows, shutters, walls, blinds, fences, and roof gutters;
- Decks and terraces;
- Cable ducts;
- Pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC.

The scope of the 2009 study was on the following 5 major applications of PVC construction and building articles:

- profiles (window and other profiles37)
- pipes
- flooring
- roofing and weatherproofing membranes
- electric cables

The categorisation of these articles is linked with existing specific sector associations that exist for each product category. Therefore specific data for each of these categories is

[37] supplementary profiles e.g. sills, widening profiles, roller shutters & boxes, and decoration profiles

available through the corresponding sector associations (like EPPA, TEPPFA, EPFLOOR, ESWA-ROOFCOLLECT).

To be able to link the applications as described in Annex XVII of REACH with the product categorisation as in the 2009 report, a correspondence table has been made up, as shown in Table 15.

Table 15. Correspondence between product categories in Annex XVII of REACH and the 2009 VinylPlus report

Entry 23, paragraph 4, ANNEX XVII of REACH	**2009 VinylPlus report**
a. Profiles and rigid sheets for building applications	Other profiles
b. Doors, windows, shutters,	Window profiles
c. Decks and terraces	Other profiles
d. Cable ducts	Pipes
e. Pipes for non-drinking water	Pipes

This correspondence table shows that the focus of the update of the 2009 study should be on profiles (both window and other profiles) and on pipes (both pressure and non-pressure pipes).

3.8.1.2. Production/Consumption of PVC products

Following paragraphs provide information on the volume of PVC profiles and pipes put on the EU market within the timeframe from 1950 until 2050, and on the cadmium contained in these products.

Amounts of PVC put on market in EU

Profiles

Figure 4 provides an overview of both the data from the 2009 study and the current update.

Data for 2009 study were provided by sector experts (based on the market in 2005 and a 2% growth per year). Data for 2017 study are provided by EuPC.

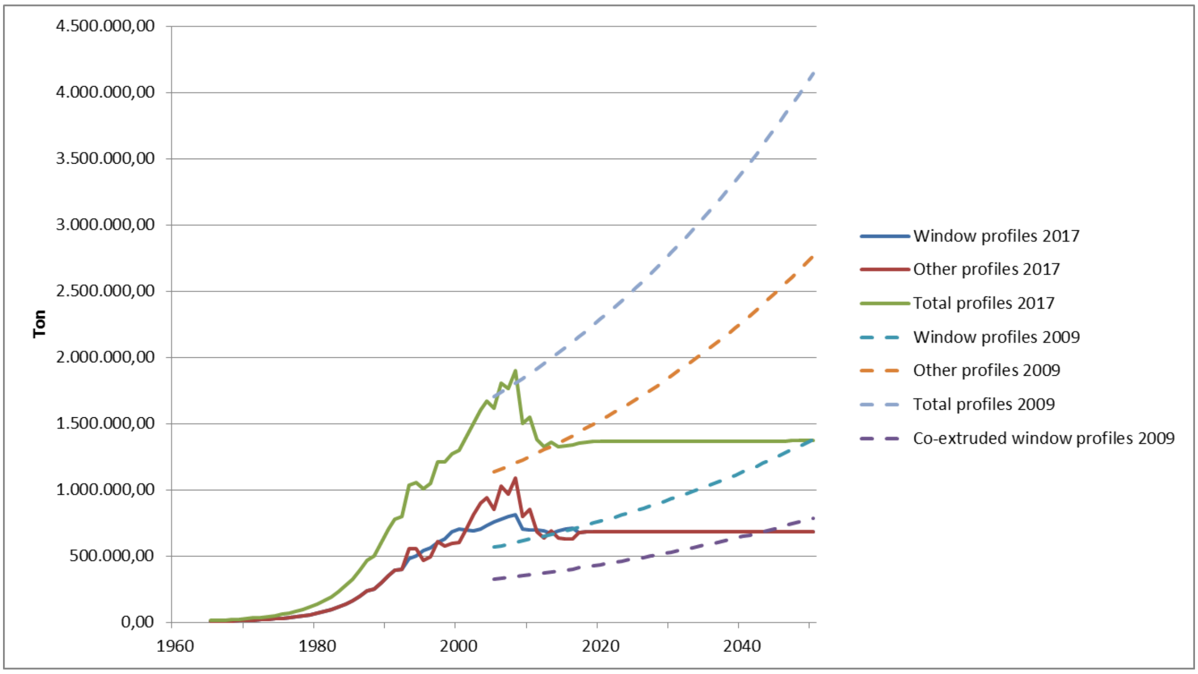

Figure 4. EU market for profiles

After the beginning of the production in 1965, growth started slowly and reached sizeable volumes in the 1980's. Especially after the collapse of the Soviet Union and the German reunification in the 1990's, production volumes grew immensely and did so until the economic crisis began in 2007/2008. Afterwards, production volumes declined and stabilized on a generally lower level. The main reason for this stagnant expectation is the high level of saturation which has been reached in Europe (especially Western Europe).

For the years for which no real data could be supplied, estimations were made. The results have been discussed with sector-experts to prove their plausibility. According to VITO, for *other profiles*, the data is scarce/sparse and not centrally organized compared to window profiles, because the other profiles product group contains many different applications and is not organized in centralized associations or comparable bodies (in contrast to EPPA for window profiles, for example).

There is a large difference between the projections in the 2009 study and the 2017 figures. The 2009 study projections, made just before or at the start of the 2008 economic crisis, were probably quite optimistic assuming a nearly exponential growth for several decades. On the contrary the 2017 figures seem quite conservative, showing no (or only very limited) economic growth[38].

Pipes

Figure 5 provides an overview of the 2017 data on pipes put on the EU market.

[38] Based on the sensitivity analysis later (Table 10), higher use volumes in the future appear to have a decreasing effect on cadmium concentration in new products containing recyclate.

In the 2009 study no data on pipe production or consumption volumes were included.

Data for 2017 study are provided by EuPC.

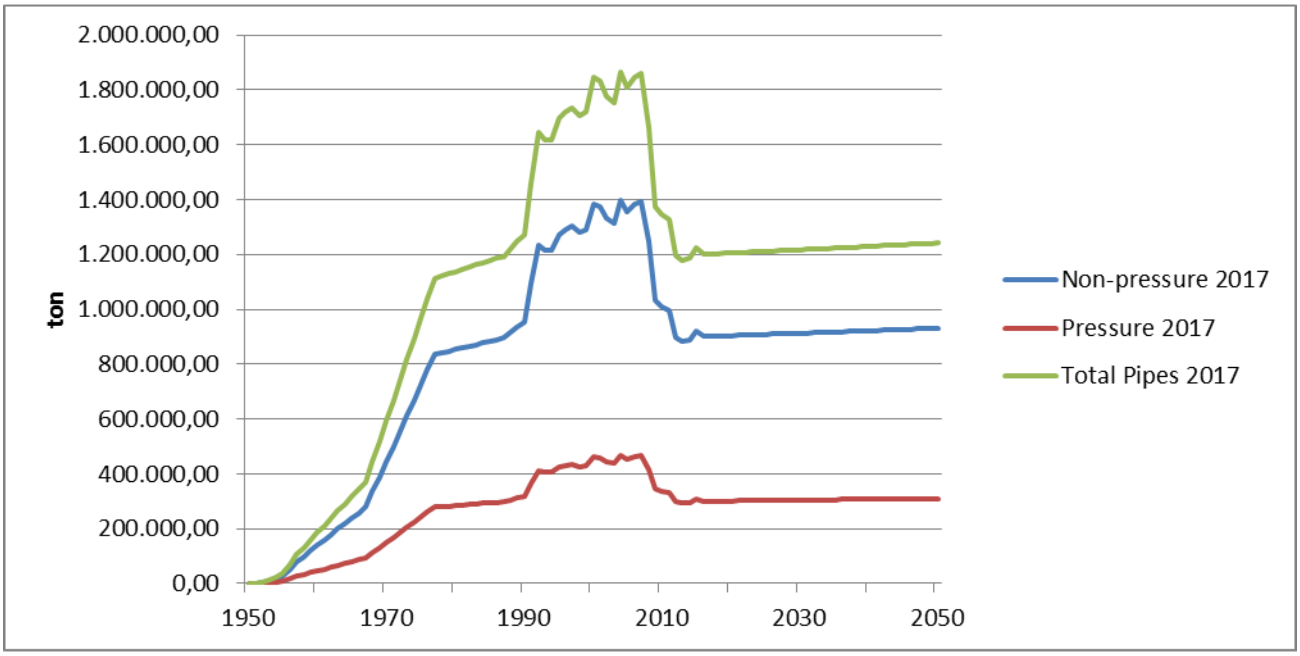

Figure 5. EU market for pipes

It can be seen that there is a development comparable to profiles but starting earlier for pipe production (and also continuing until the economic downturn in 2007/2008).

The drop in EU market for pipes after the economic crisis is more severe than for profiles, mainly due to two reasons: the European market reached a high saturation regarding PVC-pipes (especially Western Europe) and PVC was more and more replaced by polyolefins for the production of pressure pipes. For the future, only minimal growth is expected in Europe, while it might occur outside of Europe.

Similarly as for the profiles, the market expectation for pipes seems quite conservative, showing only a very limited economic growth.

Cadmium use in virgin PVC products

For the cadmium content of PVC products from virgin resin the relevant information from the 2009 report has now also been reviewed and updated based on the data by EuPC experts shown in the table below (Table 16).

Table 16. Specifications for profiles and pipes with virgin resin

Application → / **Parameter ↓**	**Profiles**		**Pipes**	
	2009	***2017***	***2009***	***2017***
Lifetime (years)	25[39]/40[40]	25[39]/35[40]	68	58[41]/60[42]
Starting year of Cd use	1965	1965	NA	
Ending year of Cd use	1996	1996	NA**Error! Bookmark not defined.**	
Average Cd concentration (additives or pigments)	0.2000 wt.%	0.3500 wt.%	NA**Error! Bookmark not defined.**	
Recycling activities started in year	1994	1994	1990	1990[43]

For the 2009 study as well as for the current update– the information is provided by sector experts from EuPC, however, the composition of the expert team significantly changed in between.

The most important modification in this table is in the ‘average cadmium concentration’ i.e. additives/stabiliser for profiles: for the 2009 study it was – according to an industry expert estimate - at 0.2%, whereas the more recent estimate suggests it to be 0.35%. The modified estimate is 75% greater than the original and significantly affects the projections made later in the text. Both these figures are based on a limited survey among sector experts. No apparent justification for the change has been provided, except for the expert judgement of the consulted experts. Recently, some information was provided on monitoring results of cadmium content in the rPVC core of PVC windows, however, representativeness of that information is unclear[44]. Such a significant, unexplained change

[39] for other profiles

[40] for window profiles

[41] Pressure pipes (gas & drinking water)

[42] Non-pressure pipes

[43] Beginning usage of recyclate out of profile waste (contaminated with cadmium) started in 2005

[44] In December 2019 ECHA received some information on cadmium content in the rPVC core of PVC windows. The information consists of averages and cover only a few most recent years. The average content values provided are all below 1000 ppm, and in most cases above 100 ppm. However, the

in the assumptions raises concerns about the reliability of the forecasts and is one of the main uncertainties underlying this assessment. A clarification of this discrepancy was asked later in the process, and in its response, an industry source restated that the higher value (0.35%) is the one to be used in the light of the current information[45]. A sensitivity analysis (reported below) shows that in case of a lower “average cadmium concentration” the *Cd concentration in waste* would be lower and *the year of Cd concentration reaching 100 ppm* would happen somewhat earlier.

The expert estimates suggest that the quantity of legacy cadmium in materials to be recycled (i.e. % Cd) has not decreased over the lifetime of the current open ended derogation. The lack of real, representative monitoring data and reliance on expert judgement raises a number of uncertainties into the calculations.

3.8.1.3. PVC waste arisings

The following paragraphs provide an overview of the estimated waste arisings for both profiles and pipes, including projections until 2050.

Profiles

Figure 6 provides an overview of the EU waste arisings for PVC profiles.

Data for both the 2009 and 2017 studies are provided by EuPC. The data for quantities of PVC waste arisings in the EU are developed using the EuPC-model based on statistics of historical sales and estimated average life times of the relevant products.

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information is in form of tables and its representativeness is uncertain (EPPA 2019; see also EPPA 2017).

[45] A personal communication (an e-mail message) received from European Council of Vinyl Manufacturers (ECVM), 1 Dec 2017, ECVM (2017).

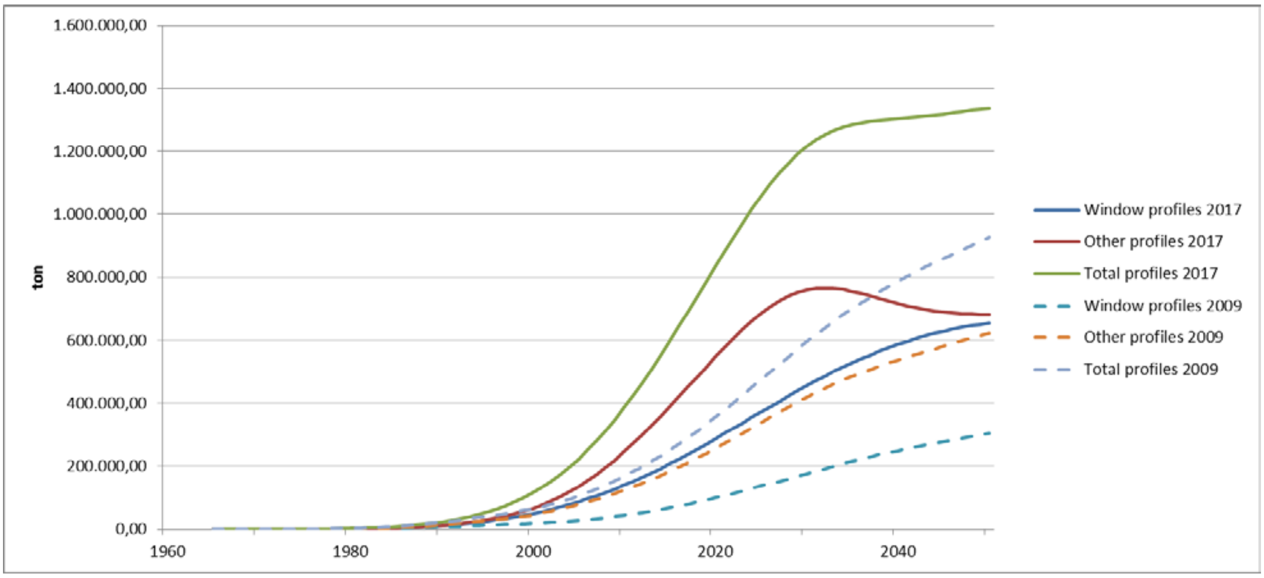


Figure 6. EU PVC profiles waste arisings

After the 2009 study both the software and the data populating the EuPC model have been revised thoroughly by EuPC and sector experts based on new insights and experiences. This has led to higher waste arisings and projections in the 2017 data compared to the 2009 data, both for window and other profiles.

Volumes of waste arising from window profiles are shown in the figure above (Figure 6). It can be seen, that – due to their long lifetime and relatively slow growth in the beginning of their production – sizeable volumes do not occur before the 1990’s. As a reason for the decline in production, the arising volumes start to slow down, from about 2040 onwards and a decrease can be expected after 2060 (roughly estimated).

The shorter lifetime of other profiles converts into an earlier decrease of waste arising already from 2030 onwards.

Pipes

Figure 7 provides an overview of the EU waste arisings for PVC pipes.
Data for both 2009 and 2017 study provided from EuPC model.

For the 2009 study data were available only until 2020.

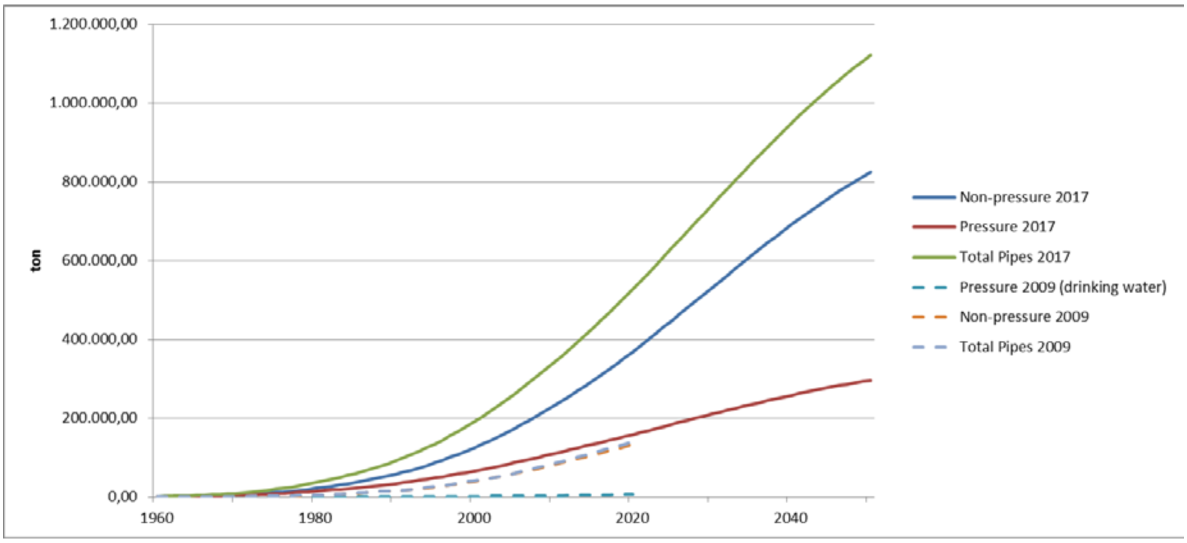


Figure 7. EU PVC pipes waste arisings

There is no real explanation why the projections differ so much between the 2009 study and the 2017 update. For both, the 2009 study and the 2017 update, the data were provided by sector experts.

Non-pressure pipes – consisting of cable-protection, sewage, drainage and roof gutters – have a mean lifetime of 60 years with a rather high deviation due to the four different applications in this group. This translates into a steadier and slower rise in the upcoming of waste. This also means that for the years after 2050 waste accumulation is still expected to continue.

3.8.1.4. PVC recycling

Technologies

Although there is some progress in technological innovation regarding mechanical recycling of plastics (i.e. where the PVC chains are not broken down), no major breakthroughs are noted with respect to elimination of additives during the mechanical recycling of plastics in one step. However, current methods are being improved and novel ones developed to obtain: better waste separation and treatment of mixed plastics waste; and improved recycling of complex waste streams.

Feedstock recycling technologies, incineration with energy recovery and material recycling have been in use since 2015 but are limited in the volumes they can deal with (estimated to be able to handle 100 000 tonnes of PVC by 2020) and do not result in PVC recyclate itself, but rather some of the components of PVC[46]. An overview of PVC recycling technologies is provided in a recent document by VinylPlus[47].

[46] Feedstock recycling, recovers the carbon contained in PVC waste from materials that are too complex to be mechanically recycled such as composites. This carbon is then used as feedstock for the production of chemicals.

[47] http://www.vinylplus.eu/uploads/2015-12-10_Recycling-Technologies-English.pdf

The situation is similar for chemical recycling in that it is a promising methodology but still needs further development. According to CEFIC's 2020 position paper[48], 'Chemical recycling is not yet a widely deployed option for the recycling of plastic waste. Scale-up requires innovation, harmonised policies, recycling-chains and clear pathways to "valorise" plastic waste that is currently incinerated, landfilled or wasted.'. The weight that is put on reducing energy requirements from recycling PVC rather than producing new PVC is not a purely technical issues that can be dealt with in this report as it is partly a policy decision, although the policy elements could be supported through a technical lifecycle assessment. In addition, the impact of the absence of recycling can be partially assessed (Scenario B). Therefore, the only way to currently eliminate additives from recycled plastics in the quantities produced per annum is by sorting out the cadmium containing components in a sorting process prior to the actual recycling/processing. For this purpose handheld XRF devices could be used to distinct between cadmium containing and cadmium free plastic parts, especially when the cadmium concentration is high (3 500 ppm) and homogeneously spread in the part (and thus detectable at the surface of the part).

One potential method for carrying out this process was VinyLoop, a proprietary recycling process which separated PVC from other materials through a process of dissolution, filtration and separation of contamination. VinyLoop-based recycled PVC's primary energy demand is 46 percent lower than conventional produced PVC. The global warming potential is 39 percent lower. However, since the process could not remove low molecular weight phthalate plasticisers during recycling the recycling plant closed as of 28 June 2018. This exemplifies the issue that recyclates often contain many legacy chemicals and therefore industry need time and incentive to find solutions.

As no other dedicated automated devices have been developed yet for this purpose, the only option to separate cadmium containing waste out of other PVC waste is to do sorting by hand. The separation process requires doubling of the storage and handling facilities and increases industrial costs and administrative burden when treating cadmium containing and cadmium free waste differently.

Recycled amounts of PVC waste

The PVC waste arisings give an impression of the total amounts of waste available, but do not provide any information on the destination of the waste. In general there are 3 destinations for (this) waste: disposal, incineration and recycling.

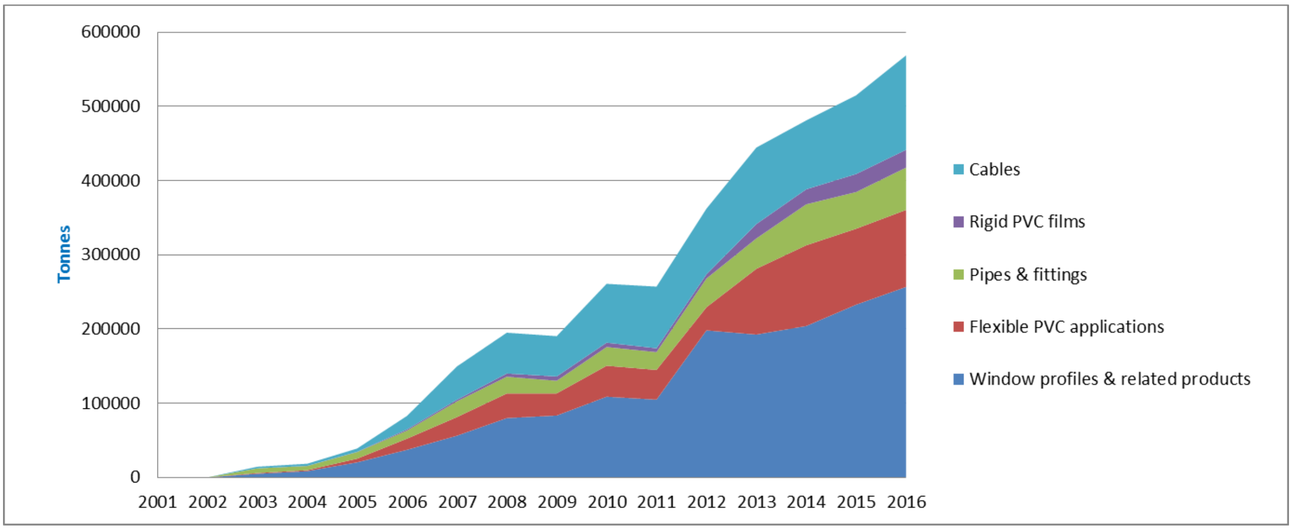
The next figure (Figure 8) gives an overview of the amount of PVC waste recycled, per product category.

Actually, these figures refer to the amount of waste arriving to a recycling facility, where the waste is treated before being processed into recyclate. During this recycling process an additional part of the waste is discarded because of not meeting the specifications for being recycled into new products, and has to disposed or incinerated. Therefore, the recycled

[48] CEFIC (2020) Introducing chemical recycling: Plastic waste becoming a resource: https://cefic.org/app/uploads/2020/03/Cefic-Position-Paper-on-Chemical-Recycling-1.pdf

amount reported may be somewhat overestimated compared to the actual amounts in practice.

Data on the effective recycled amounts of PVC are provided by VinylPlus and shown in the figure below (updated version of the figure from the 2009 report).



	2008	2009	2010	2011	2012	2013	2014	2015	2016
Window profiles & related products	79877	83288	108678	104719	198085	192419	203962	232757	256607
Flexible PVC applications	33180	29883	41790	40045	31202	88600	108791	102328	103809
Pipes & fittings	22555	16978	25172	23977	38692	40887	55225	49412	57005
Rigid PVC films	4352	5890	5891	5201	5620	19431	20214	24371	24061
Cables	54986	54285	79311	83142	88477	103131	92826	106044	127214
	194950	**190324**	**260842**	**257084**	**362076**	**444468**	**481018**	**514912**	**568696**

(Data provided by VinylPlus, 2017[49])

Figure 8. Recycled amounts of PVC in EU

The amount of recycled 'window profiles & related products' increased from 2008 till 2016 with a factor 3, while the waste arisings doubled in this same period.

Similarly, the amount of recycled 'pipes & fittings' in 2016 is 2,5 times higher than the amount in 2008, while the waste arisings increased almost with a factor 1.5.

The difference between the multiplication factors for waste arisings and waste recycled (respectively 50% for profiles and 68% for pipes) shows that the percentage amount recycled is clearly increasing and a larger share of the waste arisings are nowadays recycled.

Cadmium content of PVC waste

Profiles

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[49] http://www.vinylplus.eu/uploads/downloads/VinylPlus_Progress_Report_2017.pdf

Based on the above table information a graphical presentation of the cadmium content of window profiles can be deduced (as shown in Figure 9).

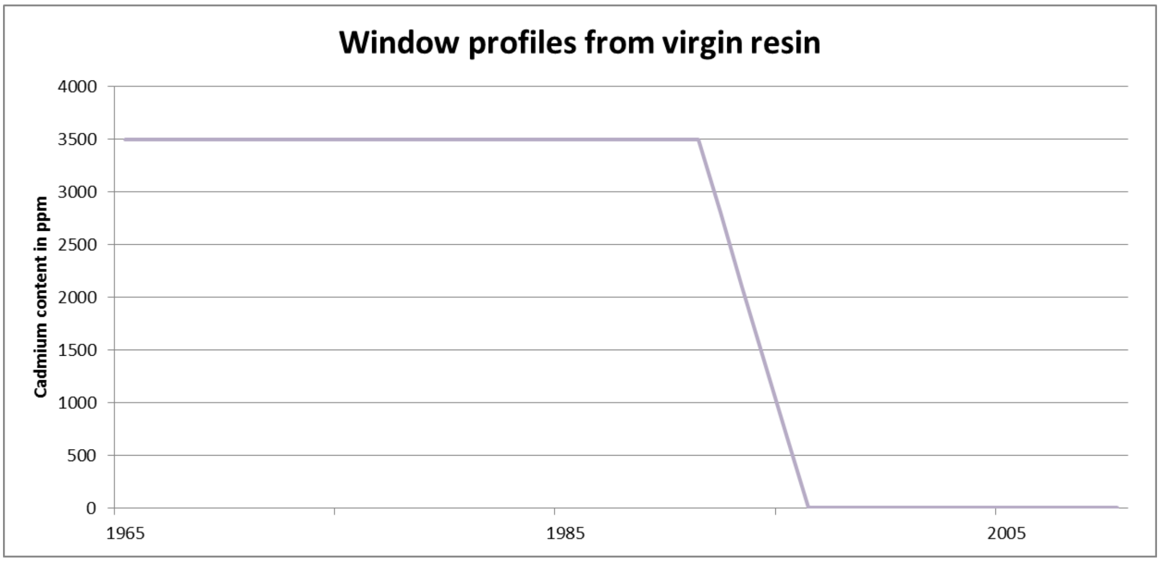

Figure 9. Cadmium concentration in PVC window profiles from virgin resin

Similarly a graph for ‘other profiles’ could be made up.

The cadmium content of PVC profiles waste is calculated based on the production data and the historic use of cadmium, taking into account a normal distribution with respect to the profile lifetime (average lifetime of 35 years for window profiles, 25 years for other profiles).

This profile is shown in the figures below, respectively for the periods 1965-2050 and 2010-2050. The latter figure re-graphs the first one on a shorter time period, such that the changes show clearer in the graph.

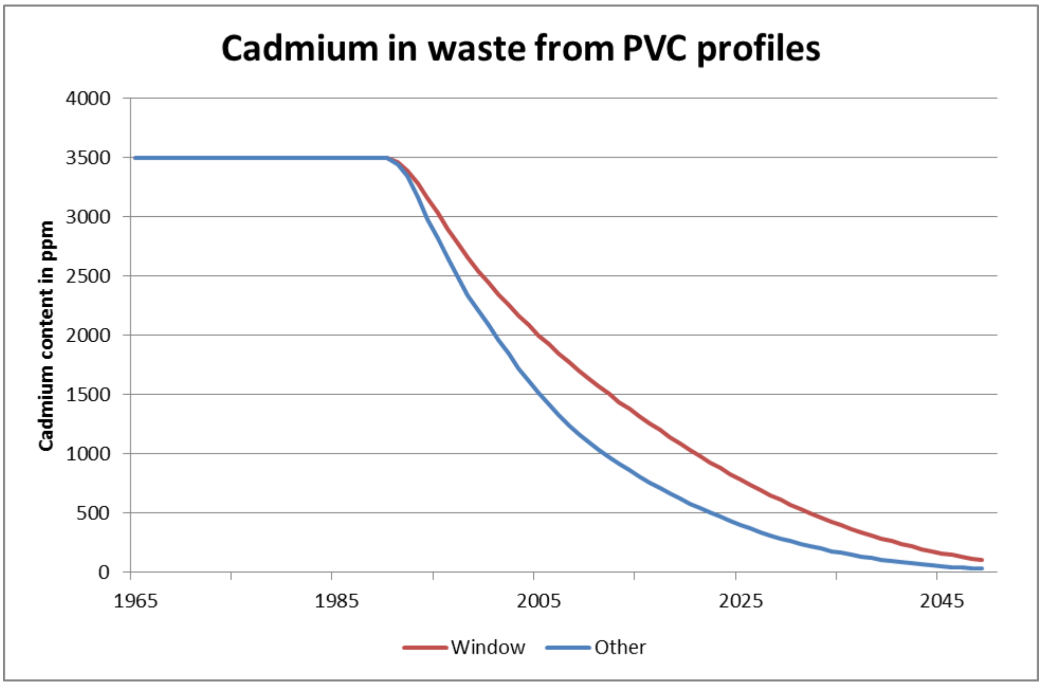

Figure 10. Cadmium concentration in waste from PVC profiles (1965-2050)

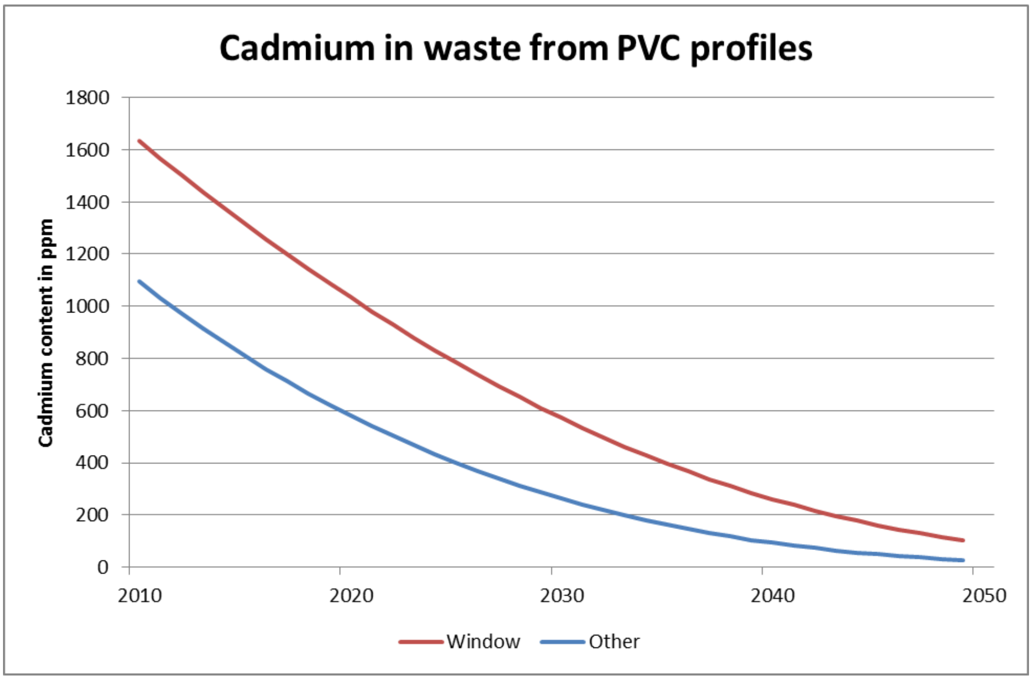

Figure 11. Cadmium concentration in waste from PVC profiles (re-graphed for 2010-2050)

These figures show that, both for window and other profiles, the cadmium content steadily decreases after a progressive reduction in use and the voluntary industry commitment to stop using cadmium as from 2000. The average decrease appears faster for other profiles compared to window profiles because of the shorter average lifetime of other profiles while the production volumes of the two groups are of the same order of magnitude.

Pipes

The production of pipes from PVC waste is based on mixed rigid PVC waste as a resource. The average cadmium concentration of mixed rigid PVC depends on the contribution of ‘window profiles’ and ‘other profiles’ and can be calculated. The composition of mixed rigid PVC waste as in the 2009 study (see the Table 17) is considered as representative for other years.

Table 17. Composition of mixed rigid PVC waste (2008)

Type	ktonnes	%
Pipes	21,9	27%
Window profiles	15,5	19%
Other profiles	38,8	48%
Rigid PVC films	4,4	5%
Total	**80,6**	**100%**

So the cadmium concentration in mixed rigid PVC waste is mainly determined by the share of (window and other) profiles and their respective cadmium content.

Cadmium content of PVC products with recyclate

As a result of recycling cadmium re-enters into the PVC product cycle. This is described in the table on use of recycled material in PVC products (Table 7 from 2009 report), as shown in Table 18.

As seen in the table, in 2009 in production of single profiles 40% of the material, on average, was recyclate (containing cadmium). The percentage had increased to 50% by 2017. The information in the graph is meant to present a relative change. The numbers are approximations.

Table 18. Approximate use of recycled material in PVC products

Application → / **Parameter ↓**	**Profiles**			**Pipes**	
	2009	***2017***		***2009***	***2017***
Production of new articles		Per single profile	Per EU28 market (average)		
Max. % use of recyclate (containing Cd)	70%	70%[50]	6%	65[51]-100%[52]	50%[53]
Average % use of recyclate (containing Cd)	40%	50%	3,5%	65-100%	30%
Yearly amount of recycled PVC produced					
Yearly amount of recycled PVC used in own sector	81%	81%		100%	100%
Yearly amount of recycled PVC sold to other (construction) sectors	19%	19%		0%	0%
Recyclate sold for use in other applications of the 5 construction applications under study (X = used in other applications; O = not used in other applications; blanc/neither = not relevant or no information)					
Window profiles & other profiles					O
Pipes and fittings	X				
Flooring	O				O
Roofing and weatherproofing membranes	O				O
(electric) cables	O				

This information (provided by EuPC) wasused to calculate the cadmium content in new PVC products using recyclate, for profiles and for pipes.

[50] For other profiles, there is an evolution to single profiles made 100% of recyclate

[51] Recyclate is only used in non-pressure (sewer or cable protection) pipes; in sewer pipes generally 65 % recyclate can be used (with an upper limit of 80 %), for cable protection pipes up to 100 %

[52] Technically it is feasible to use up to 100% recyclate, but not for marketing reasons (e.g. in some countries the use of recyclate is refused)

[53] On average a non-pressure pipe would contain 15% filler, 5% internal factory recyclate and max. 3% stabilizer/colorant, the rest being either complete virgin resin or a mixture of recyclate (max. 60%)

However, as reminded by the provider of the information, the reality tends to be more complicated than the simplified calculations: the calculations refer to closed loop recycling for profiles (window profiles waste recycled into new window profiles and similarly for other profiles) and assume average EU concentrations not taking into account the variability of concentrations resulting from the variability of origin and age of waste. However, a limit imposed by a restriction has to be complied with all the time, for each and every product put on the market. It is not sufficient that the limit is respected on average. In practice, heterogeneous waste, arriving in different forms and quantities with varying qualities over time may prompt additional needs for sorting, storing and re-mixing of variable batches to produce more homogenous recyclate suitable for use in different products. This increases costs compared to an ideal situation, where a stable flow of average qualities is assumed. Therefore the results of the calculations should be used and interpreted with care.

Profiles

The cadmium content of window profiles containing recyclate has been reported, based on the use of recyclate of 3,5; 6; 50 and 70%, being respectively the average and maximum over EU28 and the average and maximum per single profile (see below, both for the period 1965-2050 and 2010-2050).[54]

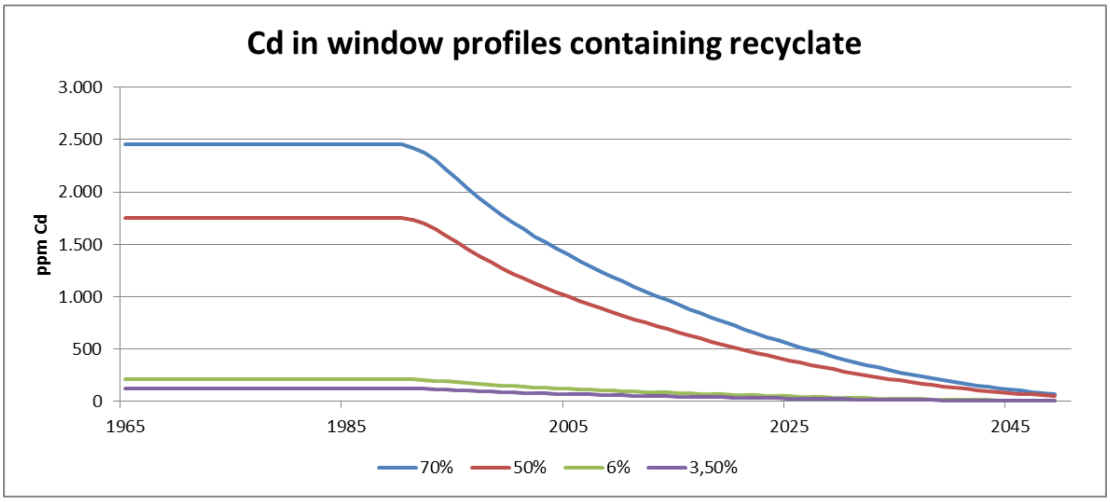

Figure 12. Cadmium concentration in window profiles containing recyclate (1965-2050)

[54] For other profiles, there is an evolution to single profiles made for 100% of recyclate

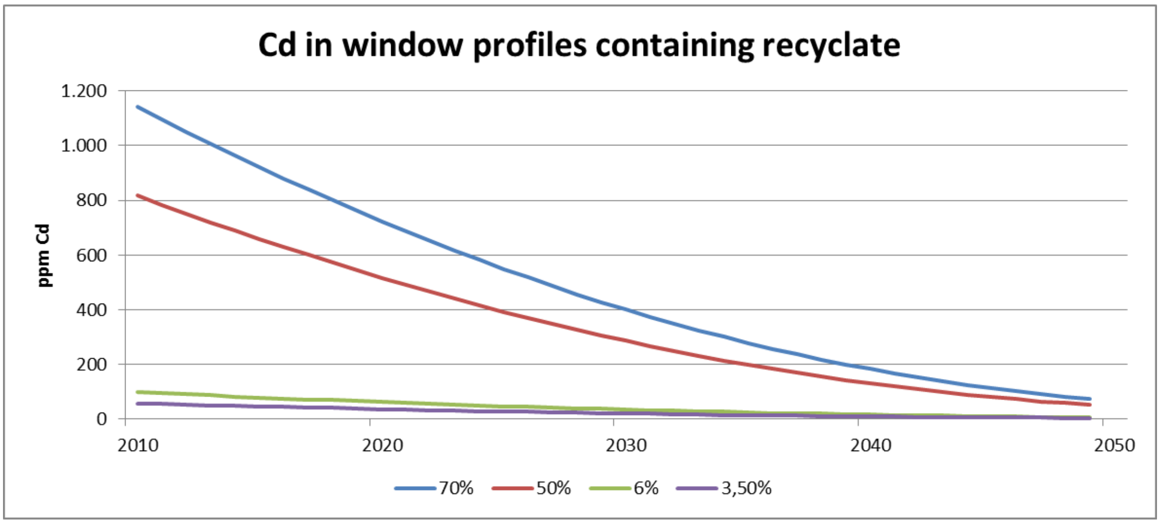

Figure 13. Cadmium concentration in window profiles containing recyclate (2010-2050)

The calculations and graphs show that the maximum cadmium concentration in new window profiles in 2017 is 839 ppm (70% recyclate). The EU average cadmium content for 2017 is estimated to be between 72 and 42 ppm (for 6% and 3,5% recyclate), depending on the average % of recyclate in the PVC profile.

The cadmium concentrations respectively in 2017 and 2030 are summarized in Table 19.

Table 19. Cadmium concentration in window profiles containing PVC waste recyclate

	% Recyclate used	Cadmium concentration (ppm)
2017	70	839
	50	599
	6	72
	3,5	42
2030	70	400
	50	286
	6	34
	3,5	20

A graph for ‘other profiles’ is presented in Figure 14.

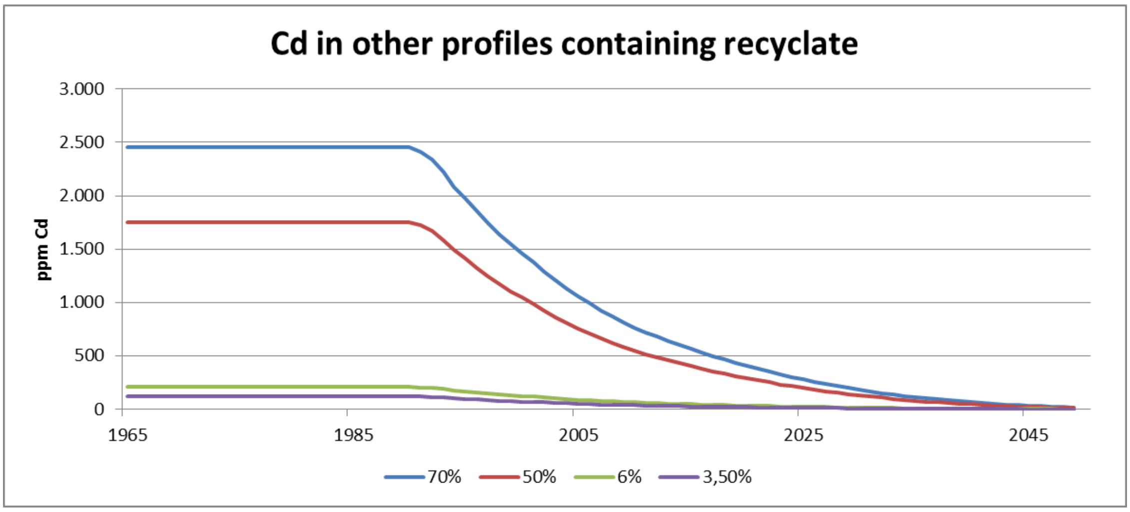

Figure 14. Cadmium concentration in other profiles containing recyclate (1965-2050)

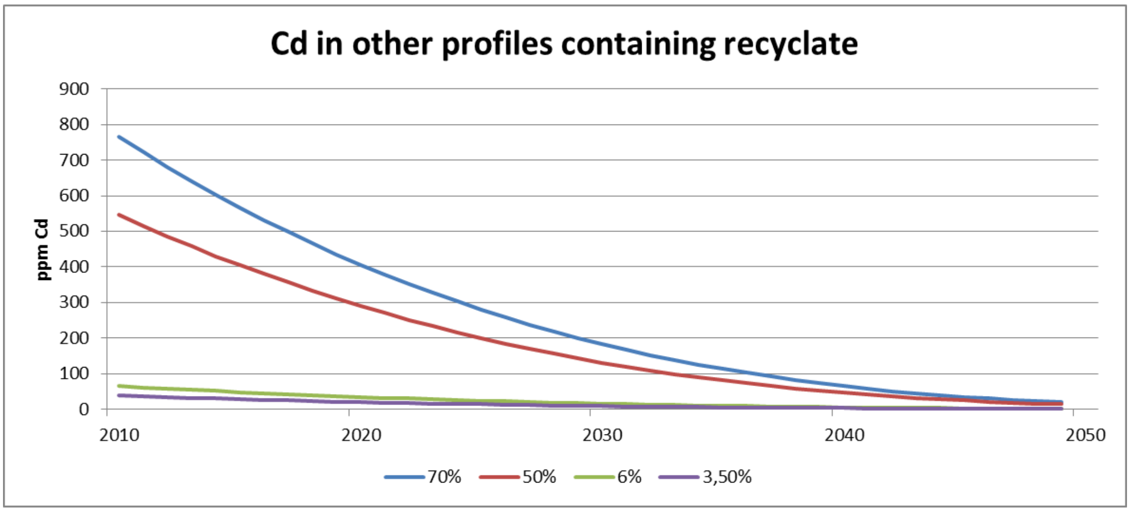

Figure 15. Cadmium concentration in other profiles containing recyclate (2010-2050)

The graphs show that for closed loop recycling the cadmium concentration in other profiles is decreasing faster over time than in window profiles, mainly because of the shorter lifetime for other profiles (25 years) compared to window profiles (35 years) and therefore a corresponding cadmium phase-out is faster.

The cadmium concentrations in other profiles respectively for 2017 and 2030 are summarised in Table 20.

Table 20. Cadmium concentration in other profiles containing PVC waste recyclate

	% recycle used	Cadmium concentration in ppm
2017	70	498
	50	356
	6	43
	3,5	25
2030	70	183
	50	131
	6	16
	3,5	9

Additionally a comparison with the results from the calculations in the 2009 study is shown in Table 21. Although the starting data (production volumes, waste arising, historic cadmium use) differ significantly, the results for cadmium in final products are similar; the results from the 2009 study can be situated between the 2017 results for window profiles and other profiles.

Table 21. Comparison of cadmium concentration results (ppm) given the amount of recyclate used for the years 2009-2017.

	2009 study	2017 update	
	Profiles[55]	Window profiles	Other profiles
2017	700 (70% recyclate) 400 (40% recyclate)	839 (70% recyclate) 599 (50% recyclate)	498 (70% recyclate) 356 (50% recyclate)
2030	240 (70% recyclate) 137 (40% recyclate)	400 (70% recyclate) 283 (50% recyclate)	183 (70% recyclate) 131 (50% recyclate)

Pipes

For pipes the cadmium concentration in new pipes using recyclate is determined by the cadmium in the window and other profiles fraction, as these are the 2 fractions containing cadmium in the mixed rigid PVC waste composition. So based on the contribution of these fractions to the mixed rigid PVC waste composition, the evolution of the cadmium in these fractions over time and the fraction of recyclate in new pipes, the concentration of cadmium in new PVC pipes is calculated and presented in the graph below for the period 1990-2050.

[55] In the 2009 study, a calculation was done for 'profiles' in general, without making a distinction between 'window profiles' and 'other profiles' as in the current update. Furthermore, in the 2009 study recyclate use percentages of 70 and 40% were used, compared to 70 and 50 % in the current update

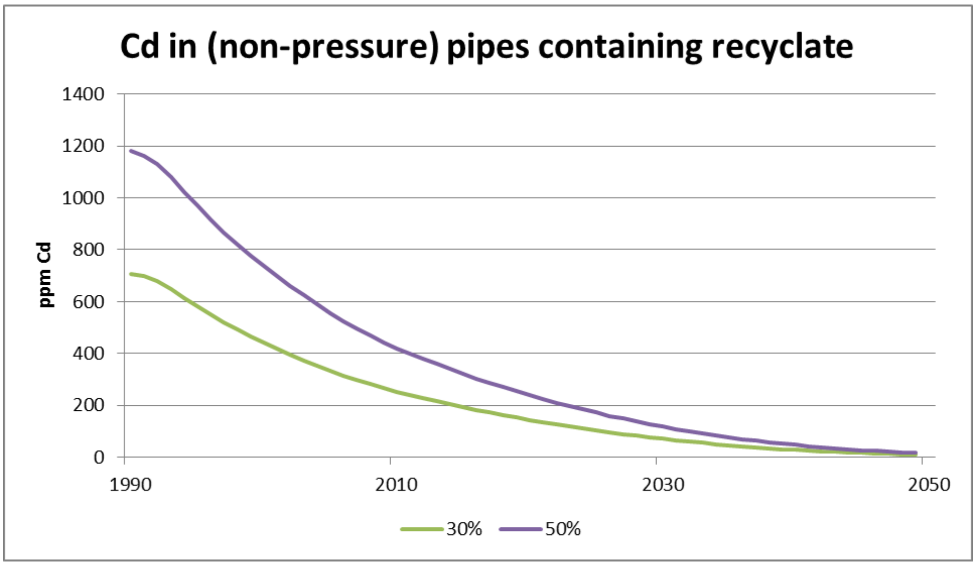

Figure 16. Cadmium concentration in pipes containing recyclate (1990-2050)

This graphs show that the cadmium concentration in PVC pipes containing recyclate has already been several years below 1000 ppm, and is steadily decreasing (in line with the cadmium concentration in window and other profiles) to reach the 100 ppm limit in 2026 or 2032, depending on a recyclate content of 30 or 50% respectively.

Table 22 provides an overview of the concentrations in 2017 and 2030.

Table 22. Cadmium concentration in pipes containing PVC waste recyclate

	% recycle used	Cadmium concentration in ppm
2017	50	287
	30	132
2030	50	118
	30	71

In Table 23 a comparison with the results from the calculations in the 2009 study is shown.

Taking into account the different recyclate use percentages, the updated cadmium concentrations (2017) appear a bit lower compared to the 2009 study.

Table 23. Comparison of cadmium concentration results (ppm) given the amount of recyclate (%) used, 2009-2017

	2009 study	2017 update
2017	436 (65% recyclate)	287 (50% recyclate) 132 (30% recyclate)
2030	144 (65% recyclate)	118 (50% recyclate) 71 (30% recyclate)

3.8.1.5. Sensitivity analysis

To check how the results of the calculations above depend on the basic data used for the calculations a sensitivity analysis has been performed for the window profiles case in VITO (2017).

In this sensitivity analysis a deviation to one of the basic data is applied, and the effect on the calculated cadmium content in waste is checked: both the cadmium concentration in 2030 and the year when the 100 ppm limit would be reached were calculated and compared with the results from the original situation. Table 24 provides an overview of the results.

The sensitivity of the following parameters is checked:

- Consumption of window profiles: the impact of a 10% increase of window profiles consumption for each year from 2017 on was checked;
- Average lifetime: the effect of an (12.5%) increase of the average lifetime of a window profile with 5 years (45 years instead of 40 years, for the total timeframe (1965-2050)) was calculated;
- Concentration of historic cadmium use: the impact of a 10% decrease of historic use of cadmium as additive at a concentration of 3150 ppm (instead of 3500 ppm) was calculated and compared to the original situation (3500 ppm).

Table 24. Sensitivity analysis for cadmium concentration calculation, window profiles case

Parameter changed	Deviation	Calculated parameter	% of recyclate used	Result sensitivity	Original
Consumption, from 2017 on	+10%	Cd concentration in 2030 in ppm	70	396	400
			50	283	286
			6	34	34
			3.5	20	20
		Year of reaching 100 ppm Cd	70	2046	2047
			50	2043	2043
			6	2010	2010
			3.5	1997	1997
Average lifetime	+5 years (12.5%)	Cd concentration in 2030 in ppm	70	543	400
			50	388	286
			6	46	34
			3.5	27	20
		Year of reaching 100 ppm Cd	70	After 2050	2047
			50	2048	2043
			6	2014	2010
			3.5	1998	1997
Concentration of historic cadmium use	-10%	Cd concentration in 2030 in ppm	70	360	400
			50	257	286
			6	31	34
			3.5	18	20
		Year of reaching 100 ppm Cd	70	2046	2047
			50	2042	2043
			6	2007	2010
			3.5	1994	1997

These results show that

- The impact of an increasing consumption of window profiles is very limited with respect to the phasing out of cadmium in window profiles; the increasing consumption will increase the corresponding (cadmium free) waste arisings and therefore impacts the dilution of cadmium containing waste arisings, although the effect is very limited;
- it is the changing lifetime that has the most impact on the cadmium concentrations: by increasing the average lifetime, the phase out of cadmium will be prolonged accordingly while the corresponding recent (and thus cadmium free) waste arisings will be stretched over time as well, and therefore lead to less dilution of cadmium. In the same time, this would be resource saving in general, concerning materials, energy, labour, etc. used;
- As could be expected, there is a linear effect of the historic cadmium use concentration on the cadmium content of new window profiles containing cadmium. The more the true value of concentration of historic cadmium use is reduced (increased) from the estimate (3500 ppm), the more the “Cd concentration in 2030 in ppm” and the “Year of reaching 100 ppm Cd” is reduced (increased) from the original estimate.

Additionally the sensitivity of the results for the pipes case from the mixed rigid PVC waste composition has been checked in a similar way (see Table 25).

For this sensitivity analysis the mixed rigid PVC waste composition was altered in 2 different ways:

1. By decreasing the contribution of profiles to mixed rigid PVC waste by 10%;
2. By decreasing the concentration of the historic cadmium use from 3500 ppm by 10% (to 3150 ppm).

Table 25. Sensitivity analysis for mixed rigid PVC waste composition for pipes case

Parameter changed	Deviation	Calculated parameter	% of recyclate use	Result sensitivity	Original
Mixed rigid PVC waste composition	Contribution of (window and other) profiles -10% (relative)	Cd concentration in 2030 in ppm	50	114	118
			30	68	71
		Year of reaching 100 ppm Cd	50	2032	2033
			30	2025	2026
Mixed rigid PVC waste composition	Historic cadmium use in window profiles -10%	Cd concentration in 2030 in ppm	50	113	118
			30	68	71
		Year of reaching 100 ppm Cd	50	2032	2033
			30	2025	2026

The results of this analysis show that both parameters have a linear effect on the results.

3.8.1.6. Conclusion

Based on updated basic data such as production volumes, waste arisings and historic cadmium use, the calculations for cadmium content in new products (profiles and pipes) containing PVC recyclate have been redone. Although the basic data differ significantly compared to the 2009 study, the results for cadmium in final products are quite similar as the effects of the changing parameters neutralise each other. An up to 75% higher concentration of cadmium compared to the historic cadmium use (as suggested by industry experts) is compensated by a large increase of cadmium-free waste arisings originating from products put on the market after 1996.

For window profiles, the cadmium concentration in new profiles containing 70% recyclate would be just below 800 ppm in 2018 and decrease to 100 ppm by 2047. For other profiles (containing 70% recyclate), the concentration in 2018 is 466 ppm and the 100 ppm limit will be reached in 2037.

For pipes (containing 50% recyclate), the concentration in 2018 is 270 ppm and the 100 ppm limit will be reached by 2032.

To check the robustness of the calculations of cadmium concentrations in new PVC products a sensitivity analysis has been performed for profiles for each of the basis parameters (being historic cadmium use concentration, consumption and average lifetime).

The results of the sensitivity analysis show that it is mainly a changing lifetime and (deviating) concentration of historic cadmium use that have the most impact on the cadmium concentrations of new window profiles containing recyclate. The impact of an increasing consumption of window profiles is very limited with respect to the phasing out of cadmium in window profiles.

4. Impact assessment

4.1. Definition of scenarios

In this chapter relevant scenarios with respect to cadmium limit value for PVC products are defined and then these scenarios are further analysed.

Based on the calculations in Chapter 3 and taking into account the current limit value and the derogation for PVC products, following scenarios and limit values are put forward:

- Scenario A: Retain the current derogation and limit value (0.1 % w/w);
- Scenario B: Revoke the derogation, as a result the 0.01% w/w limit applies for all uses, including uses of recovered PVC;
- Scenario C: Retain the derogation, however, with a lower limit value (0.08% w/w) for all PVC products[56] made from recovered PVC covered by the derogation;
- Scenario D: Retain the derogation, however, with the lower limit value (0.05%) for PVC products[57] made from recovered PVC, except for window profiles (retain the current limit value of 0.1% w/w).

Scenario A focusses on prolonging the current situation and keeping the existing derogation, with the same limit value (0.1%) for PVC product containing recycled PVC waste. This means that the ongoing efforts for recycling more PVC can be further valorised and that PVC recycling will keep increasing in the next years and decades.

Within the scope of ***Scenario B*** the derogation is abandoned, and the general cadmium limit value of 0.01 % by weight, that is applicable for all products, also applies to PVC products. In this scenario it would require a lot of effort to continue the ongoing raise of PVC recycling activities. As in the business-as-usual situation the 0.01% limit currently cannot be met by (window or other) profiles nor by pipes, additional measures should be taken to respect the 0.01% limit: cadmium containing waste should be sorted in order to limit the cadmium content of the feed for the recycling process to at least 0.01%. This would not only require an additional, potentially technically challenging, sorting step, but also double logistics and handling activities to deal both with cadmium containing and cadmium free PVC waste. Moreover, additional to these extra sorting costs, the cost for treating/disposing the cadmium containing waste will be significantly higher compared to being able to recycle it. In practise, more of the material entering into the recycling process would need to be discarded and disposed, which would decrease recycling efficiency and increase the costs per recycled amount. These extra costs might jeopardise the economic feasibility of PVC recycling activities, and this would result in larger PVC waste amounts going to incineration or disposal.

In ***Scenario C*** the limit value for PVC products is lowered to 0.08% for all PVC products. The results from the cadmium concentration calculations show that as 0.08% limit could be

[56] The scope may need to be reconsidered, e.g. whether to align the list of articles with the list of articles in the lead in PVC restriction.

[57] See the previous footnote concerning the Scenario C.

met for both PVC profiles and pipes, the quality of waste material per se would not be an obstacle for having the same level of recycling activities as in scenario A. However, the calculated average EU concentrations do not take into account the variability of waste resulting from the various origins (and age). As the limit imposed by a restriction has to be complied with all the time, lowering the limit from 0.1% to 0.08% would tighten this "acceptable" margin 20%. As quality of waste varies, a stricter limit requires more intensive (costly) sorting and re-mixing, and subsequently increased storing (of waste)[58]. Therefore, a stricter limit is expected to increase the costs of recycling, even if the quality of waste material would, on average, conform to the limit.

In ***Scenario D*** the limit value for PVC products is lowered to 0.05% in general, except for window profiles where it is kept at 0.1%. The cadmium concentration calculations show again that these limits can be met(0.05% for other profiles and pipes, 0.1% for window profiles). This means, as in the previous case, that based on the average waste quality, the amount of waste recycled could be the same as in scenario A. However, as above the tighter limit might again cause that more numerous waste loads need (costly) sorting, mixing and temporary storage.

In addition to the scenarios above, the review clause in entry 23 para 4, also specifies the need to reassess the scope of the articles included in the derogation. This was not part of the request of the Commission but ECHA notes that the recently proposed restriction of lead in PVC contained a derogation for certain types of rigid PVC articles to be made from recycled PVC (see Table 26). The basis for the lead in PVC list was the existing restriction on Cd on recycled PVC, but was extensively revised during the development of the proposal and subsequent opinion-making to limit the scope of permitted articles to those with minimal potential for exposure during service life[59]; principally by requiring the encapsulation of recycled PVC by another material or by excluding articles from the inhabited parts of buildings (requiring their use in service areas/voids). This was to ensure a high level of protection for human health. Should the restriction of lead in PVC be adopted it would appear sensible to align the list of articles derogated under the cadmium restriction with those of the lead restriction. This would simplify compliance for operators and enforcement by authorities.

[58] Quality of waste loads tends to differ such that some of them are well below the limit, whereas others are above the limit. To be able to use the maximum amount of waste in the recycling process, industry can sort and mix the loads to have as much material as possible to conform to the limit value. Such sorting and mixing, when maximising the amount of recyclable waste, also increases storage and processing costs.

[59] Combined opinion of RAC and SEAC on the Lead in PVC proposal https://echa.europa.eu/documents/10162/bf4394ef-7b75-99ec-13c1-134ba7ed713d

Table 26. Articles included in the cadmium in PVC exemption and the proposed exemption in the lead in PVC restriction.

Cadmium in PVC	Lead in Rigid PVC	Lead in Flexible PVC
Profiles and rigid sheets for building applications.	Profiles and sheets for exterior applications in buildings and civil engineering works, excluding decks and terraces.	
Doors, windows, shutters, walls, blinds, fences, and roof gutters	Profiles and sheets for use in concealed spaces or voids in buildings and civil engineering works (where they are inaccessible during normal use, excluding maintenance, for example, cable ducts). Profiles and sheets for interior building applications, provided that the entire surface of the profile or sheet facing the occupied areas of a building after installation is produced using newly produced PVC or other material, which prevents leaching and formation of lead containing dusts during article service life.	
Decks and terraces	Decks and terraces, provided that the recovered PVC is used in the middle layer and is entirely covered with a layer of newly produced PVC or other material, which prevents leaching and formation of lead containing dusts during article service life.	
Cable ducts	See row 2	
Pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced	Multi-layer pipes (excluding pipes for drinking water), provided that the recovered PVC is used in the middle layer and is entirely covered with a layer of newly produced PVC.	

Cadmium in PVC	Lead in Rigid PVC	Lead in Flexible PVC
PVC in compliance with paragraph 1 above.	Fittings, excluding fittings for pipes for drinking water.	
		Mats for stables and greenhouses.
		Noise insulation sheets.
		Multilayer hoses, articles for roofing and waterproofing, for road furniture and traffic management and professional footwear. With effect from [OP, please insert the date corresponding to [6] years after the entry into force of this Regulation], this derogation shall only apply provided that the recovered PVC used in such articles is entirely enclosed with a layer of newly produced PVC or other material, which prevents leaching or formation of lead-containing dusts during article service.

The defined scenarios (A-D) are further analysed in a targeted impact assessment (as in chapter 6 of the 2009 study). The approach for preparing the impact assessment (for a comparison of the various scenarios considered) is illustrated in Figure 17.

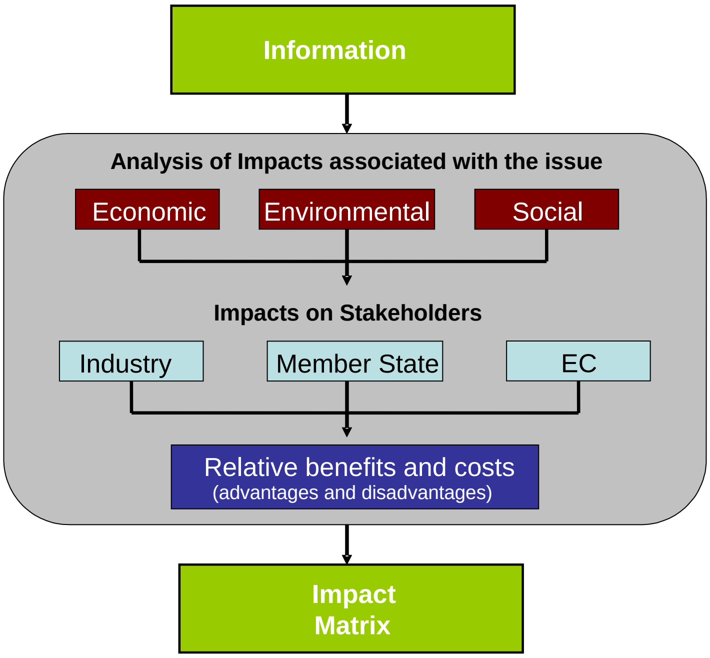

Figure 17. The Impact Assessment approach

The key issues considered include:

- The extent to which the different scenarios address the problem, i.e. the conflicting objectives of limiting Cd content in articles while allowing the recycling of post-consumer PVC waste.
- The extent to which the scenarios require legislative changes and the administrative and implementing complexity of such changes.
- Whether the scenarios reduce, maintain or improve the environmental impact.
- Potential impacts of the scenario on competitiveness.
- Social impacts such as employment (number of jobs).

Each of the scenarios is evaluated against all above criteria and a summary of the evaluation is presented in a decision-making matrix so that advantages and disadvantages of each scenario can be compared and the salient issues readily identified.

4.2. Analysis of scenarios

The key issues of the various scenarios are qualitatively analysed. For each of these issues, the relative advantages and disadvantages of each scenario are evaluated. The impact assessment matrix provided below (Table 27) summarises the results of the analysis. The process behind the rating is explained in the following sub-sections.

In each cell a qualitative score of '+', '0' or '-' has been given. A '+' signifies beneficial impact with respect to the criterion in question; '-' a negative impact; and '0' no impact. Increased magnitude of the impacts will be indicated using the notation ++ or --. In some cases, when there are other external influencing factors, a range is used, for example 0 to – or even + to -.

Table 27. Impact Assessment of different scenarios

	Scenario A: keep derogation (1000 ppm Cd limit)	Scenario B: Abandon derogation (fall back on 100 ppm Cd limit)	Scenario C: Lower Cd limit to 800 ppm for PVC products from 2018 on	Scenario D: Cd limit of 500 ppm for PVC products, and 1000 ppm for window profiles
General Issues				
Legislative changes required	0	-	-	-
Limiting the Cd content of PVC articles[60]	0	+	0	0
Environmental Issues				
Emissions to air (general)	0	--	0	0
Cadmium emissions to air[61]	0	0	0	0
Resources (depletion)	0	--	0	0
Economic Issues				
Total cost of EOL treatment	0	--	0	0
Impact on recycling business	0	--	0(-)	0(-)
Impact on PVC converters/manufacturers	0	-	0	0
Social Issues				
Confidence of the public with respect to environmental control	+/-	+/-	+/-	+/-
Number of jobs in sectors affected	0	-	0	0
Other issues				
Clarity and consistency (the latter e.g. with other national and EU legislation)	0	0	-/0	-/0

'++': substantial beneficial effect; '+': slight beneficial effect; '-': negative effect, '--': substantial negative effect; '0' no effect; N/A: Not applicable; Y/N: yes/no

4.2.1. General issues

The general issues addressed in this impact assessment are related to potential modifications of a derogation currently active in the restriction of the Cd-content to a limit of 0.01% by mass of the plastic compounded material in most new PVC articles, according to Annex XVII of the REACH Regulation.

[60] This question looks at whether the design of the option actually addresses the real issue – in the sense of focus rather than effectiveness. Effectiveness issues come after. Hence, it is the intention and targeting of the option that is assessed here and not its effect.

[61] Low in all scenarios

Legislative changes

Scenario A focusses on a prolongation of the existing derogation for PVC products, and therefore implies no or a very limited impact with respect to legislative changes, as the existing situation will just be continued.

Scenario B would require a proposal to remove the existing derogation completely and would require an Annex XV restriction dossier and subsequent opinion making in the Committees.

Scenarios C and D will require a proposal to adapt the existing exemption and would require an Annex XV restriction dossier and subsequent opinion making in the Committees. Although the impact of this procedure is expected to be limited, it is more significant than for scenario A but less than B.

Limiting the Cd content of PVC articles

Whatever scenario is chosen, the Cd-content of these PVC articles will decrease naturally over time. However, in scenario B this decrease will be much more drastic.

4.2.2. Environmental issues

Emissions to air (general)

The total emissions to air will be the smallest for the scenario with the most recycling activity, because recycling saves virgin material and avoids material being disposed in an incinerator. This lowers the use of resources and decreases CO_2-emissions.

Cadmium releases to the environment

Regarding releases of cadmium to the environment, the difference between the scenarios could be considered to be negligible because the cadmium containing waste will have to be disposed eventually: either it is disposed right away, or it is disposed after being recycled (one or many times). However, in recycling (Scenarios A, C and D) the average cadmium concentration in articles will decrease over time and cadmium releases to the environment will be distributed over a longer time period.

Resources (depletion)

As the amount of saved virgin material is always proportional to the amount of recyclate used in new articles, the scenario with more recycling scores better regarding resource depletion. In scenarios A, C and D significantly more material can be recycled than in scenario B.

Contribution to climate change (global warming potential), expressed as tonnes CO_2-equivalent

For the quantification of the environmental impacts the comparison focusses on ‘climate change’ as an important impact category.

The impact is expressed in kilograms CO_2-equivalent and is a measure for greenhouse gas emissions, such as CO_2 and methane. These emissions are causing an increase in the absorption of radiation emitted by the earth, magnifying the natural greenhouse effect.

For quantification of the environmental impact (and more specifically the global warming potential) of individual end-of-life treatment options for PVC pipe systems input and output data for each treatment option are used. A recent study for PRE[62] on plastic waste management provides specific information on the global warming potential of the end-of-life treatment of PVC, as summarized in Table 28 .

Table 28. Impact of end-of-life treatment of PVC waste, in CO_2-equivalents

For treatment of 1 kg PVC waste, in kg CO_2-eq		Impact
Production of PVC granules	Extraction raw materials + PVC granules production	1.90
Mechanical recycling	Impact recycling process	0.35
	Benefit PVC production	-1.90
	Overall	-1.55
Incineration	Impact incineration process	1.35
	Benefit energy recovery	-1.04
	Overall	0.31
Landfill	Impact landfill process	0.01

Table 28 shows that the credits for using PVC recyclate are considerably higher than the impacts of mechanical recycling of PVC waste.

So, from an environmental point of view, using PVC recyclate including mechanical recycling of PVC waste is preferable over landfill and incineration (including energy recovery). The (overall) negative impact for using PVC recyclate including mechanical recycling is due to the saving/avoiding of production of virgin PVC; so avoided impacts are awarded to the recyclate.

Although the credits for energy recovery are considered in the incineration process, the GWP for incineration is still significantly higher than for landfill.

Applied to the defined scenarios, scenario A, C and D would save at least 28 Mton of CO_2-equivalent from 2017 till 2050 compared to scenario B, as much more waste will be recycled.

4.2.3. Economic issues

Three aspects of economic impacts are considered in the proposed scenarios: the impact on

- the recycling business
- and on the PVC converters/manufacturers industry
- the total cost of the end-of-life treatment, i.e. landfilling and/or incineration versus recycling for the part of the waste that can/will be recycled (waste management).

[62] Increasing EU plastics recycling targets: environmental, economic and social impact assessment, CSR for cadmium and cadmium pigments (Plastics Recyclers Europe, 2015).

The impact on the industry is related to the price it has to pay for its input materials, manufacturing equipment and waste management.

Impact on the recycling business

Scenarios A, C and D support the recent substantial growth of the recycling market as they would not considerably hinder the use of PVC waste due to cadmium content. Scenario B on the other hand will appear to impede progress in PVC recycling and might even reverse some efforts and progress in PVC recycling.

Based on price information by Plastic Recyclers Europe (2015) the average cost to recycle a tonne of PVC waste amounts to €750-850[62]. As the average sales price for a tonne of virgin PVC is €950-1300 per tonne (Plastic Recyclers Europe, 2015)[62], this would mean that the recycling industry (on average) makes a gross margin of €100-450 per tonne recycled (assuming that virgin material and recyclate are comparable in production).

Impact on PVC converters/manufacturers

In scenario B an economic loss is assigned to occur for PVC converters having invested in co-extrusion equipment. Their investments in co-extrusion equipment which allows them to accept recycled PVC waste as a raw material will be penalized.

In other scenarios A, C and D, no direct impact is expected as recycling of PVC waste is expected to continue in its current extent. As discussed above, in practice the stricter limits in scenarios C and D may somewhat increase the costs of recycling, which affects relative prices of virgin material vs. recyclates. This issue is not quantitatively assessed here due to lack of information.

EOL treatment

In all scenarios A, C and D no impact will occur compared the current situation.

In scenario B however, a significant amount of PVC waste cannot be recycled because of the cadmium constraint and therefore will have to be landfilled or incinerated. Additionally an equal amount of virgin PVC is assumed to be produced.

4.2.4. Social issues

Number of jobs in the sectors affected

Industry underlines, that recycling makes an important contribution to the creation of new jobs. It creates more jobs at higher incomes than either landfill or incineration.[62] The plastics recycling sector[62] estimates the employment impact at 7 300 direct jobs per megatonne material recycled or 32 174 jobs per megatonne including indirect employment.[62]

For scenarios A, C and D this would mean an additional direct employment of 130000 personyears from 2017 till 2050 in plastic recycling compared to scenario B (Plastic recyclers Europe, 2015).

4.2.5. Other issues

Clarity and consistency (the latter e.g. with other national and EU legislation)

Scenario A foresees to prolong the current situation and therefore has the least impact on clarity and consistency. On the other hand, also the impact of scenario B would be limited to this aspect as it falls back on the general, existing limit value.

For scenarios C and D a new limit value would need to be adopted. This would require a preparation of a restriction dossier and SEAC and RAC opinion on that dossier. Therefore, these scenarios have a lower score for clarity and consistency.

4.3. Conclusions on the analysis of scenarios

The analysis shows that under scenarios A, C and D the alternative derogation levels would not directly affect the current development of the market i.e. the more stringent derogation as described in the scenarios would not yet be binding. As such it would not have a direct effect on the industry waste management and recycling, although it might increase the cost of recycling somewhat. In other words it would not directly hinder recycling efforts, but allow exploitation of the currently installed recycling infrastructure for using recyclate with the current exposure of the environment to cadmium. From a human health and environmental point of view, it would neither affect the amount of cadmium found in recyclate-based PVC products, nor incentives/possibilities for increased recycling compared to the existing situation (~baseline). These scenarios score on almost all considered issues similarly compared to the scenario with abolished derogation (scenario B, applying overall 0.01% limit value), which in turn would decrease the amount of cadmium found in the recycled PVC, but in the same time decrease recycling.

5. Assumptions, uncertainties and sensitivities

The data received for this analysis differs from the one used in the original VITO report, and therefore also to some extent projections and results on PVC waste arisings and cadmium concentrations presented in this analysis compared to the VITO 2009 report are altered. Two main reasons are behind the results.

First, due to the economic downturn since 2008-2009, the market volume of PVC has been considerably reduced and as such it would have also reduced projections of future PVC waste arisings as well as cadmium to be found in waste arisings. Based on this latter analysis, it becomes clear, that the general economic activity has a major impact on the PVC markets and given the abrupt changes after the VITO 2009 report, the impacts can be difficult to forecast.

Another effect, however, namely, a significant increase in cadmium concentration in PVC – an expert assumption provided during this latter analysis – works other way around. As a result of these two effects working in opposite directions, the resulting amounts of cadmium found in PVC waste and recyclate remain close to the same level as projected in the original VITO report (2009).

In both reports, the cadmium concentration was based on an estimate by industry experts. It is noteworthy that in the more recent study the estimated cadmium concentration was about 75% higher than originally. No reasoning was provided for the modification. A sensitivity analysis with respect to this parameter causes the estimates of "Cd concentration in waste in 2030" and "Year of waste Cd level reaching 100 ppm" both to appear somewhat higher. The large differences in the expert estimates underline the uncertainties affecting this data. Therefore, it would be important that from now on industry would provide information on the cadmium concentration in waste material/recyclate for the needs of enforcement and the future decision making.

When interpreting the results it has to be acknowledged that in practise, the limit imposed by a restriction has to be complied with in all circumstances. The simplified analysis is based on average concentrations and overlooks potential variability in cadmium concentration resulting from different origins and ages of waste. In practise, heterogeneous waste combined with a stricter limit value most likely increases the costs and reduces the profitability of recycling which in turn leads to somewhat more PVC material being disposed via incineration or landfill.

6. Conclusions

Background

This report assesses the potential impacts on PVC recycling and on Cd releases from PVC waste handling due to changes in allowed (derogated) concentration level of cadmium in recycled PVC products. The main concern is that tighter concentration limits may decrease recycling and subsequently increase Cd releases from PVC waste. The current derogation is based on the analysis described in the VITO 2009 report. VITO updated that analysis for this investigation report.

Based on updated data (consumption figures, waste arisings, historic cadmium use) cadmium concentrations in waste and new products, and their future evolution, are recalculated and possible future scenarios to cope with the cadmium limit for PVC product were defined.

During the development of this report, there has been also considerable separate work concerning lead in PVC. Outcomes from that work became available only when the analysis by VITO (2017) for this report was already done. One of the main outcome for this study is the conclusion that recycling can be considered to be a risk management measure in itself as long as service-life releases are minimised (agreed by RAC in relation to the lead in PVC restriction). Based on this conclusion, greater overall risks to the environment may occur should recycling rates fall. Although the information was not available when the analysis work by VITO (2017) for this study was undertaken, it is taken into account here, as it has important implications to the conclusions.

Analysis

The first important finding in the current study is that the quantity of legacy cadmium in materials to be recycled has not decreased since the implementation of the derogation. The underlying data used in the modelling has changed significantly, and current industry information suggests that the concentration of cadmium in PVC is 75% higher than thought to be in in the original VITO 2009 report. In both cases information is being based on expert assumptions, and no clear reasoning for the difference was provided other than that the experts are different and the estimates were done eight years apart. The increase is overshadowed by a large increase of cadmium-free waste arisings originating from products put on the market after 1996. Finally, the amount of PVC put on the market since 2009 appears to be also clearly lower than originally forecasted. Based on calculations on this new data, the estimated amounts of cadmium in final products end up being close to the same as forecasted in 2009.

Based on the updated data, VITO performed targeted impact analysis on four scenarios: Scenario A, which would prolong the current situation and retain the existing derogation with the same limit value (0.1% w/w); Scenario B, where the derogation is abandoned, and the generic cadmium limit value (0.01% w/w) applies to all products; Scenario C, where the concentration limit value for products containing recovered PVC is reduced from 0.1% (w/w) to 0.08% w/w; and Scenario D, where the concentration limit value for window profiles containing recovered PVC would remain at 0.1% w/w, whereas for other PVC products containing recovered PVC the concentration limit value would be reduced to 0.05% w/w.

Conclusions

The analysis of the scenarios shows that prolonging the existing derogation (cadmium limit of 0.1% for recovered PVC) allows exploitation of the currently installed recycling infrastructure for using recyclate in new products.

As a variation to this scenario, lowering the cadmium limit to 0.08% for PVC pipes and profiles (Scenario C) would result in benefits comparable to maintaining the existing derogation unchanged (potentially with some added costs). Alternatively, in Scenario D, it could be considered to lower the cadmium limit to 0.05% ppm for all PVC products with an exemption for window profiles (remaining at 0.1% ppm). This would have comparable environmental impacts as the prolonging of the existing derogation or the lowering of the limit for PVC pipes and profiles to 0.08% ppm, with some potential added costs as in the Scenario C.The main conclusion of the analysis is that maintaining scenario A or adopting the more stringent concentration limits defined in Scenarios C and D would not affect current recycling activities. The reason is, that industry appears to be able to structure its use of recyclate such that the recycled products could stay within limits used in the scenarios. The costs of sorting, storing and mixing of waste (recyclate) are expected to increase the tighter the limit values are and the more heterogeneous waste is used.

Based on the above and on the understanding of the recycling as a risk management measure, costs and the benefits for the environment or to human health from lower concentration limits would be minor as releases are minimised by maximising recycling into articles with low service life release rather than reducing the concentration of cadmium in articles. On the contrary, if lowering of the limit values would cause industry to reduce recycling activities, the change could cause a (perverse) increase in emissions (and higher resource use in general).

The last outcome, a potential increase in emissions, is most likely in the Scenario B ceasing the derogation. Lowering the cadmium limit to 0.01% ppm for all PVC products could hinder controlled-loop recycling of PVC product while causing increased costs to industry, however, not offering better environmental protection. VITO also undertook a sensitivity analysis on each of the basic parameters (being historic cadmium use concentration, consumption and average lifetime). The analysis shows that the length of article service life and the concentration of cadmium used (in original articles) have the most impact on the cadmium concentrations of new window profiles.

Assessing the above scenarios according to their administrative costs shows that the scenarios B, C and D would require administrative work in form of a preparation and an assessment of a restriction proposal, Annex XV dossier. Such costs would be avoided in the Scenario A, as it would simply mean a continuation of the current practise.

A final, regulatory conclusion would be that scenarios C and D are expected to cause close to similar level of recycling and environmental effects as the current restriction and derogation (Scenario A). Scenario B would be expected to decrease recycling (increase incineration+landfilling and subsequent environmental impacts from the current). Administrative costs are about zero for Scenario A, whereas they are positive and similar for the other scenarios B, C, D. Other additional benefits from (more vs less) recycling due to resource use efficiency/savings would be lowest for Scenario B.

Coming back to the basic problem of choosing the optimal rate of cadmium to be diverted away from the PVC stream on the market, recycling appears to offer an effective method to manage the PVC waste stream containing cadmium. As long as the cadmium in recycled PVC products stays within acceptable limits and the products are used for suitable purposes, recycling activities appear beneficial in reducing cadmium content in the products over time. Given the calculations in the current (modelling) study, this appears to be the case.

Due to the lack of measured data the modelling calculations are based on assumptions by industry experts (cadmium concentration in waste) and large scale average values. Furthermore, use of heterogeneous waste materials causes its own challenges to the work. Based on the analysis, the current situation does not call changes to the policy on recycling from the environmental impact point of view. However, it would be important to develop data provision requirements to industry, such that a regulator would have data available on cadmium concentration in waste PVC and recyclate for decision making in the future.

7. Stakeholder information

ECHA contracted VITO to carry out an update if their 2009 *study on the cadmium content of recycled PVC waste* (VITO, 2009). In preparation of this both ECHA and VITO cooperated with the EuPC for the provision of relevant information for the report. In addition, ECHA received additional information from EuPC for the preparation of the environmental risk assessment carried out.

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